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Code of Federal Regulations

42

Part 430 to End

Revised as of October 1, 2006

Public Health

Containing a codification of documents of general applicability and future effect

As of October 1, 2006

With Ancillaries

Published by
Office of the Federal Register
National Archives and Records
Administration

A Special Edition of the Federal Register

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Cite this Code: CFR

To cite the regulations in this volume use title, part and section number. Thus, 42 CFR 430.0 *refers to title 42, part 430, section 0.*

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Title 17 through Title 27.....as of April 1
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RAYMOND A. MOSLEY,
Director,
Office of the Federal Register.

October 1, 2006.

THIS TITLE

Title 42—PUBLIC HEALTH is composed of four volumes. The parts in these volumes are arranged in the following order: Parts 1–399, parts 400–413, parts 414–429, and part 430 to end. The first volume (parts 1–399) contains current regulations issued under chapter I—Public Health Service (HHS). The second and third volumes (parts 400–413 and parts 414–429) include regulations issued under chapter IV—Centers for Medicare & Medicaid Services (HHS) and the fourth volume (part 430 to end) contains the remaining regulations in chapter IV and the regulations issued under chapter V by the Office of Inspector General-Health Care (HHS). The contents of these volumes represent all current regulations codified under this title of the CFR as of October 1, 2006.

The OMB control numbers for the Centers for Medicare & Medicaid Services appear in § 400.310 of chapter IV. For the convenience of the user, subpart C consisting of §§ 400.300–400.310 is reprinted in the Finding Aids section of the third and fourth volumes.

For this volume, Ruth Green was Chief Editor. The Code of Federal Regulations publication program is under the direction of Frances D. McDonald, assisted by Kenneth R. Payne.

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(Part 430 to End)

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CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

EDITORIAL NOTE: Nomenclature changes to chapter IV appear at 66 FR 39452, July 31, 2001; 67 FR 36540, May 24, 2002; and 69 FR 18803, Apr. 9, 2004.

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SUBCHAPTER C—MEDICAL ASSISTANCE PROGRAMS

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 53 FR 36571, Sept. 21, 1988, unless otherwise noted.

Subpart A—Introduction; General Provisions

§ 430.0 Program description.

Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children or qualified pregnant women or children. The program is jointly financed by the Federal and State governments and administered by States. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services.

§ 430.1 Scope of subchapter C.

The regulations in subchapter C set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP). Each part (or subpart of section) in the subchapter describes the specific statutory basis for the regulation. However, where the basis is the Secretary's general authority to issue regulations for any program under the Act (section 1102 of the Act), or his general authority to prescribe State plan requirements needed for proper and efficient administration of the

plan (section 1902(a)(4)), those statutory provisions are simply cited without further description.

§ 430.2 Other applicable Federal regulations.

Other regulations applicable to State Medicaid programs include the following:

(a) 5 CFR part 900, subpart F, Administration of the Standards for a Merit System of Personnel Administration.

(b) The following HHS Regulations in 45 CFR subtitle A:

Part 16—Procedures of the Departmental Appeals Board.

Part 74—Administration of Grants.

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services: Effectuation of Title VI of the Civil Rights Act of 1964.

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80.

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance.

Part 95—General Administration—grant programs (public assistance and medical assistance).

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]

§ 430.3 Appeals under Medicaid.

Three distinct types of disputes may arise under Medicaid.

(a) *Compliance with Federal requirements.* Disputes that pertain to whether a State's plan or proposed plan amendments, or its practice under the plan meet or continue to meet Federal requirements are subject to the hearing provisions of subpart D of this part.

(b) *FFP in Medicaid expenditures.* Disputes that pertain to disallowances of FFP in Medicaid expenditures (mandatory grants) are heard by the Departmental Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16.

(c) *Discretionary grants disputes.* Disputes pertaining to discretionary grants, such as grants for special demonstration projects under sections 1110 and 1115 of the Act, which may be awarded to a Medicaid agency, are also heard by the Board. 45 CFR part 16, appendix A, lists all the types of disputes that the Board hears.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]

§ 430.5 Definitions.

As used in this subchapter, unless the context indicates otherwise—

Contractor means any entity that contracts with the State agency, under the State plan, in return for a payment, to process claims, to provide or pay for medical services, or to enhance the State agency's capability for effective administration of the program.

Representative has the meaning given the term by each State consistent with its laws, regulations, and policies.

[67 FR 41094, June 14, 2002]

Subpart B—State Plans

§ 430.10 The State plan.

The State plan is a comprehensive written statement submitted by the agency describing the nature and scope of its Medicaid program and giving assurance that it will be administered in conformity with the specific requirements of title XIX, the regulations in this Chapter IV, and other applicable official issuances of the Department. The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.

§ 430.12 Submittal of State plans and plan amendments.

(a) *Format.* A State plan for Medicaid consists of preprinted material that covers the basic requirements, and individualized content that reflects the characteristics of the particular State's program.

(b) *Governor's review*—(1) *Basic rules.* Except as provided in paragraph (b)(2) of this section—

(i) The Medicaid agency must submit the State plan and State plan amendments to the State Governor or his designee for review and comment before submitting them to the CMS regional office.

(ii) The plan must provide that the Governor will be given a specific period

of time to review State plan amendments, long-range program planning projections, and other periodic reports on the Medicaid program, excluding periodic statistical, budget and fiscal reports.

(iii) Any comments from the Governor must be submitted to CMS with the plan or plan amendment.

(2) *Exceptions.* (i) Submission is not required if the Governor's designee is the head of the Medicaid agency.

(ii) Governor's review is not required for preprinted plan amendments that are developed by CMS if they provide absolutely no options for the State.

(c) *Plan amendments.* (1) The plan must provide that it will be amended whenever necessary to reflect—

(i) Changes in Federal law, regulations, policy interpretations, or court decisions; or

(ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program. For changes related to advance directive requirements, amendments must be submitted as soon as possible, but no later than 60 days from the effective date of the change to State law concerning advance directives.

(2) Prompt submittal of amendments is necessary—

(i) So that CMS can determine whether the plan continues to meet the requirements for approval; and

(ii) To ensure the availability of FFP in accordance with § 430.20.

[53 FR 36571, Sept. 21, 1988, as amended at 60 FR 33293, June 27, 1995]

§ 430.14 Review of State plan material.

CMS regional staff reviews State plans and plan amendments, discusses any issues with the Medicaid agency, and consults with central office staff on questions regarding application of Federal policy.

§ 430.15 Basis and authority for action on State plan material.

(a) *Basis for action.* (1) Determinations as to whether State plans (including plan amendments and administrative practice under the plans) originally meet or continue to meet the requirements for approval are based on relevant Federal statutes and regulations.

(2) Guidelines are furnished to assist in the interpretation of the regulations.

(b) *Approval authority.* The Regional Administrator exercises delegated authority to approve the State plan and plan amendments on the basis of policy statements and precedents previously approved by the Administrator.

(c) *Disapproval authority.* (1) The Administrator retains authority for determining that proposed plan material is not approvable or that previously approved material no longer meets the requirements for approval.

(2) The Administrator does not make a final determination of disapproval without first consulting the Secretary.

§ 430.16 Timing and notice of action on State plan material.

(a) *Timing.* (1) A State plan or plan amendment will be considered approved unless CMS, within 90 days after receipt of the plan or plan amendment in the regional office, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of any additional information it needs in order to make a final determination.

(2) If CMS requests additional information, the 90-day period for CMS action on the plan or plan amendment begins on the day it receives that information.

(b) *Notice of final determination.* (1) The Regional Administrator or the Administrator notifies the Medicaid agency of the approval of a State plan or plan amendment.

(2) Only the Administrator gives notice of disapproval of a State plan or plan amendment.

§ 430.18 Administrative review of action on State plan material.

(a) *Request for reconsideration.* Any State dissatisfied with the Administrator's action on plan material under § 430.15 may, within 60 days after receipt of the notice provided under § 430.16(b), request that the Administrator reconsider the issue of whether the plan or plan amendment conforms to the requirements for approval.

(b) *Notice and timing of hearing.* (1) Within 30 days after receipt of the request, the Administrator notifies the

State of the time and place of the hearing.

(2) The hearing takes place not less than 30 days nor more than 60 days after the date of the notice, unless the State and the Administrator agree in writing on an earlier or later date.

(c) *Hearing procedures.* The hearing procedures are set forth in subpart D of this part.

(d) *Decision.* A decision affirming, modifying, or reversing the Administrator's original determination is made in accordance with § 430.102.

(e) *Effect of hearing decision.* (1) Denial of Federal funds, if required by the Administrator's original determination, will not be delayed pending a hearing decision.

(2) However, if the Administrator determines that his or her original decision was incorrect, CMS pays the State a lump sum equal to any funds incorrectly denied.

§ 430.20 Effective dates of State plans and plan amendments.

For purposes of FFP, the following rules apply:

(a) *New plans.* The effective date of a new plan—

(1) May not be earlier than the first day of the quarter in which an approvable plan is submitted to the regional office; and

(2) With respect to expenditures for medical assistance, may not be earlier than the first day on which the plan is in operation on a statewide basis.

(b) *Plan amendment.* (1) For a plan amendment that provides additional services to individuals eligible under the approved plan, increases the payment amounts for services already included in the plan, or makes additional groups eligible for services provided under the approved plan, the effective date is determined in accordance with paragraph (a) of this section.

(2) For a plan amendment that changes the State's payment method and standards, the rules of § 447.256 of this chapter apply.

(3) For other plan amendments, the effective date may be a date requested by the State if CMS approves it.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8845, Mar. 1, 1991]

§ 430.25 Waivers of State plan requirements.

(a) *Scope of section.* This section describes the purpose and effect of waivers, identifies the requirements that may be waived and the other regulations that apply to waivers, and sets forth the procedures that CMS follows in reviewing and taking action on waiver requests.

(b) *Purpose of waivers.* Waivers are intended to provide the flexibility needed to enable States to try new or different approaches to the efficient and cost-effective delivery of health care services, or to adapt their programs to the special needs of particular areas or groups of recipients. Waivers allow exceptions to State plan requirements and permit a State to implement innovative programs or activities on a time-limited basis, and subject to specific safeguards for the protection of recipients and the program. Detailed rules for waivers are set forth in subpart B of part 431, subpart A of part 440, and subpart G of part 441 of this chapter.

(c) *Effect of waivers.* (1) Waivers under section 1915(b) allow a State to take the following actions:

(i) Implement a primary care case-management system or a specialty physician system.

(ii) Designate a locality to act as central broker in assisting Medicaid recipients to choose among competing health care plans.

(iii) Share with recipients (through provision of additional services) cost-savings made possible through the recipients' use of more cost-effective medical care.

(iv) Limit recipients' choice of providers (except in emergency situations and with respect to family planning services) to providers that fully meet reimbursement, quality, and utilization standards, which are established under the State plan and are consistent with access, quality, and efficient and economical furnishing of care.

(2) A waiver under section 1915(c) of the Act allows a State to include as ''medical assistance'' under its plan home and community based services furnished to recipients who would otherwise need inpatient care that is furnished in a hospital, SNF, ICF, or ICF/

MR, and is reimbursable under the State plan.

(3) A waiver under section 1916 (a)(3) or (b)(3) of the Act allows a State to impose a deduction, cost-sharing or similar charge of up to twice the ''nominal charge'' established under the plan for outpatient services, if—

(i) The outpatient services are received in a hospital emergency room but are not emergency services; and

(ii) The State has shown that Medicaid recipients have actually available and accessible to them alternative services of nonemergency outpatient services.

(d) *Requirements that are waived.* In order to permit the activities described in paragraph (c) of this section, one or more of the title XIX requirements must be waived, in whole or in part.

(1) Under section 1915(b) of the Act, and subject to certain limitations, any of the State plan requirements of section 1902 of the Act may be waived to achieve one of the purposes specified in that section.

(2) Under section 1915(c) of the Act, the following requirements may be waived:

(i) Statewideness—section 1902(a)(1).

(ii) Comparability of services—section 1902(a)(10)(B).

(iii) Income and resource rules—section 1902(a)(10)(C)(i)(III).

(3) Under section 1916 of the Act, paragraphs (a)(3) and (b)(3) require that any cost-sharing imposed on recipients be nominal in amount, and provide an exception for nonemergency services furnished in a hospital emergency room if the conditions of paragraph (c)(3) of this section are met.

(e) *Submittal of waiver request.* The State Governor, the head of the Medicaid agency, or an authorized designee may submit the waiver request.

(f) *Review of waiver requests.* (1) This paragraph applies to initial waiver requests and to requests for renewal or amendment of a previously approved waiver.

(2) CMS regional and central office staff review waiver requests and submit a recommendation to the Administrator, who—

(i) Has the authority to approve or deny waiver requests; and

(ii) Does not deny a request without first consulting the Secretary.

(3) A waiver request is considered approved unless, within 90 days after the request is received by CMS, the Administrator denies the request, or the Administrator or the Regional Administrator sends the State a written request for additional information necessary to reach a final decision. If additional information is requested, a new 90-day period begins on the day the response to the additional information request is received by the addressee.

(g) *Basis for approval*—(1) *Waivers under section 1915 (b) and (c).* The Administrator approves waiver requests if the State's proposed program or activity meets the requirements of the Act and the regulations at §431.55 or subpart G of part 441 of this chapter.

(2) *Waivers under section 1916.* The Administrator approves a waiver under section 1916 of the Act if the State shows, to CMS's satisfaction, that the Medicaid recipients have available and accessible to them sources, other than a hospital emergency room, where they can obtain necessary nonemergency outpatient services.

(h) *Effective date and duration of waivers*—(1) *Effective date.* Waivers receive a prospective effective date determined, with State input, by the Administrator. The effective date is specified in the letter of approval to the State.

(2) *Duration of waivers*—(i) *Home and community-based services under section 1915(c).* The initial waiver is for a period of three years and may be renewed thereafter for periods of five years.

(ii) *Waivers under sections 1915(b) and 1916.* The initial waiver is for a period of two years and may be renewed for additional periods of up to two years as determined by the Administrator.

(3) *Renewal of waivers.* (i) A renewal request must be submitted at least 90 days (but not more than 120 days) before a currently approved waiver expires, to provide adequate time for CMS review.

(ii) If a renewal request for a section 1915(c) waiver proposes a change in services provided, eligible population, service area, or statutory sections

waived, the Administrator may consider it a new waiver, and approve it for a period of three years.

[56 FR 8846, Mar. 1, 1991]

Subpart C—Grants; Reviews and Audits; Withholding for Failure To Comply; Deferral and Disallowance of Claims; Reduction of Federal Medicaid Payments

§ 430.30 Grants procedures.

(a) *General provisions.* (1) Once CMS has approved a State plan, it makes quarterly grant awards to the State to cover the Federal share of expenditures for services, training, and administration.

(2) The amount of the quarterly grant is determined on the basis of information submitted by the State agency (in quarterly estimate and quarterly expenditure reports) and other pertinent documents.

(b) *Quarterly estimates.* The Medicaid agency must submit Form CMS–25 (Medicaid Program Budget Report; Quarterly Distribution of Funding Requirements) to the central office (with a copy to the regional office) 45 days before the beginning of each quarter.

(c) *Expenditure reports.* (1) The State must submit Form CMS–64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) to the central office (with a copy to the regional office) not later than 30 days after the end of each quarter.

(2) This report is the State's accounting of actual recorded expenditures. The disposition of Federal funds may not be reported on the basis of estimates.

(d) *Grant award*—(1) *Computation by CMS.* Regional office staff analyzes the State's estimates and sends a recommendation to the central office. Central office staff considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (d)(2) of this section, and computes the grant.

(2) *Content of award.* The grant award computation form shows the estimate of expenditures for the ensuring quarter, and the amounts by which that estimate is increased or decreased because of an underestimate or overestimate for prior quarters, or for any of the following reasons:

(i) Penalty reductions imposed by law.

(ii) Accounting adjustments.

(iii) Deferrals or disallowances.

(iv) Interest assessments.

(v) Mandated adjustments such as those required by section 1914 of the Act.

(3) *Effect of award.* The grant award authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements.

(4) *Drawing procedure.* The draw is through a commercial bank and the Federal Reserve system against a continuing letter of credit certified to the Secretary of the Treasury in favor of the State payee. (The letter of credit payment system was established in accordance with Treasury Department regulations—Circular No. 1075.)

(e) *General administrative requirements.* With the following exceptions, the provisions of 45 CFR part 74, which establish uniform administrative requirements and cost principles, apply to all grants made to States under this subpart:

45 CFR part 74
Subpart G—Matching and Cost Sharing
Subpart I—Financial Report Requirements

§ 430.32 Program reviews.

(a) *Review of State and local administration.* In order to determine whether the State is complying with the Federal requirements and the provisions of its plan, CMS reviews State and local administration through analysis of the State's policies and procedures, on-site review of selected aspects of agency operation, and examination of samples of individual case records.

(b) *Quality control program.* The State itself is required to carry out a continuing quality control program as set forth in part 431, subpart P, of this chapter.

(c) *Action on review findings.* If Federal or State reviews reveal serious problems with respect to compliance with any Federal requirement, the State must correct its practice accordingly.

§ 430.33 Audits.

(a) *Purpose.* The Department's Office of Inspector General (OIG) periodically audits State operations in order to determine whether—

(1) The program is being operated in a cost-efficient manner; and

(2) Funds are being properly expended for the purposes for which they were appropriated under Federal and State law and regulations.

(b) *Reports.* (1) The OIG releases audit reports simultaneously to State officials and the Department's program officials.

(2) The reports set forth OIG opinion and recommendations regarding the practices it reviewed, and the allowability of the costs it audited.

(3) Cognizant officials of the Department make final determinations on all audit findings.

(c) *Action on audit exceptions*—(1) *Concurrence or clearance.* The State agency has the opportunity of concurring in the exceptions or submitting additional facts that support clearance of the exceptions.

(2) *Appeal.* Any exceptions that are not disposed of under paragraph (c)(1) of this section are included in a disallowance letter that constitutes the Department's final decision unless the State requests reconsideration by the Appeals Board. (Specific rules are set forth in § 430.42.)

(3) *Adjustment.* If the decision by the Board requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8846, Mar. 1, 1991]

§ 430.35 Withholding of payment for failure to comply with Federal requirements.

(a) *Basis for withholding.* CMS withholds payments to the State, in whole or in part, only if, after giving the agency reasonable notice and opportunity for a hearing in accordance with subpart D of this part, the Administrator finds—

(1) That the plan no longer complies with the provisions of section 1902 of the Act; or

(2) That in the administration of the plan there is failure to comply substantially with any of those provisions.

(Hearings under subpart D are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions. These may be continued even if a date and place have been set for the hearing.)

(b) *Noncompliance of the plan.* A question of noncompliance of a State plan may arise from an unapprovable change in the approved State plan or the failure of the State to change its approved plan to conform to a new Federal requirement for approval of State plans.

(c) *Noncompliance in practice.* A question of noncompliance in practice may arise from the State's failure to actually comply with a Federal requirement, regardless of whether the plan itself complies with that requirement.

(d) *Notice and implementation of withholding.* If the Administrator makes a finding of noncompliance under paragraph (a) of this section, the following rules apply:

(1) The Administrator notifies the State:

(i) That no further payments will be made to the State (or that payments will be made only for those portions or aspects of the program that are not affected by the noncompliance); and

(ii) That the total or partial withholding will continue until the Administrator is satisfied that the State's plan and practice are, and will continue to be, in compliance with Federal requirements.

(2) CMS withholds payments, in whole or in part, until the Administrator is satisfied regarding the State's compliance.

§ 430.38 Judicial review.

(a) *Right to judicial review.* Any State dissatisfied with the Administrator's final determination on approvability of plan material (§ 430.18) or compliance with Federal requirements (§ 430.35) has a right to judicial review.

(b) *Petition for review.* (1) The State must file a petition for review with the U.S. Court of Appeals for the circuit in which the State is located, within 60

days after it is notified of the determination.

(2) The clerk of the court will file a copy of the petition with the Administrator and the Administrator will file in the court the record of the proceedings on which the determination was based.

(c) *Court action.* (1) The court is bound by the Administrator's findings of fact if they are supported by substantial evidence.

(2) The court has jurisdiction to affirm the Administrator's decision, to set it aside in whole or in part, or, for good cause, to remand the case for additional evidence.

(d) *Response to remand.* (1) If the court remands the case, the Administrator may make new or modified findings of fact and may modify his or her previous determination.

(2) The Administrator will certify to the court the transcript and record of the further proceedings.

(e) *Review by the Supreme Court.* The judgment of the appeals court is subject to review by the U.S. Supreme Court upon certiorari or certification, as provided in 28 U.S.C. 1254.

§ 430.40 Deferral of claims for FFP.

(a) *Requirements for deferral.* Payment of a claim or any portion of a claim for FFP is deferred only if—

(1) The Regional Administrator or the Administrator questions its allowability and needs additional information in order to resolve the question; and

(2) CMS takes action to defer the claim (by excluding the claimed amount from the grant award) within 60 days after the receipt of a Quarterly Statement of Expenditures (prepared in accordance with CMS instructions) that includes that claim.

(b) *Notice of deferral and State's responsibility.* (1) Within 15 days of the action described in paragraph (a)(2) of this section, the Regional Administrator sends the State a written notice of deferral that—

(i) Identifies the type and amount of the deferred claim and specifies the reason for deferral; and

(ii) Requests the State to make available all the documents and materials the regional office then believes are necessary to determine the allowability of the claim.

(2) It is the responsibility of the State to establish the allowability of a deferred claim.

(c) *Handling of documents and materials.* (1) Within 60 days (or within 120 days if the State requests an extension) after receipt of the notice of deferral, the State must make available to the regional office, in readily reviewable form, all requested documents and materials except any that it identifies as not being available.

(2) Regional office staff usually initiates review within 30 days after receipt of the documents and materials.

(3) If the Regional Administrator finds that the materials are not in readily reviewable form or that additional information is needed, he or she promptly notifies the State that it has 15 days to submit the readily reviewable or additional materials.

(4) If the State does not provide the necessary materials within 15 days, the Regional Administrator disallows the claim.

(5) The Regional Administrator has 90 days, after all documentation is available in readily reviewable form, to determine the allowability of the claim.

(6) If the Regional Administrator cannot complete review of the material within 90 days, CMS pays the claim, subject to a later determination of allowability.

(d) *Effect of decision to pay a deferred claim.* Payment of a deferred claim under paragraph (c)(6) of this section does not preclude a subsequent disallowance based on the results of an audit or financial review. (If there is a subsequent disallowance, the State may request reconsideration as provided in paragraph (e)(2) of this section.)

(e) *Notice and effect of decision on allowability.* (1) The Regional Administrator or the Administrator gives the State written notice of his or her decision to pay or disallow a deferred claim.

(2) If the decision is to disallow, the notice informs the State of its right to reconsideration in accordance with 45 CFR part 16.

§ 430.42 Disallowance of claims for FFP.

(a) *Notice of disallowance and of right to reconsideration.* When the Regional Administrator or the Administrator determines that a claim or portion of claim is not allowable, he or she promptly sends the State a disallowance letter that includes the following, as appropriate:

(1) The date or dates on which the State's claim for FFP was made.

(2) The time period during which the expenditures in question were made or claimed to have been made.

(3) The date and amount of any payment or notice of deferral.

(4) A statement of the amount of FFP claimed, allowed, and disallowed and the manner in which these amounts were computed.

(5) Findings of fact on which the disallowance determination is based or a reference to other documents previously furnished to the State or included with the notice (such as a report of a financial review or audit) which contain the findings of fact on which the disallowance determination is based.

(6) Pertinent citations to the law, regulations, guides and instructions supporting the action taken.

(7) A request that the State make appropriate adjustment in a subsequent expenditure report.

(8) Notice of the State's right to request reconsideration of the disallowance and the time allowed to make the request.

(9) A statement indicating that the disallowance letter is the Department's final decision unless the State requests reconsideration under paragraph (b)(2) of this section.

(b) *Reconsideration of FFP disallowance.* (1) The Departmental Appeals Board reviews disallowances of FFP under title XIX.

(2) A State that wishes to request reconsideration must submit the request to the Chair, Departmental Appeals Board, within 30 days after receipt of the disallowance letter, and include—

(i) A copy of the disallowance letter;

(ii) A statement of the amount in dispute; and

(iii) A brief statement of why the disallowance is wrong.

(c) *Reconsideration procedures.* The reconsideration procedures are those set forth in 45 CFR part 16 for Medicaid and for many other programs administered by the Department.

(d) *Implementation of decisions.* If the reconsideration decision requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

[53 FR 36571, Sept. 21, 1988, as amended at 56 FR 8846, Mar. 1, 1991]

§ 430.45 Reduction of Federal Medicaid payments.

(a) *Methods of reduction.* CMS may reduce Medicaid payments to a State as required under the Act by reducing—

(1) The Federal Medical Assistance Percentage;

(2) The amount of State expenditures subject to FFP;

(3) The rates of FFP; or

(4) The amount otherwise payable to the State.

(b) *Right to reconsideration.* A state that receives written final notice of a reduction under paragraph (a) of this section has a right to reconsideration. The provisions of § 430.42 (b) and (c) apply.

(c) *Other applicable rules.* Other rules regarding reduction of Medicaid payments are set forth in parts 433 and 447 of this chapter.

§ 430.48 Repayment of Federal funds by installments.

(a) *Basic conditions.* When Federal payments have been made for claims that are later found to be unallowable, the State may repay the Federal Funds by installments if the following conditions are met:

(1) The amount to be repaid exceeds 2½ percent of the estimated or actual annual State share for the Medicaid program; and

(2) The State has given the Regional Administrator written notice, before total repayment was due, of its intent to repay by installments.

(b) *Annual State share determination.* CMS determines whether the amount to be repaid exceeds 2½ percent of the annual State share as follows:

(1) If the Medicaid program is ongoing, CMS uses the annual *estimated*

State share of Medicaid expenditures. This is the sum of the estimated State shares for four consecutive quarters, beginning with the quarter in which the first installment is to be paid, as shown on the State's latest CMS–25 form.

(2) If the Medicaid program has been terminated by Federal law or by the State, CMS uses the *actual* State share. The actual State share is that shown on the State's Statement of Expenditures reports for the last four quarters before the program was terminated.

(c) *Repayment amounts, schedules, and procedures*—(1) *Repayment amount.* The repayment amount may not include any amount previously approved for installment repayment.

(2) *Repayment schedule.* The number of quarters allowed for repayment is determined on the basis of the ratio of the repayment amount to the annual State share of Medicaid expenditures. The higher the ratio of the total repayment amount is to the annual State share, the greater the number of quarters allowed, as follows:

Total repayment amount as percentage of State share of annual expenditures for Medicaid	Number of quarters to make repayment
2.5 pct. or less	1
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5	9
Greater than 47.5, but not greater than 65	10
Greater than 65, but not greater than 82.5	11
Greater than 82.5, but not greater than 100	12

(3) *Quarterly repayment amounts.* The quarterly repayment amounts for each of the quarters in the repayment schedule may not be less than the following percentages of the estimated State share of the annual expenditures for Medicaid:

For each of the following quarters	Repayment installment may not be less than these percentages
1 to 4	2.5
5 to 8	5.0
9 to 12	17.5

(4) *Extended schedule.* The repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount exceeds 100% of the estimated State share of annual expenditures. In these circumstances, paragraph (c)(2) of this section is followed for repayment of the amount equal to 100 percent of the annual State share. The remaining amount of the repayment is in quarterly amounts equal to not less than 17.5 percent of the estimated State share of annual expenditures.

(5) *Repayment process.* Repayment is accomplished through adjustment in the quarterly grants over the period covered by the repayment schedule.

If the State chooses to repay amounts representing higher percentages during the early quarters, any corresponding reduction in required minimum percentages is applied first to the last scheduled payment, then to the next to the last payment, and so forth as neccessary.

(6) *Offsetting of retroactive claims.* The amount of a retroactive claim to be paid a State will be offset against any amounts to be, or already being, repaid by the State in installments. Under this provision, the State may choose to:

(i) Suspend payments until the retroactive claim due the State has, in fact, been offset; or

(ii) Continue payments until the reduced amount of its debt (remaining after the offset), has been paid in full.

This second option would result in a shorter payment period.

A retroactive claim for the purpose of this regulation is a claim applicable to any period ending 12 months or more before the beginning of the quarter in which CMS would pay that claim.

Subpart D—Hearings on Conformity of State Medicaid Plans and Practice to Federal Requirements

§ 430.60 Scope.

(a) This subpart sets forth the rules for hearings to States that appeal a decision to disapprove State plan material (under § 430.18) or to withhold Federal funds (under § 430.35), because the

State plan or State practice in the Medicaid program is not in compliance with Federal requirements.

(b) Nothing in this subpart is intended to preclude or limit negotiations between CMS and the State, whether before, during, or after the hearing to resolve the issues that are, or otherwise would be, considered at the hearing. Such negotiations and resolution of issues are not part of the hearing, and are not governed by the rules in this subpart except as expressly provided.

§ 430.62 Records to be public.

All pleadings, correspondence, exhibits, transcripts of testimony, exceptions, briefs, decisions, and other documents filed in the docket in any proceeding may be inspected and copied in the office of the CMS Docket Clerk. Inquiries may be made to the Docket Clerk, Hearing Staff, Bureau of Eligibility, Reimbursment and Coverage, 300 East High Rise, 6325 Security Boulevard, Baltimore, Maryland, 21207. Telephone: (301) 594–8261.

§ 430.63 Filing and service of papers.

(a) *Filing.* All papers in the proceedings are filed with the CMS Docket Clerk, in an original and two copies. Originals only of exhibits and transcripts of testimony need be filed.

(b) *Service.* All papers in the proceedings are served on all parties by personal delivery or by mail. Service on the party's designated attorney is considered service upon the party.

§ 430.64 Suspension of rules.

Upon notice to all parties, the Administrator or the presiding officer may modify or waive any rule in this subpart upon determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

§ 430.66 Designation of presiding officer for hearing.

(a) The presiding officer at a hearing is the Administrator or his designee.

(b) The designation of the presiding officer is in writing. A copy of the designation is served on all parties.

§ 430.70 Notice of hearing or opportunity for hearing.

The Administrator mails the State a notice of hearing or opportunity for hearing that—

(a) Specifies the time and place for the hearing;

(b) Specifies the issues that will be considered;

(c) Identifies the presiding officer; and

(d) Is published in the FEDERAL REGISTER.

§ 430.72 Time and place of hearing.

(a) *Time.* The hearing is scheduled not less than 30 nor more than 60 days after the date of notice to the State. The scheduled date may be changed by written agreement between CMS and the State.

(b) *Place.* The hearing is conducted in the city in which the CMS regional office is located or in another place fixed by the presiding officer in light of the circumstances of the case, with due regard for the convenience and necessity of the parties or their representatives.

§ 430.74 Issues at hearing.

The list of issues specified in the notice of hearing may be augmented or reduced as provided in this section.

(a) *Additional issues.* (1) Before a hearing under § 430.35, the Administrator may send written notice to the State listing additional issues to be considered at the hearing. That notice is published in the FEDERAL REGISTER.

(2) If the notice of additional issues is furnished to the State less than 20 days before the scheduled hearing date, postponement is granted if requested by the State or any other party. The new date may be 20 days after the date of the notice, or a later date agreed to by the presiding officer.

(b) *New or modified issues.* If, as a result of negotiations between CMS and the State, the submittal of plan amendment, a change in the State program, or other actions by the State, any issue is resolved in whole or in part, but new or modified issues are presented, as specified by the presiding officer, the hearing proceeds on the new or modified issues.

(c) *Issues removed from consideration*—(1) *Basis for removal.* If at any time before, during, or after the hearing, the presiding officer finds that the State has come into compliance with Federal requirements on any issue or part of an issue, he or she removes the appropriate issue or part of an issue from consideration. If all issues are removed, the hearing is terminated.

(2) *Notice to parties.* Before removing any issue or part of an issue from consideration, the presiding officer provides all parties other than CMS and the State with—

(i) A statement of the intent to remove and the reasons for removal; and

(ii) A copy of the proposed State plan provision on which CMS and the State have agreed.

(3) *Opportunity for written comment.* The notified parties have 15 days to submit, for consideration by the presiding officer, and for the record, their views as to, or any information bearing upon, the merits of the proposed plan provision and the merits of the reasons for removing the issue from consideration.

(d) *Remaining issues.* The issues considered at the hearing are limited to those issues of which the State is notified as provided in §430.70 and paragraph (a) of this section, and new or modified issues described in paragraph (b) of this section. They do not include issues or parts of issues removed in accordance with paragraph (c) of this section.

§ 430.76 Parties to the hearing.

(a) *CMS and the State.* CMS and the State are parties to the hearing.

(b) *Other individuals*—(1) *Basis for participation.* Other individuals or groups may be recognized as parties if the issues to be considered at the hearing have caused them injury and their interest is within the zone of interests to be protected by the governing Federal statute.

(2) *Petition for participation.* Any individual or group wishing to participate as a party must, within 15 days after notice of hearing is published in the FEDERAL REGISTER, file with the CMS Docket Clerk, a petition that concisely states—

(i) Petitioner's interest in the proceeding;

(ii) Who will appear for petitioner;

(iii) The issues on which petitioner wishes to participate; and

(iv) Whether petitioner intends to present witnesses.

The petitioner must also serve a copy of the petition on each party of record at that time.

(3) *Comments on petition.* Any party may, within 5 days of receipt of the copy of the petition, file comments on it.

(4) *Action on petition.* (i) The presiding officer promptly determines whether each petitioner has the requisite interest in the proceedings and approves or denies participation accordingly.

(ii) If petitions are made by more than one individual or group with common interests, the presiding officer may—

(A) Request all those petitioners to designate a single representative; or

(B) Recognize one or more of those petitioners to represent all of them.

(iii) The presiding officer gives each petitioner written notice of the decision and, if the decision is to deny, briefly states the grounds for denial.

(c) *Amicus curiae (friend of the court)*—(1) *Petition for participation.* Any person or organization that wishes to participate as amicus curiae must, before the hearing begins, file with the CMS Docket Clerk, a petition that concisely states—

(i) The petitioners' interest in the hearing;

(ii) Who will represent the petitioner; and

(iii) The issues on which the petitioner intends to present argument.

(2) *Action on amicus curiae petition.* The presiding officer may grant the petition if he or she finds that the petitioner has a legitimate interest in the proceedings, that such participation will not unduly delay the outcome and may contribute materially to the proper disposition of the issues.

(3) *Nature of amicus participation.* An amicus curiae is not a party to the hearing but may participate by—

(i) Submitting a written statement of position to the presiding officer before the beginning of the hearing;

(ii) Presenting a brief oral statement at the hearing, at the point in the proceedings specified by the presiding officer; and

(iii) Submitting a brief or written statement when the parties submit briefs.

The amicus curiae must serve copies of any briefs or written statements on all parties.

§ 430.80 Authority of the presiding officer.

(a) The presiding officer has the duty to conduct a fair hearing, to avoid delay, maintain order, and make a record of the proceedings. He or she has the authority necessary to accomplish those ends, including but not limited to authority to take the following actions:

(1) Change the date, time, and place of the hearing after due notice to the parties. This includes authority to postpone or adjourn the hearing in whole or in part. In a hearing on disapproval of a State plan, or State plan amendments, changes in the date of the hearing are subject to the time limits imposed by section 1116(a)(2) of the Act.

(2) Hold conferences to settle or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the issues.

(3) Regulate participation of parties and amici curiae and require parties and amici curiae to state their position with respect to the various issues in the proceeding.

(4) Administer oaths and affirmations.

(5) Rule on motions and other procedural items, including issuance of protective orders or other relief to a party against whom discovery is sought.

(6) Regulate the course of the hearing and conduct of counsel.

(7) Examine witnesses.

(8) Receive, rule on, exclude or limit evidence or discovery.

(9) Fix the time for filing motions, petitions, briefs, or other items.

(10) If the presiding officer is the Administrator, make a final decision.

(11) If the presiding officer is a designee of the Administrator, certify the entire record including recommended findings and proposed decision to the Administrator.

(12) Take any action authorized by the rules in this subpart or in conformance with the provisions of 5 U.S.C. 551 through 559.

(b) The presiding officer does not have authority to compel by subpoena the production of witnesses, papers, or other evidence.

(c) If the presiding officer is a designee of the Administrator, his or her authority pertains to the issues of compliance by a State with Federal requirements, and does not extend to the question of whether, in case of any noncompliance, Federal payments will be denied in respect to the entire State plan or only for certain categories under, or parts of, the State plan affected by the noncompliance.

§ 430.83 Rights of parties.

All parties may:

(a) Appear by counsel or other authorized representative, in all hearing proceedings.

(b) Participate in any prehearing conference held by the presiding officer.

(c) Agree to stipulations as to facts which will be made a part of the record.

(d) Make opening statements at the hearing.

(e) Present relevant evidence on the issues at the hearing.

(f) Present witnesses who then must be available for cross-examination by all other parties.

(g) Present oral arguments at the hearing.

(h) Submit written briefs, proposed findings of fact, and proposed conclusions of law, after the hearing.

§ 430.86 Discovery.

CMS and any party named in the notice issued under § 430.70 has the right to conduct discovery (including depositions) against opposing parties. Rules 26–37 of the Federal Rules of Civil Procedures apply to such proceedings; there will be no fixed rule on priority of discovery. Upon written motion, the presiding officer promptly rules upon any objection to discovery action initiated under this section. The presiding officer also has the power to grant a

protective order or relief to any party against whom discovery is sought and to restrict or control discovery so as to prevent undue delay in the conduct of the hearing. Upon the failure of any party to make discovery, the presiding officer may issue any order and impose any sanction (other than contempt orders) authorized by Rule 37 of the Federal Rules of Civil Procedure.

§ 430.88 Evidence.

(a) *Evidentiary purpose.* The hearing is directed to receiving factual evidence and expert opinion testimony related to the issues involved in the proceeding. Argument is not received in evidence. It must be presented in statements, memoranda, or briefs, as determined by the presiding officer. Brief opening statements, concerning the party's position and what he or she intends to prove, may be made at hearings.

(b) *Testimony.* Testimony is given orally under oath or affirmation by witnesses at the hearing. Witnesses are available at the hearing for cross-examination by all parties.

(c) *Stipulations and exhibits.* Two or more parties may agree to stipulations of fact. Those stipulations, and any exhibit proposed by any party, are exchanged before the hearing if the presiding officer so requires.

(d) *Rules of evidence.* (1) Technical rules of evidence do not apply to hearings conducted under this subpart. However, rules or principles designed to ensure production of the most credible evidence available and to subject testimony to test by cross-examination are applied by the presiding officer when reasonably necessary.

(2) A witness may be cross-examined on any matter material to the proceeding without regard to the scope of his or her direct examination.

(3) The presiding officer may exclude irrelevant, immaterial, or unduly repetitious evidence.

(4) All documents and other evidence offered or taken for the record are open to examination by the parties and an opportunity is given to refute facts and arguments advanced on either side of the issues.

§ 430.90 Exclusion from hearing for misconduct.

The presiding officer may immediately exclude from the hearing any person who—

(a) Uses disrespectful, disorderly, or contumacious language or engages in contemptuous behavior;

(b) Refuses to comply with directions; or

(c) Uses dilatory tactics.

§ 430.92 Unsponsored written material.

Letters expressing views or urging action and other unsponsored written material regarding matters in issue in a hearing are placed in the correspondence section of the docket of the proceeding. These data are not considered part of the evidence or record in the hearing.

§ 430.94 Official transcript.

(a) *Filing.* The official transcripts of testimony, together with any stipulations, briefs, or memoranda of law, are filed with CMS.

(b) *Availability of transcripts.* CMS designates an official reporter for each hearing. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not in excess of the maximum rates fixed by the contract between CMS and the reporter.

(c) *Correction of transcript.* Upon notice to all parties, the presiding officer may authorize corrections that affect substantive matters in the transcript.

§ 430.96 Record for decision.

The transcript of testimony, exhibits, and all papers and requests filed in the proceedings, except the correspondence section of the docket, including rulings and any recommended or initial decision constitute the exclusive record for decision.

§ 430.100 Posthearing briefs.

The presiding officer fixes the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law. The presiding officer may also permit reply briefs.

§ 430.102 Decisions following hearing.

(a) *Administrator presides.* If the presiding officer is the Administrator, he or she issues the hearing decision within 60 days after expiration of the period for submission of posthearing briefs.

(b) *Administrator's designee presides.* If the presiding officer is other than the Administrator, the procedure is as follows:

(1) Upon expiration of the period allowed for submission of posthearing briefs, the presiding officer certifies the entire record, including his or her recommended findings and proposed decision, to the Administrator. The Administrator serves a copy of the recommended findings and proposed decision upon all parties and amici, if any.

(2) Any party may, within 20 days, file with the Administrator exceptions to the recommended findings and proposed decision and a supporting brief or statement.

(3) The Administrator reviews the recommended decision and, within 60 days of its issuance, issues his or her own decision.

(c) *Effect of Administrator's decision.* The decision of the Administrator under this section is the final decision of the Secretary and constitutes ''final agency action'' within the meaning of 5 U.S.C. 704 and a ''final determination'' within the meaning of section 1116(a)(3) of the Act and § 430.38. The Administrator's decision is promptly served on all parties and amici.

§ 430.104 Decisions that affect FFP.

(a) *Scope of decisions.* If the Administrator concludes that withholding of FFP is necessary because a State is out of compliance with Federal requirements, in accordance with § 430.35, the decision also specifies—

(1) Whether no further payments will be made to the State or whether payments will be limited to parts of the program not affected by the noncompliance; and

(2) The effective date of the decision to withhold.

(b) *Consultation.* The Administrator may ask the parties for recommendations or briefs or may hold conferences of the parties on the question of further payments to the State.

(c) *Effective date of decision.* The effective date of a decision to withhold Federal funds will not be earlier than the date of the Administrator's decision and will not be later than the first day of the next calendar quarter. The provisions of this section may not be waived under § 430.64.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

Sec.

431.1 Purpose.

Subpart A—Single State Agency

431.10 Single State agency.
431.11 Organization for administration.
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431.15 Methods of administration.
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AUTHORITY: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

SOURCE: 43 FR 45188, Sept. 29, 1978, unless otherwise noted.

§ 431.1 Purpose.

This part establishes State plan requirements for the designation, organization, and general administrative activities of a State agency responsible for operating the State Medicaid program, directly or through supervision of local administering agencies.

Subpart A—Single State Agency

§ 431.10 Single State agency.

(a) *Basis and purpose.* This section implements section 1902(a)(5) of the Act, which provides for designation of a single State agency for the Medicaid program.

(b) *Designation and certification.* A State plan must—

(1) Specify a single State agency established or designated to administer or supervise the administration of the plan; and

(2) Include a certification by the State Attorney General, citing the legal authority for the single State agency to—

(i) Administer or supervise the administration of the plan; and

(ii) Make rules and regulations that it follows in administering the plan or that are binding upon local agencies that administer the plan.

(c) *Determination of eligibility.* (1) The plan must specify whether the agency that determines eligibility for families and for individuals under 21 is—

(i) The Medicaid agency; or

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia), or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands.

(2) The plan must specify whether the agency that determines eligibility for the aged, blind, or disabled is—

(i) The Medicaid agency;

(ii) The single State agency for the financial assistance program under title IV-A (in the 50 States or the District of Columbia) or under title I or XVI (AABD), in Guam, Puerto Rico, or the Virgin Islands; or

(iii) The Federal agency administering the supplemental security income program under title XVI (SSI). In this case, the plan must also specify whether the Medicaid agency or the title IV-A agency determines eligibility for any groups whose eligibility is not determined by the Federal agency.

(d) *Agreement with Federal or State agencies.* The plan must provide for written agreements between the Medicaid agency and the Federal or other State agencies that determine eligibility for Medicaid, stating the relationships and respective responsibilities of the agencies.

(e) *Authority of the single State agency.* In order for an agency to qualify as the Medicaid agency—

(1) The agency must not delegate, to other than its own officials, authority to—

(i) Exercise administrative discretion in the administration or supervision of the plan, or

(ii) Issue policies, rules, and regulations on program matters.

(2) The authority of the agency must not be impaired if any of its rules, regulations, or decisions are subject to review, clearance, or similar action by other offices or agencies of the State.

(3) If other State or local agencies or offices perform services for the Medicaid agency, they must not have the authority to change or disapprove any administrative decision of that agency, or otherwise substitute their judgment for that of the Medicaid agency with respect to the application of policies, rules, and regulations issued by the Medicaid agency.

[44 FR 17930, Mar. 23, 1979]

§ 431.11 Organization for administration.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes the general organization and staffing requirements for the Medicaid agency and the State plan.

(b) *Medical assistance unit.* A State plan must provide for a medical assistance unit within the Medicaid agency, staffed with a program director and other appropriate personnel who participate in the development, analysis, and evaluation of the Medicaid program.

(c) *Description of organization.* (1) The plan must include—

(i) A description of the organization and functions of the Medicaid agency and an organization chart;

(ii) A description of the organization and functions of the medical assistance unit and an organization chart; and

(iii) A description of the kinds and number of professional medical personnel and supporting staff used in the administration of the plan and their responsibilities.

(d) *Eligibility determined by other agencies.* If eligibility is determined by State agencies other than the Medicaid agency or by local agencies under the supervision of other State agencies, the plan must include a description of the staff designated by those other agencies and the functions they perform in carrying out their responsibility.

[44 FR 17931, Mar. 23, 1979]

§ 431.12 Medical care advisory committee.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for establishment of a committee to advise the Medicaid agency about health and medical care services.

(b) *State plan requirement.* A State plan must provide for a medical care advisory committee meeting the requirements of this section to advise the Medicaid agency director about health and medical care services.

(c) *Appointment of members.* The agency director, or a higher State authority, must appoint members to the advisory committee on a rotating and continuous basis.

(d) *Committee membership.* The committee must include—

(1) Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care;

(2) Members of consumers' groups, including Medicaid recipients, and consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and

(3) The director of the public welfare department or the public health department, whichever does not head the Medicaid agency.

(e) *Committee participation.* The committee must have opportunity for participation in policy development and program administration, including furthering the participation of recipient members in the agency program.

(f) *Committee staff assistance and financial help.* The agency must provide the committee with—

(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and

(2) Financial arrangements, if necessary, to make possible the participation of recipient members.

(g) *Federal financial participation.* FFP is available at 50 percent in expenditures for the committee's activities.

§ 431.15 Methods of administration.

A State plan must provide for methods of administration that are found by the Secretary to be necessary for the proper and efficient operation of the plan.

(Sec. 1902(a)(4) of the Act)

[44 FR 17931, Mar. 23, 1979]

§ 431.16 Reports.

A State plan must provide that the Medicaid agency will—

(a) Submit all reports required by the Secretary;

(b) Follow the Secretary's instructions with regard to the form and content of those reports; and

(c) Comply with any provisions that the Secretary finds necessary to verify and assure the correctness of the reports.

[44 FR 17931, Mar. 23, 1979]

§ 431.17 Maintenance of records.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes the kinds of records a Medicaid agency must maintain, the retention period, and the conditions under which microfilm copies may be substituted for original records.

(b) *Content of records.* A State plan must provide that the Medicaid agency will maintain or supervise the maintenance of the records necessary for the proper and efficient operation of the plan. The records must include—

(1) Individual records on each applicant and recipient that contain information on—

(i) Date of application;

(ii) Date of and basis for disposition;

(iii) Facts essential to determination of initial and continuing eligibility;

(iv) Provision of medical assistance;

(v) Basis for discontinuing assistance;

(vi) The disposition of income and eligibility verification information received under §§ 435.940 through 435.960 of this subchapter; and

(2) Statistical, fiscal, and other records necessary for reporting and accountability as required by the Secretary.

(c) *Retention of records.* The plan must provide that the records required under paragraph (b) of this section will be retained for the periods required by the Secretary.

(d) *Conditions for optional use of microfilm copies.* The agency may substitute certified microfilm copies for the originals of substantiating documents required for Federal audit and review, if the conditions in paragraphs (d)(1) through (4) of this section are met.

(1) The agency must make a study of its record storage and must show that the use of microfilm is efficient and economical.

(2) The microfilm system must not hinder the agency's supervision and control of the Medicaid program.

(3) The microfilm system must—

(i) Enable the State to audit the propriety of expenditures for which FFP is claimed; and

(ii) Enable the HHS Audit Agency and CMS to properly discharge their respective responsibilities for reviewing the manner in which the Medicaid program is being administered.

(4) The agency must obtain approval from the CMS regional office indicating—

(i) The system meets the conditions of paragraphs (d)(2) and (3) of this section; and

(ii) The microfilming procedures are reliable and are supported by an adequate retrieval system.

[44 FR 17931, Mar. 23, 1979, as amended at 51 FR 7210, Feb. 28, 1986]

§ 431.18 Availability of agency program manuals.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes State plan requirements for facilitating access to Medicaid rules and policies by individuals outside the State Medicaid agency.

(b) *State plan requirements.* A State plan must provide that the Medicaid agency meets the requirements of paragraphs (c) through (g) of this section.

(c) *Availability in agency offices.* (1) The agency must maintain, in all its offices, copies of its current rules and

policies that affect the public, including those that govern eligibility, provision of medical assistance, covered services, and recipient rights and responsibilities.

(2) These documents must be available upon request for review, study, and reproduction by individuals during regular working hours of the agency.

(d) *Availability through other entities.* The agency must provide copies of its current rules and policies to—

(1) Public and university libraries;

(2) The local or district offices of the Bureau of Indian Affairs;

(3) Welfare and legal services offices; and

(4) Other entities that—

(i) Request the material in order to make it accessible to the public;

(ii) Are centrally located and accessible to a substantial number of the recipient population they serve; and

(iii) Agree to accept responsibility for filing all amendments or changes forwarded by the agency.

(e) *Availability in relation to fair hearings.* The agency must make available to an applicant or recipient, or his representative, a copy of the specific policy materials necessary—

(1) To determine whether to request a fair hearing; or

(2) To prepare for a fair hearing.

(f) *Availability for other purposes.* The agency must establish rules for making program policy materials available to individuals who request them for other purposes.

(g) *Charges for reproduction.* The agency must make copies of its program policy materials available without charge or at a charge related to the cost of reproduction.

[44 FR 17931, Mar. 23, 1979]

§ 431.20 Advance directives.

(a) *Basis and purpose.* This section, based on section 1902(a) (57) and (58) of the Act, prescribes State plan requirements for the development and distribution of a written description of State law concerning advance directives.

(b) A State Plan must provide that the State, acting through a State agency, association, or other private nonprofit entity, develop a written description of the State law (whether statutory or as recognized by the courts of the State) concerning advance directives, as defined in § 489.100 of this chapter, to be distributed by Medicaid providers and health maintenance organizations (as specified in section 1903(m)(1)(A) of the Act) in accordance with the requirements under part 489, subpart I of this chapter. Revisions to the written descriptions as a result of changes in State law must be incorporated in such descriptions and distributed as soon as possible, but no later than 60 days from the effective date of the change in State law, to Medicaid providers and health maintenance organizations.

[57 FR 8202, Mar. 6, 1992, as amended at 60 FR 33293, June 27, 1995]

Subpart B—General Administrative Requirements

SOURCE: 56 FR 8847, Mar. 1, 1991, unless otherwise noted.

§ 431.40 Basis and scope.

(a) This subpart sets forth State plan requirements and exceptions that pertain to the following administrative requirements and provisions of the Act:

(1) Statewideness—section 1902(a)(1);

(2) Proper and efficient administration—section 1902(a)(4);

(3) Comparability of services—section 1902(a)(10) (B)–(E);

(4) Payment for services furnished outside the State—section 1902(a)(16);

(5) Free choice of providers—section 1902(a)(23);

(6) Special waiver provisions applicable to American Samoa and the Northern Mariana Islands—section 1902(j); and

(7) Exceptions to, and waiver of, State plan requirements—sections 1915 (a)–(c) and 1916 (a)(3) and (b)(3).

(b) Other applicable regulations include the following:

(1) Section 430.25 Waivers of State plan requirements.

(2) Section 440.250 Limits on comparability of services.

§ 431.50 Statewide operation.

(a) *Statutory basis.* Section 1902(a)(1) of the Act requires a State plan to be

in effect throughout the State, and section 1915 permits certain exceptions.

(b) *State plan requirements.* A State plan must provide that the following requirements are met:

(1) The plan will be in operation statewide through a system of local offices, under equitable standards for assistance and administration that are mandatory throughout the State.

(2) If administered by political subdivisions of the State, the plan will be mandatory on those subdivisions.

(3) The agency will ensure that the plan is continuously in operation in all local offices or agencies through—

(i) Methods for informing staff of State policies, standards, procedures, and instructions;

(ii) Systematic planned examination and evaluation of operations in local offices by regularly assigned State staff who make regular visits; and

(iii) Reports, controls, or other methods.

(c) *Exceptions.* (1) ''Statewide operation'' does not mean, for example, that every source of service must furnish the service State-wide. The requirement does not preclude the agency from contracting with a comprehensive health care organization (such as an HMO or a rural health clinic) that serves a specific area of the State, to furnish services to Medicaid recipients who live in that area and chose to receive services from that HMO or rural health clinic. Recipients who live in other parts of the State may receive their services from other sources.

(2) Other allowable exceptions and waivers are set forth in §§ 431.54 and 431.55.

[56 FR 8847, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§ 431.51 Free choice of providers.

(a) *Statutory basis.* This section is based on sections 1902(a)(23), 1902(e)(2), and 1915(a) and (b) and 1932(a)(3) of the Act.

(1) Section 1902(a)(23) of the Act provides that recipients may obtain services from any qualified Medicaid provider that undertakes to provide the services to them.

(2) Section 1915(a) of the Act provides that a State shall not be found out of compliance with section 1902(a)(23) solely because it imposes certain specified allowable restrictions on freedom of choice.

(3) Section 1915(b) of the Act authorizes waiver of the section 1902(a)(23) freedom of choice of providers requirement in certain specified circumstances, but not with respect to providers of family planning services.

(4) Section 1902(a)(23) of the Act provides that a recipient enrolled in a primary care case management system or Medicaid managed care organization (MCO) may not be denied freedom of choice of qualified providers of family planning services.

(5) Section 1902(e)(2) of the Act provides that an enrollee who, while completing a minimum enrollment period, is deemed eligible only for services furnished by or through the MCO or PCCM, may, as an exception to the deemed limitation, seek family planning services from any qualified provider.

(6) Section 1932(a) of the Act permits a State to restrict the freedom of choice required by section 1902(a)(23), under specified circumstances, for all services except family planning services.

(b) *State plan requirements.* A State plan, except the plan for Puerto Rico, the Virgin Islands, or Guam, must provide as follows:

(1) Except as provided under paragraph (c) of this section and part 438 of this chapter, a recipient may obtain Medicaid services from any institution, agency, pharmacy, person, or organization that is—

(i) Qualified to furnish the services; and

(ii) Willing to furnish them to that particular recipient.

This includes an organization that furnishes, or arranges for the furnishing of, Medicaid services on a prepayment basis.

(2) A recipient enrolled in a primary care case-management system, a Medicaid MCO, or other similar entity will not be restricted in freedom of choice of providers of family planning services.

(c) *Exceptions.* Paragraph (b) of this section does not prohibit the agency from—

(1) Establishing the fees it will pay providers for Medicaid services;

(2) Setting reasonable standards relating to the qualifications of providers: or

(3) Subject to paragraph (b)(2) of this section, restricting recipients' free choice of providers in accordance with one or more of the exceptions set forth in § 431.54, or under a waiver as provided in § 431.55.

(d) *Certification requirement*—(1) *Content of certification.* If a State implements a project under one of the exceptions allowed under § 431.54 (d), (e) or (f), it must certify to CMS that the statutory safeguards and requirements for an exception under section 1915(a) of the Act are met.

(2) *Timing of certification.* (i) For an exception under § 431.54(d), the State may not institute the project until after it has submitted the certification and CMS has made the findings required under the Act, and so notified the State.

(ii) For exceptions under § 431.54 (e) or (f), the State must submit the certificate by the end of the quarter in which it implements the project.

[56 FR 8847, Mar. 1, 1991, as amended at 67 FR 41094, June 14, 2002]

§ 431.52 Payments for services furnished out of State.

(a) *Statutory basis.* Section 1902(a)(16) of the Act authorizes the Secretary to prescribe State plan requirements for furnishing Medicaid to State residents who are absent from the State.

(b) *Payment for services.* A State plan must provide that the State will pay for services furnished in another State to the same extent that it would pay for services furnished within its boundaries if the services are furnished to a recipient who is a resident of the State, and any of the following conditions is met:

(1) Medical services are needed because of a medical emergency;

(2) Medical services are needed and the recipient's health would be endangered if he were required to travel to his State of residence;

(3) The State determines, on the basis of medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other State;

(4) It is general practice for recipients in a particular locality to use medical resources in another State.

(c) *Cooperation among States.* The plan must provide that the State will establish procedures to facilitate the furnishing of medical services to individuals who are present in the State and are eligible for Medicaid under another State's plan.

§ 431.53 Assurance of transportation.

A State plan must—

(a) Specify that the Medicaid agency will ensure necessary transportation for recipients to and from providers; and

(b) Describe the methods that the agency will use to meet this requirement.

(Sec. 1902(a)(4) of the Act)

§ 431.54 Exceptions to certain State plan requirements.

(a) *Statutory basis.* Section 1915(a) of the Act provides that a State shall not be deemed to be out of compliance with the requirements of sections 1902(a) (1), (10), or (23) of the Act solely because it has elected any of the exceptions set forth in paragraphs (b) and (d) through (f) of this section.

(b) *Additional services under a prepayment system.* If the Medicaid agency contracts on a prepayment basis with an organization that provides services additional to those offered under the State plan, the agency may restrict the provision of the additional services to recipients who live in the area served by the organization and wish to obtain services from it.

(c) [Reserved]

(d) *Special procedures for purchase of medical devices and laboratory and X-ray tests.* The Medicaid agency may establish special procedures for the purchase of medical devices or laboratory and X-ray tests (as defined in § 440.30 of this chapter) through a competitive bidding process or otherwise, if the State assures, in the certification required under § 431.51(d), and CMS finds, as follows:

(1) Adequate services or devices are available to recipients under the special procedures.

(2) Laboratory services are furnished through laboratories that meet the following requirements:

(i) They are independent laboratories, or inpatient or outpatient hospital laboratories that provide services for individuals who are not hospital patients, or physician laboratories that process at least 100 specimens for other physicians during any calendar year.

(ii) They meet the requirements of subpart M of part 405 or part 482 of this chapter.

(iii) Laboratories that require an interstate license under 42 CFR part 74 are licensed by CMS or receive an exemption from the licensing requirement by the College of American Pathologists. (Hospital and physician laboratories may participate in competitive bidding only with regard to services to non-hospital patients and other physicians' patients, respectively.)

(3) Any laboratory from which a State purchases services under this section has no more than 75 percent of its charges based on services to Medicare beneficiaries and Medicaid recipients.

(e) *Lock-in of recipients who over-utilize Medicaid services.* If a Medicaid agency finds that a recipient has utilized Medicaid services at a frequency or amount that is not medically necessary, as determined in accordance with utilization guidelines established by the State, the agency may restrict that recipient for a reasonable period of time to obtain Medicaid services from designated providers only. The agency may impose these restrictions only if the following conditions are met:

(1) The agency gives the recipient notice and opportunity for a hearing (in accordance with procedures established by the agency) before imposing the restrictions.

(2) The agency ensures that the recipient has reasonable access (taking into account geographic location and reasonable travel time) to Medicaid services of adequate quality.

(3) The restrictions do not apply to emergency services furnished to the recipient.

(f) *Lock-out of providers.* If a Medicaid agency finds that a Medicaid provider has abused the Medicaid program, the agency may restrict the provider, through suspension or otherwise, from participating in the program for a reasonable period of time.

Before imposing any restriction, the agency must meet the following conditions:

(1) Give the provider notice and opportunity for a hearing, in accordance with procedures established by the agency.

(2) Find that in a significant number or proportion of cases, the provider has:

(i) Furnished Medicaid services at a frequency or amount not medically necessary, as determined in accordance with utilization guidelines established by the agency; or

(ii) Furnished Medicaid services of a quality that does not meet professionally recognized standards of health care.

(3) Notify CMS and the general public of the restriction and its duration.

(4) Ensure that the restrictions do not result in denying recipients reasonable access (taking into account geographic location: and reasonable travel time) to Medicaid services of adequate quality, including emergency services.

§ 431.55 Waiver of other Medicaid requirements.

(a) *Statutory basis.* Section 1915(b) of the Act authorizes the Secretary to waive most requirements of section 1902 of the Act to the extent he or she finds proposed improvements or specified practices in the provision of services under Medicaid to be cost effective, efficient, and consistent with the objectives of the Medicaid program. Sections 1915 (f) and (h) prescribe how such waivers are to be approved, continued, monitored, and terminated. Section 1902(p)(2) of the Act conditions FFP in payments to an entity under a section 1915(b)(1) waiver on the State's provision for exclusion of certain entities from participation.

(b) *General requirements.* (1) General requirements for submittal of waiver requests, and the procedures that CMS follows for review and action on those requests are set forth in § 430.25 of this chapter.

(2) In applying for a waiver to implement an approvable project under paragraph (c), (d), (e), or (f) of this section, a Medicaid agency must document in the waiver request and maintain data regarding:

(i) The cost-effectiveness of the project;

(ii) The effect of the project on the accessibility and quality of services;

(iii) The anticipated impact of the project on the State's Medicaid program and;

(iv) Assurances that the restrictions on free choice of providers do not apply to family planning services.

(3) No waiver under this section may be granted for a period longer than 2 years, unless the agency requests a continuation of the waiver.

(4) CMS monitors the implementation of waivers granted under this section to ensure that requirements for such waivers are being met.

(i) If monitoring demonstrates that the agency is not in compliance with the requirements for a waiver under this section, CMS gives the agency notice and opportunity for a hearing.

(ii) If, after a hearing, CMS finds an agency to be out of compliance with the requirements of a waiver, CMS terminates the waiver and gives the agency a specified date by which it must demonstrate that it meets the applicable requirements of section 1902 of the Act.

(5) The requirements of section 1902(s) of the Act, with regard to adjustments in payments for inpatient hospital services furnished to infants who have not attained age 1 and to children who have not attained age 6 and who receive these services in disproportionate share hospitals, may not be waived under a section 1915(b) waiver.

(c) *Case-management system.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to implement a primary care case-management system or specialty physician services system.

(i) Under a primary care case-management system the agency assures that a specific person or persons or agency will be responsible for locating, coordinating, and monitoring all primary care or primary care and other medical care and rehabilitative services on behalf of a recipient. The person or agency must comply with the requirements set forth in part 438 of this chapter for primary care case management contracts and systems.

(ii) A specialty physician services system allows States to restrict recipients of specialty services to designated providers of such services, even in the absence of a primary care case-management system.

(2) A waiver under this paragraph (c) may not be approved unless the State's request assures that the restrictions—

(i) Do not apply in emergency situations; and

(ii) Do not substantially impair access to medically necessary services of adequate quality.

(d) *Locality as central broker.* Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to allow a locality to act as a central broker to assist recipients in selecting among competing health care plans. States must ensure that access to medically necessary services of adequate quality is not substantially impaired.

(1) A locality is any defined jurisdiction, e.g., district, town, city, borough, county, parish, or State.

(2) A locality may use any agency or agent, public or private, profit or nonprofit, to act on its behalf in carrying out its central broker function.

(e) *Sharing of cost savings.* (1) Waivers of appropriate requirements of section 1902 of the Act may be authorized for a State to share with recipients the cost savings resulting from the recipients' use of more cost-effective medical care.

(2) Sharing is through the provision of additional services, including—

(i) Services furnished by a plan selected by the recipient; and

(ii) Services expressly offered by the State as an inducement for recipients to participate in a primary care case-management system, a competing health care plan or other system that furnishes health care services in a more cost-effective manner.

(f) *Restriction of freedom of choice*—(1) Waiver of appropriate requirements of section 1902 of the Act may be authorized for States to restrict recipients to obtaining services from (or through)

qualified providers or practitioners that meet, accept, and comply with the State reimbursement, quality and utilization standards specified in the State's waiver request.

(2) An agency may qualify for a waiver under this paragraph (f) only if its applicable State standards are consistent with access, quality and efficient and economic provision of covered care and services and the restrictions it imposes—

(i) Do not apply to recipients residing at a long-term care facility when a restriction is imposed unless the State arranges for reasonable and adequate recipient transfer.

(ii) Do not discriminate among classes of providers on grounds unrelated to their demonstrated effectiveness and efficiency in providing those services; and

(iii) Do not apply in emergency circumstances.

(3) Demonstrated effectiveness and efficiency refers to reducing costs or slowing the rate of cost increase and maximizing outputs or outcomes per unit of cost.

(4) The agency must make payments to providers furnishing services under a freedom of choice waiver under this paragraph (f) in accordance with the timely claims payment standards specified in §447.45 of this chapter for health care practitioners participating in the Medicaid program.

(g) [Reserved]

(h) *Waivers approved under section 1915(b)(1) of the Act*—(1) *Basic rules.* (i) An agency must submit, as part of it's waiver request, assurance that the entities described in paragraph (h)(2) of this section will be excluded from participation under an approved waiver.

(ii) FFP is available in payments to an entity that furnishes services under a section 1915(b)(1) waiver only if the agency excludes from participation any entity described in paragraph (h)(2) of this section.

(2) Entities that must be excluded. The agency must exclude an entity that meets any of the following conditions:

(i) Could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(ii) Has a substantial contractual relationship (direct or indirect) with an individual convicted of certain crimes, as described in section 1128(b)(8)(B) of the Act.

(iii) Employs or contracts directly or indirectly with one of the following:

(A) Any individual or entity that, under section 1128 or section 1128A of the Act, is precluded from furnishing health care, utilization review, medical social services, or administrative services.

(B) Any entity described in paragraph (h)(2)(i) of this section.

(3) Definitions. As used in this section, substantial contractual relationship means any contractual relationship that provides for one or more of the following services:

(i) The administration, management, or provision of medical services.

(ii) The establishment of policies, or the provision of operational support, for the administration, management, or provision of medical services.

[56 FR 8847, Mar. 1, 1991, as amended at 59 FR 4599, Feb. 1, 1994; 59 FR 36084, July 15, 1994; 67 FR 41094, June 14, 2002]

§ 431.56 Special waiver provisions applicable to American Samoa and the Northern Mariana Islands.

(a) *Statutory basis.* Section 1902(j) of the Act provides for waiver of all but three of the title XIX requirements, in the case of American Samoa and the Northern Mariana Islands.

(b) *Waiver provisions.* American Samoa or the Northern Mariana Islands may request, and CMS may approve, a waiver of any of the title XIX requirements except the following:

(1) The Federal medical assistance percentage specified in section 1903 of the Act and §433.10(b) of this chapter.

(2) The limit imposed by section 1108(c) of the Act on the amount of Federal funds payable to American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition for Medicaid assistance.

(3) The requirement that payment be made only with respect to expenditure made by American Samoa or the Northern Mariana Islands for care and services that meet the section 1905(a) definition of medical assistance.

§ 431.57 Waiver of cost-sharing requirements.

(a) Sections 1916(a)(3) and 1916(b)(3) of the Act specify the circumstances under which the Secretary is authorized to waive the requirement that cost-sharing amounts be nominal.

(b) For nonemergency services furnished in a hospital emergency room, the Secretary may by waiver permit a State to impose a copayment of up to double the ''nominal'' copayment amounts determined under § 447.54(a)(3) of this subchapter.

(c) Nonemergency services are services that do not meet the definition of emergency services at § 447.53(b)(4) of this subchapter.

(d) In order for a waiver to be approved under this section, the State must establish to the satisfaction of CMS that alternative sources of nonemergency, outpatient services are available and accessible to recipients.

(e) Although, in accordance with § 431.55(b)(3) of this part, a waiver will generally be granted for a 2-year duration, CMS will reevaluate waivers approved under this section if the State increases the nominal copayment amounts in effect when the waiver was approved.

(f) A waiver approved under this section cannot apply to services furnished before the waiver was granted.

[59 FR 4600, Feb. 1, 1994]

Subpart C—Administrative Requirements: Provider Relations

§ 431.105 Consultation to medical facilities.

(a) *Basis and purpose.* This section implements section 1902(a)(24) of the Act, which requires that the State plan provide for consultative services by State agencies to certain institutions furnishing Medicaid services.

(b) *State plan requirements.* A State plan must provide that health agencies and other appropriate State agencies furnish consultative services to hospitals, nursing homes, home health agencies, clinics, and laboratories in order to assist these facilities to—

(1) Qualify for payments under the maternal and child health and crippled children's program (title V of the Act), Medicaid or Medicare;

(2) Establish and maintain fiscal records necessary for the proper and efficient administration of the Act; and

(3) Provide information needed to determine payments due under the Act for services furnished to recipients.

(c) *State plan option: Consultation to other facilities.* The plan may provide that health agencies and other appropriate State agencies furnish consultation to other types of facilities if those facilities are specified in the plan and provide medical care to individuals receiving services under the programs specified in paragraph (b) of this section.

§ 431.107 Required provider agreement.

(a) *Basis and purpose.* This section sets forth State plan requirements, based on sections 1902(a)(4), 1902(a)(27), 1902(a)(57), and 1902(a)(58) of the Act, that relate to the keeping of records and the furnishing of information by all providers of services (including individual practitioners and groups of practitioners).

(b) *Agreements.* A State plan must provide for an agreement between the Medicaid agency and each provider or organization furnishing services under the plan in which the provider or organization agrees to:

(1) Keep any records necessary to disclose the extent of services the provider furnishes to recipients;

(2) On request, furnish to the Medicaid agency, the Secretary, or the State Medicaid fraud control unit (if such a unit has been approved by the Secretary under § 455.300 of this chapter), any information maintained under paragraph (b)(1) of this section and any information regarding payments claimed by the provider for furnishing services under the plan;

(3) Comply with the disclosure requirements specified in part 455, subpart B of this chapter; and

(4) Comply with the advance directives requirements for hospitals, nursing facilities, providers of home health care and personal care services, hospices, and HMOs specified in part 489,

subpart I, and §417.436(d) of this chapter.

[44 FR 41644, July 17, 1979, as amended at 57 FR 8202, Mar. 6, 1992]

§431.108 Effective date of provider agreements.

(a) *Applicability*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to Medicaid provider agreements with entities that, as a basis for participation in Medicaid—

(i) Are subject to survey and certification by CMS or the State survey agency; or

(ii) Are deemed to meet Federal requirements on the basis of accreditation by an accrediting organization whose program has CMS approval at the time of accreditation survey and accreditation decision.

(2) *Exception.* A Medicaid provider agreement with a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) *All requirements are met on the date of survey.* The agreement is effective on the date the onsite survey (including the Life Safety Code survey if applicable) is completed, if on that date the provider meets—

(1) All applicable Federal requirements as set forth in this chapter; and

(2) Any other requirements imposed by the State for participation in the Medicaid program. (If the provider has a time-limited agreement, the new agreement is effective on the day following expiration of the current agreement.)

(c) *All requirements are not met on the date of survey.* If on the date the survey is completed the provider fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

(1) An NF provider agreement is effective on the date on which—

(i) The NF is found to be in substantial compliance as defined in §488.301 of this chapter; and

(ii) CMS or the State survey agency receives from the NF, if applicable, an approvable waiver request.

(2) For an agreement with any other provider, the effective date is the earlier of the following:

(i) The date on which the provider meets all requirements.

(ii) The date on which a provider is found to meet all conditions of participation but has lower level deficiencies, and CMS or the State survey agency receives from the provider an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date of the agreement, regardless of when CMS approves the plan of correction or waiver request, or both.)

(d) *Accredited provider requests participation in the Medicaid program*—(1) *General rule.* If a provider is currently accredited by a national accrediting organization whose program had CMS approval at the time of accreditation survey and accreditation decision, and on the basis of accreditation, CMS has deemed the provider to meet Federal requirements, the effective date depends on whether the provider is subject to requirements in addition to those included in the accrediting organization's approved program.

(i) *Provider subject to additional requirements.* For a provider that is subject to additional requirements, Federal or State, or both, the effective date is the date on which the provider meets all requirements, including the additional requirements.

(ii) *Provider not subject to additional requirements.* For a provider that is not subject to additional requirements, the effective date is the date of the provider's initial request for participation if on that date the provider met all Federal requirements.

(2) *Special rule: Retroactive effective date.* If the provider meets the requirements of paragraphs (d)(1) and (d)(1)(i) or (d)(1)(ii) of this section, the effective date may be retroactive for up to one year, to encompass dates on which the provider furnished, to a Medicaid recipient, covered services for which it has not been paid.

[62 FR 43935, Aug. 18, 1997]

§ 431.110 Participation by Indian Health Service facilities.

(a) *Basis.* This section is based on section 1902(a)(4) of the Act, proper and efficient administration; 1902(a)(23), free choice of provider; and 1911, reimbursement of Indian Health Service facilities.

(b) *State plan requirements.* A State plan must provide that an Indian Health Service facility meeting State requirements for Medicaid participation must be accepted as a Medicaid provider on the same basis as any other qualified provider. However, when State licensure is normally required, the facility need not obtain a license but must meet all applicable standards for licensure. In determining whether a facility meets these standards, a Medicaid agency or State licensing authority may not take into account an absence of licensure of any staff member of the facility.

§ 431.115 Disclosure of survey information and provider or contractor evaluation.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(36) of the Act, which requires a State plan to provide that the State survey agency will make publicly available the findings from surveys of health care facilities, laboratories, agencies, clinics, or organizations; and

(2) Section 1106(d) of the Act, which places certain restrictions on the Medicaid agency's disclosure of contractor and provider evaluations.

(b) *Definition of State survey agency.* The State survey agency referred to in this section means the agency specified under section 1902(a)(9) of the Act as responsible for establishing and maintaining health standards for private or public institutions in which Medicaid recipients may receive services.

(c) *State plan requirements.* A State plan must provide that the requirements of this section and § 488.325 of this chapter are met.

(d) *Disclosure procedure.* The Medicaid agency must have a procedure for disclosing pertinent findings obtained from surveys made by the State survey agency to determine if a health care facility, laboratory, agency, clinic or health care organization meets the requirements for participation in the Medicaid program.

(e) *Documents subject to disclosure.* Documents subject to disclosure include—

(1) Survey reports, except for Joint Commission on the Accreditation of Hospitals reports prohibited from disclosure under § 422.426(b)(2) of this chapter;

(2) Official notifications of findings based on survey reports:

(3) Pertinent parts of written documents furnished by the health care provider to the survey agency that relate to the reports and findings; and

(4) Ownership and contract information as specified in § 455.104 of this subchapter.

(f) *Availability for inspection and copy of statements listing deficiencies.* The disclosure procedure must provide that the State survey agency will—

(1) Make statements of deficiencies based on the survey reports available for inspection and copying in both the public assistance office and the Social Security Administration district office serving the area where the provider is located; and

(2) Submit to the Regional Medicaid Director, through the Medicaid agency, a plan for making those findings available in other public assistance offices in standard metropolitan statistical areas where this information would be helpful to persons likely to use the health care provider's services.

(g) *When documents must be made available.* The disclosure procedure must provide that the State survey agency will—

(1) Retain in the survey agency office and make available upon request survey reports and current and accurate ownership information; and

(2) Make available survey reports, findings, and deficiency statements immediately upon determining that a health care provider is eligible to begin or continue participation in the Medicaid program, or within 90 days after completion of the survey, whichever occurs first.

(h) *Evaluation reports on providers and contractors.* (1) If the Secretary sends the following reports to the Medicaid

agency, the agency must meet the requirements of paragraphs (h) (2) and (3) of this section in releasing them:

(i) Individual contractor performance reviews and other formal performance evaluations of carriers, intermediaries, and State agencies, including the reports of followup reviews;

(ii) Comparative performance evaluations of those contractors, including comparisons of either overall performance or of any particular aspect of contractor operations; and

(iii) Program validation survey reports and other formal performance evaluations of providers, including the reports of followup reviews.

(2) The agency must not make the reports public until—

(i) The contractor or provider has had a reasonable opportunity, not to exceed 30 days, to comment on them; and

(ii) Those comments have been incorporated in the report.

(3) The agency must ensure that the reports contain no identification of individual patients, individual health care practitioners or other individuals.

[43 FR 45188, Sept. 29, 1978, as amended at 44 FR 41644, July 17, 1979; 59 FR 56232, Nov. 10, 1994]

§431.120 State requirements with respect to nursing facilities.

(a) *State plan requirements.* A State plan must—

(1) Provide that the requirements of subpart D of part 483 of this chapter are met; and

(2) Specify the procedures and rules that the State follows in carrying out the specified requirements, including review and approval of State-operated programs.

(3) To an NF or ICF/MR that is dissatisfied with a determination as to the effective date of its provider agreement.

(b) *Basis and scope of requirements.* The requirements set forth in part 483 of this chapter pertain to the following aspects of nursing facility services and are required by the indicated sections of the Act.

(1) Nurse aide training and competency programs, and evaluation of nurse aide competency (1919(e)(1) of the Act).

(2) Nurse aide registry (1919(e)(2) of the Act).

[56 FR 48918, Sept. 26, 1991, as amended at 62 FR 43935, Aug. 18, 1997]

Subpart D—Appeals Process for NFs and ICFs/MR

SOURCE: 44 FR 9753, Feb. 15, 1979, unless otherwise noted.

§431.151 Scope and applicability.

(a) *General rules.* This subpart sets forth the appeals procedures that a State must make available as follows:

(1) To a nursing facility (NF) that is dissatisfied with a State's finding of noncompliance that has resulted in one of the following adverse actions:

(i) Denial or termination of its provider agreement.

(ii) Imposition of a civil money penalty or other alternative remedy.

(2) To an intermediate care facility for the mentally retarded (ICF/MR) that is dissatisfied with a State's finding of noncompliance that has resulted in the denial, termination, or nonrenewal of its provider agreement.

(3) To an NF or ICF/MR that is dissatisfied with a determination as to the effective date of its provider agreement.

(b) *Special rules.* This subpart also sets forth the special rules that apply in particular circumstances, the limitations on the grounds for appeal, and the scope of review during a hearing.

[61 FR 32348, June 24, 1996, as amended at 62 FR 43935, Aug. 18, 1997]

§431.152 State plan requirements.

The State plan must provide for appeals procedures that, as a minimum, satisfy the requirements of §§431.153 and 431.154.

[59 FR 56232, Nov. 10, 1994, as amended at 61 FR 32348, June 24, 1996]

§431.153 Evidentiary hearing.

(a) *Right to hearing.* Except as provided in paragraph (b) of this section, and subject to the provisions of paragraphs (c) through (j) of this section, the State must give the facility a full evidentiary hearing for any of the actions specified in §431.151.

(b) *Limit on grounds for appeal.* The following are not subject to appeal:

(1) The choice of sanction or remedy.

(2) The State monitoring remedy.

(3) [Reserved]

(4) The level of noncompliance found by a State except when a favorable final administrative review decision would affect the range of civil money penalty amounts the State could collect.

(5) A State survey agency's decision as to when to conduct an initial survey of a prospective provider.

(c) *Notice of deficiencies and impending remedies.* The State must give the facility a written notice that includes:

(1) The basis for the decision; and

(2) A statement of the deficiencies on which the decision was based.

(d) *Request for hearing.* The facility or its legal representative or other authorized official must file written request for hearing within 60 days of receipt of the notice of adverse action.

(e) *Special rules: Denial, termination or nonrenewal of provider agreement*—(1) *Appeal by an ICF/MR.* If an ICF/MR requests a hearing on denial, termination, or nonrenewal of its provider agreement—

(i) The evidentiary hearing must be completed either before, or within 120 days after, the effective date of the adverse action; and

(ii) If the hearing is made available only after the effective date of the action, the State must, before that date, offer the ICF/MR an informal reconsideration that meets the requirements of § 431.154.

(2) *Appeal by an NF.* If an NF requests a hearing on the denial or termination of its provider agreement, the request does not delay the adverse action and the hearing need not be completed before the effective date of the action.

(f) *Special rules: Imposition of remedies.* If a State imposes a civil money penalty or other remedies on an NF, the following rules apply:

(1) *Basic rule.* Except as provided in paragraph (f)(2) of this section (and notwithstanding any provision of State law), the State must impose all remedies timely on the NF, even if the NF requests a hearing.

(2) *Exception.* The State may not collect a civil money penalty until after the 60-day period for request of hearing has elapsed or, if the NF requests a hearing, until issuance of a final administrative decision that supports imposition of the penalty.

(g) *Special rules: Dually participating facilities.* If an NF is also participating or seeking to participate in Medicare as an SNF, and the basis for the State's denial or termination of participation in Medicaid is also a basis for denial or termination of participation in Medicare, the State must advise the facility that—

(1) The appeals procedures specified for Medicare facilities in part 498 of this chapter apply; and

(2) A final decision entered under the Medicare appeals procedures is binding for both programs.

(h) *Special rules: Adverse action by CMS.* If CMS finds that an NF is not in substantial compliance and either terminates the NF's Medicaid provider agreement or imposes alternative remedies on the NF (because CMS's findings and proposed remedies prevail over those of the State in accordance with § 488.452 of this chapter), the NF is entitled only to the appeals procedures set forth in part 498 of this chapter, instead of the procedures specified in this subpart.

(i) *Required elements of hearing.* The hearing must include at least the following:

(1) Opportunity for the facility—

(i) To appear before an impartial decision-maker to refute the finding of noncompliance on which the adverse action was based;

(ii) To be represented by counsel or other representative; and

(iii) To be heard directly or through its representative, to call witnesses, and to present documentary evidence.

(2) A written decision by the impartial decision-maker, setting forth the reasons for the decision and the evidence on which the decision is based.

(j) *Limits on scope of review: Civil money penalty cases.* In civil money penalty cases—

(1) The State's finding as to a NF's level of noncompliance must be upheld unless it is clearly erroneous; and

(2) The scope of review is as set forth in § 488.438(e) of this chapter.

[61 FR 32348, June 24, 1996, as amended at 62 FR 43935, Aug. 18, 1997; 64 FR 39937, July 23, 1999]

§ 431.154 Informal reconsideration for ICFs/MR.

The informal reconsideration must, at a minimum, include—

(a) Written notice to the facility of the denial, termination or nonrenewal and the findings upon which it was based;

(b) A reasonable opportunity for the facility to refute those findings in writing, and

(c) A written affirmation or reversal of the denial, termination, or nonrenewal.

[44 FR 9753, Feb. 15, 1979, as amended at 59 FR 56233, Nov. 10, 1994; 61 FR 32349, June 24, 1996]

Subpart E—Fair Hearings for Applicants and Recipients

SOURCE: 44 FR 17932, Mar. 29, 1979, unless otherwise noted.

GENERAL PROVISIONS

§ 431.200 Basis and scope.

This subpart—

(a) Implements section 1902(a)(3) of the Act, which requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly;

(b) Prescribes procedures for an opportunity for a hearing if the State agency or PAHP takes action, as stated in this subpart, to suspend, terminate, or reduce services, or an MCO or PIHP takes action under subpart F of part 438 of this chapter; and

(c) Implements sections 1919(f)(3) and 1919(e)(7)(F) of the Act by providing an appeals process for any person who—

(1) Is subject to a proposed transfer or discharge from a nursing facility; or

(2) Is adversely affected by the preadmission screening or the annual resident review that are required by section 1919(e)(7) of the Act.

[67 FR 41094, June 14, 2002]

§ 431.201 Definitions.

For purposes of this subpart:

Action means a termination, suspension, or reduction of Medicaid eligibility or covered services. It also means determinations by skilled nursing facilities and nursing facilities to transfer or discharge residents and adverse determinations made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

Adverse determination means a determination made in accordance with sections 1919(b)(3)(F) or 1919(e)(7)(B) of the Act that the individual does not require the level of services provided by a nursing facility or that the individual does or does not require specialized services.

Date of action means the intended date on which a termination, suspension, reduction, transfer or discharge becomes effective. It also means the date of the determination made by a State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

De novo hearing means a hearing that starts over from the beginning.

Evidentiary hearing means a hearing conducted so that evidence may be presented.

Notice means a written statement that meets the requirements of § 431.210.

Request for a hearing means a clear expression by the applicant or recipient, or his authorized representative, that he wants the opportunity to present his case to a reviewing authority.

Service authorization request means a managed care enrollee's request for the provision of a service.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 67 FR 41095, June 14, 2002]

§ 431.202 State plan requirements.

A State plan must provide that the requirements of §§ 431.205 through 431.246 of this subpart are met.

§ 431.205 Provision of hearing system.

(a) The Medicaid agency must be responsible for maintaining a hearing system that meets the requirements of this subpart.

(b) The State's hearing system must provide for—

(1) A hearing before the agency; or

(2) An evidentiary hearing at the local level, with a right of appeal to a State agency hearing.

(c) The agency may offer local hearings in some political subdivisions and not in others.

(d) The hearing system must meet the due process standards set forth in *Goldberg v. Kelly*, 397 U.S. 254 (1970), and any additional standards specified in this subpart.

§ 431.206 Informing applicants and recipients.

(a) The agency must issue and publicize its hearing procedures.

(b) The agency must, at the time specified in paragraph (c) of this section, inform every applicant or recipient in writing—

(1) Of his right to a hearing;

(2) Of the method by which he may obtain a hearing; and

(3) That he may represent himself or use legal counsel, a relative, a friend, or other spokesman.

(c) The agency must provide the information required in paragraph (b) of this section—(1) At the time that the individual applies for Medicaid;

(2) At the time of any action affecting his or her claim;

(3) At the time a skilled nursing facility or a nursing facility notifies a resident in accordance with § 483.12 of this chapter that he or she is to be transferred or discharged; and

(4) At the time an individual receives an adverse determination by the State with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

NOTICE

§ 431.210 Content of notice.

A notice required under § 431.206 (c)(2), (c)(3), or (c)(4) of this subpart must contain—

(a) A statement of what action the State, skilled nursing facility, or nursing facility intends to take;

(b) The reasons for the intended action;

(c) The specific regulations that support, or the change in Federal or State law that requires, the action;

(d) An explanation of—

(1) The individual's right to request an evidentiary hearing if one is available, or a State agency hearing; or

(2) In cases of an action based on a change in law, the circumstances under which a hearing will be granted; and

(e) An explanation of the circumstances under which Medicaid is continued if a hearing is requested.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992]

§ 431.211 Advance notice.

The State or local agency must mail a notice at least 10 days before the date of action, except as permitted under §§ 431.213 and 431.214 of this subpart.

§ 431.213 Exceptions from advance notice.

The agency may mail a notice not later than the date of action if—

(a) The agency has factual information confirming the death of a recipient;

(b) The agency receives a clear written statement signed by a recipient that—

(1) He no longer wishes services; or

(2) Gives information that requires termination or reduction of services and indicates that he understands that this must be the result of supplying that information;

(c) The recipient has been admitted to an institution where he is ineligible under the plan for further services;

(d) The recipient's whereabouts are unknown and the post office returns agency mail directed to him indicating no forwarding address (See § 431.231 (d) of this subpart for procedure if the recipient's whereabouts become known);

(e) The agency establishes the fact that the recipient has been accepted for Medicaid services by another local jurisdiction, State, territory, or commonwealth;

(f) A change in the level of medical care is prescribed by the recipient's physician;

(g) The notice involves an adverse determination made with regard to the preadmission screening requirements of section 1919(e)(7) of the Act; or

(h) The date of action will occur in less than 10 days, in accordance with § 483.12(a)(5)(ii), which provides exceptions to the 30 days notice requirements of § 483.12(a)(5)(i).

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 431.214 Notice in cases of probable fraud.

The agency may shorten the period of advance notice to 5 days before the date of action if—

(a) The agency has facts indicating that action should be taken because of probable fraud by the recipient; and

(b) The facts have been verified, if possible, through secondary sources.

RIGHT TO HEARING

§ 431.220 When a hearing is required.

(a) The State agency must grant an opportunity for a hearing to the following:

(1) Any applicant who requests it because his claim for services is denied or is not acted upon with reasonable promptness.

(2) Any recipient who requests it because he or she believes the agency has taken an action erroneously.

(3) Any resident who requests it because he or she believes a skilled nursing facility or nursing facility has erroneously determined that he or she must be transferred or discharged.

(4) Any individual who requests it because he or she believes the State has made an erroneous determination with regard to the preadmission and annual resident review requirements of section 1919(e)(7) of the Act.

(5) Any MCO or PIHP enrollee who is entitled to a hearing under subpart F of part 438 of this chapter.

(6) Any PAHP enrollee who has an action as stated in this subpart.

(7) Any enrollee who is entitled to a hearing under subpart B of part 438 of this chapter.

(b) The agency need not grant a hearing if the sole issue is a Federal or State law requiring an automatic change adversely affecting some or all recipients.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56505, Nov. 30, 1992; 67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 431.221 Request for hearing.

(a) The agency may require that a request for a hearing be in writing.

(b) The agency may not limit or interfere with the applicant's or recipient's freedom to make a request for a hearing.

(c) The agency may assist the applicant or recipient in submitting and processing his request.

(d) The agency must allow the applicant or recipient a reasonable time, not to exceed 90 days from the date that notice of action is mailed, to request a hearings.

§ 431.222 Group hearings.

The agency—

(a) May respond to a series of individual requests for hearing by conducting a single group hearing;

(b) May consolidate hearings only in cases in which the sole issue involved is one of Federal or State law or policy;

(c) Must follow the policies of this subpart and its own policies governing hearings in all group hearings; and

(d) Must permit each person to present his own case or be represented by his authorized representative.

§ 431.223 Denial or dismissal of request for a hearing.

The agency may deny or dismiss a request for a hearing if—

(a) The applicant or recipient withdraws the request in writing; or

(b) The applicant or recipient fails to appear at a scheduled hearing without good cause.

PROCEDURES

§ 431.230 Maintaining services.

(a) If the agency mails the 10-day or 5-day notice as required under § 431.211 or § 431.214 of this subpart, and the recipient requests a hearing before the date of action, the agency may not terminate or reduce services until a decision is rendered after the hearing unless—

(1) It is determined at the hearing that the sole issue is one of Federal or State law or policy; and

(2) The agency promptly informs the recipient in writing that services are to be terminated or reduced pending the hearing decision.

(b) If the agency's action is sustained by the hearing decision, the agency may institute recovery procedures against the applicant or recipient to recoup the cost of any services furnished the recipient, to the extent they were furnished solely by reason of this section.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980]

§ 431.231 Reinstatement of services.

(a) The agency may reinstate services if a recipient requests a hearing not more than 10 days after the date of action.

(b) The reinstated services must continue until a hearing decision unless, at the hearing, it is determined that the sole issue is one of Federal or State law or policy.

(c) The agency must reinstate and continue services until a decision is rendered after a hearing if—

(1) Action is taken without the advance notice required under § 431.211 or § 431.214 of this subpart;

(2) The recipient requests a hearing within 10 days of the mailing of the notice of action; and

(3) The agency determines that the action resulted from other than the application of Federal or State law or policy.

(d) If a recipient's whereabouts are unknown, as indicated by the return of unforwardable agency mail directed to him, any discontinued services must be reinstated if his whereabouts become known during the time he is eligible for services.

§ 431.232 Adverse decision of local evidentiary hearing.

If the decision of a local evidentiary hearing is adverse to the applicant or recipient, the agency must—

(a) Inform the applicant or recipient of the decision;

(b) Inform the applicant or recipient that he has the right to appeal the decision to the State agency, in writing, within 15 days of the mailing of the notice of the adverse decision;

(c) Inform the applicant or recipient of his right to request that his appeal be a *de novo* hearing; and

(d) Discontinue services after the adverse decision.

§ 431.233 State agency hearing after adverse decision of local evidentiary hearing.

(a) Unless the applicant or recipient specifically requests a *de novo* hearing, the State agency hearing may consist of a review by the agency hearing officer of the record of the local evidentiary hearing to determine whether the decision of the local hearing officer was supported by substantial evidence in the record.

(b) A person who participates in the local decision being appealed may not participate in the State agency hearing decision.

§ 431.240 Conducting the hearing.

(a) All hearings must be conducted—

(1) At a reasonable time, date, and place;

(2) Only after adequate written notice of the hearing; and

(3) By one or more impartial officials or other individuals who have not been directly involved in the initial determination of the action in question.

(b) If the hearing involves medical issues such as those concerning a diagnosis, an examining physician's report, or a medical review team's decision, and if the hearing officer considers it necessary to have a medical assessment other than that of the individual involved in making the original decision, such a medical assessment must be obtained at agency expense and made part of the record.

§ 431.241 Matters to be considered at the hearing.

The hearing must cover—

(a) Agency action or failure to act with reasonable promptness on a claim for services, including both initial and subsequent decisions regarding eligibility;

(b) Agency decisions regarding changes in the type or amount of services;

(c) A decision by a skilled nursing facility or nursing facility to transfer or discharge a resident; and

(d) A State determination with regard to the preadmission screening and annual resident review requirements of section 1919(e)(7) of the Act.

[57 FR 56505, Nov. 30, 1992]

§ 431.242 Procedural rights of the applicant or recipient.

The applicant or recipient, or his representative, must be given an opportunity to—

(a) Examine at a reasonable time before the date of the hearing and during the hearing:

(1) The content of the applicant's or recipient's case file; and

(2) All documents and records to be used by the State or local agency or the skilled nursing facility or nursing facility at the hearing;

(b) Bring witnesses;

(c) Establish all pertinent facts and circumstances;

(d) Present an argument without undue interference; and

(e) Question or refute any testimony or evidence, including opportunity to confront and cross-examine adverse witnesses.

[44 FR 17932, Mar. 29, 1979, as amended at 57 FR 56506, Nov. 30, 1992]

§ 431.243 Parties in cases involving an eligibility determination.

If the hearing involves an issue of eligibility and the Medicaid agency is not responsible for eligibility determinations, the agency that is responsible for determining eligibility must participate in the hearing.

§ 431.244 Hearing decisions.

(a) Hearing recommendations or decisions must be based exclusively on evidence introduced at the hearing.

(b) The record must consist only of—

(1) The transcript or recording of testimony and exhibits, or an official report containing the substance of what happened at the hearing;

(2) All papers and requests filed in the proceeding; and

(3) The recommendation or decision of the hearing officer.

(c) The applicant or recipient must have access to the record at a convenient place and time.

(d) In any evidentiary hearing, the decision must be a written one that—

(1) Summarizes the facts; and

(2) Identifies the regulations supporting the decision.

(e) In a *de novo* hearing, the decision must—

(1) Specify the reasons for the decision; and

(2) Identify the supporting evidence and regulations.

(f) The agency must take final administrative action as follows:

(1) Ordinarily, within 90 days from the earlier of the following:

(i) The date the enrollee filed an MCO or PIHP appeal, not including the number of days the enrollee took to subsequently file for a State fair hearing; or

(ii) If permitted by the State, the date the enrollee filed for direct access to a State fair hearing.

(2) As expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, from the MCO or PIHP, the case file and information for any appeal of a denial of a service that, as indicated by the MCO or PIHP—

(i) Meets the criteria for expedited resolution as set forth in § 438.410(a) of this chapter, but was not resolved within the timeframe for expedited resolution; or

(ii) Was resolved within the timeframe for expedited resolution, but reached a decision wholly or partially adverse to the enrollee.

(3) If the State agency permits direct access to a State fair hearing, as expeditiously as the enrollee's health condition requires, but no later than 3 working days after the agency receives, directly from an MCO or PIHP enrollee, a fair hearing request on a decision to deny a service that it determines meets the criteria for expedited resolution, as set forth in §438.410(a) of this chapter.

(g) The public must have access to all agency hearing decisions, subject to the requirements of subpart F of this part for safeguarding of information.

[44 FR 17932, Mar. 29, 1979, as amended at 67 FR 41095, June 14, 2002]

§ 431.245 Notifying the applicant or recipient of a State agency decision.

The agency must notify the applicant or recipient in writing of—

(a) The decision; and

(b) His right to request a State agency hearing or seek judicial review, to the extent that either is available to him.

§ 431.246 Corrective action.

The agency must promptly make corrective payments, retroactive to the date an incorrect action was taken, and, if appropriate, provide for admission or readmission of an individual to a facility if—

(a) The hearing decision is favorable to the applicant or recipient; or

(b) The agency decides in the applicant's or recipient's favor before the hearing.

[57 FR 56506, Nov. 30, 1992]

FEDERAL FINANCIAL PARTICIPATION

§ 431.250 Federal financial participation.

FFP is available in expenditures for—

(a) Payments for services continued pending a hearing decision;

(b) Payments made—

(1) To carry out hearing decisions; and

(2) For services provided within the scope of the Federal Medicaid program and made under a court order.

(c) Payments made to take corrective action prior to a hearing;

(d) Payments made to extend the benefit of a hearing decision or court order to individuals in the same situation as those directly affected by the decision or order;

(e) Retroactive payments under paragraphs (b), (c), and (d) of this section in accordance with applicable Federal policies on corrective payments; and

(f) Administrative costs incurred by the agency for—

(1) Transportation for the applicant or recipient, his representative, and witnesses to and from the hearing;

(2) Meeting other expenses of the applicant or recipient in connection with the hearing;

(3) Carrying out the hearing procedures, including expenses of obtaining the additional medical assessment specified in §431.240 of this subpart; and

(4) Hearing procedures for Medicaid and non-Medicaid individuals appealing transfers, discharges and determinations of preadmission screening and annual resident reviews under part 483, subparts C and E of this chapter.

[44 FR 17932, Mar. 29, 1979, as amended at 45 FR 24882, Apr. 11, 1980; 57 FR 56506, Nov. 30, 1992]

Subpart F—Safeguarding Information on Applicants and Recipients

SOURCE: 44 FR 17934, Mar. 29, 1979, unless otherwise noted.

§ 431.300 Basis and purpose.

(a) Section 1902(a)(7) of the Act requires that a State plan must provide safeguards that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan. This subpart specifies State plan requirements, the types of information to be safeguarded, the conditions for release of safeguarded information, and restrictions on the distribution of other information.

(b) Section 1137 of the Act, which requires agencies to exchange information in order to verify the income and eligibility of applicants and recipients (see §435.940ff), requires State agencies to have adequate safeguards to assure that—

(1) Information exchanged by the State agencies is made available only

to the extent necessary to assist in the valid administrative needs of the program receiving the information, and information received under section 6103(l) of the Internal Revenue Code of 1954 is exchanged only with agencies authorized to receive that information under that section of the Code; and

(2) The information is adequately stored and processed so that it is protected against unauthorized disclosure for other purposes.

[51 FR 7210, Feb. 28, 1986]

§ 431.301 State plan requirements.

A State plan must provide, under a State statute that imposes legal sanctions, safeguards meeting the requirements of this subpart that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the plan.

§ 431.302 Purposes directly related to State plan administration.

Purposes directly related to plan administration include—

(a) Establishing eligibility;

(b) Determining the amount of medical assistance;

(c) Providing services for recipients; and

(d) Conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the administration of the plan.

§ 431.303 State authority for safeguarding information.

The Medicaid agency must have authority to implement and enforce the provisions specified in this subpart for safeguarding information about applicants and recipients.

§ 431.304 Publicizing safeguarding requirements.

(a) The agency must publicize provisions governing the confidential nature of information about applicants and recipients, including the legal sanctions imposed for improper disclosure and use.

(b) The agency must provide copies of these provisions to applicants and recipients and to other persons and agencies to whom information is disclosed.

§ 431.305 Types of information to be safeguarded.

(a) The agency must have criteria that govern the types of information about applicants and recipients that are safeguarded.

(b) This information must include at least—

(1) Names and addresses;

(2) Medical services provided;

(3) Social and economic conditions or circumstances;

(4) Agency evaluation of personal information;

(5) Medical data, including diagnosis and past history of disease or disability; and

(6) Any information received for verifying income eligibility and amount of medical assistance payments (see § 435.940ff). Income information received from SSA or the Internal Revenue Service must be safeguarded according to the requirements of the agency that furnished the data.

(7) Any information received in connection with the identification of legally liable third party resources under § 433.138 of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987]

§ 431.306 Release of information.

(a) The agency must have criteria specifying the conditions for release and use of information about applicants and recipients.

(b) Access to information concerning applicants or recipients must be restricted to persons or agency representatives who are subject to standards of confidentiality that are comparable to those of the agency.

(c) The agency must not publish names of applicants or recipients.

(d) The agency must obtain permission from a family or individual, whenever possible, before responding to a request for information from an outside source, unless the information is to be used to verify income, eligibility and the amount of medical assistance payment under section 1137 of this Act and §§ 435.940 through 435.965 of this chapter.

If, because of an emergency situation, time does not permit obtaining consent

before release, the agency must notify the family or individual immediately after supplying the information.

(e) The agency's policies must apply to all requests for information from outside sources, including governmental bodies, the courts, or law enforcement officials.

(f) If a court issues a subpoena for a case record or for any agency representative to testify concerning an applicant or recipient, the agency must inform the court of the applicable statutory provisions, policies, and regulations restricting disclosure of information.

(g) Before requesting information from, or releasing information to, other agencies to verify income, eligibility and the amount of assistance under §§ 435.940 through 435.965 of this chapter, the agency must execute data exchange agreements with those agencies, as specified in § 435.945(f).

(h) Before requesting information from, or releasing information to, other agencies to identify legally liable third party resources under § 433.138(d) of this chapter, the agency must execute data exchanges agreements, as specified in § 433.138(h)(2) of this chapter.

[44 FR 17934, Mar. 29, 1979, as amended at 51 FR 7210, Feb. 28, 1986; 52 FR 5975, Feb. 27, 1987]

§ 431.307 Distribution of information materials.

(a) All materials distributed to applicants, recipients, or medical providers must—

(1) Directly relate to the administration of the Medicaid program;

(2) Have no political implications except to the extent required to implement the National Voter Registration Act of 1993 (NVRA) Pub. L. 103–931; for States that are exempt from the requirements of NVRA, voter registration may be a voluntary activity so long as the provisions of section 7(a)(5) of NVRA are observed;

(3) Contain the names only of individuals directly connected with the administration of the plan; and

(4) Identify those individuals only in their official capacity with the State or local agency.

(b) The agency must not distribute materials such as ''holiday'' greetings, general public announcements, partisan voting information and alien registration notices.

(c) The agency may distribute materials directly related to the health and welfare of applicants and recipients, such as announcements of free medical examinations, availability of surplus food, and consumer protection information.

(d) Under NVRA, the agency must distribute voter information and registration materials as specified in NVRA.

[44 FR 17934, Mar. 29, 1979, as amended at 61 FR 58143, Nov. 13, 1996]

Subparts G–L [Reserved]

Subpart M—Relations With Other Agencies

§ 431.610 Relations with standard-setting and survey agencies.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(9) of the Act, concerning the designation of State authorities to be responsible for establishing and maintaining health and other standards for institutions participating in Medicaid; and

(2) Section 1902(a)(33) of the Act, concerning the designation of the State licensing agency to be responsible for determining whether institutions and agencies meet requirements for participation in the State's Medicaid program.

(3) Section 1919(g)(1)(A) of the Act, concerning responsibilities of the State for certifying the compliance of non-State operated NFs with requirements of participation in the State's Medicaid program.

(b) *Designated agency responsible for health standards.* A State plan must designate, as the State authority responsible for establishing and maintaining health standards for private or public institutions that provide services to Medicaid recipients, the same State agency that is used by the Secretary to determine qualifications of institutions and suppliers of services to participate in Medicare (see 42 CFR

405.1902). The requirement for establishing and maintaining standards does not apply with respect to religious nonmedical institutions as defined in § 440.170(b) of this chapter.

(c) *Designated agency responsible for standards other than health standards.* The plan must designate the Medicaid agency or other appropriate State authority or authorities to be responsible for establishing and maintaining standards, other than those relating to health, for private or public institutions that provide services to Medicaid recipients.

(d) *Description and retention of standards.* (1) The plan must describe the standards established under paragraphs (b) and (c) of this section.

(2) The plan must provide that the Medicaid agency keeps these standards on file and makes them available to the Administrator upon request.

(e) *Designation of survey agency.* The plan must provide that—

(1) The agency designated in paragraph (b) of this section, or another State agency responsible for licensing health institutions in the State, determines for the Medicaid agency whether institutions and agencies meet the requirements for participation in the Medicaid program; and

(2) The agency staff making the determination under paragraph (e)(1) of this section is the same staff responsible for making similar determinations for institutions or agencies participating under Medicare; and

(3) The agency designated in paragraph (e)(1) of this section makes recommendations regarding the effective dates of provider agreements, as determined under § 431.108.

(f) *Written agreement required.* The plan must provide for a written agreement (or formal written intra-agency arrangement) between the Medicaid agency and the survey agency designated under paragraph (e) of this section, covering the activities of the survey agency in carrying out its responsibilities. The agreement must specify that—

(1) Federal requirements and the forms, methods and procedures that the Administrator designates will be used to determine provider eligibility and certification under Medicaid;

(2) Inspectors surveying the premises of a provider will—

(i) Complete inspection reports;

(ii) Note on completed reports whether or not each requirement for which an inspection is made is satisfied; and

(iii) Document deficiencies in reports;

(3) The survey agency will keep on file all information and reports used in determining whether participating facilities meet Federal requirements; and

(4) The survey agency will make the information and reports required under paragraph (f)(3) of this section readily accessible to HHS and the Medicaid agency as necessary—

(i) For meeting other requirements under the plan; and

(ii) For purposes consistent with the Medicaid agency's effective administration of the program.

(g) *Responsibilities of survey agency.* The plan must provide that, in certifying NFs and ICFs/MR, the survey agency designated under paragraph (e) of this section will—

(1) Review and evaluate medical and independent professional review team reports obtained under part 456 of this subchapter as they relate to health and safety requirements;

(2) Have qualified personnel perform on-site inspections periodically as appropriate based on the timeframes in the correction plan and—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For non-State operated NFs, within the timeframes specified in § 488.308 of this chapter.

(3) Have qualified personnel perform on-site inspections—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For intermediate care facilities with deficiencies as described in §§ 442.112 and 442.113 of this subchapter, within 6 months after initial correction plan approval and every 6 months thereafter as required under those sections.

(h) *FFP for survey responsibilities.* (1) FFP is available in expenditures that the survey agency makes to carry out

its survey and certification responsibilities under the agreement specified in paragraph (f) of this section.

(2) FFP is not available in any expenditures that the survey agency makes that are attributable to the State's overall responsibilities under State law and regulations for establishing and maintaining standards.

[43 FR 45188, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980; 53 FR 20494, June 3, 1988; 57 FR 43923, Sept. 23, 1992; 59 FR 56233, Nov. 10, 1994; 62 FR 43936, Aug. 18, 1997; 64 FR 67052, Nov. 30, 1999]

§ 431.615 Relations with State health and vocational rehabilitation agencies and title V grantees.

(a) *Basis and purpose.* This section implements section 1902(a)(11) and (22)(C) of the Act, by setting forth State plan requirements for arrangements and agreements between the Medicaid agency and—

(1) State health agencies;

(2) State vocational rehabilitation agencies; and

(3) Grantees under title V of the Act, Maternal and Child Health and Crippled Children's Services.

(b) *Definitions.* For purposes of this section—

''Title V grantee'' means the agency, institution, or organization receiving Federal payments for part or all of the cost of any service program or project authorized by title V of the Act, including—

(1) Maternal and child health services;

(2) Crippled children's services;

(3) Maternal and infant care projects;

(4) Children and youth projects; and

(5) Projects for the dental health of children.

(c) *State plan requirements.* A state plan must—

(1) Describe cooperative arrangements with the State agencies that administer, or supervise the administration of, health services and vocational rehabilitation services designed to make maximum use of these services;

(2) Provide for arrangements with title V grantees, under which the Medicaid agency will utilize the grantee to furnish services that are included in the State plan;

(3) Provide that all arrangements under this section meet the requirements of paragraph (d) of this section; and

(4) Provide, if requested by the title V grantee in accordance with the arrangements made under this section, that the Medicaid agency reimburse the grantee or the provider for the cost of services furnished recipients by or through the grantee.

(d) *Content of arrangements.* The arrangements referred to in paragraph (c) must specify, as appropriate—

(1) The mutual objectives and responsibilities or each party to the arrangement;

(2) The services each party offers and in what circumstances;

(3) The cooperative and collaborative relationships at the State level;

(4) The kinds of services to be provided by local agencies; and

(5) Methods for—

(i) Early identification of individuals under 21 in need of medical or remedial services;

(ii) Reciprocal referrals;

(iii) Coordinating plans for health services provided or arranged for recipients;

(iv) Payment or reimbursement;

(v) Exchange of reports of services furnished to recipients;

(vi) Periodic review and joint planning for changes in the agreements;

(vii) Continuous liaison between the parties, including designation of State and local liaison staff; and

(viii) Joint evaluation of policies that affect the cooperative work of the parties.

(e) *Federal financial participation.* FFP is available in expenditures for Medicaid services provided to recipients through an arrangement under this section.

§ 431.620 Agreement with State mental health authority or mental institutions.

(a) *Basis and purpose.* This section implements section 1902(a)(20)(A) of the Act, for States offering Medicaid services in institutions for mental diseases for recipients aged 65 or older, by specifying the terms of the agreement those States must have with other State authorities and institutions. (See part

441, subpart C of this chapter for regulations implementing section 1902(a)(20) (B) and (C).)

(b) *Definition.* For purposes of this section, an ''institution for mental diseases'' means an institution primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases. This includes medical attention, nursing care, and related services.

(c) *State plan requirement.* A State plan that includes Medicaid for persons aged 65 or older in institutions for mental diseases must provide that the Medicaid agency has in effect a written agreement with—

(1) The State authority or authorities concerned with mental diseases; and

(2) Any institution for mental diseases that is not under the jurisdiction of those State authorities, and that provides services under Medicaid to recipients aged 65 or older.

(d) *Provisions required in an agreement.* The agreement must specify the respective responsibilities of the agency and the authority or institution, including arrangements for—

(1) Joint planning between the parties to the agreement;

(2) Development of alternative methods of care;

(3) Immediate readmission to an institution when needed by a recipient who is in alternative care;

(4) Access by the agency to the institution, the recipient, and the recipient's records when necessary to carry out the agency's responsibilities;

(5) Recording, reporting, and exchanging medical and social information about recipients; and

(6) Other procedures needed to carry out the agreement.

[44 FR 17935, Mar. 23, 1979]

§ 431.621 State requirements with respect to nursing facilities.

(a) *Basis and purpose.* This section implements sections 1919(b)(3)(F) and 1919(e)(7) of the Act by specifying the terms of the agreement the State must have with the State mental health and mental retardation authorities concerning the operation of the State's preadmission screening and annual resident review (PASARR) program.

(b) *State plan requirement.* The State plan must provide that the Medicaid agency has in effect a written agreement with the State mental health and mental retardation authorities that meets the requirements specified in paragraph (c) of this section.

(c) *Provisions required in an agreement.* The agreement must specify the respective responsibilities of the agency and the State mental health and mental retardation authorities, including arrangements for)—(1) Joint planning between the parties to the agreement;

(2) Access by the agency to the State mental health and mental retardation authorities' records when necessary to carry out the agency's responsibilities;

(3) Recording, reporting, and exchanging medical and social information about individuals subject to PASARR;

(4) Ensuring that preadmission screenings and annual resident reviews are performed timely in accordance with §§ 483.112(c) and 483.114(c) of this part;

(5) Ensuring that, if the State mental health and mental retardation authorities delegate their respective responsibilities, these delegations comply with § 483.106(e) of this part;

(6) Ensuring that PASARR determinations made by the State mental health and mental retardation authorities are not countermanded by the State Medicaid agency, except through the appeals process, but that the State mental health and mental retardation authorities do not use criteria which are inconsistent with those adopted by the State Medicaid agency under its approved State plan;

(7) Designating the independent person or entity who performs the PASARR evaluations for individuals with MI; and

(8) Ensuring that all requirements of §§ 483.100 through 483.136 are met.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 431.625 Coordination of Medicaid with Medicare part B.

(a) *Basis and purpose.* (1) Section 1843(a) of the Act requires the Secretary to have entered into an agreement with any State that requested that agreement before January 1, 1970,

or during calendar year 1981, under which the State could enroll certain Medicare-eligible recipients under Medicare Part B and agree to pay their premiums.

(2) Section 1902(a)(10) of the Act (in clause (II) following subparagraph (D)), allows the State to pay the premium, deductibles, cost sharing, and other charges for recipients enrolled under Medicare Part B without obligating itself to provide the range of Part B benefits to other recipients; and

(3) Section 1903 (a)(1) and (b) of the Act authorizes FFP for State payment of Medicare Part B premiums for certain recipients.

(4) This section—

(i) Specifies the exception, relating to Part B coverage, from the requirement to provide comparable services to all recipients; and

(ii) Prescribes FFP rules concerning State payment for Medicare premiums and for services that could have been covered under Medicare.

(5) Section 1902(a)(15) of the Act requires that if a State chooses to pay only a portion of deductibles, cost sharing or other charges for recipients enrolled under Medicare Part B, the portion that is to be paid by a Medicaid recipient must be reasonably related to the recipient's income and resources.

(b) *Exception from obligation to provide comparable services; State plan requirement.* (1) The State's payment of premiums, deductibles, cost sharing, or similar charges under Part B does not obligate it to provide the full range of Part B services to recipients not covered by Medicare.

(2) The State plan must specify this exception if it applies.

(c) *Effect of payment of premiums on State liability for cost sharing.* (1) State payment of Part B premiums on behalf of a Medicaid recipient does not obligate it to pay on the recipient's behalf the Part B deductible and coinsurance amounts for those Medicare Part B services not covered in the Medicaid State plan.

(2) If a State pays on a recipient's behalf any portion of the deductible or cost sharing amounts under Medicare Part B, the portion paid by a State must be reasonably related to the recipient's income and resources.

(d) *Federal financial participation: Medicare Part B premiums*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, FFP is not available in State expenditures for Medicare Part B premiums for Medicaid recipients unless the recipients receive money payments under title I, IV-A, X, XIV, XVI (AABD or SSI) of the Act, or State supplements as permitted under section 1616(a) of the Act, or as required by section 212 of Pub. L. 93–66.

(2) *Exception.* FFP is available in expenditures for Medicare Part B premiums for the following groups:

(i) AFDC families required to be covered under §§ 435.112 and 436.116 of this subchapter, those eligible for continued Medicaid coverage despite increased income from employment;

(ii) Recipients required to be covered under §§ 435.114, 435.134, and 436.112 of this subchapter, those eligible for continued Medicaid coverage despite increased income from monthly insurance benefits under title II of the Act;

(iii) Recipients required to be covered under § 435.135 of this subchapter, those eligible for continued Medicaid coverage despite increased income from cost-of-living increases under title II of the Act;

(iv) Recipients of foster care maintenance payments or adoption assistance payments who, under Part E of title IV of the Act are considered as receiving AFDC;

(v) Individuals required to be covered under § 435.120 of this chapter, that is, blind or disabled individuals who, under section 1619(b) of the Act, are considered to be receiving SSI;

(vi) Individuals who, in accordance with §§ 435.115 and 436.114 of this chapter are, for purposes of Medicaid eligibility, considered to be receiving AFDC. These are participants in a work supplementation program, or individuals denied AFDC because the payment would be less than $10;

(vii) Certain recipients of Veterans Administration pensions during the limited time they are, under section 310(b) of Pub. L. 96–272, considered as receiving SSI, mandatory State supplements, or AFDC;

(viii) Disabled children living at home to whom the State provides Medicaid under section 1902(e)(3) of the Act;

(ix) Individuals who become ineligible for AFDC because of the collection or increased collection of child or spousal support, but, in accordance with section 406(h) of the Act, remain eligible for Medicaid for four more months; and

(x) Individuals who become ineligible for AFDC because they are no longer eligible for the disregard of earnings of $30 or of $30 plus one-third of the remainder, but, in accordance with section 402(a)(37) of the Act, are considered as receiving AFDC for a period of 9 to 15 months.

(3) No FFP is available in State Medicaid expenditures that could have been paid for under Medicare Part B but were not because the person was not enrolled in Part B. This limit applies to all recipients eligible for enrollment under Part B, whether individually or through an agreement under section 1843(a) of the Act. However, FFP is available in expenditures required by §§ 435.914 and 436.901 of this subchapter for retroactive coverage of recipients.

[43 FR 45188, Sept. 29, 1978, as amended at 44 FR 17935, Mar. 23, 1979; 52 FR 47933, Dec. 17, 1987; 53 FR 657, Jan. 11, 1988]

§ 431.630 Coordination of Medicaid with QIOs.

(a) The State plan may provide for the review of Medicaid services through a contract with a QIO designated under Part 462 of this chapter. Medicaid requirements for medical and utilization review are deemed to be met for those services or providers subject to review under the contract.

(b) The State plan must provide that the contract with the QIO—

(1) Meets the requirements of § 434.6(a) of this part;

(2) Includes a monitoring and evaluation plan by which the State ensures satisfactory performance by the QIO;

(3) Identifies the services and providers subject to QIO review;

(4) Ensures that the review activities performed by the QIO are not inconsistent with QIO review activities of Medicare services and includes a description of whether and to what extent QIO determinations will be considered conclusive for Medicaid payment purposes.

[50 FR 15327, Apr. 17, 1985]

§ 431.635 Coordination of Medicaid with Special Supplemental Food Program for Women, Infants, and Children (WIC).

(a) *Basis.* This section implements sections 1902(a)(11)(C) and 1902(a) (53) of the Act, which provide for coordination of Medicaid with the Special Supplemental Food Program for Women, Infants, and Children (WIC) under section 17 of the Child Nutrition Act of 1966.

(b) *Definitions.* As used in this section, the terms *breastfeeding women*, *postpartum women*, and *pregnant women* mean women as defined in section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786(b)).

(c) *State plan requirements.* A State Plan must provide for—

(1) Coordinating operation of the Medicaid program with the State's operation of the Special Supplemental Food Program for Women, Infants, and Children;

(2) Providing timely written notice of the availability of WIC benefits to all individuals in the State who are determined to be eligible (including presumptively eligible) for Medicaid and who are:

(i) Pregnant women;

(ii) Postpartum women;

(iii) Breastfeeding women; and

(iv) Children under the age of 5.

(3) Referring individuals described under paragraphs (c)(2) (i) through (iv) of this section to the local agency responsible for administering the WIC program.

(d) *Notification requirements.* (1) The agency must give the written notice required under paragraph (c) of this section as soon as the agency identifies the individual (e.g., at the time of an eligibility determination for Medicaid) or immediately thereafter (e.g., at the time of notice of eligibility).

(2) The agency, no less frequently than annually, must also provide written notice of the availability of WIC benefits, including the location and telephone number of the local WIC agency or instructions for obtaining further information about the WIC program, to all Medicaid recipients (including those found to be presumptively eligible) who are under age 5 or who are women who might be pregnant, postpartum, or breastfeeding as

described in paragraphs (c)(2) (i) through (iv) of this section.

(3) The agency must effectively inform those individuals who are blind or deaf or who cannot read or understand the English language.

[57 FR 28103, June 24, 1992]

§ 431.636 Coordination of Medicaid with the State Children's Health Insurance Program (SCHIP).

(a) *Statutory basis.* This section implements—

(1) Section 2102(b)(3)(B) of the Act, which provides that children who apply for coverage under a separate child health plan under title XXI, but are found to be eligible for medical assistance under the State Medicaid plan, must be enrolled in the State Medicaid plan; and

(2) Section 2102(c)(2) of the Act, which requires coordination between a State child health program and other public health insurance programs.

(b) *Obligations of State Medicaid Agency.* The State Medicaid agency must adopt procedures to facilitate the Medicaid application process for, and the enrollment of children for whom the Medicaid application and enrollment process has been initiated in accordance with § 457.350(f) of this chapter. The procedures must ensure that—

(1) The applicant is not required to provide information or documentation that has been provided to the State agency responsible for determining eligibility under a separate child health program under title XXI and forwarded by such agency to the Medicaid agency on behalf of the child in accordance with § 457.350(f) of this chapter;

(2) Eligibility is determined in a timely manner in accordance with § 435.911 of this chapter;

(3) The Medicaid agency promptly notifies the State agency responsible for determining eligibility under a separate child health program when a child who was screened as potentially eligible for Medicaid is determined ineligible or eligible for Medicaid; and

(4) The Medicaid agency adopts a process that facilitates enrollment in a State child health program when a child is determined ineligible for Medicaid at initial application or redetermination.

[66 FR 2666, Jan. 11, 2001]

Subpart N—State Programs for Licensing Nursing Home Administrators

§ 431.700 Basis and purpose.

This subpart implements sections 1903(a)(29) and 1908 of the Act which require that the State plan include a State program for licensing nursing home administrators.

§ 431.701 Definitions.

Unless otherwise indicated, the following definitions apply for purposes of this subpart:

Agency means the State agency responsible for licensing individual practitioners under the State's healing arts licensing act.

Board means an appointed State board established to carry out a State program for licensing administrators of nursing homes, in a State that does not have a healing arts licensing act or an agency as defined in this section.

Licensed means certified by a State agency or board as meeting all of the requirements for a licensed nursing home administrator specified in this subpart.

Nursing home means any institution, facility, or distinct part of a hospital that is licensed or formally recognized as meeting nursing home standards established under State law, or that is determined under § 431.704 to be included under the requirements of this subpart. The term does not include—

(a) A religious nonmedical institution as defined in § 440.170(b) of this chapter; or

(b) A distinct part of a hospital, if the hospital meets the definition in § 440.10 or § 440.140 of this subchapter, and the distinct part is not licensed separately or formally approved as a nursing home by the State even though it is designated or certified as a skilled nursing facility.

Nursing home administrator means any person who is in charge of the general administration of a nursing home whether or not the person—

(a) Has an ownership interest in the home; or

(b) Shares his functions and duties with one or more other persons.

[43 FR 45188, Sept. 29, 1978, as amended at 64 FR 67052, Nov. 30, 1999]

§ 431.702 State plan requirement.

A State plan must provide that the State has a program for licensing administrators of nursing homes that meets the requirements of §§ 431.703 through 431.713 of this subpart.

§ 431.703 Licensing requirement.

The State licensing program must provide that only nursing homes supervised by an administrator licensed in accordance with the requirements of this subpart may operate in the State.

§ 431.704 Nursing homes designated by other terms.

If a State licensing law does not use the term ''nursing home,'' the CMS Administrator will determine the term or terms equivalent to ''nursing home'' for purposes of applying the requirements of this subpart. To obtain this determination, the Medicaid agency must submit to the Regional Medicaid Director copies of current State laws that define institutional health care facilities for licensing purposes.

§ 431.705 Licensing authority.

(a) The State licensing program must provide for licensing of nursing home administrators by—

(1) The agency designated under the healing arts act of the State; or

(2) A State licensing board.

(b) The State agency or board must perform the functions and duties specified in §§ 431.707 through 431.713 and the board must meet the membership requirements specified in § 431.706 of this subpart.

§ 431.706 Composition of licensing board.

(a) The board must be composed of persons representing professions and institutions concerned with the care and treatment of chronically ill or infirm elderly patients. However—

(1) A majority of the board members may not be representative of a single profession or category of institution; and

(2) Members not representative of institutions may not have a direct financial interest in any nursing home.

(b) For purposes of this section, nursing home administrators are considered representatives of institutions.

§ 431.707 Standards.

(a) The agency or board must develop, impose, and enforce standards that must be met by individuals in order to be licensed as a nursing home administrator.

(b) The standards must be designed to insure that nursing home administrators are—

(1) Of good character;

(2) Otherwise suitable; and

(3) Qualified to serve because of training or experience in institutional administration.

§ 431.708 Procedures for applying standards.

The agency or board must develop and apply appropriate procedures and techniques, including examinations and investigations, for determining if a person meets the licensing standards.

§ 431.709 Issuance and revocation of license.

Except as provided in § 431.714 of this subpart, the agency or board must—

(a) Issue licenses to persons who meet the agency's or board's standards; and

(b) Revoke or suspend a license if the agency or board determines that the person holding the license substantially fails to meet the standards.

§ 431.710 Provisional licenses.

To fill a position of nursing home administrator that unexpectedly becomes vacant, the agency or board may issue one provisional license, for a single period not to exceed 6 months. The license may be issued to a person who does not meet all of the licensing requirements established under § 431.707 but who—

(a) Is of good character and otherwise suitable; and

(b) Meets any other standards established for provisional licensure by the agency or board.

§ 431.711 Compliance with standards.

The agency or board must establish and carry out procedures to insure that licensed administrators comply with the standards in this subpart when they serve as nursing home administrators.

§ 431.712 Failure to comply with standards.

The agency or board must investigate and act on all complaints it receives of violations of standards.

§ 431.713 Continuing study and investigation.

The agency or board must conduct a continuing study of nursing homes and administrators within the State to improve—

(a) Licensing standards; and

(b) The procedures and methods for enforcing the standards.

§ 431.714 Waivers.

The agency or board may waive any standards developed under § 431.707 of this subpart for any person who has served in the capacity of a nursing home administrator during all of the 3 calendar years immediately preceding the calendar year in which the State first meets the requirements in this subpart.

§ 431.715 Federal financial participation.

No FFP is available in expenditures by the licensing board for establishing and maintaining standards for the licensing of nursing home administrators.

Subpart O [Reserved]

Subpart P—Quality Control

GENERAL PROVISIONS

SOURCE: Sections 431.800 through 431.808 appear at 55 FR 22166, May 31, 1990, unless otherwise noted.

§ 431.800 Scope of subpart.

This subpart—

(a) Establishes State plan requirements for a Medicaid eligibility quality control (MEQC) program designed to reduce erroneous expenditures by monitoring eligibility determinations and a claims processing assessment system that monitors claims processing operations.

(b) Establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous Medicaid payments due to eligibility and recipient liability errors as detected through the MEQC program.

§ 431.802 Basis.

This subpart implements the following sections of the Act, which establish requirements for State plans and for payment of Federal financial participation (FFP) to States:

1902(a)(4) Administrative methods for proper and efficient operation of the State plan.

1903(u) Limitation of FFP for erroneous medical assistance expenditures.

§ 431.804 Definitions.

As used in this subpart—

Active case means an individual or family determined to be currently authorized as eligible for Medicaid by the agency.

Administrative period means the period of time recognized by the MEQC program for State agencies to reflect changes in case circumstances, i.e., a change in a common program area, during which no case error based on the circumstance change would be cited. This period consists of the review month and the month prior to the review month.

Claims processing error means FFP has been claimed for a Medicaid payment that was made—

(1) For a service not authorized under the State plan;

(2) To a provider not certified for participation in the Medicaid program;

(3) For a service already paid for by Medicaid; or

(4) In an amount above the allowable reimbursement level for that service.

Eligibility error means that Medicaid coverage has been authorized or payment has been made for a recipient or family under review who—

(1) Was ineligible when authorized or when he received services; or

(2) Was eligible for Medicaid but was ineligible for certain services he received; or

(3) Had not met recipient liability requirements when authorized eligible for Medicaid; that is, he had not incurred medical expenses equal to the amount of his excess income over the State's financial eligibility level or he had incurred medical expenses that exceeded the amount of excess income over the State's financial eligibility level, or was making an incorrect amount of payment toward the cost of services.

Negative case action means an action that was taken to deny or otherwise dispose of a Medicaid application without a determination of eligibility (for instance, because the application was withdrawn or abandoned) or an action to deny, suspend, or terminate an individual or family.

State agency means either the State Medicaid agency or a State agency that is responsible for determining eligibility for Medicaid.

§ 431.806 State plan requirements.

(a) *MEQC program.* A State plan must provide for operating a Medicaid eligibility quality control program that meets the requirements of §§ 431.810 through 431.822 of this subpart.

(b) *Claims processing assessment system.* Except in a State that has an approved Medicaid Management Information System (MMIS) under subpart C of part 433 of this subchapter, a State plan must provide for operating a Medicaid quality control claims processing assessment system that meets the requirements of §§ 431.830 through 431.836 of this subpart.

§ 431.808 Protection of recipient rights.

Any individual performing activities under the MEQC program or the claims processing assessment system specified in this subpart must do so in a manner that is consistent with the provisions of §§ 435.902 and 436.901 of this subchapter concerning the rights of recipients.

MEDICAID ELIGIBILITY QUALITY CONTROL (MEQC) PROGRAM

SOURCE: Sections 431.810 through 431.822 appear at 55 FR 22167, May 31, 1990, unless otherwise noted.

§ 431.810 Basic elements of the Medicaid eligibility quality control (MEQC) program.

(a) *General requirements.* The agency must operate the MEQC program in accordance with this section and §§ 431.812 through 431.822 and other instructions established by CMS.

(b) *Review requirements.* The agency must conduct MEQC reviews in accordance with the requirements specified in § 431.812 and other instructions established by CMS.

(c) *Sampling requirements.* The agency must conduct MEQC sampling in accordance with the requirements specified in § 431.814 and other instructions established by CMS.

§ 431.812 Review procedures.

(a) *Active case reviews.* (1) Except as provided in paragraph (a)(2) of this section, the agency must review all active cases selected from the State agency's lists of cases authorized eligible for the review month, to determine if the cases were eligible for services during all or part of the month under review, and, if appropriate, whether the proper amount of recipient liability was computed.

(2) The agency is not required to conduct reviews of the following cases:

(i) Supplemental Security Income (SSI) recipient cases in States with contracts under section 1634 of the Act for determining Medicaid eligibility;

(ii) Foster care and adoption assistance cases under title IV-E of the Act found eligible for Medicaid; and

(iii) Cases under programs that are 100 percent federally funded.

(b) *Negative case reviews.* Except as provided in paragraph (c) of this section, the agency must review those negative cases selected from the State agency's lists of cases that are denied, suspended, or terminated in the review month to determine if the reason for the denial, suspension, or termination was correct and if requirements for timely notice of negative action were met. A State's negative case sample size is determined on the basis of the number of negative case actions in the universe.

(c) *Alternate systems of negative case reviews*—(1) *Basic provision.* A State may be exempt from the negative case

review requirements specified in paragraphs (b) and (e)(2) of this section and in § 431.814(d) upon CMS's approval of a plan for the use of a superior system.

(2) *Submittal of plan for alternate system.* An agency must submit its plan for the use of a superior system to CMS for approval at least 60 days before the beginning of the review period in which it is to be implemented. If a plan is unchanged from a previous period, the agency is not required to resubmit it.

The agency must receive approval for a plan before it can be implemented.

(3) *Requirement for alternate system.* To be approved, the State's plan must—

(i) Clearly define the purpose of the system and demonstrate how the system is superior to the current negative case review requirements.

(ii) Contain a methodology for identifying significant problem areas that could result in erroneous denials, suspensions, and terminations of applicants and recipients. Problem areas selected for review must contain at least as many applicants and recipients as were included in the negative case sample size previously required for the State.

(iii) Provide a detailed methodology describing how the extent of the problem area will be measured through sampling and review procedures, the findings expected from the review, and planned corrective actions to resolve the problem.

(iv) Include documentation supporting the use of the system methodology. Documentation must include the timeframes under which the system will be operated.

(v) Provide a superior means of monitoring denials, terminations, and suspensions than that required under paragraph (b) of this section.

(vi) Provide a statistically valid error rate that can be projected to the universe that is being studied.

(d) *Reviews for erroneous payments.* The agency must review all claims for services furnished during the review month and paid within 4 months of the review month to all members of each active case related in the sample to identify erroneous payments resulting from—

(1) Ineligibility for Medicaid;

(2) Ineligibility for certain Medicaid services; and

(3) Recipient understated or overstated liability.

(e) *Reviews for verification of eligibility status.* The agency must collect and verify all information necessary to determine the eligibility status of each individual included in an active case selected in the sample as of the review month and whether Medicaid payments were for services which the individual was eligible to receive.

The agency must apply the administrative period described in § 431.804 when considering the case circumstances and the case correctness. In order to verify eligibility information, the agency must—

(1) Examine and analyze each case record for all cases under review to establish what information is available for use in determining eligibility in the review month;

(2) Conduct field investigations including in-person recipient interviews for each case in the active case sample, and conduct in-person interviews only when the correctness of the agency action cannot be determined by review of the case record with recipients for cases in the negative case action sample (unless this is otherwise addressed in a superior system provided for in paragraph (c)(1) of this section);

(3) Verify all appropriate elements of eligibility for active cases through at least one primary source of evidence or two secondary sources of evidence as defined by CMS by documentation or by collateral contacts as required, or both, and fully record the information on the appropriate forms;

(4) Determine the basis on which eligibility was established and the eligibility status of the active case and each case member;

(5) Collect copies of State paid claims or recipient profiles for services delivered during the review month and, if indicated, any months prior to the review month in the agency's selected spenddown period, for all members of the active case under review;

(6) Associate dollar values with eligibility status for each active case under review; and

(7) Complete the payment, case, and review information for all individuals

in the active case under review on the appropriate forms.

§431.814 Sampling plan and procedures.

(a) *Plan approval.* The agency must submit a basic MEQC sampling plan (or revisions to a current plan) that meets the requirements of this section to the appropriate CMS regional office for approval at least 60 days before the beginning of the review period in which it is to be implemented. If a plan is unchanged from a previous period, the agency is not required to resubmit the entire plan. Universe estimates and sampling intervals are required 2 weeks before the first monthly sample selection for each review period. The agency must receive approval for a plan before it can be implemented.

(b) *Plan requirements.* The agency must have an approved sampling plan in effect for the full 6-month sampling period that includes the following:

(1) The population to be sampled;

(2) The list(s) from which the sample is selected and the following characteristics of the list(s):

(i) Sources;

(ii) All types of cases in the selection lists;

(iii) Accuracy and completeness of sample lists in reference to the population(s) of interest;

(iv) Whether or not the selection list was constructed by combining more than one list;

(v) The form of the selection list (whether the list or part of the list is automated);

(vi) Frequency and length of delays in updating the selection lists or their sources;

(vii) Number of items on the lists and proportion of listed-in-error items:

(viii) Methods of deleting unwanted items from the selection lists; and

(ix) Structure of the selection lists.

(3) The sample size, including the minimum number of reviews to be completed and the expected number of cases to be selected. Minimum sample sizes are based on the State's relative level of Medicaid annual expenditures for services for active cases, and on the total number of negative case actions in the universe for negative cases. When the sample is substratified, there can be no fewer than 75 cases in each substratum, except as provided in paragraph (c) of this section or as provided in an exception documented in an approved sampling plan which contains a statement accepting the precision and reliability of the reduced sample.

(4) The sample selection procedure. Systematic random sampling is recommended. Alternative procedures must provide a representative sample, conform to principles of probability sampling, and yield estimates with the same or better precision than achieved in systematic random sampling.

(5) Procedures used to identify amounts paid for services received in the review month.

(6) Specification as to whether the agency chooses to—

(i) Use billed amounts to offset recipient liability toward cost of care (No indication will be interpreted to mean that the agency will use paid claims); and

(ii) Use denied claims to offset recipient liability toward cost of care in the payment review. (No indication will be interpreted to mean denied claims will not be used.)

(7) Indication of whether the agency opts to drop or complete cases selected more than once in a sample period. (No indication will be interpreted to mean that the agency will complete cases selected more than once.)

(c) *Eligibility universe—active cases.* The MEQC universe for active cases must be divided into two strata, the Aid to Families with Dependent Children (AFDC) stratum and the Medical Assistance Only (MAO) stratum.

(1) All States must use the AFDC quality control sample for the AFDC stratum.

(2) States must include in the MAO stratum all cases certified as eligible for Medicaid that are not in the AFDC stratum, excluding individuals specified in paragraph (c)(4) of this section.

(3) States that do not have an agreement with the Social Security Administration under section 1634 of the Act and do not have more restrictive eligibility criteria under section 1902(f) of the Act but require a separate Medicaid application for recipients of SSI and determine Medicaid eligibility using SSI criteria must divide the MAO

stratum into two substrata: MAO cases and SSI cash cases for the first review period beginning after July 1, 1990 and for review periods thereafter. The SSI substratum sample size must be 75 cases or one-half of the total MAO sample, whichever is smaller. The non-SSI MAO substratum sample will be the remainder of the MAO stratum cases.

States may be exempt from this requirement when implementing an approved sampling option that does not accommodate this stratification method.

(4) States must exclude from the MEQC universe SSI beneficiaries whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act, individuals in foster care or receiving adoption assistance whose eligibility is determined under title IV-E of the Act, and individuals receiving Medicaid under programs that are 100 percent federally funded.

(d) *Eligibility universe—negative cases.* Unless the agency has an approved superior system under §431.812(c) that provides otherwise, the universe for negative Medicaid eligibility cases must consist of all denied applications, suspensions, and terminations occurring during the review month except transfers between counties without any break in eligibility, cases in which eligibility is exclusively determined by SSA under a section 1634 contract, cases determined eligible for foster care and adoption assistance under title IV-E of the Act, and cases under programs that are 100 percent federally funded.

(e) *Sampling procedures.* The agency must document all sampling procedures used by the State agency, including 98 percent accuracy of program identifier codes used in the sampling frame to separate listed-in-error cases from those in the population of interest, must make them available for review by CMS, and must be able to demonstrate the integrity of its sampling procedures in accordance with this section.

(f) *Sampling periods.* The agency must use 6-month sampling periods, from April through September and from October through March.

(g) *Statistical samples.* The agency must select statistically valid samples of both active and negative case actions.

(h) *Sample selection lists.* The agency must submit to CMS monthly a list of cases selected in the sample to be reviewed, after the State's sample selection and before commencing MEQC reviews on the cases in the sample.

(i) *Universe estimates and sampling intervals.* The agency must submit detailed universe estimates and sampling intervals to CMS for approval at least 2 weeks before the first sample selection of the review period if the estimates differ from the previous period. The sampling intervals must be used continuously throughout the sampling period unless otherwise specified in an approved sampling plan. Final universe counts based on the actual sampling universe must be determined and reported to CMS for each stratum/substratum designated in the sampling plan.

The agency also must submit universe counts for cases eligible for foster care and adoption assistance under title IV-E of the Act, and, for States with an agreement under section 1634 of the Act, for cases found eligible by the Social Security Administration.

(j) *Sample size and methodology options.* The agency may select a sample size in accordance with the minimum established under paragraph (b)(3) of this section or use one of the methodologies specified in paragraph (j)(1) or (2) of this section.

(1) *Increase in size.* The agency may, at its option, increase its sample size for a sampling period above the federally prescribed minimum sample size provided for under paragraph (b)(3) of this section, and receive FFP for any increased administrative costs the agency incurs by exercising this option.

(2) *Retrospective sampling.* The agency may, at its option, implement retrospective sampling in which cases are stratified by dollar value of claims paid. If the agency selects retrospective sampling, it must—

(i) Draw an initial case sample size each month that is no less than 5 times the required sample size. The sample will be selected from the universe of

cases that were certified eligible in the fourth month prior to the month of case selection;

(ii) Identify claims paid for services furnished to all individuals during the review month (and, if indicated, any months prior to the review month in the agency's selected spenddown period) for these cases;

(iii) Stratify the cases by dollar value of the claims into three strata; and

(iv) Select a second statistically valid sample within each group subject to the sample size requirements specified in paragraph (b)(3) or (j)(1) of this section.

§431.816 Case review completion deadlines and submittal of reports.

(a) The agency must complete case reviews and submit reports of findings to CMS as specified in paragraph (b) of this section in the form and at the time specified by CMS.

(b) In addition to the reporting requirements specified in §431.814 relating to sampling, the agency must complete case reviews and submit reports of findings to CMS in accordance with paragraphs (b)(1) through (6) of this section for review periods beginning after July 1, 1990.The agency must not combine or otherwise integrate case findings from the MAO and AFDC strata to meet the case percentage deadlines as specified in paragraphs (b)(1) through (6) of this section.

(1) *Active case eligibility reviews—MAO stratum.* (i) The agency must complete case eligibility reviews and report the findings electronically through the system prescribed by CMS for 90 percent of all active MAO cases within 105 days of the end of the review month for which those cases were reviewed, within 125 days for 95 percent of all active MAO cases, and within 150 days for 100 percent of all MAO active cases.

(ii) The agency must submit a report on cases selected for the review month.

(2) *Active case eligibility reviews—AFDC stratum.* (i) The agency must complete case eligibility reviews for AFDC ineligible and overpaid error cases caused by ineligible individuals and report the findings electronically through the system prescribed by CMS within 105 days of the end of the review month for which those cases were reviewed for 90 percent of the total reviews; within 125 days of the end of the review month for which those cases were reviewed for 95 percent of the total reviews; and within 150 days of the end of the review month for which those cases were reviewed for 100 percent of the total reviews.

(ii) The agency must report findings electronically through the system prescribed by CMS for 100 percent of the State agency-reported eligible individuals within 30 days after the final timeframe required by the AFDC program as specified in program regulations at 45 CFR 205.40(b)(2)(ii).

(3) *Negative case eligibility reviews.* The agency must submit a monthly progress report on negative case reviews completed during the month unless the agency has an approved superior system in effect. The agency must submit a report on its findings by June 30 of each year for the previous April-September sampling period and by December 31, for the October-March sampling period.

(4) *Payment reviews.* (i) The agency must submit payment review findings electronically through the system prescribed by CMS.

(ii) The agency must complete payment review findings for 100 percent of the active case reviews in its sample and report the findings within 60 days after the first day of the month in which the claims collection process begins. The agency must wait 5 months after the end of each review month before associating the amount of claims paid for each case for services furnished during the review month unless retrospective sampling is elected.

(iii) The agency must make any necessary corrections to claims payments during the month the claim is paid and the following month. CMS will take necessary action to reject any State adjustment adversely affecting the error rate, for example, by not paying claims on error cases.

(5) *Summary of reviews and findings.* The agency must submit summary reports of the findings for all active cases in the 6-month sample by July 31 of each year for the previous April-September sampling period and by January 31 for the October-March sampling

period. These summary reports must include findings changed in the Federal re-review process.

(6) *Other data and reports.* The agency must report other requested data and reports in a manner prescribed by CMS.

§ 431.818 Access to records: MEQC program.

(a) The agency, upon written request, must mail to the HHS staff all records, including complete local agency eligibility case files or legible copies and all other documents pertaining to its MEQC reviews to which the State has access, including information available under part 435, subpart I, of this chapter.

(b) The agency must mail requested records within 10 working days of receipt of a request, unless the State has an alternate method of submitting these records that is approved by CMS or has received, on an as-needed basis, approval from CMS to extend this timeframe by 3 additional working days to allow for exceptional circumstances.

§ 431.820 Corrective action under the MEQC program.

The agency must—

(a) Take action to correct any active or negative case action errors found in the sample cases;

(b) Take administrative action to prevent or reduce the incidence of those errors; and

(c) By September 15 each year, submit to CMS a report on its error rate analysis and a corrective action plan based on that analysis. The agency must submit revisions to the plan within 60 days of identification of additional error-prone areas, other significant changes in the error rate (that is, changes that the State experiences that increase or decrease its error rate and necessitate immediate corrective action or discontinuance of corrective actions that effectively control the cause of the error rate change), or changes in planned corrective action.

§ 431.822 Resolution of differences in State and Federal case eligibility or payment findings.

(a) When a difference exists between State and Federal case eligibility or payment findings, the Regional Office will notify the agency by a difference letter.

(b) The agency must return the difference letter to the Regional Office within 28 calendar days of the date of the letter indicating either agreement with the Federal finding or reasons for disagreement and if the agency desires a conference to resolve the difference. This period may be shortened if the Regional Office finds that it is necessary to do so in order to meet a case completion deadline, and the State still has a reasonable period of time in which to respond to the letter. If the agency fails to submit the difference letter indicating its agreement or disagreement with the Federal findings within the 28 calendar days (or the shorter period designated as described above), the Federal findings will be sustained.

(c) If the Regional Office disagrees with the agency's response, a difference conference will be scheduled within 20 days of the request of the agency. If a difference cannot be resolved, the State may request a direct presentation of its position to the Regional Administrator. The Regional Administrator has final authority for resolving the difference.

MEDICAID QUALITY CONTROL (MQC) CLAIMS PROCESSING ASSESSMENT SYSTEM

SOURCE: Sections 431.830 through 431.836 appear at 55 FR 22170, May 31, 1990, unless otherwise noted.

§ 431.830 Basic elements of the Medicaid quality control (MQC) claims processing assessment system.

An agency must—

(a) Operate the MQC claims processing assessment system in accordance with the policies, sampling methodology, review procedures, reporting forms, requirements, and other instructions established by CMS.

(b) Identify deficiencies in the claims processing operations.

(c) Measure cost of deficiencies;

(d) Provide data to determine appropriate corrective action;

(e) Provide an assessment of the State's claims processing or that of its fiscal agent;

(f) Provide for a claim-by-claim review where justifiable by data; and

(g) Produce an audit trail that can be reviewed by CMS or an outside auditor.

§ 431.832 Reporting requirements for claims processing assessment systems.

(a) The agency must submit reports and data specified in paragraph (b) of this section to CMS, in the form and at the time specified by CMS.

(b) Except when CMS authorizes less stringent reporting, States must submit:

(1) A monthly report on claims processing reviews sampled and or claims processing reviews completed during the month;

(2) A summary report on findings for all reviews in the 6-month sample to be submitted by the end of the 3rd month following the scheduled completion of reviews for that 6 month period; and

(3) Other data and reports as required by CMS.

§ 431.834 Access to records: Claims processing assessment systems.

The agency, upon written request, must provide HHS staff with access to all records pertaining to its MQC claims processing assessment system reviews to which the State has access, including information available under part 435, subpart J, of this chapter.

§ 431.836 Corrective action under the MQC claims processing assessment system.

The agency must—

(a) Take action to correct those errors identified through the claims processing assessment system review and, if cost effective, to recover those funds erroneously spent;

(b) Take administrative action to prevent and reduce the incidence of those errors; and

(c) By August 31 of each year, submit to CMS a report of its error analysis and a corrective action plan on the reviews conducted since the cut-off-date of the previous corrective action plan.

FEDERAL FINANCIAL PARTICIPATION

§§ 431.861–431.864 [Reserved]

§ 431.865 Disallowance of Federal financial participation for erroneous State payments (for annual assessment periods ending after July 1, 1990).

(a) *Purpose and applicability*—

(1) *Purpose.* This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous medical assistance payments due to eligibility and beneficiary liability errors, as detected through the Medicaid eligibility quality control (MEQC) program required under § 431.806 in effect on and after July 1, 1990.

(2) *Applicability.* This section applies to all States except Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, and American Samoa beginning July 1, 1990.

(b) *Definitions.* For purposes of this section—

Administrator means the Administrator, Centers for Medicare & Medicaid Services or his or her designee.

Annual assessment period means the 12-month period October 1 through September 30 and includes two 6-month sample periods (October-March and April-September).

Beneficiary liability means—

(1) The amount of excess income that must be offset with incurred medical expenses to gain eligibility; or

(2) The amount of payment a recipient must make toward the cost of services.

Erroneous payments means the Medicaid payment that was made for an individual or family under review who—

(1) Was ineligible for the review month or, if full month coverage is not provided, at the time services were received;

(2) Was ineligible to receive a service provided during the review month; or

(3) Had not properly met enrollee liability requirements prior to receiving Medicaid services.

(4) The term does not include payments made for care and services covered under the State plan and furnished to children during a presumptive eligibility period as described in § 435.1102 of this chapter.

National mean error rate means the payment weighted average of the eligibility payment error rates for all States.

National standard means a 3-percent eligibility payment error rate.

State payment error rate means the ratio of erroneous payments for medical assistance to total expenditures for medical assistance (less payments to Supplemental Security Income beneficiaries in section 1634 contract States and payments for children eligible for foster care and adoption assistance under title IV-E of the Act) for cases under review under the MEQC system for each assessment period.

Technical error means an error in an eligibility condition that, if corrected, would not result in a difference in the amount of medical assistance paid. These errors include work incentive program requirements, assignment of social security numbers, the requirement for a separate Medicaid application, monthly reporting requirements, assignment of rights to third party benefits, and failure to apply for benefits for which the family or individual is not eligible. Errors other than those listed in this definition, identified by CMS in subsequent instructions, or approved by CMS are not technical errors.

(c) *Setting of State's payment error rate.* (1) Each State must, for each annual assessment period, have a payment error rate no greater than 3 percent or be subject to a disallowance of FFP.

(2) A payment error rate for each State is determined by CMS for each annual assessment period by computing the statistical estimate of the ratio of erroneous payments for medical assistance made on behalf of individuals or cases in the sample for services received during the review month to total expenditures for medical assistance for that State made on behalf of individuals or cases in the sample for services received during the review month. This ratio incorporates the findings of a federally re-reviewed subsample of the State's review findings and is projected to the universe of total medical assistance payments for calculating the amount of disallowance under paragraph (d)6) of this section.

(3) The State's payment error rate does not include payments made on behalf of individuals whose eligibility determinations were made exclusively by the Social Security Administration under an agreement under section 1634 of the Act or children found eligible for foster care and adoption assistance under title IV-E of the Act.

(4) The amount of erroneous payments is determined as follows:

(i) For ineligible cases resulting from excess resources, the amount of error is the lesser of—

(A) The amount of the payment made on behalf of the family or individual for the review month; or

(B) The difference between the actual amount of countable resources of the family or individual for the review month and the State's applicable resources standard.

(ii) For ineligible cases resulting from other than excess resources, the amount of error is the total amount of medical assistance payments made for the individual or family under review for the review month.

(iii) For erroneous payments resulting from failure to properly meet beneficiary liability, the amount of error is the lesser of—

(A) The amount of payments made on behalf of the family or individual for the review month; or

(B) The difference between the correct amount of beneficiary liability and the amount of beneficiary liability met by the individual or family for the review month.

(iv) The amount of payments made for services provided during the review month for which the individual or family was not eligible.

(5) In determining the amount of erroneous payments, errors caused by technical errors are not included.

(6) If a State fails to cooperate in completing a valid MEQC sample or individual reviews in a timely and appropriate fashion as required, CMS will establish the State's payment error rate based on either—

(i) A special sample or audit;

(ii) The Federal subsample; or

(iii) Other arrangements as the Administrator may prescribe.

(7) When it is necessary for CMS to exercise the authority in paragraph

(c)(6) of this section, the amount that would otherwise be payable to the State under title XIX of the Act is reduced by the full costs incurred by CMS in making these determinations. CMS may make these determinations either directly or under contractual or other arrangements.

(d) *Computation of anticipated error rate.* (1) Before the beginning of each quarter, CMS will project the anticipated medical assistance payment error rate for each State for that quarter. The anticipated error rate is the lower of the weighted average error rate of the two most recent 6-month review periods or the error rate of the most recent 6-month review period. In either case, cases in the review periods must have been completed by the State and CMS. If a State fails to provide CMS with information needed to project anticipated excess erroneous expenditures, CMS will assign the State an error rate as prescribed in paragraph (c)(6) of this section.

(2) If the State believes that the anticipated error rate established in accordance with paragraph (d)(1) of this section is based on erroneous data, the State may submit evidence that demonstrates the data were erroneous. If the State satisfactorily demonstrates that CMS's data were erroneous, the State's anticipated error rate will be adjusted accordingly. Submittal of evidence is subject to the following conditions:

(i) The State must inform CMS of its intent to submit evidence at least 70 days prior to the beginning of the quarter.

(ii) The State may request copies of data that CMS used to compute its anticipated error rate within 7 days of receiving notification of its projected error rate.

(iii) The State has up to 40 days before the quarter begins to present the evidence.

(iv) The evidence is restricted to documentation of suspected CMS data entry errors, processing errors, and resolutions of Federal subsample difference cases subsequent to calculation of the error rate projection as contained in the original notice to the State.

(v) The State may not submit other evidence, such as that consisting of revisions to State errors as a result of changes to the original State review findings submitted to CMS.

(vi) The State may not submit evidence challenging the error rate computational methodology.

(3) Based on the anticipated error rate established in paragraph (d)(1) or (d)(2) of this section, CMS reduces its estimate of the State's requirements for FFP for medical assistance for the quarter by the percentage by which the anticipated payment error rate exceeds the 3-percent national standard. This reduction is applied against CMS's total estimate of FFP for medical assistance expenditures (less payments to Supplemental Security Income beneficiaries in 1634 contract States and payments to children found eligible for foster care and adoption assistance under title IV-E of the Act) prior to any other required reductions. The reduction is noted on the State's grant award for the quarter and does not constitute a disallowance, and, therefore, is not appealable.

(4) After the end of each quarter, an adjustment to the reduction will be made based on the State's actual expenditures.

(5) After the actual payment error rate has been established for each annual assessment period, CMS will compute the actual amount of the disallowance and adjust the FFP payable to each State based on the difference between the amounts previously withheld for each of the quarters during the appropriate assessment period and the amount that should have been withheld based on the State's actual final error rate. If CMS determines that the amount withheld for the period exceeds the amount of the actual disallowance, the excess amount withheld will be returned to the States through the normal grant awards process within 30 days of the date the actual disallowance is calculated.

(6) CMS will compute the amount to be withheld or disallowed as follows:

(i) Subtract the 3-percent national standard from the State's anticipated or actual payment error rate percentage.

(ii) If the difference is greater than zero, the Federal medical assistance funds for the period, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement and children found eligible for foster care and adoption assistance under title IV-E of the Act, are multiplied by that percentage. This product is the amount of the disallowance or withholding.

(7) A State's payment error rate for an annual assessment period is the weighted average of the payment error rates in the two 6-month review periods comprising the annual assessment period.

(8) The weights are established as the percent of the total annual payments, excluding payments for those individuals whose eligibility for Medicaid was determined exclusively by the Social Security Administration under a section 1634 agreement and children found eligible for foster care and adoption assistance under title IV-E of the Act, that occur in each of the 6-month periods.

(e) *Notice to States and showing of good faith.* (1) When the actual payment error rate data are finalized for each annual assessment period ending after July 1, 1990, CMS will establish each State's error rate and the amount of any disallowance. States that have error rates above the national standard will be notified by letter of their error rates and the amount of the disallowance.

(i) The State has 65 days from the date of receipt of this notification to show that this disallowance should not be made because it failed to meet the national standard despite a good faith effort to do so.

(ii) If CMS is satisfied that the State did not meet the national standard despite a good faith effort, CMS may reduce the funds being disallowed in whole or in part as it finds appropriate under the circumstances shown by the State.

(iii) A finding that a State did not meet the national standard despite a good faith effort will be limited to extraordinary circumstances.

(iv) The burden of establishing that a good faith effort was made rests entirely with the State.

(2) Some examples of circumstances under which CMS may find that a State did not meet the national standard despite a good faith effort are—

(i) Disasters such as fire, flood, or civil disorders that—

(A) Require the diversion of significant personnel normally assigned to Medicaid eligibility administration; or

(B) Destroyed or delayed access to significant records needed to make or maintain accurate eligibility determinations;

(ii) Strikes of State staff or other government or private personnel necessary to the determination of eligibility or processing of case changes;

(iii) Sudden and unanticipated workload changes that result from changes in Federal law and regulation, or rapid, unpredictable caseload growth in excess of, for example, 15 percent for a 6-month period;

(iv) State actions resulting from incorrect written policy interpretations to the State by a Federal official reasonably assumed to be in a position to provide that interpretation; and

(v) The State has taken the action it believed was needed to meet the national standard, but the national standard was not met. CMS will consider request for a waiver under this criterion only if a State has achieved an error rate for the sample period that (after reducing the error rate by taking into account the cases determined by CMS to be in error as a result of conditions listed in paragraphs (e)(2) (i) through (iv) of this section) is less than its error rate for the preceding sample year and does not exceed the national mean error rate for the sample period under review (unless that national mean error rate is at or below the 3-percent national standard). If the agency has met this error reduction requirement or had error rates of 3 percent or below for the prior two review periods, and its error rate for the review period under consideration is less than one-third above the national standard, CMS will evaluate a request for a good faith waiver based on the following factors:

(A) The State has fully met the performance standards in the operation of a quality control system in accordance with Federal regulations and CMS guidelines (e.g., adherence to Federal case completion timeliness requirements and verification standards).

(B) The State has achieved substantial performance in the formulation of error reduction initiatives based on the following processes:

(*1*) Performance of an accurate and thorough statistical and program analysis for error reduction which utilized quality control and other data:

(*2*) The translation of such analysis into specific and appropriate error reduction practices for major error elements; and

(*3*) The use of monitoring systems to verify that the error reduction initiatives were implemented at the local office level.

(C) The State has achieved substantial performance in the operation of the following systems supported by evidence of the timely utilization of their outputs in the determination of case eligibility:

(*1*) The operation of the Income and Eligibility Verification System in accordance with the requirements of parts 431 and 435 of this chapter, and

(*2*) The operation of systems that interface with Social Security data and, where State laws do not restrict agency access, records from agencies responsible for motor vehicles, vital statistics, and State or local income and property taxes (where these taxes exist).

(D) The State has achieved substantial performance in the use of the following accountability mechanisms to ensure that agency staff adhere to error reduction initiatives. The following are minimum requirements:

(*1*) Accuracy of eligibility and liability determinations and timely processing of case actions are used as quantitative measures of employee performance and reflected in performance standards and appraisal forms:

(*2*) Selective second-party case reviews are conducted. The second-party review results are periodically reported to higher level management, as well as supervisors and workers and are used in performance standards and appraisal forms; and

(*3*) Regular operational reviews of local offices are performed by the State to evaluate the offices' effectiveness in meeting error reduction goals with periodic monitoring to ensure that review recommendations have been implemented.

(vi) A State that meets the performance standards specified in paragraphs (e)(2)(v) (A) through (D) of this section will be considered for a full or partial waiver of its disallowance amount. The State must submit only specific documentation that verifies that the necessary actions were accomplished. For example, a State could submit worker performance standards reflecting timeliness and case accuracy as quantitative measures of performance.

(3) The failure of a State to act upon necessary legislative changes or to obtain budget authorization for needed resources is not a basis for finding that a State failed to meet the national standard despite a good faith effort.

(f) *Disallowance subject to appeal.* (1) If a State does not agree with a disallowance imposed under paragraph (e) of this section, it may appeal to the Departmental Appeals Board within 30 days from the date of the final disallowance notice from CMS. The regular procedures for an appeal of a disallowance will apply, including review by the Appeals Board under 45 CFR part 16.

(2) This appeal provision, as it applies to MEQC disallowances, is not applicable to the Administrator's decision on a State's waiver request provided for under paragraph (e) of this section.

[55 FR 22171, May 31, 1990, as amended at 61 FR 38398, July 24, 1996; 66 FR 2666, Jan. 11, 2001]

Subpart Q—Requirements for Estimating Improper Payments in Medicaid and SCHIP

SOURCE: 71 FR 51081, Aug. 28, 2006, unless otherwise noted.

§ 431.950 Purpose.

This subpart requires States and providers to submit information necessary

to enable the Secretary to produce national improper payment estimates for Medicaid and the State Children's Health Insurance Program (SCHIP).

§ 431.954 Basis and scope.

(a) *Basis.* The statutory bases for this subpart are sections 1102, 1902(a)(6), and 2107(b)(1) of the Act, which contain the Secretary's general rulemaking authority and obligate States to provide information, as the Secretary may require, to monitor program performance. In addition, this rule supports the Improper Payments Information Act of 2002 (Pub. L. 107–300), which requires Federal agencies to review and identify annually those programs and activities that may be susceptible to significant erroneous payments, estimate the amount of improper payments, report such estimates to the Congress, and submit a report on actions the agency is taking to reduce erroneous payments. Section 1902(a)(27)(B) of the Act requires States to require providers to agree to furnish the State Medicaid agencies and the Secretary with information regarding payments claimed by Medicaid providers for furnishing Medicaid services.

(b) *Scope.* (1) This subpart requires States under the statutory provisions cited in paragraph (a) of this section to submit information as set forth in § 431.970 for, among other purposes, estimating improper payments in the fee-for-service (FFS) and managed care components of the Medicaid and SCHIP programs and to determine whether eligibility was correctly determined. This subpart also requires providers to submit to the Secretary any medical records and other information necessary to disclose the extent of services provided to individuals receiving assistance, and to furnish information regarding any payments claimed by the provider for furnishing such services, as requested by the Secretary.

(2) All information must be furnished in accordance with section 1902(a)(7)(A) of the Act, regarding confidentiality.

(3) This subpart does not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands or American Samoa.

§ 431.958 Definitions and use of terms.

Active case means a case containing information on a beneficiary who is enrolled in the Medicaid or SCHIP program in the month that eligibility is reviewed.

Active fraud investigation means a beneficiary's name has been referred to the State Fraud and Abuse Control or similar investigation unit and the unit is currently actively pursuing an investigation to determine whether the beneficiary committed fraud.

Adjudication date means either the date on which money was obligated to pay a claim or the date the decision was made to deny a claim.

Agency means, for purposes of the PERM eligibility reviews and this regulation, the agency that performs the Medicaid and SCHIP eligibility determinations under PERM and excludes the State agency as defined in the regulation.

Application means an application form for Medicaid or SCHIP benefits deemed complete by the State, with respect to which such State approved or denied eligibility.

Beneficiary means an applicant for, or recipient of, Medicaid or SCHIP program benefits.

Case means an individual beneficiary.

Case error rate means an error rate that reflects the number of cases in error in the eligibility sample for the active cases plus the number of cases in error in the eligibility sample for the negative cases expressed as a percentage of the total number of cases examined in the sample.

Case record means either a hardcopy or electronic file that contains information on a beneficiary regarding program eligibility.

Eligibility means meeting the State's categorical and financial criteria for receipt of benefits under the Medicaid or SCHIP programs.

Improper payment means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and includes any payment to an ineligible recipient, any duplicate payment, any payment for

services not received, any payment incorrectly denied, and any payment that does not account for credits or applicable discounts.

Last action means the most recent date on which the State agency took action to grant, deny, or terminate program benefits based on the State agency's eligibility determination; and is the point in time for the PERM eligibility reviews unless the last action occurred outside of 12 months prior to the sample month.

Medicaid means the joint Federal and State program, authorized and funded under Title XIX of the Act, that provides medical care to people with low incomes and limited resources.

Negative case means a case containing information on a beneficiary who applied for benefits and was denied or whose program benefits were terminated, based on the State agency's eligibility determination or on a completed redetermination.

Payment means any payment to a provider, insurer, or managed care organization for a Medicaid or SCHIP beneficiary for which there is Medicaid or SCHIP Federal financial participation. It may also mean a direct payment to a Medicaid or SCHIP beneficiary in limited circumstances permitted by CMS regulation or policy.

Payment error rate means an annual estimate of improper payments made under Medicaid and SCHIP equal to the sum of the overpayments and underpayments in the sample, that is, the absolute value of such payments, expressed as a percentage of total payments made in the sample.

Payment review means the process by which payments for services are associated with cases reviewed for eligibility. Payments are collected for services received in the review month or in the sample month, depending on the case reviewed.

PERM means the Payment Error Rate Measurement process to measure improper payment in Medicaid and SCHIP.

Provider means any qualified provider recognized under Medicaid and SCHIP statute and regulations.

Review cycle means the complete timeframe to complete the improper payments measurement including the fiscal year being measured; generally this timeframe begins in October of the fiscal year reviewed and ends in August of the following fiscal year.

Review month means the month in which eligibility is reviewed and is usually when the State took its last action to grant or redetermine eligibility. If the State's last action was taken beyond 12 months prior to the sample month, the review month shall be the sample month.

Review year means the Federal fiscal year being analyzed for errors by Federal contractors or the State.

Sample month means the month the State selects a case from the sample for an eligibility review.

State agency means the State agency that is responsible for determining program eligibility for Medicaid and SCHIP, as applicable, based on applications and redeterminations.

State Children's Health Insurance Program (SCHIP) means the program authorized and funded under Title XXI of the Act.

States means the 50 States and the District of Columbia.

Undetermined means a beneficiary case subject to a Medicaid or SCHIP eligibility determination under this regulation about which a definitive determination of eligibility could not be made.

§431.970 Information submission requirements.

(a) States must submit information to the Secretary for, among other purposes, estimating improper payments in Medicaid and SCHIP, that include but are not limited to—

(1) All adjudicated fee-for-service (FFS) and managed care claims information, on a quarterly basis, from the review year with FFS claims stratified by service;

(2) Upon request from CMS, provider contact information that has been verified by the State as current;

(3) All medical and other related policies in effect and any quarterly policy updates;

(4) Current managed care contracts, rate information, and any quarterly updates applicable to the review year for SCHIP and, as requested, for Medicaid;

(5) Data processing systems manuals;

(6) Repricing information for claims that are determined during the review to have been improperly paid;

(7) Information on claims that were selected as part of the sample, but changed in substance after selection, for example, successful provider appeals;

(8) Adjustments made within 60 days of the adjudication dates for the original claims or line items with sufficient information to indicate the nature of the adjustments and to match the adjustments to the original claims or line items;

(9) For the eligibility improper payment measurement, information as set forth in § 431.978 through § 431.988;

(10) A corrective action plan for purposes of reducing erroneous payments in FFS, managed care, and eligibility; and

(11) Other information that the Secretary determines is necessary for, among other purposes, estimating improper payments and determining error rates in Medicaid and SCHIP.

(b) Providers must submit information to the Secretary for, among other purposes, estimating improper payments in Medicaid and SCHIP, which include but are not limited to, Medicaid and SCHIP beneficiary medical records.

§ 431.974 Basic elements of Medicaid and SCHIP eligibility reviews.

(a) *General requirements.* (1) States selected in any given year for Medicaid and SCHIP improper payments measurement under the Improper Payments Information Act of 2002 must conduct reviews of a statistically valid random sample of beneficiary cases for such programs to determine if improper payments were made based on errors in the State agency's eligibility determinations.

(2) The agency and personnel responsible for the development, direction, implementation, and evaluation of the eligibility reviews and associated activities, including calculation of the error rates under this section, must be functionally and physically separate from the State agencies and personnel that are responsible for Medicaid and SCHIP policy and operations, including eligibility determinations.

(3) Any individual performing activities under this section must do so in a manner that is consistent with the provisions of § 435.901, concerning the rights of recipients.

(b) *Sampling requirements.* The State must have in effect a CMS-approved sampling plan for the review year in accordance with the requirements specified in § 431.978.

(c) *Review requirements.* The State must conduct eligibility reviews in accordance with the requirements specified in § 431.980.

§ 431.978 Eligibility sampling plan and procedures.

(a) *Plan approval.* For the review year beginning October 1, 2006, the agency must submit a Medicaid and a SCHIP sampling plan for both active and negative cases to CMS for approval by November 15, 2006. For review years beginning October 1, 2007 and beyond, the agency must submit a Medicaid or SCHIP sampling plan (or revisions to a current plan) for both active and negative cases to CMS for approval by the August 1 before the review year and must receive approval of the plan before implementation. The agency must notify CMS that it will be using the same plan from the previous review year if the plan is unchanged.

(b) *Maintain current plan.* States must keep the plan current, for example, by making adjustments to the plan when necessary due to fluctuations in the universe. The State must review and determine that the approved plan is unchanged from the previous review year and submit a revised plan for CMS approval if changes have occurred.

(c) *Sample size.* Total sample size must be estimated to achieve within a 3 percent precision level at 95 percent confidence interval for the eligibility component of the program.

(d) *Sample selection.* The sample must be stratified in accordance with § 431.978(d)(3). Cases must be selected each month throughout the fiscal year under review. Each month throughout the year and before commencing the eligibility reviews, States must submit to CMS a monthly sample selection list

that identifies the cases selected in that month.

(1) *Eligibility universe-active cases*—(i) *Medicaid*. The Medicaid active universe consists of all active Medicaid cases funded through Title XIX for the sample month. Cases for which the Social Security Administration, under a section 1634 agreement with a State, determines Medicaid eligibility for Supplemental Security Income recipients are excluded from the universe. All foster care and adoption assistance cases under Title IV–E of the Act are excluded from the universe in all States. Cases under active fraud investigations shall be excluded from the universe. If the State cannot identify cases under active fraud investigations for exclusion from the universe previous to the sample selection, the State shall drop these cases from review if they are selected in the sample and are later determined to be under active fraud investigation at the time of selection.

(ii) *SCHIP*. The SCHIP active universe consists of all active SCHIP and Medicaid expansion cases that are funded through Title XXI for the sample month. Cases under active fraud investigations shall be excluded from the SCHIP active universe. If the State cannot identify cases under active fraud investigations for exclusion from the universe previous to sample selection, the State shall drop these cases from review if they are selected in the sample and are later determined to be under active fraud investigation at the time of selection.

(2) *Eligibility universe-negative cases*. The Medicaid and SCHIP negative universe consists of all negative cases for the sample month. Cases denied or terminated based upon incomplete applications or cases where beneficiaries who do not complete the redetermination process are excluded. The negative case universe is not stratified.

(3) *Stratifying the universe*. Each month, the State stratifies the Medicaid and SCHIP active case universe into three strata:

(i) Program applications completed by the beneficiaries in which the State took action in the sample month to approve such beneficiaries for Medicaid or SCHIP based on the eligibility determination.

(ii) Redeterminations of eligibility in which the State took action in the sample month to approve the beneficiaries for Medicaid or SCHIP based on information obtained through the completed redetermination.

(iii) All other cases.

(4) *Sample selection*. Each month, an equal number of cases are selected from each stratum for review, unless otherwise provided for in the plan approved by CMS.

§ 431.980 Eligibility review procedures.

(a) *Active case reviews*. The agency must verify eligibility for all selected active cases for Medicaid and SCHIP for the review month for compliance with the State's eligibility criteria.

(b) *Negative case reviews*. The agency must review all selected negative cases for Medicaid and SCHIP for the review month to determine whether the cases were properly denied or terminated.

(c) *Payment review*. The agency must identify all Medicaid and SCHIP payments made for services furnished, either in the first 30 days of eligibility or in the review month for applications under § 431.978(d)(3)(i) and redeterminations under § 431.978(d)(3)(ii) in accordance to State policy or from the sample month for all other cases under § 431.978(d)(3)(iii), to identify erroneous payments resulting from ineligibility for services or for the program.

(d) *Eligibility determination*. The agency must verify program eligibility for all active cases in the sample based on acceptable documentation contained in the case file or obtained independently through the review process.

(1) *Active cases—Medicaid*. The agency must—

(i) Review the cases specified at § 431.978(d)(3)(i) and § 431.978(d)(3)(ii) in accordance with the State's categorical and financial eligibility criteria as of the review month and identify with a specific beneficiary payments made on behalf of such beneficiary for services received in the first 30 days of eligibility or in the review month;

(ii) For cases specified in § 431.978(d)(3)(iii), if the last action was 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility

criteria as of the last action and identify with a specific beneficiary payments made on behalf of such beneficiary for services received in the sample month. If the last action occurred more than 12 months prior to the sample month, review in accordance with the State's categorical and financial eligibility criteria as of the sample month and identify payments made on behalf of the specific beneficiary for services received in the sample month;

(iii) Examine the evidence in the case file that supports categorical and financial eligibility for the category of coverage in which the case is assigned, and independently verify information that is missing, older than 12 months, likely to change, based on self declaration, or otherwise as needed, to verify eligibility; and

(iv) For managed care cases, also verify residency and eligibility for and actual enrollment in the managed care plan during the month under review.

(v) If the case is ineligible under paragraphs (d)(1)(i) through (d)(1)(iv) of this section, review the case to determine whether the case is eligible under any coverage category within the program.

(vi) As a result of paragraphs (d)(1)(i) through (d)(1)(v) of this section—

(A) Cite the case as eligible or ineligible based on the review findings and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the first 30 days of eligibility, the review month or sample month, as appropriate; or

(B) Cite the case as undetermined if after due diligence an eligibility determination could not be made and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the first 30 days of eligibility, the review month or sample month, as appropriate.

(2) *Active cases—SCHIP.* In addition to the procedures for active cases as set forth in paragraphs (d)(1)(i) through (d)(1)(v) of this section, once the agency establishes SCHIP eligibility, the agency must verify that the case is not eligible for Medicaid by determining that the child has income above the Medicaid levels in accordance with the requirements in § 457.350 of this chapter. Upon verification, the agency must—

(i) Cite the case as eligible or ineligible based on the review findings and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the review month or sample month, as appropriate; or

(ii) Cite the case as undetermined if after due diligence an eligibility determination could not be made and identify with the particular beneficiary the payments made on behalf of the particular beneficiary for services received in the review month or sample month, as appropriate.

(e) *Negative cases—Medicaid and SCHIP.* The agency must—

(1) Identify the reason the State agency determined ineligibility;

(2) Examine the evidence in the case file to determine whether the State agency's denial or termination was correct or whether there is any reason the case should have been denied or terminated; and

(i) Record the State agency's finding as correct if the case record review substantiates that the individual was not eligible; or

(ii) Record the case as an error if there is no valid reason for the denial or termination.

§ 431.988 Eligibility case review completion deadlines and submittal of reports.

(a) States must complete and report to CMS the findings, including the error causes if known, for all active case reviews listed on the monthly sample selection lists, including cases dropped from review due to active fraud investigations and cases for which eligibility could not be determined. States must submit a summary report of the active case eligibility and payment review findings to CMS by July 1 following the review year.

(b) The agency must report by July 1 following the review year, information as follows:

(1) Case and payment error rates for active cases.

(2) Case error rates for negative cases.

(3) The number and amounts of undetermined cases in the sample and the total amount of payments from all undetermined cases.

(4) The number of cases dropped from review due to active fraud investigations.

§ 431.992 Corrective action plan.

The State agency must submit to CMS a corrective action plan to reduce improper payments in its Medicaid and SCHIP programs based on its analysis of the error causes in the FFS, managed care, and eligibility components.

§ 431.998 Difference resolution process.

(a) The State may file, in writing, a request with the Federal contractor to resolve differences in the Federal contractor's findings based on medical or data processing reviews on FFS and managed care claims in Medicaid and SCHIP. The State must have a factual basis for filing the difference and must provide the Federal contractor with valid evidence directly related to the error finding to support the State's position that the claim was properly paid.

(b) For a claim in which the State and the Federal contractor cannot resolve the difference in findings, the State may appeal to CMS for final resolution.

(1) The difference in findings must be in the amount of $100 or greater; and

(2) The agency must provide CMS with the facts and valid documentation to support its determination that the claim was correctly paid, as well as the Federal contractor's justification for upholding its initial error finding.

(3) CMS will make the final decision on the claim. There will be no further judicial or administrative review of CMS' decision.

(c) All differences, including those pending in CMS for final decision that are not resolved in time to be included in the error rate calculation, will be considered as errors for meeting the reporting requirements of the IPIA. Upon State request, CMS will calculate a subsequent State-specific error rate that reflects any reversed disposition of the unresolved claims.

§ 431.1002 Recoveries.

(a) *Medicaid*. States must return to CMS the Federal share of overpayments based on medical and processing errors in accordance with section 1903(d)(2) of the Act and related regulations at part 433, subpart F of this chapter. Payments based on erroneous Medicaid eligibility determinations are addressed under section 1903(u) of the Act and related regulations at part 431, subpart P of this chapter.

(b) *SCHIP*. Quarterly Federal payments to the States under Title XXI of the Act must be reduced in accordance with section 2105(e) of the Act and related regulations at part 457, subpart B of this chapter.

PART 432—STATE PERSONNEL ADMINISTRATION

Subpart A—General Provisions

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432.50 FFP: Staffing and training costs.
432.55 Reporting training and administrative costs.

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45199, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 432.1 Basis and purpose.

This part prescribes regulations to implement section 1902(a)(4) of the Act, which relates to a merit system of State personnel administration and training and use of subprofessional staff and volunteers in State Medicaid programs, and section 1903(a), rates of

FFP for Medicaid staffing and training costs. It also prescribes regulations, based on the general administrative authority in section 1902(a)(4), for State training programs for all staff.

§ 432.2 Definitions.

As used in this part—

Community service aides means subprofessional staff, employed in a variety of positions, whose duties are an integral part of the agency's responsibility for planning, administration, and for delivery of health services.

Directly supporting staff means secretarial, stenographic, and copying personnel and file and records clerks who provide clerical services that directly support the responsibilities of skilled professional medical personnel, who are directly supervised by the skilled professional medical personnel, and who are in an employer-employee relationship with the Medicaid agency.

Fringe benefits means the employer's share of premiums for workmen's compensation, employees' retirement, unemployment compensation, health insurance, and similar expenses.

Full-time training means training that requires employees to be relieved of all responsibility for performance of current agency work to participate in a training program.

Part-time training means training that allows employees to continue full-time in their agency jobs or requires only partial reduction of work activities to participate in the training activity.

Skilled professional medical personnel means physicians, dentists, nurses, and other specialized personnel who have professional education and training in the field of medical care or appropriate medical practice and who are in an employer-employee relationship with the Medicaid agency. It does not include other nonmedical health professionals such as public administrators, medical analysts, lobbyists, senior managers or administrators of public assistance programs or the Medicaid program.

Staff of other public agencies means skilled professional medical personnel and directly supporting staff who are employed in State or local agencies other than the Medicaid agency who perform duties that directly relate to the administration of the Medicaid program.

Subprofessional staff means persons performing tasks that demand little or no formal education; a high school diploma; or less than 4 years of college.

Supporting staff means secretarial, stenographic, clerical, and other subprofessional staff whose activities are directly necessary to the carrying out of the functions which are the responsibility of skilled professional medical personnel, as defined in this section.

Training program means a program of educational activities based on the agency's training needs and aimed at insuring that agency staff acquire the knowledge and skills necessary to perform their jobs.

Volunteer means a person who contributes personal service to the community through the agency's program but is not a replacement or substitute for paid staff.

[43 FR 45199, Sept. 29, 1978, as amended at 50 FR 46663, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 432.10 Standards of personnel administration.

(a) *State plan requirement.* A State plan must provide that the requirements of paragraphs (c) through (h) of this section are met.

(b) *Terms.* In this section, ''standards'' refer to those specified in paragraph (c) of this section.

(c) *Methods of personnel administration.* Methods of personnel administration must be established and maintained, in the Medicaid agency and in local agencies administering the propgram, in conformity with:

(1) [Reserved]

(2) 5 CFR part 900, subpart F, Administration of the Standards for Merit System of Personnel Administration.

(d) *Compliance of local jurisdictions.* The Medicaid agency must have in effect methods to assure compliance with the standards by local jurisdictions included in the plan.

(e) *Review and adequacy of State laws, regulations, and policies.* The agency must—

(1) Assure that the U.S. Civil Service Commission has determined the adequacy of current State laws, regulations, and policy statements that effect

methods of personnel administration in conformity with the standards, and

(2) Submit any changes in them to the Commission for review.

(f) *Statements of acceptance by local agencies.* If the Medicaid agency changes from a State-administered to a State-supervised, locally administered program, it must obtain statements of acceptance of the standards from the local agencies.

(g) *Affirmative action plan.* The Medicaid agency must have in effect an affirmative action plan for equal employment opportunity, that includes specific action steps and timetables to assure that opportunity, and meets all other requirements of 45 CFR 70.4.[1]

(h) *Submittal of requested materials.* The Medicaid agency must submit to HHS, upon request, copies of the affirmative action plan and of the State and local materials that assure compliance with the standards.

[43 FR 45199, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

Subpart B—Training Programs; Subprofessional and Volunteer Programs

§ 432.30 Training programs: General requirements.

(a) A State plan must provide for a program of training for Medicaid agency personnel. (See also §§ 432.31 and 432.32 for training programs for subprofessional staff and for volunteers.)

(b) The program must—

(1) Include initial inservice training for newly appointed staff, and continuing training opportunities to improve the operation of the program;

(2) Be related to job duties performed or to be performed by the persons trained; and

(3) Be consistent with the program objectives of the agency.

§ 432.31 Training and use of subprofessional staff.

(a) *State plan requirement.* A State plan must provide for the training and effective use of subprofessional staff as community service aides, in accordance with the requirements of this section.

(b) *Recruitment and selection.* The Medicaid agency must have methods of recruitment and selection that afford opportunity for full-time or part-time employment of persons of low income, including:

(1) Young, middle-aged, and older persons;

(2) Physically and mentally disabled; and

(3) Recipients.

(c) *Merit system.* Subprofessional positions must be subject to merit system requirements except where special exemption is approved on the basis of a State alternative plan for employment of disadvantaged persons.

(d) *Staffing plan.* The agency staffing plan must include the kinds of jobs that subprofessional staff can perform.

(e) *Career service.* The agency must have a career service program that allows persons:

(1) To enter employment at the subprofessional level; and

(2) To progress to positions of increasing responsibility and reward:

(i) In accordance with their abilities; and

(ii) Through work experience and preservice and in-service training.

(f) *Training, supervision and supportive services.* The agency must have an organized training program, supervision, and supportive services for subprofessional staff.

(g) *Progressive expansion.* The agency must provide for annual increase in the number of subprofessional staff until:

(1) An appropriate ratio of subprofessional and professional staff has been achieved; and

(2) There is maximum use of subprofessional staff as community aides in the operation of the program.

§ 432.32 Training and use of volunteers.

(a) *State plan requirement.* A State plan must provide for the training and use of non-paid or partially paid volunteers in accordance with the requirements of this section.

(b) *Functions of volunteers.* The Medicaid agency must make use of volunteers in:

[1] Editorial Note: The regulations formerly contained in 45 CFR 70.4 were revised and reissued by the Office of Personnel Management at 5 CFR Part 900, (Subpart F).

(1) Providing services to applicants and recipients; and

(2) Assisting any advisory committees established by the agency.

As used in this paragraph, ''partially paid volunteers'' means volunteers who are reimbursed only for actual expenses incurred in giving service, without regard to the value of the service or the time required to provide it.

(c) *Staffing.* The agency must designate a position whose incumbent is responsible for:

(1) The development, organization, and administration of the volunteer program; and

(2) Coordination of the program with related functions.

(d) *Recruitment, selection, training, and supervision.* The agency must have:

(1) Methods of recruitment and selection that assure participation of volunteers of all income levels, in planning capacities and service provision; and

(2) A program of organized training and supervision of volunteers.

(e) *Reimbursement of expenses.* The agency must—

(1) Reimburse volunteers for actual expenses incurred in providing services; and

(2) Assure that no volunteer is deprived of the opportunity to serve because of the expenses involved.

(f) *Progressive expansion.* The agency must provide for annual increase in the number of volunteers used until the volunteer program is adequate for the achievement of the agency's service goals.

Subpart C—Staffing and Training Expenditures

§ 432.45 Applicability of provisions in subpart.

The rates of FFP specified in this subpart C do not apply to State personnel who conduct survey activities and certify facilities for participation in Medicaid, as provided for under section 1902(a)(33)(B) of the Act.

[50 FR 46663, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 432.50 FFP: Staffing and training costs.

(a) *Availability of FFP.* FFP is available in expenditures for salary or other compensation, fringe benefits, travel, per diem, and training, at rates determined on the basis of the individual's position, as specified in paragraph (b) of this section.

(b) *Rates of FFP.* (1) For skilled professional medical personnel and directly supporting staff of the Medicaid agency or of other public agencies (as defined in § 432.2), the rate is 75 percent.

(2) For personnel engaged directly in the operation of mechanized claims processing and information retrieval systems, the rate is 75 percent.

(3) For personnel engaged in the design, development, or installation of mechanized claims processing and information retrieval systems, the rate is 50 percent for training and 90 percent for all other costs specified in paragraph (a) of this section.

(4) [Reserved]

(5) For personnel administering family planning services and supplies, the rate is 90 percent.

(6) For all other staff of the Medicaid agency or other public agencies providing services to the Medicaid agency, and for training and other expenses of volunteers, the rate is 50 percent.

(c) *Application of rates.* (1) FFP is prorated for staff time that is split among functions reimbursed at different rates.

(2) Rates of FFP in excess of 50 percent apply only to those portions of the individual's working time that are spent carrying out duties in the specified areas for which the higher rate is authorized.

(3) The allocation of personnel and staff costs must be based on either the actual percentages of time spent carrying out duties in the specified areas, or another methodology approved by CMS.

(d) *Other limitations for FFP rate for skilled professional medical personnel and directly supporting staff*—(1) *Medicaid agency personnel and staff.* The rate of 75 percent FFP is available for skilled professional medical personnel and directly supporting staff of the Medicaid agency if the following criteria, as applicable, are met:

(i) The expenditures are for activities that are directly related to the administration of the Medicaid program, and as such do not include expenditures for medical assistance;

(ii) The skilled professional medical personnel have professional education and training in the field of medical care or appropriate medical practice. ''Professional education and training'' means the completion of a 2-year or longer program leading to an academic degree or certificate in a medically related profession. This is demonstrated by possession of a medical license, certificate, or other document issued by a recognized National or State medical licensure or certifying organization or a degree in a medical field issued by a college or university certified by a professional medical organization. Experience in the administration, direction, or implementation of the Medicaid program is not considered the equivalent of professional training in a field of medical care.

(iii) The skilled professional medical personnel are in positions that have duties and responsibilities that require those professional medical knowledge and skills.

(iv) A State-documented employer-employee relationship exists between the Medicaid agency and the skilled professional medical personnel and directly supporting staff; and

(v) The directly supporting staff are secretarial, stenographic, and copying personnel and file and records clerks who provide clerical services that are directly necessary for the completion of the professional medical responsibilities and functions of the skilled professional medical staff. The skilled professional medical staff must directly supervise the supporting staff and the performance of the supporting staff's work.

(2) *Staff of other public agencies.* The rate of 75 percent FFP is available for staff of other public agencies if the requirements specified in paragraph (d)(1) of this section are met and the public agency has a written agreement with the Medicaid agency to verify that these requirements are met.

(e) *Limitations on FFP rates for staff in mechanized claims processing and information retrieval systems.* The special matching rates for persons working on mechanized claims processing and information retrieval systems (paragraphs (b)(2) and (3) of this section) are applicable only if the design, development and installation, or the operation, have been approved by the Administrator in accordance with part 433, subchapter C, of this chapter.

[43 FR 45199, Sept. 29, 1978, as amended at 46 FR 48566, Oct. 1, 1981; 50 FR 46663, Nov. 12, 1985]

§ 432.55 Reporting training and administrative costs.

(a) *Scope.* This section identifies activities and costs to be reported as training or administrative costs on quarterly estimate and expenditure reports to CMS.

(b) *Activities and costs to be reported on training expenditures.* (1) For fulltime training (with no assigned agency duties): Salaries, fringe benefits, dependency allowances, travel, tuition, books, and educational supplies.

(2) For part-time training: Travel, per diem, tuition, books and educational supplies.

(3) For State and local Medicaid agency staff development personnel (including supporting staff) assigned fulltime training functions: Salaries, fringe benefits, travel, and per diem. Costs for staff spending less than full time on training for the Medicaid program must be allocated between training and administration in accordance with § 433.34 of this subchapter.

(4) For experts engaged to develop or conduct special programs: Salary, fringe benefits, travel, and per diem.

(5) For agency training activities directly related to the program: Use of space, postage, teaching supplies, and purchase or development of teaching materials and equipment, for example, books and audiovisual aids.

(6) For field instruction in Medicaid: Instructors' salaries and fringe benefits, rental of space, travel, clerical assistance, teaching materials and equipment such as books and audiovisual aids.

(c) *Activities and costs not to be reported as training expenditures.* The following activities are to be reported as administrative costs:

(1) Salaries of supervisors (day-to-day supervision of staff is not a training activity); and

(2) Cost of employing students on a temporary basis, for instance, during summer vacation.

[43 FR 45199, Sept. 29, 1978, as amended at 44 FR 17935, Mar. 23, 1979]

PART 433—STATE FISCAL ADMINISTRATION

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AUTHORITY: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

SOURCE: 43 FR 45201, Sept. 29, 1978, unless otherwise noted.

§ 433.1 Purpose.

This part specifies the rates of FFP for services and administration, and prescribes requirements, prohibitions, and FFP conditions relating to State fiscal activities.

Subpart A—Federal Matching and General Administration Provisions

§ 433.8 [Reserved]

§ 433.10 Rates of FFP for program services.

(a) *Basis.* Sections 1903(a)(1), 1903(g), and 1905(b) provide for payments to States, on the basis of a Federal medical assistance percentage, for part of their expenditures for services under an approved State plan.

(b) *Federal medical assistance percentage (FMAP)—Computations.* The FMAP is determined by the formula described in section 1905(b) of the Act. Under the formula, if a State's per capita income is equal to the national average per capita income, the Federal share is 55 percent. If a State's per capita income exceeds the national average, the Federal share is lower, with a statutory minimum of 50 percent. If a State's per capita income is lower than the national average, the Federal share is increased, with a statutory maximum of 83 percent. The formula used in determining the State and Federal share is as follows:

State Share = [(State per capita income)^2/(National per capita income)^2] × 45 percent
Federal share=100 percent minus the State share (with a minimum of 50 percent and a maximum of 83 percent)

The formula provides for squaring both the State and national average per capita incomes; this procedure magnifies any difference between the State's income and the national average. Consequently, Federal matching to lower income States is increased, and Federal matching to higher income States is decreased, within the statutory 50–83 percent limits. The FMAP for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is set by statute at 50 percent and is subject to dollar limitations specified in section 1108 of the Act.

(c) *Special provisions.* (1) Under section 1903(a)(5) of the Act, the Federal share of State expenditures for family planning services is 90 percent.

(2) Under section 1905(b), the Federal share of State expenditures for services provided through Indian Health Service facilities is 100 percent.

(3) Under section 1903(g), the FMAP is reduced if the State does not have an effective program to control use of institutional services.

(4) Under section 1905(b) of the Social Security Act, the Federal share of State expenditures described in § 433.11(a) for services provided to children, is the enhanced FMAP rate determined in accordance with § 457.622(b) of this chapter, subject to the conditions explained in § 433.11(b).

(5)(i) Under section 1933(d) of the Act, the Federal share of State expenditures for Medicare Part B premiums described in section 1905(p)(3)(A)(ii) of the Act on behalf of Qualifying Individuals described in section 1902(a)(10)(E)(iv) of the Act, is 100 percent, to the extent that the assistance does not exceed the State's allocation under paragraph (c)(5)(ii) of this section. To the extent that the assistance exceeds that allocation, the Federal share is 0 percent.

(ii) Under section 1933(c)(2) of the Act and subject to paragraph (c)(5)(iii) of this section, the allocation to each

State is equal to the total allocation specified in section 1933(c)(1) of the Act multiplied by the Secretary's estimate of the ratio of the total number of individuals described in section 1902(a)(10)(E)(iv) of the Act in the State to the total number of individuals described in section 1902(a)(10)(E)(iv) of the Act for all eligible States. In estimating that ratio, the Secretary will use data from the U.S. Census Bureau.

(iii) If, based on projected expenditures for a fiscal year, the Secretary determines that the expenditures described in paragraph (c)(5)(i) of this section for one or more States are projected to exceed the allocation made to the State, the Secretary may adjust each State's fiscal year 2005, 2006, or 2007 allocation, as follows:

(A) The Secretary will compare each State's projected total expenditures for the expenses described in paragraph (c)(5)(i) of this section to the State's initial allocation determined under paragraph (c)(5)(ii) of this section, to determine the extent of each State's projected surplus or deficit.

(B) The surplus of each State with a projected surplus, as determined in accordance with paragraph (c)(5)(iii)(A) of this section will be added together to arrive at the Total Projected Surplus.

(C) The deficit of each State with a projected deficit, as determined in accordance with paragraph (c)(5)(iii)(A) of this section will be added together to arrive at the Total Projected Deficit.

(D) Each State with a projected deficit will receive an additional allocation equal to the amount of its projected deficit. The amount to be reallocated from each State with a projected surplus will be equal to A × B, where A equals the Total Projected Deficit and B equals the amount of the State's projected surplus as a percentage of the Total Projected Surplus.

(iv) CMS will notify States of any changes in allotments resulting from any reallocations.

(v) The provisions of this paragraph (c)(5) will be in effect through the end of calendar year 2007.

(Sections 1902(a)(10), 1933 of the Social Security Act (42 U.S.C. 1396a), and Pub. L. 105–33)

[43 FR 45201, Sept. 29, 1978, as amended at 46 FR 48559, Oct. 1, 1981; 51 FR 41350, Nov. 14, 1986; 54 FR 21066, May 16, 1989; 66 FR 2666, Jan. 11, 2001; 70 FR 50220, Aug. 26, 2005; 71 FR 25092, Apr. 28, 2006]

§ 433.11 Enhanced FMAP rate for children.

(a) Subject to the conditions in paragraph (b) of this section, the enhanced FMAP determined in accordance with § 457.622 of this chapter will be used to determine the Federal share of State expenditures, except any expenditures pursuant to section 1923 of the Act for payments to disproportionate share hospitals for—

(1) Services provided to optional targeted low-income children described in § 435.4 or § 436.3 of this chapter; and

(2) Services provided to children born before October 1, 1983, with or without group health coverage or other health insurance coverage, who would be described in section 1902(l)(1)(D) of the Act (poverty-level-related children's groups) if—

(i) They had been born on or after that date; and

(ii) They would not qualify for medical assistance under the State plan in effect on March 31, 1997.

(b) Enhanced FMAP is not available if—

(1) A State adopts income and resource standards and methodologies for purposes of determining a child's eligibility under the Medicaid State plan that are more restrictive than those applied under policies of the State plan (as described in the definition of optional targeted low-income children at § 435.4 of this chapter) in effect on June 1, 1997; or

(2) No funds are available in the State's title XXI allotment, as determined under part 457, subpart F of this chapter for the quarter enhanced FMAP is claimed; or

(3) The State fails to maintain a valid method of identifying services provided on behalf of children listed in paragraph (a) of this section.

[66 FR 2666, Jan. 11, 2001]

§ 433.15 Rates of FFP for administration.

(a) *Basis.* Section 1903(a) (2) through (5) and (7) of the Act provide for payments to States, on the basis of specified percentages, for part of their expenditures for administration of an approved State plan.

(b) *Activities and rates.* (1) [Reserved]

(2) Administration of family planning services: 90 percent. (Section 1903 (a)(5); 42 CFR 432.50(b)(5).)

(3) Design, development, or installation of mechanized claims processing and information retrieval systems: 90 percent. (Section 1903(a)(3)(A)(i); 42 CFR part 433, subpart C, and § 432.50 (b)(3).)

(4) Operation of mechanized claims processing and information retrieval systems: 75 percent. (Section 1903(a) (3)(B); 42 CFR part 433, subpart C and § 432.50(b)(2).)

(5) Compensation and training of skilled professional medical personnel and staff directly supporting those personnel if the criteria specified in § 432.50 (c) and (d) are met: 75 percent. (Section 1903(a)(2); 42 CFR 432.50(b)(1).)

(6)(i) Funds expended for the performance of medical and utilization review by a QIO under a contract entered into under section 1902(d) of the Act: 75 percent (section 1903(a)(3)(C) of the Act).

(ii) If a State contracts for medical and utilization review with any individual or organization not designated under Part B of Title XI of the Act, funds expended for such review will be reimbursed as provided in paragraph (b)(7) of this section.

(7) All other activities the Secretary finds necessary for proper and efficient administration of the State plan: 50 percent. (Section 1903(a)(7).) (See also § 455.300 of this subchapter for FFP at 90 percent for State Medicaid fraud control units under section 1903(a)(6).)

(8) Nurse aide training and competency evaluation programs and competency evaluation programs described in 1919(e)(1) of the Act: for calendar quarters beginning on or after July 1, 1988 and before July 1, 1990: The lesser of 90% or the Federal medical assistance percentage plus 25 percentage points; for calendar quarters beginning on or after October 1, 1990: 50%. (Section 1903(a)(2)(B) of the Act.)

(9) Preadmission screening and annual resident review (PASARR) activities conducted by the State: 75 percent. (Sections 1903(a)(2)(C) and 1919(e)(7); 42 CFR part 483, subparts C and E.)

(10) Funds expended for the performance of external quality review or the related activities described in § 438.358 of this chapter when they are performed by an external quality review organization as defined in § 438.320 of this chapter: 75 percent.

[43 FR 45201, Sept. 29, 1978, as amended at 46 FR 48566, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981; 50 FR 15327, Apr. 17, 1985; 50 FR 46664, Nov. 12, 1985; 56 FR 48918, Sept. 26, 1991; 57 FR 56506, Nov. 30, 1992; 68 FR 3635, Jan. 24, 2003]

§ 433.32 Fiscal policies and accountability.

A State plan must provide that the Medicaid agency and, where applicable, local agencies administering the plan will—

(a) Maintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements;

(b) Retain records for 3 years from date of submission of a final expenditure report;

(c) Retain records beyond the 3-year period if audit findings have not been resolved; and

(d) Retain records for nonexpendable property acquired under a Federal grant for 3 years from the date of final disposition of that property.

[44 FR 17935, Mar. 23, 1979]

§ 433.34 Cost allocation.

A State plan under Title XIX of the Social Security Act must provide that the single or appropriate Agency will have an approved cost allocation plan on file with the Department in accordance with the requirements contained in subpart E of 45 CFR part 95. Subpart E also sets forth the effect on FFP if the requirements contained in that subpart are not met.

[47 FR 17490, Apr. 23, 1982]

§ 433.35 Equipment—Federal financial participation.

Claims for Federal financial participation in the cost of equipment under the Medicaid Program are determined in accordance with subpart G of 45 CFR part 95. Requirements concerning the management and disposition of equipment under the Medicaid Program are also prescribed in subpart G of 45 CFR part 95.

[47 FR 41564, Sept. 21, 1982]

§ 433.36 Liens and recoveries.

(a) *Basis and purpose.* This section implements sections 1902(a)(18) and 1917(a) and (b) of the Act, which describe the conditions under which an agency may impose a lien against a recipient's property, and when an agency may make an adjustment or recover funds in satisfaction of the claim against the individual's estate or real property.

(b) *Definition of property.* For purposes of this section, ''property'' includes the homestead and all other personal and real property in which the recipient has a legal interest.

(c) *State plan requirement.* If a State chooses to impose a lien against an individual's real property (or as provided in paragraph (g)(1) of this section, personal property), the State plan must provide that the provisions of paragraphs (d) through (i) of this section are met.

(d) *Procedures.* The State plan must specify the process by which the State will determine that an institutionalized individual cannot reasonably be expected to be discharged from the medical institution and return home as provided in paragraph (g)(2)(ii) of this section. The description of the process must include the type of notice to be given the individual, the process by which the individual will be given the opportunity for a hearing, the hearing procedures, and by whom and on what basis the determination that the individual cannot reasonably be expected to be discharged from the institution will be made. The notice to the individual must explain what is meant by the term lien, and that imposing a lien does not mean that the individual will lose ownership of the home.

(e) *Definitions.* The State plan must define the following terms used in this section:

(1) Individual's home.

(2) Equity interest in home.

(3) Residing in the home for at least 1 (or 2) year(s).

(4) On a continuing basis.

(5) Discharge from the medical institution and return home.

(6) Lawfully residing.

(f) *Exception.* The State plan must specify the criteria by which a son or daughter can establish to the agency's satisfaction that he or she has been providing care which permitted the individual to reside at home rather than in an institution, as provided in paragraph (h)(2)(iii)(B) of this section.

(g) *Lien provisions*—(1) *Incorrect payments.* The agency may place a lien against an individual's property, both personal and real, before his or her death because of Medicaid claims paid or to be paid on behalf of that individual following a court judgement which determined that benefits were incorrectly paid for that individual.

(2) *Correct payments.* Except as provided in paragraph (g)(3) of this section, the agency may place a lien against the real property of an individual at any age before his or her death because of Medicaid claims paid or to be paid for that individual when–

(i) An individual is an inpatient of a medical institution and must, as a condition of receiving services in the institution under the State plan, apply his or her income to the cost of care as provided in §§ 435.725, 435.832 and 436.832; and

(ii) The agency determines that he or she cannot reasonably be expected to be discharged and return home. The agency must notify the individual of its intention to make that determination and provide an opportunity for a hearing in accordance with State established procedures before the determination is made. The notice to an individual must include an explanation of liens and the effect on an individual's ownership of property.

(3) *Restrictions on placing liens.* The agency may not place a lien on an individual's home under paragraph (g)(2) of

this section if any of the following individuals is lawfully residing in the home:

(i) The spouse;

(ii) The individual's child who is under age 21 or blind or disabled as defined in the State plan; or

(iii) The individual's sibling (who has an equity interest in the home, and who was residing in the individual's home for at least one year immediately before the date the individual was admitted to the medical institution).

(4) *Termination of lien.* Any lien imposed on an individual's real property under paragraph (g)(2) of this section will dissolve when that individual is discharged from the medical institution and returns home.

(h) *Adjustments and recoveries.* (1) The agency may make an adjustment or recover funds for Medicaid claims correctly paid for an individual as follows:

(i) From the estate of any individual who was 65 years of age or older when he or she received Medicaid; and

(ii) From the estate or upon sale of the property subject to a lien when the individual is institutionalized as described in paragraph (g)(2) of this section.

(2) The agency may make an adjustment or recovery under paragraph (h)(1) of this section only:

(i) After the death of the individual's surviving spouse; and

(ii) When the individual has no surviving child under age 21 or blind or disabled as defined in the State plan; and

(iii) In the case of liens placed on an individual's home under paragraph (g)(2) of this section, when there is no—

(A) Sibling of the individual residing in the home, who has resided there for at least one year immediately before the date of the individual's admission to the institution, and has resided there on a continuous basis since that time; or

(B) Son or daughter of the individual residing in the home, who has resided there for at least two years immediately before the date of the individual's admission to the institution, has resided there on a continuous basis since that time, and can establish to the agency's satisfaction that he or she has been providing care which permitted the individual to reside at home rather than in an institution.

(i) *Prohibition of reduction of money payments.* No money payment under another program may be reduced as a means of recovering Medicaid claims incorrectly paid.

[43 FR 45201, Sept. 29, 1978, as amended at 47 FR 43647, Oct. 1, 1982; 47 FR 49847, Nov. 3, 1982]

§ 433.37 Reporting provider payments to Internal Revenue Service.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes requirements concerning—

(1) Identification of providers; and

(2) Compliance with the information reporting requirements of the Internal Revenue Code.

(b) *Identification of providers.* A State plan must provide for the identification of providers by—

(1) Social security number if—

(i) The provider is in solo practice; or

(ii) The provider is not in solo practice but billing is by the individual practitioner; or

(2) Employer identification number for all other providers.

(c) *Compliance with section 6041 of the Internal Revenue Code.* The plan must provide that the Medicaid agency complies with the information reporting requirements of section 6041 of the Internal Revenue Code (26 U.S.C. 6041). Section 6041 requires the filing of annual information returns showing amounts paid to providers, who are identified by name, address, and social security number or employer identification number.

§ 433.38 Interest charge on disallowed claims for FFP.

(a) *Basis and scope.* This section is based on section 1903(d)(5) of the Act, which requires that the Secretary charge a State interest on the Federal share of claims that have been disallowed but have been retained by the State during the administrative appeals process under section 1116(d) of the Act and the Secretary later recovers after the administrative appeals process has been completed. This section does not apply to—

(1) Claims that have been deferred by the Secretary and disallowed within

the time limits of § 430.40 of this chapter. Deferral of claims for FFP; or

(2) Claims for expenditures that have never been paid on a grant award; or

(3) Disallowances of any claims for services furnished before October 1, 1980, regardless of the date of the claim submitted to CMS.

(b) *General principles.* (1) CMS will charge a State interest on FFP when—

(i) CMS has notified the Medicaid agency under 45 CFR 74.304 that a State claim for FFP is not allowable;

(ii) The agency has appealed the disallowance to the Grant Appeals Board under 45 CFR Part 16 and has chosen to retain the FFP during the administrative appeals process in accordance with paragraph (c)(2) of this section; and

(iii)(A) The Board has made a final determination upholding part or all of the disallowance; (B) the agency has withdrawn its appeal on all or part of the disallowance; or (C) the agency has reversed its decision to retain the funds without withdrawing its appeal and the Board upholds all or part of the disallowance.

(2) If the courts overturn, in whole or in part, a Board decision that has sustained a disallowance, CMS will return the principal and the interest collected on the funds that were disallowed, upon the completion of all judicial appeals.

(3) Unless an agency decides to withdraw its appeal on part of the disallowance and therefore returns only that part of the funds on which it has withdrawn its appeal, any decision to retain or return disallowed funds must apply to the entire amount in dispute.

(4) If the agency elects to have CMS recover the disputed amount, it may not reverse that election.

(c) *State procedures.* (1) If the Medicaid agency has appealed a disallowance to the Board and wishes to retain the disallowed funds until the Board issues a final determination, the agency must notify the CMS Regional Administrator in writing of its decision to do so.

(2) The agency must mail its notice to the CMS Regional Administrator within 30 days of the date of receipt of the notice of the disallowance, as established by the certified mail receipt accompanying the notices.

(3) If the agency withdraws either its decision to retain the FFP or its appeal on all or part of the FFP or both, the agency must notify CMS in writing.

(4) If the agency does not notify the CMS Regional Administrator within the time limit set forth in paragraph (c)(2) of this section. CMS will recover the amount of the disallowed funds from the next possible Medicaid grant award to the State.

(d) *Amount of interest charged.* (1) If the agency retains funds that later become subject to an interest charge under paragraph (b) of this section, CMS will offset from the next Medicaid grant award to the State the amount of the funds subject to the interest charge, plus interest on that amount.

(2) The interest charge is at the rate CMS determines to be the average of the bond equivalent of the weekly 90-day Treasury bill auction rates during the period for which interest will be charged.

(e) *Duration of interest.* (1) The interest charge on the amount of disallowed FFP retained by the agency will begin on the date of the disallowance notice and end—

(i) On the date of the final determination by the Board;

(ii) On the date CMS receives written notice from the State that it is withdrawing its appeal on all of the disallowed funds; or

(iii) If the agency withdraws its appeal on part of the funds, on (A) the date CMS receives written notice from the agency that it is withdrawing its appeal on a specified part of the disallowed funds for the part on which the agency withdraws its appeal; and (B) the date of the final determination by the Board on the part for which the agency pursues its appeal; or

(iv) The date CMS receives written notice from the agency that it no longer chooses to retain the funds.

(2) CMS will not charge interest on FFP retained by an agency for more than 12 months for disallowances of FFP made between October 1, 1980 and August 13, 1981.

[48 FR 29485, June 27, 1983]

§ 433.40 Treatment of uncashed or cancelled (voided) Medicaid checks.

(a) *Purpose.* This section provides the rules to ensure that States refund the Federal portion of uncashed or cancelled (voided) checks under title XIX.

(b) *Definitions.* As used in this section—

Cancelled (voided) check means a Medicaid check issued by a State or fiscal agent which prior to its being cashed is cancelled (voided) by the State or fiscal agent, thus preventing disbursement of funds.

Check means a check or warrant that a State or local agency uses to make a payment.

Fiscal agent means an entity that processes or pays vendor claims for the Medicaid State agency.

Uncashed check means a Medicaid check issued by a State or fiscal agent which has not been cashed by the payee.

Warrant means an order by which the State agency or local agency without the authority to issue checks recognizes a claim. Presentation of a warrant by the payee to a State officer with authority to issue checks will result in release of funds due.

(c) *Refund of Federal financial participation (FFP) for uncashed checks*—(1) *General provisions.* If a check remains uncashed beyond a period of 180 days from the date it was issued; i.e., the date of the check, it will no longer be regarded as an allowable program expenditure. If the State has claimed and received FFP for the amount of the uncashed check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the State must identify those checks which remain uncashed beyond a period of 180 days after issuance. The State agency must refund all FFP that it received for uncashed checks by adjusting the Quarterly Statement of Expenditures for that quarter. If an uncashed check is cashed after the refund is made, the State may file a claim. The claim will be considered to be an adjustment to the costs for the quarter in which the check was originally claimed. This claim will be paid if otherwise allowed by the Act and the regulations issued pursuant to the Act.

(3) If the State does not refund the appropriate amount as specified in paragraph (c)(2) of this section, the amount will be disallowed.

(d) *Refund of FFP for cancelled (voided) checks*—(1) *General provision.* If the State has claimed and received FFP for the amount of a cancelled (voided) check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the State agency must identify those checks which were cancelled (voided). The State must refund all FFP that it received for cancelled (voided) checks by adjusting the Quarterly Statement of Expenditures for that quarter.

(3) If the State does not refund the appropriate amount as specified in paragraph (d)(2) of this section, the amount will be disallowed.

[51 FR 36227, Oct. 9, 1986]

Subpart B—General Administrative Requirements State Financial Participation

SOURCE: 57 FR 55138, Nov. 24, 1992, unless otherwise noted.

§ 433.50 Basis, scope, and applicability.

(a) *Basis.* This subpart interprets and implements—

(1) Section 1902(a)(2) of the Act, which requires States to share in the cost of medical assistance expenditures and permits both State and local governments to participate in the financing of the non-Federal portion of medical assistance expenditures.

(2) Section 1903(a) of the Act, which requires the Secretary to pay each State an amount equal to the Federal medical assistance percentage of the total amount expended as medical assistance under the State's plan.

(3) Section 1903(w) of the Act, which specifies the treatment of revenues from provider-related donations and health care-related taxes in determining a State's medical assistance expenditures for which Federal financial participation (FFP) is available under the Medicaid program.

(b) *Scope.* This subpart—

(1) Specifies State plan requirements for State financial participation in expenditures for medical assistance.

(2) Defines provider-related donations and health care-related taxes that may be received without a reduction in FFP.

(3) Specifies rules for revenues received from provider-related donations and health care-related taxes during a transition period.

(4) Establishes limitations on FFP when States receive funds from provider-related donations and revenues generated by health care-related taxes.

(c) *Applicability.* The provisions of this subpart apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

[57 FR 55138, Nov. 24, 1992; 58 FR 6095, Jan. 26, 1993]

§ 433.51 Public funds as the State share of financial participation.

(a) Public funds may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraphs (b) and (c) of this section.

(b) The public funds are appropriated directly to the State or local Medicaid agency, or transferred from other public agencies (including Indian tribes) to the State or local agency and under its administrative control, or certified by the contributing public agency as representing expenditures eligible for FFP under this section.

(c) The public funds are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

[57 FR 55138, Nov. 24, 1992; 58 FR 6095, Jan. 26, 1993]

§ 433.52 General definitions.

As used in this subpart—

Entity related to a health care provider means—

(1) An organization, association, corporation, or partnership formed by or on behalf of a health care provider;

(2) An individual with an ownership or control interest in the provider, as defined in section 1124(a)(3) of the Act;

(3) An employee, spouse, parent, child, or sibling of the provider, or of a person with an ownership or control interest in the provider, as defined in section 1124(a)(3) of the Act; or

(4) A supplier of health care items or services or a supplier to providers of health care items or services.

Health care provider means the individual or entity that receives any payment or payments for health care items or services provided.

Provider-related donation means a donation or other voluntary payment (in cash or in kind) made directly or indirectly to a State or unit of local government by or on behalf of a health care provider, an entity related to such a health care provider, or an entity providing goods or services to the State for administration of the State's Medicaid plan.

(1) Donations made by a health care provider to an organization, which in turn donates money to the State, may be considered to be a donation made indirectly to the State by a health care provider.

(2) When an organization receives less than 25 percent of its revenues from providers and/or provider-related entities, its donations will not generally be presumed to be provider-related donations. Under these circumstances, a provider-related donation to an organization will not be considered a donation made indirectly to the State. However, if the donations from providers to an organization are subsequently determined to be indirect donations to the State or unit of local government for administration of the State's Medicaid program, then such donations will be considered to be health care related.

(3) When the organization receives more than 25 percent of its revenue from donations from providers or provider-related entities, the organization always will be considered as acting on behalf of health care providers if it makes a donation to the State. The amount of the organization's donation to the State, in a State fiscal year, that will be considered health care related, will be based on the percentage of donations the organization received from the providers during that period.

§ 433.53 State plan requirements.

A State plan must provide that—

(a) State (as distinguished from local) funds will be used both for medical assistance and administration;

(b) State funds will be used to pay at least 40 percent of the non-Federal share of total expenditures under the plan; and

(c) State and Federal funds will be apportioned among the political subdivisions of the State on a basis that assures that—

(1) Individuals in similar circumstances will be treated similarly throughout the State; and

(2) If there is local financial participation, lack of funds from local sources will not result in lowering the amount, duration, scope, or quality of services or level of administration under the plan in any part of the State.

[57 FR 55138, Nov. 24, 1992; 58 FR 6095, Jan. 26, 1993]

§ 433.54 Bona fide donations.

(a) A bona fide donation means a provider-related donation, as defined in § 433.52, made to the State or unit of local government, that has no direct or indirect relationship, as described in paragraph (b) of this section, to Medicaid payments made to—

(1) The health care provider;

(2) Any related entity providing health care items and services; or

(3) Other providers furnishing the same class of items or services as the provider or entity.

(b) Provider-related donations will be determined to have no direct or indirect relationship to Medicaid payments if those donations are not returned to the individual provider, the provider class, or related entity under a hold harmless provision or practice, as described in paragraph (c) of this section.

(c) A hold harmless practice exists if any of the following applies:

(1) The amount of the payment received (other than under title XIX of the Act) is positively correlated either to the amount of the donation or to the difference between the amount of the donation and the amount of the payment received under the State plan;

(2) All or any portion of the payment made under Medicaid to the donor, the provider class, or any related entity, varies based only on the amount of the total donation received; or

(3) The State or other unit of local government receiving the donation provides for any payment, offset, or waiver that guarantees to return any portion of the donation to the provider.

(d) CMS will presume provider-related donations to be bona fide if the voluntary payments, including, but not limited to, gifts, contributions, presentations or awards, made by or on behalf of individual health care providers to the State, county, or any other unit of local government does not exceed—

(1) $5,000 per year in the case of an individual provider donation; or

(2) $50,000 per year in the case of a donation from any health care organizational entity.

(e) To the extent that a donation presumed to be bona fide contains a hold harmless provision, as described in paragraph (c) of this section, it will not be considered a bona fide donation. When provider-related donations are not bona fide, CMS will deduct this amount from the State's medical assistance expenditures before calculating FFP. This offset will apply to all years the State received such donations and any subsequent fiscal year in which a similar donation is received.

§ 433.55 Health care-related taxes defined.

(a) A health care-related tax is a licensing fee, assessment, or other mandatory payment that is related to—

(1) Health care items or services;

(2) The provision of, or the authority to provide, the health care items or services; or

(3) The payment for the health care items or services.

(b) A tax will be considered to be related to health care items or services under paragraph (a)(1) of this section if at least 85 percent of the burden of the tax revenue falls on health care providers.

(c) A tax is considered to be health care related if the tax is not limited to health care items or services, but the treatment of individuals or entities providing or paying for those health care items or services is different than the tax treatment provided to other individuals or entities.

(d) A health care-related tax does not include payment of a criminal or civil

fine or penalty, unless the fine or penalty was imposed instead of a tax.

(e) Health care insurance premiums and health maintenance organization premiums paid by an individual or group to ensure coverage or enrollment are not considered to be payments for health care items and services for purposes of determining whether a health care-related tax exists.

§ 433.56 Classes of health care services and providers defined.

(a) For purposes of this subpart, each of the following will be considered as a separate class of health care items or services:

(1) Inpatient hospital services;

(2) Outpatient hospital services;

(3) Nursing facility services (other than services of intermediate care facilities for the mentally retarded);

(4) Intermediate care facility services for the mentally retarded, and similar services furnished by community-based residences for the mentally retarded, under a waiver under section 1915(c) of the Act, in a State in which, as of December 24, 1992, at least 85 percent of such facilities were classified as ICF/MRs prior to the grant of the waiver;

(5) Physician services;

(6) Home health care services;

(7) Outpatient prescription drugs;

(8) Services of health maintenance organizations and health insuring organizations;

(9) Ambulatory surgical center services, as described for purposes of the Medicare program in section 1832(a)(2)(F)(i) of the Social Security Act. These services are defined to include facility services only and do not include surgical procedures;

(10) Dental services;

(11) Podiatric services;

(12) Chiropractic services;

(13) Optometric/optician services;

(14) Psychological services;

(15) Therapist services, defined to include physical therapy, speech therapy, occupational therapy, respiratory therapy, audiological services, and rehabilitative specialist services;

(16) Nursing services, defined to include all nursing services, including services of nurse midwives, nurse practitioners, and private duty nurses;

(17) Laboratory and x-ray services, defined as services provided in a licensed, free-standing laboratory or x-ray facility. This definition does not include laboratory or x-ray services provided in a physician's office, hospital inpatient department, or hospital outpatient department;

(18) Emergency ambulance services; and

(19) Other health care items or services not listed above on which the State has enacted a licensing or certification fee, subject to the following:

(i) The fee must be broad based and uniform or the State must receive a waiver of these requirements;

(ii) The payer of the fee cannot be held harmless; and

(iii) The aggregate amount of the fee cannot exceed the State's estimated cost of operating the licensing or certification program.

(b) Taxes that pertain to each class must apply to all items and services within the class, regardless of whether the items and services are furnished by or through a Medicaid-certified or licensed provider.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43180, Aug. 13, 1993]

§ 433.57 General rules regarding revenues from provider-related donations and health care-related taxes.

Effective January 1, 1992, CMS will deduct from a State's expenditures for medical assistance, before calculating FFP, funds from provider-related donations and revenues generated by health care-related taxes received by a State or unit of local government, in accordance with the requirements, conditions, and limitations of this subpart, if the donations and taxes are not—

(a) Donations and taxes that meet the requirements specified in § 433.58, except for certain revenue received during a specified transition period;

(b) Permissible provider-related donations, as specified in § 433.66(b); or

(c) Health care-related taxes, as specified in § 433.68(b).

§ 433.58 Provider-related donations and health care-related taxes during a State's transition period.

(a) *General rule.* During the State's transition period specified in paragraph

(b) of this section, a State may receive certain provider-related donations and health care-related taxes without a reduction in FFP. These provider-related donations and health care-related taxes must meet the conditions specified in this section and are subject to limitations specified in § 433.60.

(b) *Transition periods for States.* (1) Except as provided in paragraph (b)(2) of this section, the provisions of this section apply for the period beginning January 1, 1992 and ending—

(i) September 30, 1992, for States whose State fiscal year begins on or before July 1, 1992; or

(ii) December 31, 1992, for States whose State fiscal year begins after July 1, 1992.

(2) The provisions of this section apply for the period beginning January 1, 1992 and ending June 30, 1993 for States that—

(i) Are not scheduled to have a regular legislative session in calendar year 1992;

(ii) Are not scheduled to have a regular legislative session in calendar year 1993; or

(iii) Had enacted a health care-related tax program on November 4, 1991.

(c) *Provider-related donations during the transition period.* Subject to the limitations specified in § 433.60, a State may receive, without a reduction in FFP, provider-related donations described in paragraph (d)(3) of this section during the applicable transition period.

(d) *Permissible donations.* To be permissible donations, the donations must be—

(1) Bona fide donations, as defined in § 433.54;

(2) Donations made by a hospital, clinic, or similar entity (such as a Federally-qualified health center) for the direct costs of State or local agency personnel who are stationed at that facility to determine the eligibility (including eligibility redeterminations) of individuals for Medicaid and/or to provide outreach services to eligible (or potentially eligible) Medicaid individuals. Direct costs of outstationed eligibility workers refers to the costs of training, salaries and fringe benefits associated with each outstationed worker and similar allocated costs of State or local agency support staff, and a prorated cost of outreach activities applicable to the outstationed workers at these sites. The prorated costs of outreach activities will be calculated taking the percent of State outstationed eligibility workers at a facility to total outstationed eligibility workers in the State, and multiplying the percent by the total cost of outreach activities in the State. Costs for such items as State agency overhead and provider office space are not allowable for this purpose; or

(3) Provider-related donations, even if the donations do not qualify under the provisions of paragraph (d) (1) or (2) of this section, that meet the following conditions:

(i) The donation program was in effect on September 30, 1991, described in State plan amendments or related documents submitted to CMS by that date, or substantiated by written documentary evidence (as described in paragraph (e) of this section) that was in existence as of that date; and

(ii) The donation program is applicable to the State's fiscal year 1992, as demonstrated by written documentary evidence as described in paragraph (e) of this section.

(e) *Written documentary evidence.* The State must have written documentation, which was in existence on September 30, 1991, of a donation program described in paragraph (d)(3) of this section that includes the dollar amounts it received in State fiscal year 1992 and the amounts it intended to receive, as evidenced by one or more of the following:

(1) Reference to a donation program in a State plan amendment or related documents, including a satisfactory response, as determined by CMS, to a CMS request for additional information;

(2) State budget documents identifying the amounts States expected to be received in donations;

(3) Written agreements with the parties donating the funds; and/or

(4) Other written documents that identify amounts that the States planned to receive in donations from specified organizations during that period.

(f) *Application of rules to State fiscal year 1993.* For any portion of a State's fiscal year 1993 that occurs during the transition period, the State may receive, without a reduction in FFP, the amount of provider-related donations that it received in the corresponding period in State fiscal year 1992, including the 5 days after the end of that period, subject to the limitations specified in § 433.60(a).

(g) *Health care-related taxes during the transition period.* (1) Subject to the limitations specified in § 433.60, States may receive, without a reduction in FFP, health care-related taxes during the State's transition period if:

(i) The health care-related taxes are broad-based and uniformly imposed, and the taxpayer will not be held harmless, as specified in § 433.68; or

(ii) The health care-related taxes are imposed under—

(A) A tax program that was in effect as of November 22, 1991; or

(B) Legislation or regulations that were enacted or adopted as of November 22, 1991.

(2) A State may not modify health care-related taxes in existence as of November 22, 1991, without a reduction of FFP, unless the modification only—

(i) Extends a tax program that was scheduled to expire before the end of the State's transition period;

(ii) Makes technical changes that do not alter the rate of the tax or the base of the tax (for example, the providers on which the tax is imposed) and do not otherwise increase the proceeds of the tax;

(iii) Decreases the rate of the tax, without altering the base of the tax; or

(iv) Modifies the tax program to bring it into compliance with § 433.68(f).

[57 FR 55138, Nov. 24, 1992; 58 FR 6095, Jan. 26, 1993, as amended at 58 FR 43180, Aug. 13, 1993]

§ 433.60 Limitations on level of FFP in State expenditures from provider-related donations and health care-related taxes during the transition period.

(a) *Maximum amounts.* The maximum amount of total provider-related donations, as specified in § 433.58(d)(3), and health care-related taxes that a State may receive without a reduction in FFP during a State fiscal year in the State's transition period specified in § 433.58(b) is calculated by multiplying—

(1) The State's total medical assistance expenditures for the fiscal year; by

(2) The greater of:

(i) 25 percent; or

(ii) The ''State base percentage'' (as described in paragraph (b) of this section).

(b) *State base percentage.* (1) The State's base percentage is calculated by dividing the amount of the provider-related donations and health care-related taxes identified in § 433.58 and estimated by CMS to be received in the State's fiscal year 1992 by the total non-Federal share of medical assistance expenditures (including administrative costs) in that fiscal year based on the best available CMS data.

(2) In calculating the amount of taxes specified in paragraph (b)(1) of this section, taxes (including the tax rate or base) that were not in effect for the entire State fiscal year, but for which legislation or regulations imposing such taxes were enacted or adopted as of November 22, 1991, will be estimated as if they were in effect for the entire fiscal year.

(c) *Deductions before calculating FFP.* Before calculating FFP, CMS will deduct from a State's medical assistance expenditures the total amount of any provider-related donations described in § 433.58(d)(3), and health care-related taxes in excess of the limit calculated under paragraph (a) of this section.

[57 FR 55138, Nov. 24, 1992; 58 FR 6095, Jan. 26, 1993]

§ 433.66 Permissible provider-related donations after the transition period.

(a) *General rule.* (1) Except as specified in paragraph (a)(2) of this section, subsequent to the end of a State's transition period, as defined in § 433.58(b), a State may receive revenues from provider-related donations without a reduction in FFP, only in accordance with the requirements of this section.

(2) The provisions of this section relating to provider-related donations for outstationed eligibility workers are effective on October 1, 1992, whether or

not the State's transition period continues beyond that date.

(b) *Permissible donations.* Subject to the limitations specified in § 433.67, a State may receive, without a reduction in FFP, provider-related donations that meet at least one of the following requirements:

(1) The donations must be bona fide donations, as defined in § 433.54; or

(2) The donations are made by a hospital, clinic, or similar entity (such as a Federally-qualified health center) for the direct costs of State or local agency personnel who are stationed at the facility to determine the eligibility (including eligibility redeterminations) of individuals for Medicaid or to provide outreach services to eligible (or potentially eligible) Medicaid individuals. Direct costs of outstationed eligibility workers refers to the costs of training, salaries and fringe benefits associated with each outstationed worker and similar allocated costs of State or local agency support staff, and a prorated cost of outreach activities applicable to the outstationed workers at these sites. The prorated costs of outreach activities will be calculated taking the percent of State outstationed eligibility workers at a facility to total outstationed eligibility workers in the State, and multiplying the percent by the total cost of outreach activities in the State. Costs for such items as State agency overhead and provider office space are not allowable for this purpose.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43180, Aug. 13, 1993]

§ 433.67 Limitations on level of FFP for permissible provider-related donations.

(a)(1) *Limitations on bona fide donations.* There are no limitations on the amount of bona fide provider-related donations that a State may receive without a reduction in FFP, as long as the bona fide donations meet the requirements of § 433.66(b)(1).

(2) *Limitations on donations for outstationed eligibility workers.* Effective October 1, 1992, regardless of when a State's transition period ends, the maximum amount of provider-related donations for oustationed eligibility workers, as described in § 433.66(b)(2), that a State may receive without a reduction in FFP may not exceed 10 percent of a State's medical assistance administrative costs (both the Federal and State share), excluding the costs of family planning activities. The 10 percent limit for provider-related donations for outstationed eligibility workers is not included in the limit in effect through September 30, 1995, for health care-related taxes as described in § 433.70.

(b) *Calculation of FFP.* CMS will deduct from a State's quarterly medical assistance expenditures, before calculating FFP, any provider-related donations received in that quarter that do not meet the requirements of § 433.66(b)(1) and provider donations for outstationed eligibility workers in excess of the limits specified under paragraph (a)(2) of this section.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43180, Aug. 13, 1993]

§ 433.68 Permissible health care-related taxes after the transition period.

(a) *General rule.* Beginning on the day after a State's transition period, as defined in § 433.58(b), ends, a State may receive health care-related taxes, without a reduction in FFP, only in accordance with the requirements of this section.

(b) *Permissible health care-related taxes.* Subject to the limitations specified in § 433.70, a State may receive, without a reduction in FFP, health care-related taxes if all of the following are met:

(1) The taxes are broad based, as specified in paragraph (c) of this section;

(2) The taxes are uniformly imposed throughout a jurisdiction, as specified in paragraph (d) of this section; and

(3) The tax program does not violate the hold harmless provisions specified in paragraph (f) of this section.

(c) *Broad based health care-related taxes.* (1) A health care-related tax will be considered to be broad based if the tax is imposed on at least all health care items or services in the class or providers of such items or services furnished by all non-Federal, non-public providers in the State, and is imposed

uniformly, as specified in paragraph (d) of this section.

(2) If a health care-related tax is imposed by a unit of local government, the tax must extend to all items or services or providers (or to all providers in a class) in the area over which the unit of government has jurisdiction.

(3) A State may request a waiver from CMS of the requirement that a tax program be broad based, in accordance with the procedures specified in § 433.72. Waivers from the uniform and broad-based requirements will automatically be granted in cases of variations in licensing and certification fees for providers if the amount of such fees is not more than $1,000 annually per provider and the total amount raised by the State from the fees is used in the administration of the licensing or certification program.

(d) *Uniformly imposed health care-related taxes.* A health care-related tax will be considered to be imposed uniformly even if it excludes Medicaid or Medicare payments (in whole or in part), or both; or, in the case of a health care-related tax based on revenues or receipts with respect to a class of items or services (or providers of items or services), if it excludes either Medicaid or Medicare revenues with respect to a class of items or services, or both. The exclusion of Medicaid revenues must be applied uniformly to all providers being taxed.

(1) A health care-related tax will be considered to be imposed uniformly if it meets any one of the following criteria:

(i) If the tax is a licensing fee or similar tax imposed on a class of health care services (or providers of those health care items or services), the tax is the same amount for every provider furnishing those items or services within the class.

(ii) If the tax is a licensing fee or similar tax imposed on a class of health care items or services (or providers of those items or services) on the basis of the number of beds (licensed or otherwise) of the provider, the amount of the tax is the same for each bed of each provider of those items or services in the class.

(iii) If the tax is imposed on provider revenue or receipts with respect to a class of items or services (or providers of those health care items or services), the tax is imposed at a uniform rate for all services (or providers of those items or services) in the class on all the gross revenues or receipts, or on net operating revenues relating to the provision of all items or services in the State, unit, or jurisdiction. Net operating revenue means gross charges of facilities less any deducted amounts for bad debts, charity care, and payer discounts.

(iv) The tax is imposed on items or services on a basis other than those specified in paragraphs (d)(1) (i) through (iii) of this section, e.g., an admission tax, and the State establishes to the satisfaction of the Secretary that the amount of the tax is the same for each provider of such items or services in the class.

(2) A tax imposed with respect to a class of health care items or services will not be considered to be imposed uniformly if it meets either one of the following two criteria:

(i) The tax provides for credits, exclusions, or deductions which have as its purpose, or results in, the return to providers of all, or a portion, of the tax paid, and it results, directly or indirectly, in a tax program in which—

(A) The net impact of the tax and payments is not generally redistributive, as specified in paragraph (e) of this section; and

(B) The amount of the tax is directly correlated to payments under the Medicaid program.

(ii) The tax holds taxpayers harmless for the cost of the tax, as described in paragraph (f) of this section.

(3) If a tax does not meet the criteria specified in paragraphs (d)(1)(i) through (iv) of this section, but the State establishes that the tax is imposed uniformly in accordance with the procedures for a waiver specified in § 433.72, the tax will be treated as a uniform tax.

(e) *Generally redistributive.* A tax will be considered to be generally redistributive if it meets the requirements of this paragraph. If the State desires

waiver of only the broad-based tax requirement, it must demonstrate compliance with paragraph (e)(1) of this section. If the State desires waiver of the uniform tax requirement, whether or not the tax is broad-based, it must demonstrate compliance with paragraph (e)(2) of this section.

(1) *Waiver of broad-based requirement only*. This test is applied on a per class basis to a tax that is imposed on all revenues but excludes certain providers. For example, a tax that is imposed on all revenues (including Medicare and Medicaid) but excludes teaching hospitals would have to meet this test. This test cannot be used when a State excludes any or all Medicaid revenue from its tax in addition to the exclusion of providers, since the test compares the proportion of Medicaid revenue being taxed under the proposed tax with the proportion of Medicaid revenue being taxed under a broad-based tax.

(i) A State seeking waiver of the broad-based tax requirement only must demonstrate that its proposed tax plan meets the requirement that its plan is generally redistributive by:

(A) Calculating the proportion of the tax revenue applicable to Medicaid if the tax were broad based and applied to all providers or activities within the class (called P1);

(B) Calculating the proportion of the tax revenue applicable to Medicaid under the tax program for which the State seeks a waiver (called P2); and

(C) Calculating the value of P1/P2.

(ii) If the State demonstrates to the Secretary's satisfaction that the value of P1/P2 is at least 1, CMS will automatically approve the waiver request.

(iii) If a tax is enacted and in effect prior to August 13, 1993, and the State demonstrates to the Secretary's satisfaction that the value of P1/P2 is at least 0.90, CMS will review the waiver request. Such a waiver will be approved only if the following two criteria are met:

(A) The value of P1/P2 is at least 0.90; and

(B) The tax excludes or provides credits or deductions only to one or more of the following providers of items and services within the class to be taxed:

(*1*) Providers that furnish no services within the class in the State;

(*2*) Providers that do not charge for services within the class;

(*3*) Rural hospitals (defined as any hospital located outside of an urban area as defined in § 412.62(f)(1)(ii) of this chapter);

(*4*) Sole community hospitals as defined in § 412.92(a) of this chapter;

(*5*) Physicians practicing primarily in medically underserved areas as defined in section 1302(7) of the Public Health Service Act;

(*6*) Financially distressed hospitals if:

(*i*) A financially distressed hospital is defined by the State law;

(*ii*) The State law specifies reasonable standards for determining financially distressed hospitals, and these standards are applied uniformly to all hospitals in the State; and

(*iii*) No more than 10 percent of nonpublic hospitals in the State are exempt from the tax;

(*7*) Psychiatric hospitals; or

(*8*) Hospitals owned and operated by HMOs.

(iv) If a tax is enacted and in effect after August 13, 1993, and the State demonstrates to the Secretary's satisfaction that the value of P1/P2 is at least 0.95, CMS will review the waiver request. Such a waiver request will be approved only if the following two criteria are met:

(A) The value of P1/P2 is at least 0.95; and

(B) The tax complies with the provisions of § 433.68(e)(1)(iii)(B).

(2) *Waiver of uniform tax requirement*. This test is applied on a per class basis to all taxes that are not uniform. This includes those taxes that are neither broad based (as specified in § 433.68(c)) nor uniform (as specified in § 433.68(d)).

(i) A State seeking waiver of the uniform tax requirement (whether or not the tax is broad based) must demonstrate that its proposed tax plan meets the requirement that its plan is generally redistributive by:

(A) Calculating, using ordinary least squares, the slope (designated as (*B*) (that is. the value of the x coefficient) of two linear regressions, in which the dependent variable is each provider's percentage share of the total tax paid

by all taxpayers during a 12-month period, and the independent variable is the taxpayer's ''Medicaid Statistic''. The term ''Medicaid Statistic'' means the number of the provider's taxable units applicable to the Medicaid program during a 12-month period. If, for example, the State imposed a tax based on provider charges, the amount of a provider's Medicaid charges paid during a 12-month period would be its ''Medicaid Statistic''. If the tax were based on provider inpatient days, the number of the provider's Medicaid days during a 12-month period would be its ''Medicaid Statistic''. For the purpose of this test, it is not relevant that a tax program exempts Medicaid from the tax.

(B) Calculating the slope (designated as B1) of the linear regression, as described in paragraph (e)(2)(i) of this section, for the State's tax program, if it were broad based and uniform.

(C) Calculating the slope (designated as B2) of the linear regression, as described in paragraph (e)(2)(i) of this section, for the State's tax program, as proposed.

(ii) If the State demonstrates to the Secretary's satisfaction that the value of B1/B2 is at least 1, CMS will automatically approve the waiver request.

(iii) If the State demonstrates to the Secretary's satisfaction that the value of B1/B2 is at least 0.95, CMS will review the waiver request. Such a waiver will be approved only if the following two criteria are met:

(A) The value of B1/B2 is at least 0.95; and

(B) The tax excludes or provides credits or deductions only to one or more of the following providers of items and services within the class to be taxes:

(*1*) Providers that furnish no services within the class in the State;

(*2*) Providers that do not charge for services within the class;

(*3*) Rural hospitals (defined as any hospital located outside of an urban area as defined in § 412.62(f)(1)(ii) of this chapter;

(*4*) Sole community hospitals as defined in § 412.92(a) of this chapter;

(*5*) Physicians practicing primarily in medically underserved areas as defined in section 1302(7) of the Public Health Service Act;

(*6*) Financially distressed hospitals if:

(*i*) A financially distressed hospital is defined by the State law;

(*ii*) The State law specifies reasonable standards for determining financially distressed hospitals, and these standards are applied uniformly to all hospitals in the State; and

(*iii*) No more than 10 percent of nonpublic hospitals in the State are exempt from the tax;

(*7*) Psychiatric hospitals; or

(*8*) Providers or payers with tax rates that vary based exclusively on regions, but only if the regional variations are coterminous with preexisting political (and not special purpose) boundaries. Taxes within each regional boundary must meet the broad-based and uniformity requirements as specified in paragraphs (c) and (d) of this section.

(iv) A B1/B2 value of 0.70 will be applied to taxes that vary based exclusively on regional variations, and enacted and in effect prior to November 24, 1992, to permit such variations.

(f) *Hold harmless.* A taxpayer will be considered to be held harmless under a tax program if any of the following conditions applies:

(1) The State (or other unit of government) imposing the tax provides directly or indirectly for a non-Medicaid payment to those providers or others paying the tax and the amount of the payment is positively correlated to either the amount of the tax or to the difference between the Medicaid payment and the total tax cost.

(2) All or any portion of the Medicaid payment to the taxpayer varies based only on the amount of the total tax payment.

(3) The State (or other unit of local government) imposing the tax provides, directly or indirectly, for any payment, offset, or waiver that guarantees to hold taxpayers harmless for all or a portion of the tax.

(i) An indirect guarantee will be determined to exist under a two prong ''guarantee'' test. This specific hold harmless test is effective September 13, 1993. In this instance, if the health care-related tax or taxes on each health care class are applied at a rate that produces revenues less than or equal to 6 percent of the revenues received by the taxpayer, the tax or

taxes are permissible under this test. When the tax or taxes are applied at a rate that produces revenues in excess of 6 percent of the revenue received by the taxpayer, CMS will consider a hold harmless provision to exist if 75 percent or more of the taxpayers in the class receive 75 percent or more of their total tax costs back in enhanced Medicaid payments or other State payments. The second prong of the hold harmless test is applied in the aggregate to all health care taxes applied to each class. If this standard is violated, the amount of tax revenue to be offset from medical assistance expenditures is the total amount of the taxpayers' revenues received by the State.

(ii) If, as of August 13, 1993, a State has enacted a tax in excess of 6 percent that does not meet the requirements in paragraph (f)(3)(i) of this section, CMS will not disallow funds received by the State resulting from the tax if the State modifies the tax to comply with this requirement by September 13, 1993. If, by September 13, 1993, the tax is not modified, funds received by States on or after September 13, 1993 will be disallowed.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43181, Aug. 13, 1993; 62 FR 53572, Oct. 15, 1997]

§ 433.70 Limitations on level of FFP for revenues from health care-related taxes after the transition period.

(a) *Limitations.* (1) Subsequent to the end of a State's transition period (as defined in § 433.58(b)), and extending through September 30, 1995, the maximum amount of health care-related taxes specified in § 433.68 that a State may receive during a State fiscal year (or portion thereof), without a reduction in FFP, is limited to—

(i) The greater of 25 percent or the State base percentage as described in § 433.60(b); multiplied by

(ii) The State's share of total medical assistance expenditures for the State fiscal year, less all health care-related taxes other than those described in § 433.68 that are deducted separately pursuant to paragraph (b) of this section.

(2) Beginning October 1, 1995, there is no limitation on the amount of health care-related taxes that a State may receive without a reduction in FFP, as long as the health care-related taxes meet the requirements specified in § 433.68.

(b) *Calculation of FFP.* CMS will deduct from a State's medical assistance expenditures, before calculating FFP, revenues from health care-related taxes that do not meet the requirements of § 433.68 and any health care-related taxes in excess of the limits specified in paragraph (a)(1) of this section.

§ 433.72 Waiver provisions applicable to health care-related taxes.

(a) *Bases for requesting waiver.* (1) A State may submit to CMS a request for a waiver if a health care-related tax does not meet any or all of the following:

(i) The tax does not meet the broad based criteria specified in § 433.68c); and/or

(ii) The tax is not imposed uniformly but meets the criteria specified in § 433.68(d)(2) or (d)(3).

(2) When a tax that meets the criteria specified in paragraph (a)(1) of this section is imposed on more than one class of health care items or services, a separate waiver must be obtained for each class of health care items and services subject to the tax.

(b) *Waiver conditions.* In order for CMS to approve a waiver request that would permit a State to receive tax revenue (within specified limitations) without a reduction in FFP, the State must demonstrate, to CMS's satisfaction, that its tax program meets all of the following requirements:

(1) The net impact of the tax and any payments made to the provider by the State under the Medicaid program is generally redistributive, as described in § 433.68(e);

(2) The amount of the tax is not directly correlated to Medicaid payments; and

(3) The tax program does not fall within the hold harmless provisions specified in § 433.68(f).

(c) *Effective date.* A waiver will be effective:

(1) The date of enactment of the tax for programs in existence prior to August 13, 1993 or;

(2) For tax programs commencing on or after August 13, 1993, on the first day in the quarter in which the waiver is received by CMS.

[57 FR 55138, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

§ 433.74 Reporting requirements.

(a) Beginning with the first quarter of Federal fiscal year 1993, each State must submit to CMS quarterly summary information on the source and use of all provider-related donations (including all bona fide and presumed-to-be bona fide donations) received by the State or unit of local government, and health care-related taxes collected. Each State must also provide any additional information requested by the Secretary related to any other donations made by, or any taxes imposed on, health care providers. States' reports must present a complete, accurate, and full disclosure of all of their donation and tax programs and expenditures.

(b) Each State must provide the summary information specified in paragraph (a) of this section on a quarterly basis in accordance with procedures established by CMS.

(c) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description and legal basis for each donation and tax program being reported, as well as the source and use of all donations received and taxes collected. This information must be made available to Federal reviewers upon request.

(d) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP CMS estimates is attributable to the sums raised by tax and donation programs as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited by law, FFP for those expenditures will be released when the State complies with all reporting requirements.

Subpart C—Mechanized Claims Processing and Information Retrieval Systems

§ 433.110 Basis, purpose, and applicability.

(a) This subpart implements the following sections of the Act:

(1) Section 1903(a)(3) of the Act, which provides for FFP in State expenditures for the design, development, or installation of mechanized claims processing and information retrieval systems and for the operation of certain systems. Additional HHS regulations and CMS procedures for implementing these regulations are in 45 CFR part 74, 45 CFR part 95, subpart F, and part 11, State Medicaid Manual; and

(2) Section 1903(r) of the Act, which—

(i) Requires reductions in FFP otherwise due a State under section 1903(a) if a State fails to meet certain deadlines for operating a mechanized claims processing and information retrieval system or if the system fails to meet certain conditions of approval or conditions of reapproval;

(ii) Requires a Federal performance review at least every three years of the mechanized claims processing and information retrieval systems; and

(iii) Allows waivers of conditions of approval, conditions of reapproval, and FFP reductions under certain circumstances.

(b) The requirements under section 1903(r) of the Act do not apply to Puerto Rico, Guam, the Virgin Islands, American Samoa and the Northern Mariana Islands.

[50 FR 30846, July 30, 1985, as amended at 54 FR 41973, Oct. 13, 1989]

§ 433.111 Definitions.

For purposes of this section:

(a) The following terms are defined at 45 CFR part 95, subpart F § 95.605:

''Advance Planning Document''; ''Design'' or ''System Design''; ''Development''; ''Enhancement''; ''Hardware''; ''Installation''; ''Operation''; and, ''Software''.

(b) ''Mechanized claims processing and information retrieval system'' or ''system'' means the system of software and hardware used to process

Medicaid claims from providers of medical care and services for the medical care and services furnished to recipients under the medical assistance program and to retrieve and produce service utilization and management information required by the Medicaid single State agency and Federal Government for program administration and audit purposes. The system consists of

(1) Required subsystems specified in the State Medicaid Manual;

(2) Required changes to the required system or subsystem that are published in accordance with §433.123 of this subpart and specified in the State Medicaid Manual; and

(3) Approved enhancements to the system. Eligibility determination systems are not part of mechanized claims processing and information retrieval systems or enhancements to those systems.

[51 FR 45330, Dec. 18, 1986, as amended at 54 FR 41973, Oct. 13, 1989]

§433.112 FFP for design, development, installation or enhancement of mechanized claims processing and information retrieval systems.

(a) FFP is available at the 90 percent rate in State expenditures for the design, development, installation, or enhancement of a mechanized claims processing and information retrieval system only if the APD is approved by CMS prior to the State's expenditure of funds for these purposes.

(b) CMS will approve the system described in the APD if the following conditions are met:

(1) CMS determines the system is likely to provide more efficient, economical, and effective administration of the State plan.

(2) The system meets the system requirements and performance standards in Part 11 of the State Medicaid Manual, as periodically amended.

(3) The system is compatible with the claims processing and information retrieval systems used in the administration of Medicare for prompt eligibility verification and for processing claims for persons eligible for both programs.

(4) The system supports the data requirements of quality improvement organizations established under Part B of title XI of the Act.

(5) The State owns any software that is designed, developed, installed or improved with 90 percent FFP.

(6) The Department has a royalty free, non-exclusive, and irrevocable license to reproduce, publish, or otherwise use and authorize others to use, for Federal Government purposes, software, modifications to software, and documentation that is designed, developed, installed or enhanced with 90 percent FFP.

(7) The costs of the system are determined in accordance with 45 CFR 74.171.

(8) The Medicaid agency agrees in writing to use the system for the period of time specified in the advance planning document approved by CMS or for any shorter period of time that CMS determines justifies the Federal funds invested.

(9) The agency agrees in writing that the information in the system will be safeguarded in accordance with subpart F, part 431 of this subchapter.

(c) Eligibility determination systems are not part of mechanized claims processing and information retrieval systems and are not eligible for 75 percent FFP under this subpart. These systems are also not eligible for 90 percent FFP for any APD approved after November 13, 1989.

[43 FR 45201, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979; 45 FR 14213, Mar. 5, 1980; 50 FR 30846, July 30, 1985; 51 FR 45330, Dec. 18, 1986; 54 FR 41973, Oct. 13, 1989; 55 FR 1820, Jan. 19, 1990; 55 FR 4375, Feb. 7, 1990]

§433.113 Reduction of FFP for failure to operate a system and obtain initial approval.

(a) Except as waived under §433.130 or 433.131, FFP will be reduced as specified in paragraph (b) of this section unless the Medicaid agency has in continuous operation a mechanized claims processing and information retrieval system that meets the following conditions:

(1) The APD for the system was approved by CMS;

(2) The system is operational by September 30, 1985; and

(3) The system is initially approved by the last day of the fourth quarter that begins after the date the system

became operational as determined by CMS.

(b) CMS will reduce FFP in expenditures for compensation and training of skilled professional medical personnel and support staff under section 1903(a)(2) of the Act, and for general administration under section 1903(a)(7) of the Act, by the following increments applied separately to those two categories of expenditures:

(1) Five percentage points for the first two quarters beginning after a deadline in paragraph (a) of this section;

(2) An additional five percentage points during each additional two-quarter period, through the quarter in which the State achieves compliance with the conditions for initial operation or initial approval of an operating system. FFP reductions will not exceed 25 percentage points for each type of reduction.

(c) The amount of FFP (determined under section 1903(a)(3)(B)) that would be available retroactively for operating a system that later receives initial approval will be reduced by CMS by the same percentage points for the identical periods of time described in subparagraph (b)(1) of this section, until the system is initially approved. No reduction will be made after the first quarter during which the system is initially approved.

[50 FR 30847, July 30, 1985, as amended at 54 FR 41973, Oct. 13, 1989]

§ 433.114 Procedures for obtaining initial approval; notice of decision.

(a) To obtain initial approval, the Medicaid agency must inform CMS in writing that the system meets the conditions specified in § 433.116(c) through (h).

(b) If CMS disapproves the system, or determines that the system met requirements for initial approval on a date later than the date required under § 433.113(a)(3), the notice will include—

(1) The findings of fact upon which the determination was made; and

(2) The procedures for appeal of the determination in the context of a reconsideration of the resulting disallowance, to the Departmental Appeals Board.

[50 FR 30847, July 30, 1985, as amended at 54 FR 41973, Oct. 13, 1989]

§ 433.116 FFP for operation of mechanized claims processing and information retrieval systems.

(a) Subject to 42 CFR 433.113(c), FFP is available at 75 percent of expenditures for operation of a mechanized claims processing and information retrieval system approved by CMS, from the first day of the calendar quarter after the date the system met the conditions of initial approval, as established by CMS (including a retroactive adjustment of FFP if necessary to provide the 75 percent rate beginning on the first day of that calendar quarter). Subject to 45 CFR 95.611(a), the State shall obtain prior written approval from CMS when it plans to acquire ADP equipment or services, when it anticipates the total acquisition costs will exceed thresholds, and meets other conditions of the subpart.

(b) CMS will approve the system operation if the conditions specified in paragraphs (c) through (h) of this section are met.

(c) The conditions of § 433.112(b) (1) through (4) and (7) through (9), as periodically modified under § 433.112(b)(2), must be met.

(d) The system must have been operating continuously during the period for which FFP is claimed.

(e) The system must provide individual notices, within 45 days of the payment of claims, to all or a sample group of the persons who received services under the plan.

(f) The notice required by paragraph (e) of this section—

(1) Must specify—

(i) The service furnished;

(ii) The name of the provider furnishing the service;

(iii) The date on which the service was furnished; and

(iv) The amount of the payment made under the plan for the service; and

(2) Must not specify confidential services (as defined by the State) and must not be sent if the only service furnished was confidential.

(g) The system must provide both patient and provider profiles for program management and utilization review purposes.

(h) If the State has a Medicaid fraud control unit certified under section 1903(q) of the Act and § 455.300 of this chapter, the Medicaid agency must have procedures to assure that information on probable fraud or abuse that is obtained from, or developed by, the system is made available to that unit. (See § 455.21 of this chapter for State plan requirements.)

[45 FR 14213, Mar. 5, 1980. Redesignated and amended at 50 FR 30847, July 30, 1985; 55 FR 4375, Feb. 7, 1990]

§ 433.117 Initial approval of replacement systems.

(a) A replacement system must meet all conditions of initial approval of a mechanized claims processing and information retrieval system.

(b) The agency must submit a APD that includes—

(1) The date the replacement system will be in operation; and

(2) A plan for orderly transition from the system being replaced to the replacement system.

(c) FFP is available at—

(1) 90 percent in expenditures for design, development, and installation in accordance with the provisions of § 433.112; and

(2) 75 percent in expenditures for operation of an approved replacement system in accordance with the provisions of § 433.116(b) through (h), from the date that the system met the conditions of initial approval, as established by CMS.

(d) FFP is available at 75 percent in expenditures for the operation of an approved system that is being replaced (or at a reduced rate determined under § 433.120 of this subpart for a system that has been disapproved) until the replacement system is in operation and approved.

[50 FR 30847, July 30, 1985]

§ 433.119 Conditions for reapproval; notice of decision.

(a) CMS will review at least once every three years each system operation initially approved under § 433.114 and reapprove it for FFP at 75 percent of expenditures if the following conditions are met:

(1) The system meets the conditions of § 433.112(b) (1), (3), (4), and (7) through (9).

(2) The system meets the conditions of § 433.116 (d) through (h).

(3) The system meets the performance standards for reapproval and the system requirements in part 11 of the State Medicaid Manual as periodically amended.

(4) Automated eligibility determination systems approved or operating on or before November 13, 1989, will not qualify for FFP at 75 percent of expenditures after November 13, 1989.

(b) CMS may review an entire system operation or focus its review on parts of the operation. However, at a minimum, CMS will review standards, system requirements and other conditions of reapproval that have demonstrated weakness in a previous review or reviews.

(c) CMS will issue to each Medicaid agency, by the end of the first quarter after the review period, a written notice informing the agency whether its system is reapproved or disapproved. If the system is disapproved, the notice will also include—

(1) CMS's decision to reduce FFP for system operations, and the percentage to which it is reduced, beginning with the next calender quarter;

(2) The findings of fact upon which the determination was made; and

(3) A statement that State claims in excess of the reduced FFP rate will be disallowed and that any such disallowance will be appealable to the Departmental Appeals Board.

[54 FR 41973, Oct. 13, 1989; 55 FR 1820, Jan. 19, 1990]

§ 433.120 Procedures for reduction of FFP after reapproval review.

(a) If CMS determines after the reapproval review that the system no longer meets the conditions of reapproval in § 433.119, CMS will reduce FFP for system operations for at least four quarters. However, no system will be subject to reduction of FFP for at least the first four quarters after the quarter in which the system is initially approved as eligible for 75 percent FFP.

(b) CMS will reduce FFP in expenditures for system operations from 75 percent to no more than 70 percent and no less than 50 percent; however, CMS will not reduce FFP by more than 10 percentage points in any four-quarter period. The percentage to which the FFP is reduced will depend primarily on the following criteria:

(1) The number of conditions judged unsatisfactory;

(2) The extent to which conditions were not met;

(3) The significance of the unsatisfactory conditions in overall mechanized claims processing and information retrieval system operations; and

(4) The actual and potential program impact attributable to the unsatisfactory conditions.

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989]

§ 433.121 Reconsideration of the decision to reduce FFP after reapproval review.

(a) The agency may appeal to the Departmental Appeals Board under 45 CFR part 16, a disallowance concerning a reduction in FFP claimed for system operation caused by a disapproval of the State's system. If the Board finds such a disallowance to be appropriate, the discretionary determination to reduce FFP by a particular percentage amount (instead of by a lesser percentage) is not subject to review by the Board unless the percentage reduction exceeds the range authorized by section 1903(r)(4)(B) of the Act.

(b) The decisions concerning whether to restore any FFP retroactively and the actual number of quarters for which FFP will be restored under § 433.122 of this subpart are not subject to administrative appeal to the Departmental Appeals Board under 45 CFR part 16.

(c) An agency's request for a reconsideration before the Board under paragraph (a) of this section does not delay implementation of the reduction in FFP. However, any reduction is subject to retroactive adjustment if required by the Board's determination on reconsideration.

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989; 55 FR 1820, Jan. 19, 1990]

§ 433.122 Reapproval of a disapproved system.

When FFP has been reduced under § 433.120(a), and CMS determines upon subsequent review that the system meets all current performance standards, system requirements and other conditions of reapproval, the following provisions apply:

(a) CMS will resume FFP in expenditures for system operations at the 75 percent level beginning with the quarter following the review determination that the system again meets conditions of reapproval.

(b) CMS may retroactively waive a reduction of FFP in expenditures for system operations if CMS determines that the waiver could improve the administration of the State Medicaid plan. However, CMS cannot waive this reduction for any quarter before the fourth quarter immediately preceding the quarter in which CMS issues the determination (as part of the review process) stating that the system is reapproved.

[54 FR 41974, Oct. 13, 1989]

§ 433.123 Notification of changes in system requirements, performance standards or other conditions for approval or reapproval.

(a) Whenever CMS modifies system requirements or other conditions for approval under § 433.112 or § 433.116, CMS will—

(1) Publish a notice in the FEDERAL REGISTER making available the proposed changes for public comment;

(2) Respond in a subsequent FEDERAL REGISTER notice to comments received; and

(3) Issue the new or modified requirements or conditions in the State Medicaid Manual.

(b) For changes in system requirements or other conditions for approval, CMS will allow an appropriate period for Medicaid agencies to meet the requirement determining this period on the basis of the requirement's complexity and other relevant factors.

(c) Whenever CMS modifies performance standards and other conditions for reapproval under § 433.119, CMS will notify Medicaid agencies at least one calendar quarter before the review period

to which the new or modified standards or conditions apply.

[57 FR 38782, Aug. 27, 1992]

§ 433.127 Termination of FFP for failure to provide access to claims processing and information retrieval systems.

CMS will terminate FFP at any time if the Medicaid agency fails to provide State and Federal representatives with full access to the system, including onsite inspection. CMS may request such access at any time to determine whether the conditions in this subpart are being met.

[43 FR 45201, Sept. 29, 1978. Redesignated and amended at 50 FR 30847 and 30848, July 30, 1985]

§ 433.130 Waiver of conditions of initial operation and approval.

(a) CMS will waive requirements for initial operation and approval of systems under § 433.113 for a State meeting the requirements of paragraph (b) of this section and that had a 1976 population of less than one million and made total Federal and State Medicaid expenditures of less than $100 million in fiscal year 1976. Population figures are those reported by the Bureau of the Census. Expenditures for fiscal year 1976 are those reported by the State for that year.

(b) To be eligible for this waiver, the agency must submit its reasons to CMS in writing and demonstrate to CMS's satisfaction that a system will not significantly improve the efficiency of the administration of the State plan.

(c) If CMS denies the waiver request, the notice of denial will include—

(1) The findings of fact upon which the denial was made; and

(2) The procedures for appeal of the denial.

(d) If CMS determines, after granting a waiver, that a system would significantly improve the administration of the State Medicaid program, CMS may withdraw the waiver and require that a State obtain initial approval of a system within two years of the date of waiver withdrawal.

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989]

§ 433.131 Waiver for noncompliance with conditions of approval and reapproval.

If a State is unable to comply with the conditions of approval or of reapproval and the noncompliance will cause a percentum reduction in FFP, CMS will waive the FFP reduction in the following circumstances:

(a) *Good cause.* If CMS determines that good cause existed, CMS will waive the FFP reduction attributable to those items for which the good cause existed. A waiver of FFP consequences of the failure to meet the conditions of approval or reapproval based upon good cause will not extend beyond two consecutive quarters.

(b) *Circumstances beyond the control of a State.* The State must satisfactorily explain the circumstances that are beyond its control. When CMS grants the waiver, CMS will also defer all other system deadlines for the same length of time that the waiver applies.

[50 FR 30848, July 30, 1985, as amended at 54 FR 41974, Oct. 13, 1989]

Subpart D—Third Party Liability

SOURCE: 45 FR 8984, Feb. 11, 1980, unless otherwise noted.

§ 433.135 Basis and purpose.

This subpart implements sections 1902(a)(25), 1902(a)(45), 1903(d)(2), 1903(o), 1903(p), and 1912 of the Act by setting forth State plan requirements concerning—

(a) The legal liability of third parties to pay for services provided under the plan;

(b) Assignment to the State of an individual's rights to third party payments; and

(c) Cooperative agreements between the Medicaid agency and other entities for obtaining third party payments.

[50 FR 46664, Nov. 12, 1985]

§ 433.136 Definitions.

For purposes of this subpart—

Private insurer means:

(1) Any commercial insurance company offering health or casualty insurance to individuals or groups (including both experience-rated insurance contracts and indemnity contracts);

(2) Any profit or nonprofit prepaid plan offering either medical services or full or partial payment for services included in the State plan; and

(3) Any organization administering health or casualty insurance plans for professional associations, unions, fraternal groups, employer-employee benefit plans, and any similar organization offering these payments or services, including self-insured and self-funded plans.

Third party means any individual, entity or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a State plan.

Title IV-D agency means the organizational unit in the State that has the responsibility for administering or supervising the administration of a State plan for child support enforcement under title IV-D of the Act.

[49 FR 8984, Feb. 11, 1980, as amended at 50 FR 46664, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 433.137 State plan requirements.

(a) A State plan must provide that the requirements of §§ 433.138 and 433.139 are met for identifying third parties liable for payment of services under the plan and for payment of claims involving third parties.

(b) A State plan must provide that—

(1) The requirements of §§ 433.145 through 433.148 are met for assignment of rights to benefits, cooperation with the agency in obtaining medical support or payments, and cooperation in identifying and providing information to assist the State in pursuing any liable third parties; and

(2) The requirements of §§ 433.151 through 433.154 are met for cooperative agreements and incentive payments for third party collections.

(c) The requirements of paragraph (b)(1) of this section relating to assignment of rights to benefits and cooperation in obtaining medical support or payments and paragraph (b)(2) of this section are effective for medical assistance furnished on or after October 1, 1984. The requirements of paragraph (b)(1) of this section relating to cooperation in identifying and providing information to assist the State in pursuing liable third parties are effective for medical assistance furnished on or after July 1, 1986.

[50 FR 46665, Nov. 12, 1985, as amended at 55 FR 48606, Nov. 21, 1990; 55 FR 52130, Dec. 19, 1990; 60 FR 35502, July 10, 1995]

§ 433.138 Identifying liable third parties.

(a) *Basic provisions.* The agency must take reasonable measures to determine the legal liability of the third parties who are liable to pay for services furnished under the plan. At a minimum, such measures must include the requirements specified in paragraphs (b) through (k) of this section, unless waived under paragraph (l) of this section.

(b) *Obtaining health insurance information: Initial application and redetermination processes for Medicaid eligibility.* (1) If the Medicaid agency determines eligibility for Medicaid, it must, during the initial application and each redetermination process, obtain from the applicant or recipient such health insurance information as would be useful in identifying legally liable third party resources so that the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f). Health insurance information may include, but is not limited to, the name of the policy holder, his or her relationship to the applicant or recipient, the social security number (SSN) of the policy holder, and the name and address of insurance company and policy number.

(2) If Medicaid eligibility is determined by the Federal agency administering the supplemental security income program under title XVI in accordance with a written agreement under section 1634 of the Act, the Medicaid agency must take the following action. It must enter into an agreement with CMS or must have, prior to February 1, 1985, executed a modified section 1634 agreement that is still in effect to provide for—

(i) Collection, from the applicant or recipient during the initial application and each redetermination process, of health insurance information in the form and manner specified by the Secretary; and

(ii) Transmittal of the information to the Medicaid agency.

(3) If Medicaid eligibility is determined by any other agency in accordance with a written agreement, the Medicaid agency must modify the agreement to provide for—

(i) Collection, from the applicant or recipient during the initial application and each redetermination process, of such health insurance information as would be useful in identifying legally liable third party resources so that the Medicaid agency may process claims under the third party liability payment procedures specified in §433.139 (b) through (f). Health insurance information may include, but is not limited to, those elements described in paragraph (b)(1) of this section; and

(ii) Transmittal of the information to the Medicaid agency.

(c) *Obtaining other information.* Except as provided in paragraph (l) of this section, the agency must, for the purpose of implementing the requirements in paragraphs (d)(1)(ii) and (d)(4)(i) of this section, incorporate into the eligibility case file the names and SSNs of absent or custodial parents of Medicaid recipients to the extent such information is available.

(d) *Exchange of data.* Except as provided in paragraph (l) of this section, to obtain and use information for the purpose of determining the legal liability of the third parties so that the agency may process claims under the third party liability payment procedures specified in §433.139(b) through (f), the agency must take the following actions:

(1) Except as specified in paragraph (d)(2) of this section, as part of the data exchange requirements under §435.945 of this chapter, from the State wage information collection agency (SWICA) defined in §435.4 of this chapter and from the SSA wage and earnings files data as specified in §435.948(a)(2) of this chapter, the agency must—

(i) Use the information that identifies Medicaid recipients that are employed and their employer(s); and

(ii) Obtain and use, if their names and SSNs are available to the agency under paragraph (c) of this section, information that identifies employed absent or custodial parents of recipients and their employer(s).

(2) If the agency can demonstrate to CMS that it has an alternate source of information that furnishes information as timely, complete and useful as the SWICA and SSA wage and earnings files in determining the legal liability of third parties, the requirements of paragraph (d)(1) of this section are deemed to be met.

(3) The agency must request, as required under §435.948(a)(6)(i), from the State title IV-A agency, information not previously reported that identifies those Medicaid recipients that are employed and their employer(s).

(4) Except as specified in paragraph (d)(5) of this section, the agency must attempt to secure agreements (to the extent permitted by State law) to provide for obtaining—

(i) From State Workers' Compensation or Industrial Accident Commission files, information that identifies Medicaid recipients and, (if their names and SSNs were available to the agency under paragraph (c) of this section) absent or custodial parents of Medicaid recipients with employment-related injuries or illnesses; and

(ii) From State Motor Vehicle accident report files, information that identifies those Medicaid recipients injured in motor vehicle accidents, whether injured as pedestrians, drivers, passengers, or bicyclists.

(5) If unable to secure agreements as specified in paragraph (d)(4) of this section, the agency must submit documentation to the regional office that demonstrates the agency made a reasonable attempt to secure these agreements. If CMS determines that a reasonable attempt was made, the requirements of paragraph (d)(4) of this section are deemed to be met.

(e) *Diagnosis and trauma code edits.* (1) Except as specified under paragraph (e)(2) or (l) of this section, or both, the agency must take action to identify those paid claims for Medicaid recipients that contain diagnosis codes 800 through 999 International Classification of Disease, 9th Revision, Clinical Modification, Volume 1 (ICD–9–CM) inclusive, for the purpose of determining the legal liability of third parties so that the agency may process claims under the third party liability payment

procedures specified in § 433.139(b) through (f).

(2) The agency may exclude code 994.6, Motion Sickness, from the edits required under paragraph (e)(1) of this section.

(f) *Data exchanges and trauma code edits: Frequency.* Except as provided in paragraph (l) of this section, the agency must conduct the data exchanges required in paragraphs (d)(1) and (d)(3) of this section in accordance with the intervals specified in § 435.948 of this chapter, and diagnosis and trauma edits required in paragraphs (d)(4) and (e) of this section on a routine and timely basis. The State plan must specify the frequency of these activities.

(g) *Followup procedures for identifying legally liable third party resources.* Except as provided in paragraph (l) of this section, the State must meet the requirements of this paragraph.

(1) *SWICA, SSA wage and earnings files, and title IV-A data exchanges.* With respect to information obtained under paragraphs (d)(1) through (d)(3) of this section—

(i) Except as specified in § 435.952(d) of this chapter, within 45 days, the agency must followup (if appropriate) on such information in order to identify legally liable third party resources and incorporate such information into the eligibility case file and into its third party data base and third party recovery unit so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f); and

(ii) The State plan must describe the methods the agency uses for meeting the requirements of paragraph (g)(1)(i) of this section.

(2) *Health insurance information and workers' compensation data exchanges.* With respect to information obtained under paragraphs (b) and (d)(4)(i) of this section—

(i) Within 60 days, the agency must followup on such information (if appropriate) in order to identify legally liable third party resources and incorporate such information into the eligibility case file and into its third party data base and third party recovery unit so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f); and

(ii) The State plan must describe the methods the agency uses for meeting the requirements of paragraph (g)(2)(i) of this section.

(3) *State motor vehicle accident report file data exchanges.* With respect to information obtained under paragraph (d)(4)(ii) of this section—

(i) The State plan must describe the methods the agency uses for following up on such information in order to identify legally liable third party resources so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f);

(ii) After followup, the agency must incorporate all information that identifies legally liable third party resources into the eligibility case file and into its third party data base and third party recovery unit; and

(iii) The State plan must specify timeframes for incorporation of the information.

(4) *Diagnosis and trauma code edits.* With respect to the paid claims identified under paragraph (e) of this section—

(i) The State plan must describe the methods the agency uses to follow up on such claims in order to identify legally liable third party resources so the agency may process claims under the third party liability payment procedures specified in § 433.139 (b) through (f) (Methods must include a procedure for periodically identifying those trauma codes that yield the highest third party collections and giving priority to following up on those codes.);

(ii) After followup, the agency must incorporate all information that identifies legally liable third party resources into the eligibility case file and into its third party data base and third party recovery unit; and

(iii) The State plan must specify the timeframes for incorporation of the information.

(h) *Obtaining other information and data exchanges: Safeguarding information.* (1) The agency must safeguard information obtained from and exchanged under this section with other

agencies in accordance with the requirements set forth in part 431, subpart F of this chapter.

(2) Before requesting information from, or releasing information to other agencies to identify legally liable third party resources under paragraph (d) of this section the agency must execute data exchange agreements with those agencies. The agreements, at a minimum, must specify—

(i) The information to be exchanged;

(ii) The titles of all agency officials with the authority to request third party information;

(iii) The methods, including the formats to be used, and the timing for requesting and providing the information;

(iv) The safeguards limiting the use and disclosure of the information as required by Federal or State law or regulations; and

(v) The method the agency will use to reimburse reasonable costs of furnishing the information if payment is requested.

(i) *Reimbursement.* The agency must, upon request, reimburse an agency for the reasonable costs incurred in furnishing information under this section to the Medicaid agency.

(j) *Reports.* The agency must provide such reports with respect to the data exchanges and trauma code edits set forth in paragraphs (d)(1) through (d)(4) and paragraph (e) of this section, respectively, as the Secretary prescribes for the purpose of determining compliance under §433.138 and evaluating the effectiveness of the third party liability identification system. However, if the State is not meeting the provisions of paragraph (e) of this section because it has been granted a waiver of those provisions under paragraph (l) of this section, it is not required to provide the reports required in this paragraph.

(k) *Integration with the State mechanized claims processing and information retrieval system. Basic requirement—Development of an action plan.* (1) If a State has a mechanized claims processing and information retrieval system approved by CMS under subpart C of this part, the agency must have an action plan for pursuing third party liability claims and the action plan must be integrated with the mechanized claims processing and information retrieval system.

(2) The action plan must describe the actions and methodologies the State will follow to—

(i) Identify third parties;

(ii) Determine the liability of third parties;

(iii) Avoid payment of third party claims as required in §433.139;

(iv) Recover reimbursement from third parties after Medicaid claims payment as required in §433.139; and,

(v) Record information and actions relating to the action plan.

(3) The action plan must be consistent with the conditions for reapproval set forth in §433.119. The portion of the plan which is integrated with MMIS is monitored in accordance with those conditions and if the conditions are not met; it is subject to FFP reduction in accordance with procedures set forth in §433.120. The State is not subject to any other penalty as a result of other monitoring, quality control, or auditing requirements for those items in the action plan.

(4) The agency must submit its action plan to the CMS Regional Office within 120 days from the date CMS issues implementing instructions for the State Medicaid Manual. If a State does not have an approved MMIS on the date of issuance of the State Medicaid Manual but subsequently implements an MMIS, the State must submit its action plan within 90 days from the date the system is operational. The CMS Regional Office approves or disapproves the action plan.

(l) *Waiver of requirements.* (1) The agency may request initial and continuing waiver of the requirements to determine third party liability found in paragraphs (c), (d)(4), (d)(5), (e), (f), (g)(1), (g)(2), (g)(3), and (g)(4) of this section if the State determines the activity to be not cost-effective. An activity would not be cost-effective if the cost of the required activity exceeds the third party liability recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the State.

(i) The agency must submit a request for waiver of the requirement in writing to the CMS regional office.

(ii) The request must contain adequate documentation to establish that to meet a requirement specified by the agency is not cost-effective. Examples of documentation are claims recovery data and a State analysis documenting a cost-effective alternative that accomplished the same task.

(iii) The agency must agree, if a waiver is granted, to notify CMS of any event that occurs that changes the conditions upon which the waiver was approved.

(2) CMS will review a State's request to have a requirement specified under paragraph (l)(1) of this section waived and will request additional information from the State, if necessary. CMS will notify the State of its approval or disapproval determination within 30 days of receipt of a properly documented request.

(3) CMS may rescind a waiver at any time that it determines that the agency no longer meets the criteria for approving the waiver. If the waiver is rescinded, the agency has 6 months from the date of the rescission notice to meet the requirement that had been waived.

[52 FR 5975, Feb. 27, 1987, as amended at 54 FR 8741, Mar. 2, 1989; 55 FR 1432, Jan. 16, 1990; 55 FR 5118, Feb. 13, 1990; 60 FR 35502, July 10, 1995]

§ 433.139 Payment of claims.

(a) *Basic provisions.* (1) For claims involving third party liability that are processed on or after May 12, 1986, the agency must use the procedures specified in paragraphs (b) through (f) of this section.

(2) The agency must submit documentation of the methods (e.g., cost avoidance, pay and recover later) it uses for payment of claims involving third party liability to the CMS Regional Office.

(b) *Probable liability is established at the time claim is filed.* Except as provided in paragraph (e) of this section—

(1) If the agency has established the probable existence of third party liability at the time the claim is filed, the agency must reject the claim and return it to the provider for a determination of the amount of liability. The establishment of third party liability takes place when the agency receives confirmation from the provider or a third party resource indicating the extent of third party liability. When the amount of liability is determined, the agency must then pay the claim to the extent that payment allowed under the agency's payment schedule exceeds the amount of the third party's payment.

(2) The agency may pay the full amount allowed under the agency's payment schedule for the claim and then seek reimbursement from any liable third party to the limit of legal liability if the claim is for labor and delivery and postpartum care. (Costs associated with the inpatient hospital stay for labor and delivery and postpartum care must be cost-avoided.)

(3) The agency must pay the full amount allowed under the agency's payment schedule for the claim and seek reimbursement from any liable third party to the limit of legal liability (and for purposes of paragraph (b)(3)(ii) of this section, from a third party, if the third party liability is derived from an absent parent whose obligation to pay support is being enforced by the State title IV-D agency), consistent with paragraph (f) of this section if—

(i) The claim is prenatal care for pregnant women, or preventive pediatric services (including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B of this chapter), that is covered under the State plan; or

(ii) The claim is for a service covered under the State plan that is provided to an individual on whose behalf child support enforcement is being carried out by the State title IV-D agency. The agency prior to making any payment under this section must assure that the following requirements are met:

(A) The State plan specifies whether or not providers are required to bill the third party.

(B) The provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited 30 days from the date of the service and has not received payment from the third party.

(C) The State plan specifies the method used in determining the provider's compliance with the billing requirements.

(c) *Probable liability is not established or benefits are not available at the time claim is filed.* If the probable existence of third party liability cannot be established or third party benefits are not available to pay the recipient's medical expenses at the time the claim is filed, the agency must pay the full amount allowed under the agency's payment schedule.

(d) *Recovery of reimbursement.* (1) If the agency has an approved waiver under paragraph (e) of this section to pay a claim in which the probable existence of third party liability has been established and then seek reimbursement, the agency must seek recovery of reimbursement from the third party to the limit of legal liability within 60 days after the end of the month in which payment is made unless the agency has a waiver of the 60-day requirement under paragraph (e) of this section.

(2) Except as provided in paragraph (e) of this section, if the agency learns of the existence of a liable third party after a claim is paid, or benefits become available from a third party after a claim is paid, the agency must seek recovery of reimbursement within 60 days after the end of the month it learns of the existence of the liable third party or benefits become available.

(3) Reimbursement must be sought unless the agency determines that recovery would not be cost effective in accordance with paragraph (f) of this section.

(e) *Waiver of requirements.* (1) The agency may request initial and continuing waiver of the requirements in paragraphs (b)(1), (d)(1), and (d)(2) of this section, if it determines that the requirement is not cost-effective. An activity would not be cost-effective if the cost of the required activity exceeds the third party liability recoupment and the required activity accomplishes, at the same or at a higher cost, the same objective as another activity that is being performed by the State.

(i) The agency must submit a request for waiver of the requirement in writing to the CMS regional office.

(ii) The request must contain adequate documentation to establish that to meet a requirement specified by the agency is not cost-effective. Examples of documentation are costs associated with billing, claims recovery data, and a State analysis documenting a cost-effective alternative that accomplishes the same task.

(iii) The agency must agree, if a waiver is granted, to notify CMS of any event that occurs that changes the conditions upon which the waiver was approved.

(2) CMS will review a State's request to have a requirement specified under paragraph (e)(1) of this section waived and will request additional information from the State, if necessary. CMS will notify the State of its approval or disapproval determination within 30 days of receipt of a properly documented request.

(3) CMS may rescind the waiver at any time that it determines that the State no longer meets the criteria for approving the waiver. If the waiver is rescinded, the agency has 6 months from the date of the rescission notice to meet the requirement that had been waived.

(4) An agency requesting a waiver of the requirements specifically concerning either the 60-day limit in paragraph (d)(1) or (d)(2) of this section must submit documentation of written agreement between the agency and the third party, including Medicare fiscal intermediaries and carriers, that extension of the billing requirement is agreeable to all parties.

(f) *Suspension or termination of recovery of reimbursement.* (1) An agency must seek reimbursement from a liable third party on all claims for which it determines that the amount it reasonably expects to recover will be greater than the cost of recovery. Recovery efforts may be suspended or terminated only if they are not cost effective.

(2) The State plan must specify the threshold amount or other guideline that the agency uses in determining whether to seek recovery of reimbursement from a liable third party, or describe the process by which the agency determines that seeking recovery of reimbursement would not be cost effective.

(3) The State plan must also specify the dollar amount or period of time for

which it will accumulate billings with respect to a particular liable third party in making the decision whether to seek recovery of reimbursement.

[50 FR 46665, Nov. 12, 1985, as amended at 51 FR 16319, May 2, 1986; 60 FR 35503, July 10, 1995; 62 FR 23140, Apr. 29, 1997]

§ 433.140 FFP and repayment of Federal share.

(a) FFP is not available in Medicaid payments if—

(1) The agency failed to fulfill the requirements of §§ 433.138 and 433.139 with regard to establishing liability and seeking reimbursement from a third party;

(2) The agency received reimbursement from a liable third party; or

(3) A private insurer would have been obligated to pay for the service except that its insurance contract limits or excludes payments if the individual is eligible for Medicaid.

(b) FFP is available at the 50 percent rate for the agency's expenditures in carrying out the requirements of this subpart.

(c) If the State receives FFP in Medicaid payments for which it receives third party reimbursement, the State must pay the Federal government a portion of the reimbursement determined in accordance with the FMAP for the State. This payment may be reduced by the total amount needed to meet the incentive payment in § 433.153.

ASSIGNMENT OF RIGHTS TO BENEFITS

§ 433.145 Assignment of rights to benefits—State plan requirements.

(a) A State plan must provide that, as a condition of eligibility, each legally able applicant or recipient is required to:

(1) Assign to the Medicaid agency his or her rights, or the rights of any other individual eligible under the plan for whom he or she can legally make an assignment, to medical support and to payment for medical care from any third party;

(2) Cooperate with the agency in establishing paternity and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in section 1902(l)(1)(A) of the Act (poverty level pregnant women), who are exempt from cooperating in establishing paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(3) Cooperate in identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan, unless the individual establishes good cause for not cooperating.

(b) A State plan must provide that the requirements for assignments, cooperation in establishing paternity and obtaining support, and cooperation in identifying and providing information to assist the State in pursuing any liable third party under §§ 433.146 through 433.148 are met.

(c) A State plan must provide that the assignment of rights to benefits obtained from an applicant or recipient is effective only for services that are reimbursed by Medicaid.

[55 FR 48606, Nov. 21, 1990, as amended at 58 FR 4907, Jan. 19, 1993]

§ 433.146 Rights assigned; assignment method.

(a) Except as specified in paragraph (b) of this section, the agency must require the individual to assign to the State—

(1) His own rights to any medical care support available under an order of a court or an administrative agency, and any third party payments for medical care; and

(2) The rights of any other individual eligible under the plan, for whom he can legally make an assignment.

(b) Assignment of rights to benefits may not include assignment of rights to Medicare benefits.

(c) If assignment of rights to benefits is automatic because of State law, the agency may substitute such an assignment for an individual executed assignment, as long as the agency informs the individual of the terms and consequences of the State law.

§ 433.147 Cooperation in establishing paternity and in obtaining medical support and payments and in identifying and providing information to assist in pursuing third parties who may be liable to pay.

(a) *Scope of requirement.* The agency must require the individual who assigns his or her rights to cooperate in—

(1) Establishing paternity of a child born out of wedlock and obtaining medical support and payments for himself or herself and any other person for whom the individual can legally assign rights, except that individuals described in section 1902(l)(1)(A) of the Act (poverty level pregnant women) are exempt from these requirements involving paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(2) Identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan.

(b) *Essentials of cooperation.* As part of a cooperation, the agency may require an individual to—

(1) Appear at a State or local office designated by the agency to provide information or evidence relevant to the case;

(2) Appear as a witness at a court or other proceeding;

(3) Provide information, or attest to lack of information, under penalty of perjury;

(4) Pay to the agency any support or medical care funds received that are covered by the assignment of rights; and

(5) Take any other reasonable steps to assist in establishing paternity and securing medical support and payments, and in identifying and providing information to assist the State in pursuing any liable third party.

(c) *Waiver of cooperation for good cause.* The agency must waive the requirements in paragraphs (a) and (b) of this section if it determines that the individual has good cause for refusing to cooperate.

(1) With respect to establishing paternity of a child born out of wedlock or obtaining medical care support and payments, or identifying or providing information to assist the State in pursuing any liable third party for a child for whom the individual can legally assign rights, the agency must find the cooperation is against the best interests of the child, in accordance with factors specified for the Child Support Enforcement Program at 45 CFR part 232. If the State title IV-A agency has made a finding that good cause for refusal to cooperate does or does not exist, the Medicaid agency must adopt that finding as its own for this purpose.

(2) With respect to obtaining medical care support and payments for an individual and identifying and providing information to assist in pursuing liable third parties in any case not covered by paragraph (c)(1) of this section, the agency must find that cooperation is against the best interests of the individual or the person to whom Medicaid is being furnished because it is anticipated that cooperation will result in reprisal against, and cause physical or emotional harm to, the individual or other person.

(d) *Procedures for waiving cooperation.* With respect to establishing paternity, obtaining medical care support and payments, or identifying and providing information to assist the State in pursuing liable third parties for a child for whom the individual can legally assign rights, the agency must use the procedures specified for the Child Support Enforcement Program at 45 CFR part 232. With respect to obtaining medical care support and payments or to identifying and providing information to assist the State in pursuing liable third parties for any other individual, the agency must adopt procedures similar to those specified in 45 CFR part 232, excluding those procedures applicable only to children.

[45 FR 8984, Feb. 11, 1980, as amended at 55 FR 48606, Nov. 21, 1990; 58 FR 4907, Jan. 19, 1993]

§ 433.148 Denial or termination of eligibility.

In administering the assignment of rights provision, the agency must:

(a) Deny or terminate eligibility for any applicant or recipient who—

(1) Refuses to assign his own rights or those of any other individual for whom he can legally make an assignment; or

(2) Refuses to cooperate as required under § 433.147(a) unless cooperation has been waived;

(b) Provide Medicaid to any individual who—

(1) Cannot legally assign his own rights; and

(2) Would otherwise be eligible for Medicaid but for the refusal, by a person legally able to assign his rights, to assign his rights or to cooperate as required by this subpart; and

(c) In denying or terminating eligibility, comply with the notice and hearing requirements of part 431, subpart E of this subchapter.

COOPERATIVE AGREEMENTS AND INCENTIVE PAYMENTS

§ 433.151 Cooperative agreements and incentive payments—State plan requirements.

For medical assistance furnished on or after October 1, 1984—

(a) A State plan must provide for entering into written cooperative agreements for enforcement of rights to and collection of third party benefits with at least one of the following entities: The State title IV-D agency, any appropriate agency of any State, and appropriate courts and law enforcement officials. The agreements must be in accordance with the provisions of § 433.152.

(b) A State plan must provide that the requirements for making incentive payments and for distributing third party collections specified in §§ 433.153 and 433.154 are met.

[50 FR 46665, Nov. 12, 1985; 50 FR 49389, Dec. 2, 1985]

§ 433.152 Requirements for cooperative agreements for third party collections.

(a) Except as specified in paragraph (b) of this section, the State agency may develop the specific terms of cooperative agreements with other agencies as it determines appropriate for individual circumstances.

(b) Agreements with title IV-D agencies must specify that the Medicaid agency will—

(1) Meet the requirements of the Office of Child Support Enforcement for cooperative agreements under 45 CFR Part 306; and

(2) Provide reimbursement to the IV-D agency only for those child support services performed that are not reimbursable by the Office of Child Support Enforcement under title IV-D of the Act and that are necessary for the collection of amounts for the Medicaid program.

[50 FR 46666, Nov. 12, 1985]

§ 433.153 Incentive payments to States and political subdivisions.

(a) *When payments are required.* The agency must make an incentive payment to a political subdivision, a legal entity of the subdivision such as a prosecuting or district attorney or a friend of the court, or another State that enforces and collects medical support and payments for the agency.

(b) *Amount and source of payment.* The incentive payment must equal 15 percent of the amount collected, and must be made from the Federal share of that amount.

(c) *Payment to two or more jurisdictions.* If more than one State or political subdivision is involved in enforcing and collecting support and payments:

(1) The agency must pay all of the incentive payment to the political subdivision, legal entity of the subdivision, or another State that collected medical support and payments at the request of the agency.

(2) The political subdivision, legal entity or other State that receives the incentive payment must then divide the incentive payment equally with any other political subdivisions, legal entities, or other States that assisted in the collection, unless an alternative allocation is agreed upon by all jurisdictions involved.

§ 433.154 Distribution of collections.

The agency must distribute collections as follows—

(a) To itself, an amount equal to State Medicaid expenditures for the individual on whose right the collection was based.

(b) To the Federal Government, the Federal share of the State Medicaid expenditures, minus any incentive payment made in accordance with § 433.153.

(c) To the recipient, any remaining amount. This amount must be treated as income or resources under part 435 or part 436 of this subchapter, as appropriate.

Subpart E [Reserved]

Subpart F—Refunding of Federal Share of Medicaid Overpayments to Providers

SOURCE: 54 FR 5460, Feb. 3, 1989, unless otherwise noted.

§ 433.300 Basis.

This subpart implements—

(a) Section 1903(d)(2)(A) of the Act, which directs that quarterly Federal payments to the States under title XIX (Medicaid) of the Act are to be reduced or increased to make adjustment for prior overpayments or underpayments that the Secretary determines have been made.

(b) Section 1903(d)(2) (C) and (D) of the Act, which provides that a State has 60 days from discovery of an overpayment for Medicaid services to recover or attempt to recover the overpayment from the provider before adjustment in the Federal Medicaid payment to the State is made; and that adjustment will be made at the end of the 60 days, whether or not recovery is made, unless the State is unable to recover from a provider because the overpayment is a debt that has been discharged in bankruptcy or is otherwise uncollectable.

(c) Section 1903(d)(3) of the Act, which provides that the Secretary will consider the pro rata Federal share of the net amount recovered by a State during any quarter to be an overpayment.

§ 433.302 Scope of subpart.

This subpart sets forth the requirements and procedures under which States have 60 days following discovery of overpayments made to providers for Medicaid services to recover or attempt to recover that amount before the States must refund the Federal share of these overpayments to CMS, with certain exceptions.

§ 433.304 Definitions.

As used in this subpart—

Abuse (in accordance with § 455.2) means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.

Discovery (or *discovered*) means identification by any State Medicaid agency official or other State official, the Federal Government, or the provider of an overpayment, and the communication of that overpayment finding or the initiation of a formal recoupment action without notice as described in § 433.316.

Fraud (in accordance with § 455.2) means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

Overpayment means the amount paid by a Medicaid agency to a provider which is in excess of the amount that is allowable for services furnished under section 1902 of the Act and which is required to be refunded under section 1903 of the Act.

Provider (in accordance with § 400.203) means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

Recoupment means any formal action by the State or its fiscal agent to initiate recovery of an overpayment without advance official notice by reducing future payments to a provider.

Third party (in accordance with § 433.136) means an individual, entity, or program that is or may be liable to pay for all or part of the expenditures for medical assistance furnished under a State plan.

[54 FR 5460, Feb. 3, 1989; 54 FR 8435, Feb. 28, 1989]

§ 433.310 Applicability of requirements.

(a) *General rule.* Except as provided in paragraphs (b) and (c) of this section,

the provisions of this subpart apply to—

(1) Overpayments made to providers that are discovered by the State;

(2) Overpayments made to providers that are initially discovered by the provider and made known to the State agency; and

(3) Overpayments that are discovered through Federal reviews.

(b) *Third party payments and probate collections.* The requirements of this subpart do not apply to—

(1) Cases involving third party liability because, in these situations, recovery is sought for a Medicaid payment that would have been made had another party not been legally responsible for payment; and

(2) Probate collections from the estates of deceased Medicaid recipients, as they represent the recovery of payments properly made from resources later determined to be available to the State.

(c) *Unallowable costs paid under rate-setting systems.* (1) Unallowable costs for a prior year paid to an institutional provider under a rate-setting system that a State recovers through an adjustment to the per diem rate for a subsequent period do not constitute overpayments that are subject to the requirements of this subpart.

In such cases, the State is not required to refund the Federal share explicitly related to the original overpayment in accordance with the regulations in this subpart. Refund of the Federal share occurs when the State claims future expenditures made to the provider at a reduced rate.

(2) Unallowable costs for a prior year paid to an institutional provider under a rate-setting system that a State seeks to recover in a lump sum, by an installment repayment plan, or through reduction of future payments to which the provider would otherwise be entitled constitute overpayments that are subject to the requirements of this subpart.

(d) *Recapture of depreciation upon gain on the sale of assets.* Depreciation payments are considered overpayments for purposes of this subpart if a State requires their recapture in a discrete amount(s) upon gain on the sale of assets.

§ 433.312 Basic requirements for refunds.

(a) *Basic rules.* (1) Except as provided in paragraph (b) of this section, the Medicaid agency has 60 days from the date of discovery of an overpayment to a provider to recover or seek to recover the overpayment before the Federal share must be refunded to CMS.

(2) The agency must refund the Federal share of overpayments at the end of the 60-day period following discovery in accordance with the requirements of this subpart, whether or not the State has recovered the overpayment from the provider.

(b) *Exception.* The agency is not required to refund the Federal share of an overpayment made to a provider when the State is unable to recover the overpayment amount because the provider has been determined bankrupt or out of business in accordance with § 433.318.

(c) *Applicability.* (1) The requirements of this subpart apply to overpayments made to Medicaid providers that occur and are discovered in any quarter that begins on or after October 1, 1985.

(2) The date upon which an overpayment occurs is the date upon which a State, using its normal method of reimbursement for a particular class of provider (e.g., check, interfund transfer), makes the payment involving unallowable costs to a provider.

§ 433.316 When discovery of overpayment occurs and its significance.

(a) *General rule.* The date on which an overpayment is discovered is the beginning date of the 60-calendar day period allowed a State to recover or seek to recover an overpayment before a refund of the Federal share of an overpayment must be made to CMS.

(b) *Requirements for notification.* Unless a State official or fiscal agent of the State chooses to initiate a formal recoupment action against a provider without first giving written notification of its intent, a State Medicaid agency official or other State official must notify the provider in writing of any overpayment it discovers in accordance with State agency policies and procedures and must take reasonable actions to attempt to recover the

overpayment in accordance with State law and procedures.

(c) *Overpayments resulting from situations other than fraud or abuse.* An overpayment resulting from a situation other than fraud or abuse is discovered on the earliest of—

(1) The date on which any Medicaid agency official or other State official first notifies a provider in writing of an overpayment and specifies a dollar amount that is subject to recovery;

(2) The date on which a provider initially acknowledges a specific overpaid amount in writing to the medicaid agency; or

(3) The date on which any State official or fiscal agent of the State initiates a formal action to recoup a specific overpaid amount from a provider without having first notified the provider in writing.

(d) *Overpayments resulting from fraud or abuse.* An overpayment that results from fraud or abuse is discovered on the date of the final written notice of the State's overpayment determination that a Medicaid agency official or other State official sends to the provider.

(e) *Overpayments identified through Federal reviews.* If a Federal review at any time indicates that a State has failed to identify an overpayment or a State has identified an overpayment but has failed to either send written notice of the overpayment to the provider that specified a dollar amount subject to recovery or initiate a formal recoupment from the provider without having first notified the provider in writing, CMS will consider the overpayment as discovered on the date that the Federal official first notifies the State in writing of the overpayment and specifies a dollar amount subject to recovery.

(f) *Effect of changes in overpayment amount.* Any adjustment in the amount of an overpayment during the 60-day period following discovery (made in accordance with the approved State plan, Federal law and regulations governing Medicaid, and the appeals resolution process specified in State administrative policies and procedures) has the following effect on the 60-day recovery period:

(1) A downward adjustment in the amount of an overpayment subject to recovery that occurs after discovery does not change the original 60-day recovery period for the outstanding balance.

(2) An upward adjustment in the amount of an overpayment subject to recovery that occurs during the 60-day period following discovery does not change the 60-day recovery period for the original overpayment amount. A new 60-day period begins for the incremental amount only, beginning with the date of the State's written notification to the provider regarding the upward adjustment.

(g) *Effect of partial collection by State.* A partial collection of an overpayment amount by the State from a provider during the 60-day period following discovery does not change the 60-day recovery period for the original overpayment amount due to CMS.

(h) *Effect of administrative or judicial appeals.* Any appeal rights extended to a provider do not extend the date of discovery.

[54 FR 5460, Feb. 3, 1989; 54 FR 8435, Feb. 28, 1989]

§433.318 Overpayments involving providers who are bankrupt or out of business.

(a) *Basic rules.* (1) The agency is not required to refund the Federal share of an overpayment made to a provider as required by §433.312(a) to the extent that the State is unable to recover the overpayment because the provider has been determined bankrupt or out of business in accordance with the provisions of this section.

(2) The agency must notify the provider that an overpayment exists in any case involving a bankrupt or out-of-business provider and, if the debt has not been determined uncollectable, take reasonable actions to recover the overpayment during the 60-day recovery period in accordance with policies prescribed by applicable State law and administrative procedures.

(b) *Overpayment debts that the State need not refund.* Overpayments are considered debts that the State is unable to recover within the 60-day period following discovery if the following criteria are met:

(1) The provider has filed for bankruptcy, as specified in paragraph (c) of this section; or

(2) The provider has gone out of business and the State is unable to locate the provider and its assets, as specified in paragraph (d) of this section.

(c) *Bankruptcy.* The agency is not required to refund to CMS the Federal share of an overpayment at the end of the 60-day period following discovery, if—

(1) The provider has filed for bankruptcy in Federal court at the time of discovery of the overpayment or the provider files a bankruptcy petition in Federal court before the end of the 60-day period following discovery; and

(2) The State is on record with the court as a creditor of the petitioner in the amount of the Medicaid overpayment.

(d) *Out of business.* (1) The agency is not required to refund to CMS the Federal share of an overpayment at the end of the 60-day period following discovery if the provider is out of business on the date of discovery of the overpayment or if the provider goes out of business before the end of the 60-day period following discovery.

(2) A provider is considered to be out of business on the effective date of a determination to that effect under State law. The agency must—

(i) Document its efforts to locate the party and its assets. These efforts must be consistent with applicable State policies and procedures; and

(ii) Make available an affidavit or certification from the appropriate State legal authority establishing that the provider is out of business and that the overpayment cannot be collected under State law and procedures and citing the effective date of that determination under State law.

(3) A provider is not out of business when ownershp is transferred within the State unless State law and procedures deem a provider that has transferred ownership to be out of business and preclude collection of the overpayment from the provider.

(e) *Circumstances requiring refunds.* If the 60-day recovery period has expired before an overpayment is found to be uncollectable under the provisions of this section, if the State recovers an overpayment amount under a court-approved discharge of bankruptcy, or if a bankruptcy petition is denied, the agency must refund the Federal share of the overpayment in accordance with the procedures specified in § 433.320.

[54 FR 5460, Feb. 3, 1989; 54 FR 8435, Feb. 28, 1989]

§ 433.320 Procedures for refunds to CMS.

(a) *Basic requirements.* (1) The agency must refund the Federal share of overpayments that are subject to recovery to CMS through a credit on its Quarterly Statement of Expenditures (Form CMS–64).

(2) The Federal share of overpayments subject to recovery must be credited on the Form CMS–64 report submitted for the quarter in which the 60-day period following discovery, established in accordance with § 433.316, ends.

(3) A credit on the Form CMS–64 must be made whether or not the overpayment has been recovered by the State from the provider.

(b) *Effect of reporting collections and submitting reduced expenditure claims.* (1) The State is not required to refund the Federal share of an overpayment when the State reports a collection or submits an expenditure claim reduced by a discrete amount to recover an overpayment prior to the end of the 60-day period following discovery.

(2) The State is not required to report on the Form CMS–64 any collections made on overpayment amounts for which the Federal share has been refunded previously.

(3) If a State has refunded the Federal share of an overpayment as required under this subpart and the State subsequently makes recovery by reducing future provider payments by a discrete amount, the State need not reflect that reduction in its claim for Federal financial participation.

(c) *Reclaiming overpayment amounts previously refunded to CMS.* If the amount of an overpayment is adjusted downward after the agency has credited CMS with the Federal share, the agency may reclaim the amount of the downward adjustment on the Form CMS–64. Under this provision—

(1) Downward adjustment to an overpayment amount previously credited to CMS is allowed only if it is properly based on the approved State plan, Federal law and regulations governing Medicaid, and the appeals resolution processes specified in State administrative policies and procedures.

(2) The 2-year filing limit for retroactive claims for Medicaid expenditures does not apply. A downward adjustment is not considered a retroactive claim but rather a reclaiming of costs previously claimed.

(d) *Expiration of 60-day recovery period.* If an overpayment has not been determined uncollectable in accordance with the requirements of §433.318 at the end of the 60-day period following discovery of the overpayment, the agency must refund the Federal share of the overpayment to CMS in accordance with the procedures specified in paragraph (a) of this section.

(e) *Court-approved discharge of bankruptcy.* If the State recovers any portion of an overpayment under a court-approved discharge of bankruptcy, the agency must refund to CMS the Federal share of the overpayment amount collected on the next quarterly expenditure report that is due to CMS for the period that includes the date on which the collection occurs.

(f) *Bankruptcy petition denied.* If a provider's petition for bankruptcy is denied in Federal court, the agency must credit CMS with the Federal share of the overpayment on the later of—

(1) The Form CMS–64 submission due to CMS immediately following the date of the decision of the court; or

(2) The Form CMS–64 submission for the quarter in which the 60-day period following discovery of the overpayment ends.

(g) *Reclaim of refunds.* (1) If a provider is determined bankrupt or out of business under this section after the 60-day period following discovery of the overpayment ends and the State has not been able to make complete recovery, the agency may reclaim the amount of the Federal share of any unrecovered overpayment amount previously refunded to CMS. CMS allows the reclaim of a refund by the agency if the agency submits to CMS documentation that it has made reasonable efforts to obtain recovery.

(2) If the agency reclaims a refund of the Federal share of an overpayment—

(i) In bankruptcy cases, the agency must submit to CMS a statement of its efforts to recover the overpayment during the period before the petition for bankruptcy was filed; and

(ii) In out-of-business cases, the agency must submit to CMS a statement of its efforts to locate the provider and its assets and to recover the overpayment during any period before the provider is found to be out of business in accordance with §433.318.

(h) *Supporting reports.* The agency must report the following information to support each Quarterly Statement of Expenditures Form CMS–64:

(1) Amounts of overpayments not collected during the quarter but refunded because of the expiration of the 60-day period following discovery;

(2) Upward and downward adjustments to amounts credited in previous quarters;

(3) Amounts of overpayments collected under court-approved discharges of bankruptcy;

(4) Amounts of previously reported overpayments to providers certified as bankrupt or out of business during the quarter; and

(5) Amounts of overpayments previously credited and reclaimed by the State.

§433.322 Maintenance of records.

The Medicaid agency must maintain a separate record of all overpayment activities for each provider in a manner that satisfies the retention and access requirements of 45 CFR part 74, subpart D.

PART 434—CONTRACTS

Subpart A—General Provisions

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 48 FR 54020, Nov. 30, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 434.1 Basis and scope.

(a) *Statutory basis.* This part is based on section 1902(a)(4) of the Act, which requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) *Scope.* This part sets forth the requirements for contracts with certain organizations for furnishing Medicaid services or processing or paying Medicaid claims, or enchancing the agency's capability for effective administration of the program.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983, as amended at 67 FR 41095, June 14, 2002]

§ 434.2 Definitions.

As used in this part, unless the context indicates otherwise—

Fiscal agent means an entity that processes or pays vendor claims for the agency.

Health care projects grant center means an entity that—

(a) Is supported in whole or in part by Federal project grant financial assistance; and

(b) Provides or arranges for medical services to recipients.

Private nonmedical institution means an institution (such as a child-care facility or a maternity home) that—

(a) Is not, as a matter of regular business, a health insuring organization or a community health care center;

(b) Provides medical care to its residents through contracts or other arrangements with medical providers; and

(c) Receives capitation payments from the Medicaid agency, under a nonrisk contract, for its residents who are eligible for Medicaid.

Professional management service or consultant firm means a firm that performs management services such as auditing or staff training, or carries out studies or provides consultation aimed at improving State Medicaid operations, for example, with respect to reimbursement formulas or accounting systems.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983, as amended at 52 FR 22322, June 11, 1987; 55 FR 51295, Dec. 13, 1990; 67 FR 41095, June 14, 2002]

§ 434.4 State plan requirement.

If the State plan provides for contracts of the types covered by this part, the plan must also provide for meeting the applicable requirements of this part.

§ 434.6 General requirements for all contracts and subcontracts.

(a) *Contracts.* All contracts under this part must—

(1) Include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74;

(2) Identify the population covered by the contract;

(3) Specify any procedures for enrollment or reenrollment of the covered population;

(4) Specify the amount, duration, and scope of medical services to be provided or paid for;

(5) Provide that the agency and HHS may evaluate through inspection or other means, the quality, appropriateness and timeliness of services performed under the contract;

(6) Specify procedures and criteria for terminating the contract, including a requirement that the contractor promptly supply all information necessary for the reimbursement of any outstanding Medicaid claims;

(7) Provide that the contractor maintains an appropriate record system for services to enrolled recipients;

(8) Provide that the contractor safeguards information about recipients as required by part 431, subpart F of this chapter;

(9) Specify any activities to be performed by the contractor that are related to third party liability requirements in part 433, subpart D of this chapter;

(10) Specify which functions may be subcontracted; and

(11) Provide that any subcontracts meet the requirements of paragraph (b) of this section.

(b) *Subcontracts.* All subcontracts must be in writing and fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(c) *Continued responsibility of contractor.* No subcontract terminates the legal responsibility of the contractor to the agency to assure that all activities under the contract are carried out.

[48 FR 54020, Nov. 30, 1983, as amended at 67 FR 41095, June 14, 2002]

Subpart B—Contracts with Fiscal Agents and Private Nonmedical Institutions

§ 434.10 Contracts with fiscal agents.

Contracts with fiscal agents must—

(a) Meet the requirements of § 434.6;

(b) Include termination procedures that require the contractors to supply promptly all material necessary for continued operation of payment and related systems. This material includes—

(1) Computer programs;

(2) Data files;

(3) User and operation manuals, and other documentation;

(4) System and program documentation; and

(5) Training programs for Medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system;

(c) Offer to the State one or both of the following options, if the fiscal agent or the fiscal agent's subcontractor has a proprietary right to material specified in paragraph (b) of this section:

(1) Purchasing the material; or

(2) Purchasing the use of the material through leasing or other means; and

(d) State that payment to providers will be made in accordance with part 447 of this chapter.

§ 434.12 Contracts with private nonmedical institutions.

Contracts with private nonmedical institutions must—

(a) Meet the requirements of § 434.6;

(b) Specify a capitation fee based on the cost of the services provided, in accordance with the reimbursement requirements prescribed in part 447 of this chapter; and

(c) Specify when the capitation fee must be paid.

§ 434.14 [Reserved]

Subpart C [Reserved]

Subpart D—Contracts With Health Insuring Organizations

§ 434.40 Contract requirements.

(a) Contracts with health insuring organizations that are not subject to the requirements in section 1903(m)(2)(A) must:

(1) Meet the general requirements for all contracts and subcontracts specified in § 434.6;

(2) Specify that the contractor assumes at least part of the underwriting risk and;

(i) If the contractor assumes the full underwriting risk, specify that payment of the capitation fees to the contractor during the contract period constitutes full payment by the agency for the cost of medical services provided under the contract;

(ii) If the contractor assumes less than the full underwriting risk, specify how the risk is apportioned between the agency and the contractor;

(3) Specify whether the contractor returns to the agency part of any savings remaining after the allowable costs are deducted from the capitations fees, and if savings are returned, the apportionment between agency and the contractor; and

(4) Specify the extent, if any, to which the contractor may obtain reinsurance of a portion of the underwriting risk.

(b) The contract must—

(1) Specify that the capitation fee will not exceed the limits set forth under part 447 of this chapter.

(2) Specify that, except as permitted under paragraph (b) of this section, the capitation fee paid on behalf of each recipient may not be renegotiated—

(i) During the contract period if the contract period is 1 year or less; or

(ii) More often than annually if the contract period is for more than 1 year.

(3) Specify that the capitation fee will not include any amount for recoupment of any specific losses suffered by the contractor for risks assumed under the same contract or a prior contract with the agency; and

(4) Specify the actuarial basis for computation of the capitation fee.

(c) The capitation fee may be renegotiated more frequently than annually for recipients who are not enrolled at the time of renegotiation or if the renegotiation is required by changes in Federal or State law.

[55 FR 51295, Dec. 13, 1990]

Subpart E [Reserved]

Subpart F—Federal Financial Participation

SOURCE: 48 FR 54020, Nov. 20, 1983, unless otherwise noted. Redesignated at 55 FR 51295, Dec. 13, 1990.

§ 434.70 Conditions for Federal Financial Participation (FFP).

(a) *Basic requirements.* FFP is available only for periods during which the contract—

(1) Meets the requirements of this part;

(2) Meets the applicable requirements of 45 CFR part 74; and

(3) Is in effect.

(b) *Basis for withholding.* CMS may withhold FFP for any period during which the State fails to meet the State plan requirements of this part.

[67 FR 41095, June 14, 2002]

§ 434.76 Costs under fiscal agent contracts.

Under each contract with a fiscal agent—

(a) The amount paid to the provider of medical services is a medical assistance cost; and

(b) The amount paid to the contractor for performing the agreed-upon functions is an administrative cost.

§ 434.78 Right to reconsideration of disallowance.

A Medicaid agency dissatisfied with a disallowance of FFP under this subpart may request and will be granted reconsideration in accordance with 45 CFR part 16.

PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45204, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 435.2 Purpose and applicability.

This part sets forth, for the 50 States, the District of Columbia, the Northern Mariana Islands, and American Samoa—

(a) The eligibility provisions that a State plan must contain;

(b) The mandatory and optional groups of individuals to whom Medicaid is provided under a State plan;

(c) The eligibility requirements and procedures that the Medicaid agency must use in determining and redetermining eligibility, and requirements it may not use;

(d) The availability of FFP for providing Medicaid and for administering the eligibility provisions of the plan; and

(e) Other requirements concerning eligibility determinations, such as use

of an institutionalized individual's income for the cost of care.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979; 51 FR 41350, Nov. 14, 1986]

§ 435.3 Basis.

(a) This part implements the following sections of the Act and public laws that mandate eligibility requirements and standards:

402(a)(22) Eligibility of deemed recipients of AFDC who receive zero payments because of recoupment of overpayments.
402(a)(37) Eligibility of individuals who lose AFDC eligibility due to increased earnings.
414(g) Eligibility of certain individuals participating in work supplementation programs.
473(b) Eligibility of children in foster care and adopted children who are deemed AFDC recipients.
1619(b) Benefits for blind individuals or those with disabling impairments whose income equals or exceeds a specific SSI limit.
1634(b) Preservation of benefit status for disabled widows and widowers who lost SSI benefits because of 1983 changes in actuarial reduction formula.
1634(d) Individuals who lose eligibility for SSI benefits due to entitlement to early widow's or widower's social security disability benefits under section 202(e) or (f) of the Act.
1902(a)(8) Opportunity to apply; assistance must be furnished promptly.
1902(a)(10) Required and optional groups.
1902(a)(12) Determination of blindness.
1902(a)(17) Standards for determining eligibility: flexibility in the application of income eligibility standards.
1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.
1902(a)(34) Three-month retroactive eligibility.
1902(a) (second paragraph after (47)) Eligibility despite increased monthly insurance benefits under title II.
1902(a)(55) Mandatory use of outstation locations other than welfare offices to receive and initially process applications of certain low-income pregnant women, infants, and children under age 19.
1902(b) Prohibited conditions for eligibility: Age requirement of more that 65 years; State residence requirements excluding individuals who reside in the state; and Citizenship requirement excluding United States citizens.
1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.
1902(e)(2) Minimum eligibility period for recipient enrolled in an HMO.
1902(e)(3) Optional coverage of certain disabled children being cared for at home.
1902(e)(4) Eligibility of newborn children of Medicaid eligible women.
1902(e)(5) Eligibility of pregnant woman for extended coverage for specified postpartum period after pregnancy ends.
1902(f) State option to restrict Medicaid eligibility for aged, blind, or disabled individuals to those who would have been eligible under State plan in effect in January 1972.
1902(j) Medicaid program in American Samoa.
1903(f) Income limitations for medically needy and individuals covered by State supplement eligibility requirements.
1903(v) Payment for emergency services under Medicaid provided to aliens.
1905(a) (clause following (21)) Prohibitions against providing Medicaid to certain institutionalized individuals.
1905(a) (second sentence) Definition of essential person.
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1905(d)(2) Definition of resident of an intermediate care facility for the mentally retarded.
1905(j) Definition of State supplementary payment.
1905(k) Eligibility of essential spouses of eligible individuals.
1905(n) Definition of qualified pregnant woman and child.
1912(a) Conditions of eligibility.
1915(c) Home or community-based services.
1915(d) Home or community-based services for individuals age 65 or older.
412(e)(5) of Immigration and Nationality Act—Eligibility of certain refugees.
Pub. L. 93–66, section 230 Deemed eligibility of certain essential persons.
Pub. L. 93–66, section 231 Deemed eligibility of certain persons in medical institutions.
Pub. L. 93–66, section 232 Deemed eligibility of certain blind and disabled medically indigent persons.
Pub. L. 93–233, section 13(c) Deemed eligibility of certain individuals receiving mandatory State supplementary payments.
Pub. L. 94–566, section 503 Deemed eligibility of certain individuals who would be eligible for supplemental security income benefits but for cost-of-living increases in social security benefits.
Pub. L. 96–272, section 310(b)(1) Continued eligibility of certain recipients of Veterans Administration pensions.
Pub. L. 99–509, section 9406 Payment for emergency medical services provided to aliens.
Pub. L. 99–603, section 201 Aliens granted legalized status under section 245A of the Immigration and Nationality Act (8 U.S.C. 1255a) may under certain circumstances be eligible for Medicaid.

Pub. L. 99–603, section 302 Aliens granted legalized status under section 210 of the Immigration and Nationality Act may under certain circumstances be eligible for Medicaid (8 U.S.C. 1160).

Pub. L. 99–603, section 303 Aliens granted legal status under section 210A of the Immigration and Nationality Act may under certain circumstances be eligible for Medicaid (8 U.S.C. 1161).

(b) This part implements the following other provisions of the Act or public laws that establish additional State plan requirements:

1618 Requirement for operation of certain State supplementation programs.

Pub. L. 93–66, section 212(a) Required mandatory minimum State supplementation of SSI benefits programs.

[52 FR 43071, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987, as amended at 55 FR 36819, Sept. 7, 1990; 55 FR 48607, Nov. 21, 1990; 57 FR 29155, June 30, 1992; 59 FR 48809, Sept. 23, 1994]

§ 435.4 Definitions and use of terms.

As used in this part—

AABD means aid to the aged, blind, and disabled under title XVI of the Act;

AB means aid to the blind under title X of the Act;

AFDC means aid to families with dependent children under title IV-A of the Act;

APTD means aid to the permanently and totally disabled under title XIV of the Act;

Categorically needy refers to families and children, aged, blind, or disabled individuals, and pregnant women, described under subparts B and C of this part who are eligible for Medicaid. Subpart B of this part describes the mandatory eligibility groups who, generally, are receiving or deemed to be receiving cash assistance under the Act. These mandatory groups are specified in sections 1902(a)(10)(A)(i), 1902(e), 1902(f), and 1928 of the Act. Subpart C of this part describes the optional eligibility groups of individuals who, generally, meet the categorical requirements or income or resource requirements that are the same as or less restrictive than those of the cash assistance programs and who are not receiving cash payments. These optional groups are specified in sections 1902(a)(10)(A)(ii), 1902(e), and 1902(f) of the Act.

Families and children refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90, 233.100). In addition, this group includes individuals under age 21 who are not deprived of parental support or care but are financially eligible under AFDC rules or medically needy rules (see optional coverage group, § 435.222). It does not include individuals under age 21 whose eligibility for Medicaid is based on blindness or disability—for these individuals, SSI rules govern;

Mandatory State supplement means a cash payment a State is required to make under section 212, Pub. L. 93–66 (July 9, 1973) to an aged, blind, or disabled individual. Its purpose is to provide an individual with the same amount of cash assistance he was receiving under OAA, AB, APTD, or AABD if his SSI payment is less than that amount;

Medically needy refers to families, children, aged, blind, or disabled individuals, and pregnant women listed under subpart D of this part who are not listed in subparts B and C of this part as categorically needy but who may be eligible for Medicaid under this part because their income and resources are within limits set by the State under its Medicaid plan (including persons whose income and resources fall within these limits after their incurred expenses for medical or remedial care are deducted) (Specific financial requirements for determining eligibility of the medically needy appear in subpart I of this part.);

OAA means old age assistance under title I of the Act;

OASDI means old age, survivors, and disability insurance under title II of the Act;

Optional State supplement means a cash payment made by a State, under section 1616 of the Act, to an aged, blind, or disabled individual;

Optional targeted low-income child means a child under age 19 who meets the financial and categorical standards described below.

(1) *Financial need.* An optional targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved; and

(ii) Resides in a State with no Medicaid applicable income level (as defined at § 457.10 of this chapter); or

(iii) Resides in a State that has a Medicaid applicable income level (as defined at § 457.10 of this chapter) and has family income that either:

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points; or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under the policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage and State maintenance of effort.* An optional targeted low-income child is not covered under a group health plan or health insurance coverage, or would not be eligible for Medicaid under the policies of the State plan in effect on March 31, 1997; except that, for purposes of this standard—

(i) A child shall not be considered to be covered by health insurance coverage based on coverage offered by the State under a program in operation prior to July 1, 1997 if that program received no Federal financial participation;

(ii) A child shall not be considered to be covered under a group health plan or health insurance coverage if the child did not have reasonable geographic access to care under that coverage.

(3) For purposes of this section, policies of the State plan a under title XIX plan include policies under a Statewide demonstration project under section 1115(a) of the Act other than a demonstration project that covered an expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

SSI means supplemental security income under title XVI of the Act.

SWICA means the State Wage Information Collection Agency under section 1137(a) of the Act. It is the State agency administering the State unemployment compensation law; a separate agency administering a quarterly wage reporting system; or a State agency administering an alternative system which has been determined by the Secretary of Labor, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, to be as effective and timely in providing employment related income and eligibility data.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980; 46 FR 6909, Jan. 22, 1981; 46 FR 47984, Sept. 30, 1981; 51 FR 7211, Feb. 28, 1986; 58 FR 4925, Jan. 19, 1993; 66 FR 2666, Jan. 11, 2001]

§ 435.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom Medicaid is provided, as specified in subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§ 435.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

MANDATORY COVERAGE OF FAMILIES AND CHILDREN

§ 435.110 Individuals receiving aid to families with dependent children.

(a) A Medicaid agency must provide Medicaid to individuals receiving AFDC.

(b) For purposes of this section, an individual is receiving AFDC if his needs are included in determining the amount of the AFDC payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient (see 45 CFR 233.20(a)(2)(vi)) and who could be a recipient under the State's AFDC plan if that plan were as broad as allowed under the Act for FFP.

§ 435.112 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide Medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4 calendar month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4 calendar month period also begins retroactively with the first month in which AFDC was erroneously paid.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

§ 435.113 Individuals who are ineligible for AFDC because of requirements that do not apply under title XIX of the Act.

The agency must provide Medicaid to:

(a) Individuals denied AFDC solely because of policies requiring the deeming of income and resources of the following individuals who are not included as financially responsible relatives under section 1902(a)(17)(D) of the Act;

(1) Stepparents who are not legally liable for support of stepchildren under a State law of general applicability;

(2) Grandparents;

(3) Legal guardians;

(4) Alien sponsors who are not organizations; and

(5) Siblings.

(b) [Reserved]

[58 FR 4926, Jan. 19, 1993, as amended at 59 FR 43052, Aug. 22, 1994]

§ 435.114 Individuals who would be eligible for AFDC except for increased OASDI income under Pub. L. 92–336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving AFDC; or

(2) He would have been eligible for AFDC if he had applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for AFDC if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for AFDC except that the increase in OASDI under Pub. L. 92–336 raised his income over the limit allowed under AFDC. This includes an individual who—

(1) Meets all current AFDC requirements except for the requirement to file an application; or

(2) Would meet all current AFDC requirements if he were not in a medical institution or intermediate care facility, and the current Medicaid plan covers this optional group.

§ 435.115 Individuals deemed to be receiving AFDC.

(a) The Medicaid agency must provide Medicaid to individuals deemed to be receiving AFDC, as specified in this section.

(b) The State must deem individuals to be receiving AFDC who are denied a cash payment from the title IV-A State agency solely because the amount of the AFDC payment would be less than $10.

(c) The State may deem participants in a work supplementation program to be receiving AFDC under section 414(g) of the Act. This section permits States, for purposes of title XIX, to deem an individual and any child or relative of the individual (or other individual living in the same household) to be receiving AFDC, if the individual—

(1) Participates in a State-operated work supplementation program under section 414 of the Act; and

(2) Would be eligible for an AFDC cash payment if the individual were not participating in the work supplementation program.

(d) The State must deem to be receiving AFDC those individuals who are denied AFDC payments from the title IV-A State agency solely because that agency is recovering an overpayment.

(e) The State must deem to be receiving AFDC individuals described in section 473(a)(1) of the Act—

(1) For whom an adoption assistance agreement is in effect under title IV-E of the Act, whether or not adoption assistance is being provided or an interlocutory or other judicial decree of adoption has been issued; or

(2) For whom foster care maintenance payments are made under title IV-E of the Act.

(f) The State must deem an individual to be receiving AFDC if a new collection or increased collection of child or spousal support under title IV-D of the Social Security Act results in the termination of AFDC eligibility in accordance with section 406(h) of the Social Security Act. States must continue to provide Medicaid for four consecutive calendar months, beginning with the first month of AFDC ineligibility, to each dependent child and each relative with whom such a child is living (including the eligible spouse of such relative as described in section 406(b) of the Social Security Act) who:

(1) Becomes ineligible for AFDC on or after August 16, 1984; and

(2) Has received AFDC for at least three of the six months immediately preceding the month in which the individual becomes ineligible for AFDC; and

(3) Becomes ineligible for AFDC wholly or partly as a result of the initiation of or an increase in the amount of the child or spousal support collection under title IV-D.

(g)(1) Except as provided in paragraph (g)(2) of this section, individuals who are eligible for extended Medicaid lose this coverage if they move to another State during the 4-month period. However, if they move back to and reestablish residence in the State in which they have extended coverage, they are eligible for any of the months remaining in the 4-month period in which they are residents of the State.

(2) If a State has chosen in its State plan to provide Medicaid to non-residents, the State may continue to provide the 4-month extended benefits to individuals who have moved to another State.

(h) For purposes of paragraph (f) of this section:

(1) The new collection or increased collection of child or spousal support results in the termination of AFDC eligibility when it actively causes or contributes to the termination. This occurs when:

(i) The change in support collection in and of itself is sufficient to cause ineligibility. This rule applies even if the support collection must be added to other, stable income. It also applies even if other independent factors, alone or in combination with each other, might simultaneously cause ineligibility; or

(ii) The change in support contributes to ineligibility but does not by itself cause ineligibility. Ineligibility must result when the change in support is combined with other changes in income or changes in other circumstances and the other changes in income or circumstances cannot alone or in combination result in termination without the change in support.

(2) In cases of increases in the amounts of both support collections and earned income, eligibility under this section does not preclude eligibility under 45 CFR 233.20(a)(14) or section 1925 of the Social Security Act (which was added by section 303(a) of the Family Support Act of 1988 (42 U.S.C. 1396r–6)). Extended periods resulting from both an increase in the amount of the support collection and from an increase in earned income must run concurrently.

[46 FR 47985, Sept. 30, 1981, as amended at 52 FR 43071, Nov. 9, 1987; 55 FR 48607, Nov. 21, 1990; 59 FR 59376, Nov. 17, 1994]

MANDATORY COVERAGE OF PREGNANT WOMEN, CHILDREN UNDER 8, AND NEWBORN CHILDREN

§ 435.116 Qualified pregnant women and children who are not qualified family members.

(a) The agency must provide Medicaid to a pregnant woman whose pregnancy has been medically verified and who—

(1) Would be eligible for an AFDC cash payment (or would be eligible for an AFDC cash payment if coverage under the State's AFDC plan included an AFDC-unemployed parents program) if her child had been born and was living with her in the month of payment;

(2) Is a member of a family that would be eligible for an AFDC cash payment if the State's AFDC plan included an AFDC-unemployed parents program; or

(3) Meets the income and resource requirements of the State's approved AFDC plan. In determining whether the woman meets the AFDC income and resource requirements, the unborn child or children are considered members of the household, and the woman's family is treated as though deprivation exists.

(b) The provisions of paragraphs (a)(1) and (2) of this section are effective October 1, 1984. The provisions of paragraph (a)(3) of this section are effective July 1, 1986.

(c) The agency must provide Medicaid to children who meet all of the following criteria:

(1) They are born after September 30, 1983;

(2) Effective October 1, 1988, they are under age 6 (or if designated by the State, any age that exceeds age 6 but does not exceed age 8), and effective October 1, 1989, they are under age 7 (or if designated by the State, any age that exceeds age 7 but does not exceed age 8); and

(3) They meet the income and resource requirements of the State's approved AFDC plan.

[52 FR 43071, Nov. 9, 1987, as amended at 55 FR 48607, Nov. 21, 1990; 58 FR 48614, Sept. 17, 1993]

§ 435.117 Newborn children.

(a) The agency must provide categorically needy Medicaid eligibility to a child born to a woman who is eligible as categorically needy and is receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as categorically needy for one year so long as the woman remains eligible as categorically needy and the child is a member of the woman's household. If the mother's basis of eligibility changes to medically needy, the child is eligible as medically needy under § 435.301(b)(1)(iii).

(b) The requirements under paragraph (a) of this section apply to children born on or after October 1, 1984.

[52 FR 43071, Nov. 9, 1987]

MANDATORY COVERAGE OF QUALIFIED FAMILY MEMBERS

§ 435.119 Qualified family members.

(a) *Definition.* A *qualified family member* is any member of a family, including pregnant women and children eligible for Medicaid under § 435.116 of this subpart, who would be receiving AFDC cash benefits on the basis of the unemployment of the principal wage earner under section 407 of the Act had the State not chosen to place time limits on those benefits as permitted under section 407(b)(2)(B)(i) of the Act.

(b) *State plan requirement.* The State plan must provide that the State makes Medicaid available to any individual who meets the definition of ''qualified family member'' as specified in paragraph (a) of this section.

(c) *Applicability.* The provisions in this section are applicable in the 50 States and the District of Columbia from October 1, 1990, through September 30, 1998. The provisions are applicable in American Samoa from October 1, 1992, through September 30, 1998.

[58 FR 48614, Sept. 17, 1993]

MANDATORY COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.120 Individuals receiving SSI.

Except as allowed under § 435.121, the agency must provide Medicaid to aged,

blind, and disabled individuals or couples who are receiving or are deemed to be receiving SSI. This includes individuals who are—

(a) Receiving SSI pending a final determination of blindness or disability;

(b) Receiving SSI under an agreement with the Social Security Administration to dispose of resources that exceed the SSI dollar limits on resources; or

(c) Receiving benefits under section 1619(a) of the Act or in section 1619(b) status (blind individuals or those with disabling impairments whose income equals or exceeds a specific Supplemental Security Income limit). (Regulations at 20 CFR 416.260 through 416.269 contain requirements governing determinations of eligibility under this provision.) For purposes of this paragraph (c), this mandatory categorically needy group of individuals includes those qualified severely impaired individuals defined in section 1905(q) of the Act.

[55 FR 33705, Aug. 17, 1990]

§ 435.121 Individuals in States using more restrictive requirements for Medicaid than the SSI requirements.

(a) *Basic eligibility group requirements.* (1) If the agency does not provide Medicaid under § 435.120 to aged, blind, and disabled individuals who are SSI recipients, the agency must provide Medicaid to aged, blind, and disabled individuals who meet eligibility requirements that are specified in this section.

(2) Except to the extent provided in paragraph (a)(3) of this section, the agency may elect to apply more restrictive eligibility requirements to the aged, blind, and disabled that are more restrictive than those of the SSI program. The more restrictive requirements may be no more restrictive than those requirements contained in the State's Medicaid plan in effect on January 1, 1972. If any of the State's 1972 Medicaid plan requirements were more liberal than of the SSI program, the State must use the SSI requirement instead of the more liberal requirements, except to the extent the State elects to use more liberal criteria under § 435.601.

(3) The agency must not apply a more restrictive requirement under the provisions of paragraph (a)(2) of this section if:

(i) The requirement conflicts with the requirements of section 1924 of the Act, which governs the eligibility and post-eligibility treatment of income and resources of institutionalized individuals with community spouses;

(ii) The requirement conflicts with a more liberal requirement which the agency has elected to use under § 435.601; or

(iii) The more restrictive requirement conflicts with a more liberal requirement the State has elected to use under § 435.234(c) in determining eligibility for State supplementary payments.

(b) *Mandatory coverage.* If the agency chooses to apply more restrictive requirements than SSI to aged, blind, or disabled individuals, it must provide Medicaid to:

(1) Individuals who meet the requirements of section 1619(b)(3) of the Act even though they may not continue to meet the requirements of this section; and

(2) Qualified Medicare beneficiaries described in section 1905(p) of the Act and qualified working disabled individuals described in section 1905(s) of the Act without consideration of the more restrictive eligibility requirements specified in this section.

(3) Individuals who:

(i) Qualify for benefits under section 1619(a) or are in eligibility status under section 1619(b)(1) of the Act as determined by SSA; and

(ii) Were eligible for Medicaid under the more restrictive criteria in the State's approved Medicaid plan in the reference month—the month immediately preceding the first month in which they became eligible under section 1619(a) or (b)(1) of the Act. ''Were eligible for Medicaid'' means that individuals were issued Medicaid cards by the State for the reference month. Under this provision, the reference month for determining Medicaid eligibility for all individuals under section 1619 of the Act is the month immediately preceding the first month of the most recent period of eligibility under section 1619 of the Act.

(c) *Group composition.* The agency may apply more restrictive requirements only to the aged, to the blind, to the disabled, or to any combination of these groups. For example, the agency may apply more restrictive requirements to the aged and disabled under this provision and provide Medicaid to all blind individuals who are SSI recipients.

(d) *Nonfinancial conditions.* The agency may apply more restrictive requirements that are nonfinancial conditions of eligibility. For example, the agency may use a more restrictive definition of disability or may limit eligibility of the disabled to individuals age 18 and older, or both. If the agency limits eligibility of disabled individuals to individuals age 18 or older, it must provide Medicaid to individuals under age 18 who receive SSI benefits and who would be eligible to receive AFDC under the State's approved plan if they did not receive SSI. If the agency imposed an age limit for disabled individuals under its 1972 approved State plan but does not use that limit, it must apply the same nonfinancial requirement to individuals under age 18 that it applies to disabled individuals age 18 and older.

(e) *Financial conditions.* (1) The agency may apply more restrictive requirements that are financial conditions of eligibility.

(2) Any income eligibility standards that the agency applies must:

(i) Equal the income standard (or Federal Benefit Rate (FBR)) that would be used under SSI based on an individual's living arrangement; or

(ii) Be a more restrictive standard which is no more restrictive than that under the approved State's January 1, 1972 Medicaid plan.

(3) If the categorically needy income standard established under paragraph (e)(2) of this section is less than the optional categorically needy standard established under §435.230, the agency must provide Medicaid to all aged, blind, and disabled individuals who have income equal to or below the higher standard.

(4) In a State that does not have a medically needy program that covers aged, blind, and disabled individuals, the agency must allow individuals to deduct from income incurred medical and remedial expenses (that is, spend down) to become eligible under this section. However, individuals with income above the categorically needy standards may only spend down to the standard selected by the State under paragraph (e)(2) of this section which applies to the individual's living arrangement.

(5) In a State that elects to provide medically needy coverage to aged, blind, and disabled individuals, the agency must allow individuals to deduct from income incurred medical and remedial care expenses (spend down) to become categorically needy when they are SSI recipients (including individuals deemed to be SSI recipients under §§435.135, 435.137, and 435.138), eligible spouses of SSI recipients, State supplement recipients, and individuals who are eligible for a supplement but who do not receive supplementary payments. Such persons may only spend down to the standard selected by the State under paragraph (e)(2) of this section. Individuals who are not SSI recipients, eligible spouses of SSI recipients, State supplement recipients, or individuals who are eligible for a supplement must spend down to the State's medically needy income standards for aged, blind, and disabled individuals in order to become Medicaid eligible.

(f) *Deductions from income.* (1) In addition to any income disregards specified in the approved State plan in accordance with §435.601(b), the agency must deduct from income:

(i) SSI payments;

(ii) State supplementary payments that meet the conditions specified in §§435.232 and 435.234; and

(iii) Expenses incurred by the individual or financially responsible relatives for necessary medical and remedial services that are recognized under State law and are not subject to payment by a third party, unless the third party is a public program of a State or political subdivision of a State. These expenses include Medicare and other health insurance premiums, deductions and coinsurance charges, and copayments or deductibles imposed under §447.51 or §447.53 of this chapter. The agency may set reasonable limits on

the amounts of incurred medical expenses that are deducted.

(2) For purposes of counting income with respect to individuals who are receiving benefits under section 1619(a) f the Act or are in section 1619(b)(1) of the Act status but who do not meet the requirements of paragraph (b)(3)(ii) of this section, the agency may disregard some or all of the amount of the individual's income that is in excess of the SSI Federal benefit rate under section 1611(b) of the Act.

[58 FR 4926, Jan. 19, 1993]

§ 435.122 Individuals who are ineligible for SSI or optional State supplements because of requirements that do not apply under title XIX of the Act.

If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or optional State supplements, it must provide Medicaid to individuals who would be eligible for SSI or optional State supplements except for an eligibility requirement used in those programs that is specifically prohibited under title XIX.

[47 FR 43648, Oct. 1, 1982; 47 FR 49847, Nov. 3, 1982]

§ 435.130 Individuals receiving mandatory State supplements.

The agency must provide Medicaid to individuals receiving mandatory State supplements.

§ 435.131 Individuals eligible as essential spouses in December 1973.

(a) The agency must provide Medicaid to any person who was eligible for Medicaid in December 1973 as an essential spouse of an aged, blind, or disabled individual who was receiving cash assistance, if the conditions in paragraph (b) of this section are met. An ''essential spouse'' is defined in section 1905(a) of the Act as one who is living with the individual; whose needs were included in determining the amount of cash payment to the individual under OAA, AB, APTD, or AABD; and who is determined essential to the individual's well-being.

(b) The agency must continue Medicaid if—

(1) The aged, blind, or disabled individual continues to meet the December 1973 eligibility requirements of the applicable State cash assistance plan; and

(2) The essential spouse continues to meet the conditions that were in effect in December 1973 under the applicable cash assistance plan for having his needs included in computing the payment to the aged, blind, or disabled individual.

§ 435.132 Institutionalized individuals who were eligible in December 1973.

The agency must provide Medicaid to individuals who were eligible for Medicaid in December 1973, or any part of that month, as inpatients of medical institutions or residents of intermediate care facilities that were participating in the Medicaid program and who—

(a) For each consecutive month after December 1973—

(1) Continue to meet the requirements for Medicaid eligibility that were in effect under the State's plan in December 1973 for institutionalized individuals; and

(2) Remain institutionalized; and

(b) Are determined by the State or a professional standards review organization to continue to need institutional care.

§ 435.133 Blind and disabled individuals eligible in December 1973.

The agency must provide Medicaid to individuals who—

(a) Meet all current requirements for Medicaid eligibility except the criteria for blindness or disability;

(b) Were eligible for Medicaid in December 1973 as blind or disabled individuals, whether or not they were receiving cash assistance in December 1973; and

(c) For each consecutive month after December 1973, continue to meet the criteria for blindness or disability and the other conditions of eligibility used under the Medicaid plan in December 1973.

§ 435.134 Individuals who would be eligible except for the increase in OASDI benefits under Pub. L. 92–336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving OAA, AB, APTD, or AABD; or

(2) He would have been eligible for one of those programs except that he had not applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for one of those programs if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for SSI or a State supplement except that the increase in OASDI under Pub. L. 92–336 raised his income over the limit allowed under SSI. This includes an individual who—

(1) Meets all current SSI requirements except for the requirement to file an application; or

(2) Would meet all current SSI requirements if he were not in a medical institution or intermediate care facility, and the State's Medicaid plan covers this optional group.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24883, Apr. 11, 1980]

§ 435.135 Individuals who become ineligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977.

(a) If an agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, it must provide Medicaid to individuals who—

(1) Are receiving OASDI;

(2) Were eligible for and receiving SSI or State supplements but became ineligible for those payments after April 1977; and

(3) Would still be eligible for SSI or State supplements if the amount of OASDI cost-of-living increases paid under section 215(i) of the Act, after the last month after April 1977 for which those individuals were both eligible for and received SSI or a State supplement and were entitled to OASDI, were deducted from current OASDI benefits.

(b) Cost-of-living increases include the increases received by the individual or his or her financially responsible spouse or other family member (e.g., a parent).

(c) If the agency adopts more restrictive eligibility requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or State supplements. If the individual incurs enough medical expenses to reduce his or her income to the financial eligibility standard for the categorically needy, the agency must cover that individual as categorically needy. In determining the amount of his or her income, the agency may deduct the cost-of-living increases paid under section 215(i) after the last month after April 1977 for which that individual was both eligible for and received SSI or a State supplement and was entitled to OASDI, up to the amount that made him or her ineligible for SSI.

[51 FR 12330, Apr. 10, 1986]

§ 435.136 State agency implementation requirements for one-time notice and annual review system.

An agency must—

(a) Provide a one-time notice of potential Medicaid eligibility under § 435.135 to all individuals who meet the requirements of § 435.135 (a) or (c) who were not receiving Medicaid as of March 9, 1984; and

(b) Establish an annual review system to identify individuals who meet the requirements of § 435.135 (a) or (c) and who lose categorically needy eligibility for Medicaid because of a loss of SSI. States without medically needy programs must send notices of potential eligibility for Medicaid to these individuals for 3 consecutive years following their identification through the annual review system.

[51 FR 12330, Apr. 10, 1986]

§ 435.137 Disabled widows and widowers who would be eligible for SSI except for the increase in disability benefits resulting from elimination of the reduction factor under Pub. L. 98–21.

(a) If the agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, the agency much provide Medicaid to disabled widows and widowers who—

(1) Became ineligible for SSI or a mandatory or optional State supplement as a result of the elimination of the additional reduction factor for disabled widows and widowers under age 60 required by section 134 of Pub. L. 98–21, and for purposes of title XIX, are deemed to be title XVI payment recipients under section 1634(b) of the Social Security Act; and

(2) Meet the conditions of paragraphs (b) and (e) of this section.

(b) The individuals must meet the following conditions:

(1) They were entitled to monthly OASDI benefits under title II of the Act for December 1983:

(2) They were entitled to and received widow's or widower's disability benefits under section 202(e) or (f) of the Act for January 1984;

(3) They became ineligible for SSI or a mandatory or optional State supplement in the first month in which the increase under Pub. L. 98–21 was paid (and in which a retroactive payment for that increase for prior months was not made);

(4) They have been continously entitled to widow's or widower's disability benefits under section 202(e) or (f) from the first month that the increase under Pub. L. 98–21 was received; and

(5) They would be eligible for SSI benefits or a mandatory or optional State supplement if the amount of the increase under Pub. L. 98–21 and subsequent cost-of-living adjustments in widow's or widower's benefits under section 215(i) of the Act were deducted from their income.

(c) If the agency adopts more restrictive requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or a mandatory or optional State supplement. The State must consider the individuals specified in paragraph (a) of this section to have no more income than the SSI Federal benefit rate if the individual was eligible for SSI in the month prior to the first month in which the increase under Public Law 98–21 was paid (and in which retroactive payments for that increase for prior months was not being made), and the individual would be eligible for SSI except for the amount of the increase under Public Law 98–21 and subsequent cost-of-living adjustments in his or her widow's or widower's benefits under section 215(i) of the Act. The State must consider individuals who qualify under paragraph (a) of this section on the basis of loss of a mandatory or optional State supplementary payment, rather than the loss of SSI, to have no more income than the relevant SSP rate. If the State's income eligibility level is lower than the SSP or SSI Federal benefit rates, individuals qualifying under paragraph (a) of this section who are deemed to have income at either the SSP rate or the SSI Federal benefit rate may further reduce their countable income by incurring medical expenses in the amount by which their income exceeds the State's income eligibility standard. When the individual has reduced his or her income by this amount, he or she will be eligible for Medicaid as categorically needy.

(d) The agency must notify each individual who may be eligible for Medicaid under this section of his or her potential eligibility, in accordance with instructions issued by the Secretary.

(e)(1) Except as provided in paragraph (e)(2) of this section, the provisions of this section apply only to those individuals who filed a written application for Medicaid on or before June 30, 1988, to obtain protected Medicaid coverage.

(2) Individuals who may be eligible under this section residing in States that use a more restrictive income standard than that of the SSI program, under section 1902(f) of the Act, have up to six months after the State sends notice pursuant to the District Court's order in *Darling* v. *Bowen* (685 F. Supp. 1125 (W.D.Mo. 1988) to file a written application to obtain protected Medicaid coverage.

[55 FR 48607, Nov. 21, 1990]

§ 435.138 Disabled widows and widowers aged 60 through 64 who would be eligible for SSI except for early receipt of social security benefits.

(a) If the agency provides Medicaid to aged, blind, or disabled individuals receiving SSI or State supplements, the

agency must provide Medicaid to disabled widows and widowers who—

(1) Are at least age 60;

(2) Are not entitled to hospital insurance benefits under Medicare Part A; and

(3) Become ineligible for SSI or a State supplement because of mandatory application (under section 1611(e)(2)) for and receipt of widow's or widower's social security disability benefits under section 202(e) or (f) (or any other provision of section 202 if they are also eligible for benefits under subsections (e) or (f)) of the Act.

For purposes of title XIX, individuals who meet these requirements are deemed to be title XVI payment recipients under section 1634(d) of the Act.

(b) If the agency adopts more restrictive eligibility requirements than those under SSI, it must provide Medicaid to individuals specified in paragraph (a) of this section on the same basis as Medicaid is provided to individuals continuing to receive SSI or a mandatory or optional State supplement. If the individual incurs enough medical expenses to reduce his or her income to the financial eligibility standard for the categorically needy under the State's more restrictive eligibility criteria, the agency must cover the individual as categorically needy. In determining the amount of his or her income, the agency may deduct all, part, or none of the amount of the social security disability benefits that made him or her ineligible for SSI or a State supplement, up to the amount that made him or her ineligible for SSI.

(c) Individuals who may be eligible under this section must file a written application for Medicaid. Medicaid coverage may begin no earlier than July 1, 1988.

(d) The agency must determine whether individuals may be eligible for Medicaid under this section.

[55 FR 48608, Nov. 21, 1990]

MANDATORY COVERAGE OF CERTAIN ALIENS

§ 435.139 Coverage for certain aliens.

The agency must provide services necessary for the treatment of an emergency medical condition, as defined in § 440.255(c) of this chapter, to those aliens described in § 435.406(c) of this subpart.

[55 FR 36819, Sept. 7, 1990]

MANDATORY COVERAGE OF ADOPTION ASSISTANCE AND FOSTER CARE CHILDREN

§ 435.145 Children for whom adoption assistance or foster care maintenance payments are made.

The agency must provide Medicaid to children for whom adoption assistance or foster care maintenance payments are made under title IV-E of the Act.

[47 FR 28665, July 1, 1982. Redesignated at 55 FR 48607, Nov. 21, 1990. Redesignated at 58 FR 48614, Sept. 17, 1993]

MANDATORY COVERAGE OF SPECIAL GROUPS

§ 435.170 Pregnant women eligible for extended coverage.

(a) The agency must provide categorically needy Medicaid eligibility for an extended period following termination of pregnancy to women who, while pregnant, applied for, were eligible for, and received Medicaid services on the day that their pregnancy ends. This period extends from the last day of pregnancy through the end of the month in which a 60-day period, beginning on the last day of the pregnancy, ends. Eligibility must be provided regardless of changes in the woman's financial circumstances that may occur within this extended period. These women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(b) The provisions of paragraph (a) of this section apply to Medicaid furnished on or after April 7, 1986.

[55 FR 48608, Nov. 21, 1990]

Subpart C—Options for Coverage as Categorically Needy

§ 435.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 435.201 Individuals included in optional groups.

(a) The agency may choose to cover as optional categorically needy any group or groups of the following individuals who are not receiving cash assistance and who meet the appropriate eligibility criteria for groups specified in the separate sections of this subpart:

(1) Aged individuals (65 years of age of older);

(2) Blind individuals (as defined in § 435.530);

(3) Disabled individuals (as defined in § 435.541);

(4) Individuals under age 21 (or, at State option, under age 20, 19, or 18) or reasonable classifications of these individuals;

(5) Specified relatives under section 406(b)(1) of the Act who have in their care an individual who is determined to be dependent (or would, if needy, be dependent) as specified in § 435.510; and

(6) Pregnant women.

(b) If the agency provides Medicaid to any individual in an optional group specified in paragraph (a) of this section, the agency must provide Medicaid to all individuals who apply and are found eligible to be members of that group.

(c) States that elect to use more restrictive eligibility requirements for Medicaid than the SSI requirements for any group or groups of aged, blind, and disabled individuals under § 435.121 must apply the specific requirements of § 435.230 in establishing eligibility of these groups of individuals as optional categorically needy.

[58 FR 4927, Jan. 19, 1993]

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN AND THE AGED, BLIND, AND DISABLED

§ 435.210 Individuals who meet the income and resource requirements of the cash assistance programs.

The agency may provide Medicaid to any group or groups of individuals specified in § 435.201 (a)(1) through (a)(3) and (a)(5) and (a)(6) who are not mandatory categorically needy, who meet the income and resource requirements of the appropriate cash assistance program for their status (that is, the State's approved AFDC plan or SSI, or optional State supplements in States that provide Medicaid to optional State supplement recipients).

[58 FR 4927, Jan. 19, 1993]

§ 435.211 Individuals who would be eligible for cash assistance if they were not in medical institutions.

The agency may provide Medicaid to any group or groups of individuals specified in § 435.201(a) who are in title XIX reimbursable medical institutions and who:

(a) Are ineligible for the cash assistance program appropriate for their status (that is, AFDC or SSI, or optional State supplements in States that provide Medicaid to optional State supplement recipients) because of lower income standards used under the program to determine eligibility for institutionalized individuals; but

(b) Would be eligible for aid or assistance under the State's approved AFDC plan, SSI, or an optional State supplement as specified in §§ 435.232 and 435.234 if they were not institutionalized.

[58 FR 4927, Jan. 19, 1993]

§ 435.212 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

The State agency may provide that a recipient who is enrolled in an MCO or PCCM and who becomes ineligible for Medicaid is considered to continue to be eligible—

(a) For a period specified by the agency, ending no later than 6 months from the date of enrollment; and

(b) Except for family planning services (which the recipient may obtain from any qualified provider) only for services furnished to him or her as an MCO enrollee.

[56 FR 8849, Mar. 1, 1991, as amended at 67 FR 41095, June 14, 2002]

§ 435.217 Individuals receiving home and community-based services.

The agency may provide Medicaid to any group or groups of individuals in the community who meet the following requirements:

(a) The group would be eligible for Medicaid if institutionalized.

(b) In the absence of home and community-based services under a waiver granted under part 441—

(1) Subpart G of this subchapter, the group would otherwise require the level of care furnished in a hospital, NF, or an ICF/MR; or

(2) Subpart H of this subchapter, the group would otherwise require the level of care furnished in an NF and are age 65 or older.

(c) The group receives the waivered services.

[57 FR 29155, June 30, 1992]

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN

§ 435.220 Individuals who would meet the income and resource requirements under AFDC if child care costs were paid from earnings.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 435.201 (a)(4), (a)(5), and (a)(6) who would meet the income and resource requirements under the State's approved AFDC plan if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State's AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.

[43 FR 45204, Sept. 29, 1978, as amended at 58 FR 4927, Jan. 19, 1993]

§ 435.221 [Reserved]

§ 435.222 Individuals under age 21 who meet the income and resource requirements of AFDC.

(a) The agency may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18); or reasonable categories of these individuals as specified in paragraph (b) of this section, who are not receiving cash assistance under any program but who meet the income and resource requirements of the State's approved AFDC plan.

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals under age 21 receiving active treatment as inpatients in pyschiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47985, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981, as amended at 58 FR 4927, Jan. 19, 1993]

§ 435.223 Individuals who would be eligible for AFDC if coverage under the State's AFDC plan were as broad as allowed under title IV-A.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 435.210 (a)(4), (a)(5), and (a)(6) who:

(1) Would be eligible for AFDC if the State's AFDC plan included individuals whose coverage under title IV-A is optional (for example, Medicaid may be provided to members of families with an unemployed parent even though AFDC is not available to them under the State's AFDC plan); or

(2) Would be eligible for AFDC if the State's AFDC plan did not contain eligibility requirements more restrictive than, or in addition to, those required under title IV-A.

(b) The agency may cover any AFDC optional group without covering all such groups.

[46 FR 47985, Sept. 30, 1981, as amended at 58 FR 4927, Jan. 19, 1993]

§ 435.225 Individuals under age 19 who would be eligible for Medicaid if they were in a medical institution.

(a) The agency may provide Medicaid to children 18 years of age or younger who qualify under section 1614(a) of the Act, who would be eligible for Medicaid if they were in a medical institution, and who are receiving, while living at home, medical care that would be provided in a medical institution.

(b) If the agency elects the option provided by paragraph (a) of this section, it must determine, in each case, that the following conditions are met:

(1) The child requires the level of care provided in a hospital, SNF, or ICF.

(2) It is appropriate to provide that level of care outside such an institution.

(3) The estimated Medicaid cost of care outside an institution is no higher than the estimated Medicaid cost of appropriate institutional care.

(c) The agency must specify in its State plan the method by which it determines the cost-effectiveness of caring for disabled children at home.

[55 FR 48608, Nov. 21, 1990]

§ 435.227 Individuals under age 21 who are under State adoption assistance agreements.

(a) The agency may provide Medicaid to individuals under the age of 21 (or, at State option, age 20, 19, or 18)—

(1) For whom an adoption agreement (other than an agreement under title IV-E) between the State and the adoptive parent(s) is in effect;

(2) Who, the State agency responsible for adoption assistance, has determined cannot be placed with adoptive parents without Medicaid because the child has special needs for medical or rehabilitative care; and

(3) Who meet either of the following:

(i) Were eligible for Medicaid under the State plan before the adoption agreement was entered into; or

(ii) Would have been eligible for Medicaid before the adoption agreement was entered into, if the eligibility standards and methodologies of the title IV-E foster care program were used without employing the threshold title IV-A eligibility determination.

(b) For adoption assistance agreements entered into before April 7, 1986—

(1) The agency must deem the requirements of paragraphs (a)(1) and (2) of this section to be met if the State adoption assistance agency determines that—

(i) At the time of the adoption placement, the child had special needs for medical or rehabilitative care that made the child difficult to place; and

(ii) There is in effect an adoption assistance agreement between the State and the adoptive parent(s).

(2) The agency must deem the requirements of paragraph (a)(3) of this section to be met if the child was found by the State to be eligible for Medicaid before the adoption assistance agreement was entered into.

[55 FR 48608, Nov. 21, 1990]

§ 435.229 Optional targeted low-income children.

The agency may provide Medicaid to—

(a) All individuals under age 19 who are optional targeted low-income children as defined in § 435.4; or

(b) Reasonable categories of these individuals.

[66 FR 2667, Jan. 11, 2001]

OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.230 Aged, blind, and disabled individuals in States that use more restrictive requirements for Medicaid than SSI requirements: Optional coverage.

(a) *Basic optional coverage rule.* If the agency elects the option under § 435.121 to provide mandatory eligibility for aged, blind, and disabled SSI recipients using more restrictive requirements than those used under SSI, the agency may provide eligibility as optional categorically needy to additional individuals who meet the requirements of this section.

(b) *Group composition.* Subject to the conditions specified in paragraphs (d) and (e) of this section, the agency may provide Medicaid to individuals who:

(1) Meet the nonfinancial criteria that the State has elected to apply under § 435.121;

(2) Meet the resource requirements that the State has elected to apply under § 435.121; and

(3) Meet the income eligibility standards specified in paragraph (c) of this section.

(c) *Criteria for income standards.* The agency may provide Medicaid to the following individuals who meet the requirements of paragraphs (b)(1) and (b)(2) of this section:

(1) Individuals who are financially eligible for but not receiving SSI benefits and who, before deduction of incurred medical and remedial expenses, meet the State's more restrictive eligibility requirements described in § 435.121;

(2) Individuals who meet the income standards of the following eligibility groups:

(i) Individuals who would be eligible for cash assistance except for institutional status described in § 435.211;

(ii) Individuals who are enrolled in an HMO or other entity and who are deemed to continue to be Medicaid eligible for a period specified by the agency up to 6 months from the date of enrollment and who became ineligible during the specified enrollment period, as described in § 435.212;

(iii) Individuals receiving home and community-based waiver services described in § 435.217;

(iv) Individuals receiving only optional State supplements described in § 435.234;

(v) Institutionalized individuals with income below a special income level described in § 435.236;

(vi) Aged and disabled individuals who have income below 100 percent of the Federal poverty level described in section 1905(m) of the Act.

(3) Individuals who qualify for special status under §§ 435.135 and 435.138, and with respect to whom the State elects to disregard some or the maximum amount of title II payments permitted to be disregarded under those sections.

(d) *Use of more liberal methods.* The agency may elect to apply more liberal methods of counting income and resources that are approved for this eligibility group under the provisions of § 435.601.

[58 FR 4928, Jan. 19, 1993]

§ 435.232 Individuals receiving only optional State supplements.

(a) If the agency provides Medicaid to individuals receiving SSI under § 435.120, it may provide Medicaid, in one or more of the following classifications, to individuals who receive only an optional State supplement that meets the conditions specified in paragraph (b) of this section and who would be eligible for SSI except for the level of their income.

(1) All aged individuals.

(2) All blind individuals.

(3) All disabled individuals.

(4) Only aged individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(5) Only blind individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(6) Only disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(7) Individuals receiving a federally administered optional State supplement that meets the conditions specified in this section.

(8) Individuals in additional classifications specified by the Secretary for federally administered supplementary payments under 20 CFR 416.2020(d).

(9) Reasonable groups of individuals, as specified by the State, receiving State-administered supplementary payments.

(b) Payments under the optional supplement program must be—

(1) Based on need and paid in cash on a regular basis;

(2) Equal to the difference between the individual's countable income and the income standard used to determine eligibility for supplement. Countable income is income remaining after deductions required under SSI or, at State option, more liberal deductions are made (see § 435.1006 for limitations on FFP in Medicaid expenditures for individuals receiving optional State supplements); and

(3) Available to all individuals in each classification in paragraph (a) of

this section and available on a statewide basis. However, the plan may provide for variations in the income standard by political subdivision according to cost-of-living differences.

[43 FR 45204, Sept. 29, 1978. Redesignated and amended at 58 FR 4928, Jan. 19, 1993]

§ 435.234 Individuals receiving only optional State supplements in States using more restrictive eligibility requirements than SSI and certain States using SSI criteria.

(a) In States using more restrictive eligibility requirements than SSI or in States that use SSI criteria but do not have section 1616 or 1634 agreements with the Social Security Administration for eligibility determinations, the agency may provide Medicaid to individuals specified in paragraph (b) of this section who receive only a State supplement if the State supplement meets the conditions specified in paragraph (c) of this section.

(b) The agency may provide Medicaid to all individuals receiving only State supplements if, except for their income, the individuals meet the more restrictive eligibility requirements under § 435.121 or SSI criteria, or to one or more of the following classifications of individuals who meet these criteria:

(1) All aged individuals.

(2) All blind individuals.

(3) All disabled individuals.

(4) Only aged individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(5) Only blind individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(6) Only disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(7) Individuals receiving a Federally-administered optional State supplement that meets the conditions specified in this section.

(8) Individuals in additional classifications specified by the Secretary.

(9) Reasonable groups of individuals, as specified by the State, receiving State-administered supplementary payments.

(c) Payments under the optional supplement program must be:

(1) Based on need and paid in cash on a regular basis;

(2) Equal to the difference between the individual's countable income and the income standard used to determine eligibility for supplements. Countable income is income remaining after deductions are applied. The income deductions may be more restrictive than required under SSI (see § 435.1006 for limitations on FFP in Medicaid expenditures for individuals receiving optional State supplements); and

(3) Available to all individuals in each classification in paragraph (b) of this section and available on a statewide basis. However, the plan may provide for variations in the income standard by political subdivision according to cost-of-living differences.

[58 FR 4928, Jan. 19, 1993]

§ 435.236 Individuals in institutions who are eligible under a special income level.

(a) If the agency provides Medicaid under § 435.211 to individuals in institutions who would be eligible for AFDC, SSI, or State supplements except for their institutional status, it may also cover aged, blind, and disabled individuals in institutions who—

(1) Because of their income, would not be eligible for SSI or State supplements if they were not institutionalized; but

(2) Have income below a level specified in the plan under § 435.722. (See § 435.1005 for limitations on FFP in Medicaid expenditures for individuals specified in this section.)

(b) The agency may cover individuals under this section whether or not the State pays optional supplements.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980. Redesignated at 58 FR 4928, Jan. 19, 1993]

Subpart D—Optional Coverage of the Medically Needy

§ 435.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§ 435.301 General rules.

(a) An agency may provide Medicaid to individuals specified in this subpart who:

(1) Either:

(i) Have income that meets the applicable standards in §§ 435.811 and 435.814; or

(ii) If their income is more than allowed under the standard, have incurred medical expenses at least equal to the difference between their income and the applicable income standard; and

(2) Have resources that meet the applicable standards in §§ 435.840 and 435.843.

(b) If the agency chooses this option, the following provisions apply:

(1) The agency must provide Medicaid to the following individuals who meet the requirements of paragraph (a) of this section:

(i) All pregnant women during the course of their pregnancy who, except for income and resources, would be eligible for Medicaid as mandatory or optional categorically needy under subparts B or C of this part;

(ii) All individuals under 18 years of age who, except for income and resources, would be eligible for Medicaid as mandatory categorically needy under subpart B of this part;

(iii) All newborn children born on or after October 1, 1984, to a woman who is eligible as medically needy and is receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as medically needy for one year so long as the woman remains eligible and the child is a member of the woman's household. If the woman's basis of eligibility changes to categorically needy, the child is eligible as categorically needy under § 435.117. The woman is considered to remain eligible if she meets the spend-down requirements in any consecutive budget period following the birth of the child.

(iv) Women who, while pregnant, applied for, were eligible for, and received Medicaid services as medically needy on the day that their pregnancy ends. The agency must provide medically needy eligibility to these women for an extended period following termination of pregnancy. This period extends from the last day of the pregnancy through the end of the month in which a 60-day period, beginning on the last day of pregnancy, ends. Eligibility must be provided, regardless of changes in the woman's financial circumstances that may occur within this extended period. These women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(2) The agency may provide Medicaid to any of the following groups of individuals;

(i) Individuals under age 21 (§ 435.308).

(ii) Specified relatives (§ 435.310).

(iii) Aged (§ 435.330.320 and 435.330).

(iv) Blind (§§ 435.322, 435.330 and 435.340).

(v) Disabled (§§ 435.324, 435.330, and 435.340).

(3) If the agency provides Medicaid to any individual in a group specified in paragraph (b)(2) of this section, the agency must provide Medicaid to all individuals eligible to be members of that group.

[46 FR 47986, Sept. 30, 1981, as amended at 52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987; 55 FR 48609, Nov. 21, 1990; 58 FR 4929, Jan. 19, 1993]

§ 435.308 Medically needy coverage of individuals under age 21.

(a) If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals under age 21 (or, at State option, under age 20, 19, or 18), as specified in paragraph (b) of this section:

(1) Who would not be covered under the mandatory medically needy group of individuals under 18 under § 435.301(b)(1)(ii); and

(2) Who meet the income and resource requirements of subpart I of this part.

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. When the agency covers such individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47986, Sept. 30, 1981, as amended at 58 FR 4929, Jan. 19, 1993]

§ 435.310 Medically needy coverage of specified relatives.

(a) If the agency provides for the medically needy, it may provide Medicaid to specified relatives, as defined in paragraph (b) of this section, who meet the income and resource requirements of subpart I of this part.

(b) *Specified relatives* means individuals who:

(1) Are listed under section 406(b)(1) of the Act and 45 CFR 233.90(c)(1)(v)(A); and

(2) Have in their care an individual who is determined to be (or would, if needy, be) dependent, as specified in § 435.510.

[58 FR 4929, Jan. 19, 1993]

§ 435.320 Medically needy coverage of the aged in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to individuals who—

(a) Are 65 years of age and older, as specified in § 435.520; and

(b) Meet the income and resource requirements of subpart I of this part.

[46 FR 47986, Sept. 30, 1981]

§ 435.322 Medically needy coverage of the blind in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to blind individuals who meet—

(a) The requirements for blindness, as specified in §§ 435.530 and 435.531; and

(b) The income and resource requirements of subpart I of this part.

[46 FR 47986, Sept. 30, 1981]

§ 435.324 Medically needy coverage of the disabled in States that cover individuals receiving SSI.

If the agency provides Medicaid to individuals receiving SSI and elects to cover the medically needy, it may provide Medicaid to disabled individuals who meet—

(a) The requirements for disability, as specified in §§ 435.540 and 435.541; and

(b) The income and resource requirements of Subpart I of this part.

[46 FR 47986, Sept. 30, 1981; 46 FR 54743, Nov. 11, 1981]

§ 435.326 Individuals who would be ineligible if they were not enrolled in an MCO or PCCM.

If the agency provides Medicaid to the categorically needy under § 435.212, it may provide it under the same rules to medically needy recipients who are enrolled in MCOs or PCCMs.

[67 FR 41095, June 14, 2002]

§ 435.330 Medically needy coverage of the aged, blind, and disabled in States using more restrictive eligibility requirements for Medicaid than those used under SSI.

(a) If an agency provides Medicaid as categorically needy only to those aged, blind, or disabled individuals who meet more restrictive requirements than used under SSI and elects to cover the medically needy, it may provide Medicaid as medically needy to those aged, blind, or disabled individuals who:

(1) Do not qualify for Medicaid as categorically needy under § 435.121 or § 435.230; and

(2) If applying as blind or disabled, meet the definition of blindness or disability established under § 435.121.

(b) Except as specified in paragraph (c) of this section, the agency must apply to individuals covered under the option of this section the same financial and nonfinancial requirements that are applied to individuals covered

as categorically needy under §§ 435.121 and 435.230.

(c) In determining the financial eligibility of individuals who are considered as medically needy under this section, the agency must apply the financial eligibility requirements of subparts G and I of this part.

[58 FR 4929, Jan. 19, 1993]

§ 435.340 Protected medically needy coverage for blind and disabled individuals eligible in December 1973.

If an agency provides Medicaid to the medically needy, it must cover individuals who—

(a) Where eligible as medically needy under the Medicaid plan in December 1973 on the basis of the blindness or disability criteria of the AB, APTD, or AABD plan;

(b) For each consecutive month after December 1973, continue to meet—

(1) Those blindness or disability criteria; and

(2) The eligibility requirements for the medically needy under the December 1973 Medicaid plan; and

(c) Meet the current requirements for eligibility as medically needy under the Medicaid plan except for blindness or disability criteria.

[46 FR 47987, Sept. 30, 1981]

§ 435.350 Coverage for certain aliens.

If an agency provides Medicaid to the medically needy, it must provide the services necessary for the treatment of an emergency medical condition, as defined in § 440.255(c) of this chapter, to those aliens described in § 435.406(c) of this subpart.

[55 FR 36819, Sept. 7, 1990]

Subpart E—General Eligibility Requirements

§ 435.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part.

§ 435.401 General rules.

(a) A Medicaid agency may not impose any eligibility requirement that is prohibited under Title XIX of the Act.

(b) The agency must base any optional group covered under subparts B and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and that are consistent with the objectives of Title XIX.

(c) The agency must not use requirements for determining eligibility for optional coverage groups that are—

(1) For families and children, more restrictive than those used under the State's AFDC plan; and

(2) For aged, blind, and disabled individuals, more restrictive than those used under SSI, except for individuals receiving an optional State supplement as specified in § 435.230 or individuals in categories specified by the agency under § 435.121.

§ 435.402 [Reserved]

§ 435.403 State residence.

(a) *Requirement.* The agency must provide Medicaid to eligible residents of the State, including residents who are absent from the State. The conditions under which payment for services is provided to out-of-State residents are set forth in § 431.52 of this chapter.

(b) *Definition.* For purposes of this section—*Institution* has the same meaning as *Institution* and *Medical institution*, as defined in § 435.1010. For purposes of State placement, the term also includes *foster care homes*, licensed as set forth in 45 CFR 1355.20, and providing food, shelter and supportive services to one or more persons unrelated to the proprietor.

(c) *Incapability of indicating intent.* For purposes of this section, an individual is considered incapable of indicating intent if the individual—

(1) Has an I.Q. of 49 or less or has a mental age of 7 or less, based on tests acceptable to the mental retardation agency in the State:

(2) Is judged legally incompetent; or

(3) Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist, or other person licensed by the

State in the field of mental retardation.

(d) *Who is a State resident.* A resident of a State is any individual who:

(1) Meets the conditions in paragraphs (e) through (i) of this section; or

(2) Meets the criteria specified in an interstate agreement under paragraph (k) of this section.

(e) *Placement by a State in an out-of-State institution*—(1) *General rule.* Any agency of the State, including an entity recognized under State law as being under contract with the State for such purposes, that arranges for an individual to be placed in an institution located in another State, is recognized as acting on behalf of the State in making a placement. The State arranging or actually making the placement is considered as the individual's State of residence.

(2) Any action beyond providing information to the individual and the individual's family would constitute arranging or making a State placement. However, the following actions do not constitute State placement:

(i) Providing basic information to individuals about another State's Medicaid program, and information about the availability of health care services and facilities in another State.

(ii) Assisting an individual in locating an institution in another State, provided the individual is capable of indicating intent and independently decides to move.

(3) When a competent individual leaves the facility in which the individual is placed by a State, that individual's State of residence for Medicaid purposes is the State where the individual is physically located.

(4) Where a placement is initiated by a State because the State lacks a sufficient number of appropriate facilities to provide services to its residents, the State making the placement is the individual's State of residence for Medicaid purposes.

(f) *Individuals receiving a State supplementary payment (SSP).* For individuals of any age who are receiving an SSP, the State of residence is the State paying the SSP.

(g) *Individuals receiving Title IV-E payments.* For individuals of any age who are receiving Federal payments for foster care and adoption assistance under title IV-E of the Social Security Act, the State of residence is the State where the child lives.

(h) *Individuals under Age 21.* (1) For any individual who is emancipated from his or her parents or who is married and capable of indicating intent, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(2) For any individual not residing in an institution as defined in paragraph (b) whose Medicaid eligibility is based on blindness or disability, the State of residence is the State in which the individual is living.

(3) For any other non-institutionalized individual not subject to paragraph (h)(1) or (h)(2) of this section, the State of residence is determined in accordance with 45 CFR 233.40, the rules governing residence under the AFDC program.

(4) For any institutionalized individual who is neither married nor emancipated, the State of residence is—

(i) The parent's or legal guardian's State of residence at the time of placement (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's); or

(ii) The current State of residence of the parent or legal guardian who files the application if the individual is institutionalized in that State (if a legal guardian has been appointed and parental rights are terminated, the State or residence of the guardian is used instead of the parent's).

(iii) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(i) *Individuals Age 21 and over.* (1) For any individual not residing in an institution as defined in paragraph (b), the State of residence is the State where the individual is—

(i) Living with the intention to remain there permanently or for an indefinite period (or if incapable of stating intent, where the individual is living); or

(ii) Living and which the individual entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized individual who became incapable of indicating intent before age 21, the State of residence is—

(i) That of the parent applying for Medicaid on the individual's behalf, if the parents reside in separate States (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's);

(ii) The parent's or legal guardian's State of residence at the time of placement (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's); or

(iii) The current State of residence of the parent or legal guardian who files the application if the individual is institutionalized in that State (if a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the parent's).

(iv) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(3) For any institutionalized individual who became incapable of indicating intent at or after age 21, the State of residence is the State in which the individual is physically present, except where another State makes a placement.

(4) For any other institutionalized individual, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(j) *Specific prohibitions.* (1) The agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) The agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) The agency may not deny or terminate a resident's Medicaid eligibility because of that person's temporary absence from the State if the person intends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(k) *Interstate agreements.* A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (c) through (i) of this section, but must not include criteria that result in loss of residency in both States or that are prohibited by paragraph (j) of this section. The agreements must contain a procedure for providing Medicaid to individuals pending resolution of the case. States may use interstate agreeements for purposes other than cases of disputed residency to facilitate administration of the program, and to facilitate the placement and adoption of title IV-E individuals when the child and his or her adoptive parent(s) move into another State.

(l) *Continued Medicaid for institutionalized recipients.* If an agency is providing Medicaid to an institutionalized recipient who, as a result of this section, would be considered a resident of a different State—

(1) The agency must continue to provide Medicaid to that recipient from June 24, 1983 until July 5, 1984, unless it makes arrangements with another State of residence to provide Medicaid at an earlier date: and

(2) Those arrangements must not include provisions prohibited by paragraph (h) of this section.

(m) *Cases of disputed residency*. Where two or more States cannot resolve which State is the State of residence, the State where the individual is physically located is the State of residence.

[49 FR 13531, Apr. 5, 1984, as amended at 55 FR 48609, Nov. 21, 1990; 71 FR 39222, July 12, 2006]

§ 435.404 Applicant's choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

§ 435.406 Citizenship and alienage.

(a) The agency must provide Medicaid to otherwise eligible residents of the United States who are—

(1) Citizens: (i) Under a declaration required by section 1137(d) of the Act that the individual is a citizen or national of the United States; and

(ii) The individual has provided satisfactory documentary evidence of citizenship or national status, as described in § 435.407.

(iii) An individual for purposes of the citizenship requirement is a Medicaid applicant or recipient or an individual receiving any services under a section 1115 demonstration for which States receive Federal financial participation in their expenditures as though they were medical assistance, for example, family planning demonstrations or Medicaid demonstrations.

(iv) Individuals must declare their citizenship and the State must document the individual's citizenship in the individual's eligibility file on initial applications and initial redeterminations effective July 1, 2006.

(2) Qualified aliens as described in section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1641) who have provided satisfactory documentary evidence of Qualified Alien status, which status has been verified with the Department of Homeland Security (DHS) under a declaration required by section 1137(d) of the Act that the applicant or recipient is an alien in a satisfactory immigration status.

(b) The agency must provide payment for the services described in § 440.255(c) of this chapter to residents of the State who otherwise meet the eligibility requirements of the State plan (except for receipt of AFDC, SSI, or State Supplementary payments and the presentation of a social security number) but who do not meet the requirements of paragraphs (a) and (b) of this section.

[55 FR 36819, Sept. 7, 1990, as amended at 56 FR 10807, Mar. 14, 1991; 71 FR 39222, July 12, 2006]

§ 435.407 Types of acceptable documentary evidence of citizenship.

(a) *Primary evidence of citizenship and identity.* The following evidence must be accepted as satisfactory documentary evidence of both identity and citizenship:

(1) *A U.S. passport.* The Department of State issues this. A U.S. passport does not have to be currently valid to be accepted as evidence of U.S. citizenship, as long as it was originally issued without limitation. NOTE: Spouses and children were sometimes included on one passport through 1980. U.S. passports issued after 1980 show only one person. Consequently, the citizenship and identity of the included person can be established when one of these passports is presented. Exception: Do not accept any passport as evidence of U.S. citizenship when it was issued with a limitation. However, such a passport may be used as proof of identity.

(2) *A Certificate of Naturalization (DHS Forms N–550 or N–570.)* Department of Homeland Security issues for naturalization.

(3) *A Certificate of U.S. Citizenship (DHS Forms N–560 or N–561.)* Department of Homeland Security issues certificates of citizenship to individuals who derive citizenship through a parent.

(4) A valid State-issued driver's license, but only if the State issuing the license requires proof of U.S. citizenship before issuance of such license or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen. (This provision is not effective until such time as a State makes providing evidence of citizenship a condition of issuing a driver's license and evidence that the license holder is a citizen is included on the license or in a system of records available to the Medicaid agency. The State must ensure that the process complies with this statutory provision in section 6036 of the Deficit Reduction Act of 2005.

CMS will monitor compliance of States implementing this provision.); or

(5) At the State's option, for States which do not provide Medicaid to individuals by virtue of their receiving SSI, a State match with the State Data Exchange for Supplementary Security Income recipients. The statute gives the Secretary authority to establish other acceptable forms of citizenship documentation. SSA documents citizenship and identity for SSI applicants and recipients and includes such information in the database provided to the States.

(b) *Secondary evidence of citizenship.* If primary evidence from the list in paragraph (a) of this section is unavailable, an applicant or recipient should provide satisfactory documentary evidence of citizenship from the list specified in this section to establish citizenship and satisfactory documentary evidence from paragraph (e) of this section to establish identity, in accordance with the rules specified in this section.

(1) *A U.S. public birth certificate showing birth in one of the 50 States, the District of Columbia, Puerto Rico (if born on or after January 13, 1941), Guam (on or after April 10, 1899), the Virgin Islands of the U.S. (on or after January 17, 1917), American Samoa, Swain's Island, or the Northern Mariana Islands (after November 4, 1986 (NMI local time)).* A State, at its option, may use a cross match with a State vital statistics agency to document a birth record. The birth record document may be issued by the State, Commonwealth, Territory or local jurisdiction. It must have been issued before the person was 5 years of age. An amended birth record document that is amended after 5 years of age is considered fourth level evidence of citizenship. NOTE: If the document shows the individual was born in Puerto Rico, Guam, the Virgin Islands of the U.S., or the Northern Mariana Islands before these areas became part of the U.S., the individual may be a collectively naturalized citizen. Collective naturalization occurred on the dates listed for each of the Territories. The following will establish U.S. citizenship for collectively naturalized individuals:

(i) *Puerto Rico*:

(A) Evidence of birth in Puerto Rico on or after April 11, 1899 and the applicant's statement that he or she was residing in the U.S., a U.S. possession or Puerto Rico on January 13, 1941; or

(B) Evidence that the applicant was a Puerto Rican citizen and the applicant's statement that he or she was residing in Puerto Rico on March 1, 1917 and that he or she did not take an oath of allegiance to Spain.

(ii) *U.S. Virgin Islands*:

(A) Evidence of birth in the U.S. Virgin Islands, and the applicant's statement of residence in the U.S., a U.S. possession or the U.S. Virgin Islands on February 25, 1927; or

(B) The applicant's statement indicating resident in the U.S. Virgin Islands as a Danish citizen on January 17, 1917 and residence in the U.S., a U.S. possession or the U.S. Virgin Islands on February 25, 1927, and that he or she did not make a declaration to maintain Danish citizenship; or

(C) Evidence of birth in the U.S. Virgin Islands and the applicant's statement indicating residence in the U.S., a U.S. possession or Territory or the Canal Zone on June 28, 1932.

(iii) *Northern Mariana Islands (NMI) (formerly part of the Trust Territory of the Pacific Islands (TTPI)):*

(A) Evidence of birth in the NMI, TTPI citizenship and residence in the NMI, the U.S., or a U.S. Territory or possession on November 3, 1986 (NMI local time) and the applicant's statement that he or she did not owe allegiance to a foreign state on November 4, 1986 (NMI local time); or

(B) Evidence of TTPI citizenship, continuous residence in the NMI since before November 3, 1981 (NMI local time), voter registration prior to January 1, 1975 and the applicant's statement that he or she did not owe allegiance to a foreign state on November 4, 1986 (NMI local time); or

(C) Evidence of continuous domicile in the NMI since before January 1, 1974 and the applicant's statement that he or she did not owe allegiance to a foreign state on November 4, 1986 (NMI local time).

(D) NOTE: If a person entered the NMI as a nonimmigrant and lived in the NMI since January 1, 1974, this does not

constitute continuous domicile and the individual is not a U.S. citizen.

(2) *A Certification of Report of Birth (DS–1350).* The Department of State issues a DS–1350 to U.S. citizens in the U.S. who were born outside the U.S. and acquired U.S. citizenship at birth, based on the information shown on the FS–240. When the birth was recorded as a Consular Report of Birth (FS–240), certified copies of the Certification of Report of Birth Abroad (DS–1350) can be issued by the Department of State in Washington, DC. The DS–1350 contains the same information as that on the current version of Consular Report of Birth FS–240. The DS–1350 is not issued outside the U.S.

(3) *A Report of Birth Abroad of a U.S. Citizen (Form FS–240).* The Department of State consular office prepares and issues this. A Consular Report of Birth can be prepared only at an American consular office overseas while the child is under the age of 18. Children born outside the U.S. to U.S. military personnel usually have one of these.

(4) *A Certification of birth issued by the Department of State (Form FS–545 or DS–1350).* Before November 1, 1990, Department of State consulates also issued Form FS–545 along with the prior version of the FS–240. In 1990, U.S. consulates ceased to issue Form FS–545. Treat an FS–545 the same as the DS–1350.

(5) *A U.S. Citizen I.D. card.* (This form was issued as Form I–197 until the 1980's by INS. Although no longer issued, holders of this document may still use it consistent with the provisions of section 1903(x) of the Act. Note that section 1903(x) of the Act incorrectly refers to the same document as an I–97.) INS issued the I–179 from 1960 until 1973. It revised the form and renumbered it as Form I–197. INS issued the I–197 from 1973 until April 7, 1983. INS issued Form I–179 and I–197 to naturalized U.S. citizens living near the Canadian or Mexican border who needed it for frequent border crossings. Although neither form is currently issued, either form that was previously issued is still valid.

(6) *A Northern Mariana Identification Card (I–873).* (Issued by the DHS to a collectively naturalized citizen of the United States who was born in the Northern Mariana Islands before November 4, 1986.) The former Immigration and Naturalization Service (INS) issued the I–873 to a collectively naturalized citizen of the U.S. who was born in the NMI before November 4, 1986. The card is no longer issued, but those previously issued are still valid.

(7) *An American Indian Card (I–872) issued by the Department of Homeland Security with the classification code ''KIC.''* (Issued by DHS to identify U.S. citizen members of the Texas Band of Kickapoos living near the United States/Mexican border.) DHS issues this card to identify a member of the Texas Band of Kickapoos living near the U.S./Mexican border. A classification code ''KIC'' and a statement on the back denote U.S. citizenship.

(8) *A final adoption decree showing the child's name and U.S. place of birth.* The adoption decree must show the child's name and U.S. place of birth. In situations where an adoption is not finalized and the State in which the child was born will not release a birth certificate prior to final adoption, a statement from a State approved adoption agency that shows the child's name and U.S. place of birth is acceptable. The adoption agency must state in the certification that the source of the place of birth information is an original birth certificate.

(9) *Evidence of U.S. Civil Service employment before June 1, 1976.* The document must show employment by the U.S. government before June 1, 1976. Individuals employed by the U.S. Civil Service prior to June 1, 1976 had to be U.S. citizens.

(10) *U.S. Military Record showing a U.S. place of birth.* The document must show a U.S. place of birth (for example a DD–214 or similar official document showing a U.S. place of birth.)

(c) *Third level evidence of citizenship.* Third level evidence of U.S. citizenship is documentary evidence of satisfactory reliability that is used when neither primary nor secondary evidence is available. Third level evidence may be used only when primary evidence cannot be obtained within the State's reasonable opportunity period, secondary evidence does not exist or cannot be obtained, and the applicant or recipient alleges being born in the U.S. A

second document from paragraph (e) of this section to establish identity must also be presented:

(1) *Extract of a hospital record on hospital letterhead established at the time of the person's birth that was created 5 years before the initial application date and that indicates a U.S. place of birth.* (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Do not accept a souvenir ''birth certificate'' issued by the hospital. Note: For children under 16 the document must have been created near the time of birth or 5 years before the date of application.

(2) *Life, health, or other insurance record showing a U.S. place of birth that was created at least 5 years before the initial application date and that indicates a U.S. place of birth.* Life or health insurance records may show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth.

(d) *Fourth level evidence of citizenship.* Fourth level evidence of citizenship is documentary evidence of the lowest reliability. Fourth level evidence should only be used in the rarest of circumstances. This level of evidence is used only when primary evidence is unavailable, both secondary and third level evidence do not exist or cannot be obtained within the State's reasonable opportunity period, and the applicant alleges a U.S. place of birth. In addition, a second document establishing identity must be presented as described in paragraph (e) of this section.

(1) *Federal or State census record showing U.S. citizenship or a U.S. place of birth.* (Generally for persons born 1900 through 1950.) The census record must also show the applicant's age. NOTE: Census records from 1900 through 1950 contain certain citizenship information. To secure this information the applicant, recipient or State should complete a Form BC–600, Application for Search of Census Records for Proof of Age. Add in the remarks portion ''U.S. citizenship data requested.'' Also add that the purpose is for Medicaid eligibility. This form requires a fee.

(2) *One of the following documents that show a U.S. place of birth and was created at least 5 years before the application for Medicaid.* This document must be one of the following and show a U.S. place of birth:

(i) Seneca Indian tribal census record.

(ii) Bureau of Indian Affairs tribal census records of the Navajo Indians.

(iii) U.S. State Vital Statistics official notification of birth registration.

(iv) An amended U.S. public birth record that is amended more than 5 years after the person's birth.

(v) Statement signed by the physician or midwife who was in attendance at the time of birth.

(3) *Institutional admission papers from a nursing facility, skilled care facility or other institution.* Admission papers generally show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth.

(4) *Medical (clinic, doctor, or hospital) record created at least 5 years before the initial application date that indicates a U.S. place of birth.* (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Medical records generally show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth. NOTE: An immunization record is not considered a medical record for purposes of establishing U.S. citizenship. NOTE: For children under 16 the document must have been created near the time of birth or 5 years before the date of application.

(5) *Written affidavit.* Affidavits should ONLY be used in rare circumstances. If the documentation requirement needs to be met through affidavits, the following rules apply:

(i) There must be at least two affidavits by two individuals who have personal knowledge of the event(s) establishing the applicant's or recipient's claim of citizenship (the two affidavits could be combined in a joint affidavit).

(ii) At least one of the individuals making the affidavit cannot be related to the applicant or recipient. Neither of the two individuals can be the applicant or recipient.

(iii) In order for the affidavit to be acceptable the persons making them must be able to provide proof of their own citizenship and identity.

(iv) If the individual(s) making the affidavit has (have) information which explains why documentary evidence establishing the applicant's claim or citizenship does not exist or cannot be readily obtained, the affidavit should contain this information as well.

(v) The State must obtain a separate affidavit from the applicant/recipient or other knowledgeable individual (guardian or representative) explaining why the evidence does not exist or cannot be obtained.

(vi) The affidavits must be signed under penalty of perjury.

(e) *Evidence of identity.* The following documents may be accepted as proof of identity and must accompany a document establishing citizenship from the groups of documentary evidence of citizenship in the groups in paragraphs (b) through (d) of this section.

(1) A driver's license issued by a State or Territory either with a photograph of the individual or other identifying information such as name, age, sex, race, height, weight, or eye color.

(2) School identification card with a photograph of the individual.

(3) U.S. military card or draft record.

(4) Identification card issued by the Federal, State, or local government with the same information included on driver's licenses.

(5) Military dependent's identification card.

(6) Native American Tribal document.

(7) U.S. Coast Guard Merchant Mariner card.

(8) Identity documents described in 8 CFR 274a.2(b)(1)(v)(B)(1).

(i) Driver's license issued by State or Territory either with a photograph of the individual or other identifying information of the individual such as name, age, sex, race, height, weight or eye color.

(ii) School identification card with a photograph of the individual.

(iii) U.S. military card or draft record.

(iv) Identification card issued by the Federal, State, or local government with the same information included on driver's licenses.

(v) Military dependent's identification card.

(vi) Native American Tribal document.

(vii) U.S. Coast Guard Merchant Mariner card.

NOTE TO PARAGRAPH (E)(8): Exception: Do not accept a voter's registration card or Canadian driver's license as listed in 8 CFR 274a.2(b)(1)(v)(B)(1). CMS does not view these as reliable for identity.

(9) Certificate of Degree of Indian Blood, or other U.S. American Indian/Alaska Native Tribal document with a photograph or other personal identifying information relating to the individual. Acceptable if the document carries a photograph of the applicant or recipient, or has other personal identifying information relating to the individual.

(10) At State option, a State may use a cross match with a Federal or State governmental, public assistance, law enforcement or corrections agency's data system to establish identity if the agency establishes and certifies true identity of individuals. Such agencies may include food stamps, child support, corrections, including juvenile detention, motor vehicle, or child protective services. The State Medicaid Agency is still responsible for assuring the accuracy of the identity determination.

(f) *Special identity rules for children.* For children under 16, school records may include nursery or daycare records. If none of the above documents in the preceding groups are available, an affidavit may be used. An affidavit is only acceptable if it is signed under penalty of perjury by a parent or guardian stating the date and place of the birth of the child and cannot be used if an affidavit for citizenship was provided.

(g) *Special populations needing assistance.* States must assist individuals to secure satisfactory documentary evidence of citizenship when because of incapacity of mind or body the individual would be unable to comply with the requirement to present satisfactory documentary evidence of citizenship in a timely manner and the individual

lacks a representative to assist him or her.

(h) *Documentary evidence.*

(1) All documents must be either originals or copies certified by the issuing agency. Copies or notarized copies may not be accepted.

(2) States must maintain copies of citizenship and identification documents in the case record or electronic data base and make these copies available for compliance audits.

(3) States may permit applicants and recipients to submit such documentary evidence without appearing in person at a Medicaid office. States may accept original documents in person, by mail, or by a guardian or authorized representative.

(4) If documents are determined to be inconsistent with pre-existing information, are counterfeit, or altered, States should investigate for potential fraud and abuse, including but not limited to, referral to the appropriate State and Federal law enforcement agencies.

(5) Presentation of documentary evidence of citizenship is a one time activity; once a person's citizenship is documented and recorded in a State database subsequent changes in eligibility should not require repeating the documentation of citizenship unless later evidence raises a question of the person's citizenship. The State need only check its databases to verify that the individual already established citizenship.

(6) CMS requires that as a check against fraud, using currently available automated capabilities, States will conduct a match of the applicant's name against the corresponding Social Security number that was provided. In addition, in cooperation with other agencies of the Federal government, CMS encourages States to use automated capabilities to verify citizenship and identity of Medicaid applicants. Automated capabilities may fall within the computer matching provisions of the Privacy Act of 1974, and CMS will explore any implementation issues that may arise with respect to those requirements. When these capabilities become available, States will be required to match files for individuals who used third or fourth tier documents to verify citizenship and documents to verify identity, and CMS will make available to States necessary information in this regard. States must ensure that all case records within this category will be so identified and made available to conduct these automated matches. CMS may also require States to match files for individuals who used first or second level documents to verify citizenship as well. CMS may provide further guidance to States with respect to actions required in a case of a negative match.

(i) *Record retention.* The State must retain documents in accordance with 45 CFR 74.53.

(j) *Reasonable opportunity to present satisfactory documentary evidence of citizenship.* States must give an applicant or recipient a reasonable opportunity to submit satisfactory documentary evidence of citizenship before taking action affecting the individual's eligibility for Medicaid. The time States give for submitting documentation of citizenship should be consistent with the time allowed to submit documentation to establish other facets of eligibility for which documentation is requested. (*See* § 435.930 and § 435.911.)

[71 FR 39222, July 12, 2006]

Subpart F—Categorical Requirements for Eligibility

§ 435.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part.

DEPENDENCY

§ 435.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures set forth under the State's AFDC plan to determine whether—

(a) An individual is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.

[43 FR 45204, Sept. 29, 1978, as amended at 58 FR 4929, Jan. 19, 1993]

AGE

§ 435.520 Age requirements for the aged.

The agency must not impose an age requirement of more than 65 years.

[58 FR 4929, Jan. 19, 1993]

§ 435.522 Determination of age.

(a) Except as specified in paragraphs (b) and (c) of this section, in determining age, the agency must use the common-law method (under which an age reached the day before the anniversary of birth).

(b) For families and children, the agency must use the popular usage method (under which an age is reached on the anniversary of birth), if this method is used under the State's AFDC plan.

(c) For aged, blind, or disabled individuals, the agency must use the popular usage method, if the plan provides under § 435.121, § 435.230, or § 435.330, for coverage of aged, blind, or disabled individuals who meet more restrictive eligibility requirements than those under SSI.

(d) The agency may use an arbitrary date, such as July 1, for determining an individual's age if the year, but not the month, of his birth is known.

[58 FR 4929, Jan. 19, 1993]

BLINDNESS

§ 435.530 Definition of blindness.

(a) *Definition.* The agency must use the same definition of blindness as used under SSI, except that—

(1) In determining the eligibility of individuals whose Medicaid eligibility is protected under §§ 435.130 through 435.134, the agency must use the definition of blindness that was used under the Medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under § 435.121, if the definition is no more restrictive than that used under the Medicaid plan on January 1, 1972.

(b) *State plan requirement.* The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 435.531 Determinations of blindness.

(a) Except as specified in paragraph (b) of this section, in determining blindness—

(1) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant's eyes are missing;

(2) The examiner must submit a report of examination to the Medicaid agency; and

(3) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—

(i) Whether the individual meets the definition of blindness; and

(ii) Whether and when re-examinations are necessary for periodic redeterminations of eligibility, as required under § 435.916 of this part.

(b) If an agency provides Medicaid to individuals receiving SSI on the basis of blindness, this section does not apply for those individuals.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17937, Mar. 23, 1979]

DISABILITY

§ 435.540 Definition of disability.

(a) *Definition.* The agency must use the same definition of disability as used under SSI, except that—

(1) In determining the eligibility of individuals whose Medicaid eligibility is protected under §§ 435.130 through 435.134, the agency must use the definition of disability that was used under the Medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under § 435.121, if the definition is no more restrictive than that used under the Medicaid plan on January 1, 1972.

(b) *State plan requirements.* The State plan must contain the definition of disability.

§ 435.541 Determinations of disability.

(a) *Determinations made by SSA.* The following rules and those under paragraph (b) of this section apply where an individual has applied for Medicaid on the basis of disability.

(1) If the agency has an agreement with the Social Security Administration (SSA) under section 1634 of the Act, the agency may not make a determination of disability when the only application is filed with SSA.

(2) The agency may not make an independent determination of disability if SSA has made a disability determination within the time limits set forth in § 435.911 on the same issues presented in the Medicaid application. A determination of eligibility for SSI payments based on disability that is made by SSA automatically confers Medicaid eligibility, as provided for under § 435.909.

(b) *Effect of SSA determinations.* (1) Except in the circumstances specified in paragraph (c)(3) of this section—

(i) An SSA disability determination is binding on an agency until the determination is changed by SSA.

(ii) If the SSA determination is changed, the new determination is also binding on the agency.

(2) The agency must refer to SSA all applicants who allege new information or evidence affecting previous SSA determinations of ineligibility based upon disability for reconsideration or reopening of the determination, except in cases specified in paragraph (c)(4) of this section.

(c) *Determinations made by the Medicaid agency.* The agency must make a determination of disability in accordance with the requirements of this section if any of the following circumstances exist:

(1) The individual applies for Medicaid as a non-cash recipient and has not applied to SSA for SSI cash benefits, whether or not a State has a section 1634 agreement with SSA; or an individual applies for Medicaid and has applied to SSA for SSI benefits and is found ineligible for SSI for a reason other than disability.

(2) The individual applies both to SSA for SSI and to the State Medicaid agency for Medicaid, the State agency has a section 1634 agreement with SSA, and SSA has not made an SSI disability determination within 90 days from the date of the individual's application for Medicaid.

(3) The individual applies to SSA for SSI and to the State Medicaid agency for Medicaid, the State does not have a section 1634 agreement with SSA, and either the State uses more restrictive criteria than SSI for determining Medicaid eligibility under its section 1902(f) option or, in the case of a State that uses SSI criteria, SSA has not made an SSI disability determination in time for the State to comply with the Medicaid time limit for making a prompt determination on an individual's application for Medicaid.

(4) The individual applies for Medicaid as a non-cash recipient, whether or not the State has a section 1634 agreement with SSA, and—

(i) Alleges a disabling condition different from, or in addition to, that considered by SSA in making its determination; or

(ii) Alleges more than 12 months after the most recent SSA determination denying disability that his or her condition has changed or deteriorated since that SSA determination and alleges a new period of disability which meets the durational requirements of the Act, and has not applied to SSA for a determination with respect to these allegations.

(iii) Alleges less than 12 months after the most recent SSA determination denying disability that his or her condition has changed or deteriorated since that SSA determination, alleges a new period of disability which meets the durational requirements of the Act, and—

(A) Has applied to SSA for reconsideration or reopening of its disability decision and SSA refused to consider the new allegations; and/or

(B) He or she no longer meets the nondisability requirements for SSI but may meet the State's nondisability requirements for Medicaid eligibility.

(d) *Basis for determinations.* The agency must make a determination of disability as provided in paragraph (c) of this section—

(1) On the basis of the evidence required under paragraph (e) of this section; and

(2) In accordance with the requirements for evaluating that evidence under the SSI program specified in 20 CFR 416.901 through 416.998.

(e) *Medical and nonmedical evidence.* The agency must obtain a medical report and other nonmedical evidence for individuals applying for Medicaid on the basis of disability. The medical report and nonmedical evidence must include diagnosis and other information in accordance with the requirements for evidence applicable to disability determinations under the SSI program specified in 20 CFR part 416, subpart I.

(f) *Disability review teams*—(1) *Function.* A review team must review the medical report and other evidence required under paragraph (e) of this section and determine on behalf of the agency whether the individual's condition meets the definition of disability.

(2) *Composition.* The review team must be composed of a medical or psychological consultant and another individual who is qualified to interpret and evaluate medical reports and other evidence relating to the individual's physical or mental impairments and, as necessary, to determine the capacities of the individual to perform substantial gainful activity, as specified in 20 CFR part 416, subpart J.

(3) *Periodic reexaminations.* The review team must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under § 435.916 of this part, using the principles set forth in 20 CFR 416.989 and 416.990. If a State uses the same definition of disability as SSA, as provided for under § 435.540, and a recipient is Medicaid eligible because he or she receives SSI, this paragraph (f)(3) does not apply. The reexamination will be conducted by SSA.

[54 FR 50761, Dec. 11, 1989]

Subpart G—General Financial Eligibility Requirements and Options

§ 435.600 Scope.

This subpart prescribes:

(a) General financial requirements and options for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part. Subparts H and I of this part prescribe additional financial requirements.

(b) [Reserved]

[58 FR 4929, Jan. 19, 1993, as amended at 59 FR 43052, Aug. 22, 1994]

§ 435.601 Application of financial eligibility methodologies.

(a) *Definitions.* For purposes of this section, *cash assistance financial methodologies* refers to the income and resources methodologies of the AFDC, SSI, or State supplement programs, or, for aged, blind, and disabled individuals in States that use more restrictive criteria than SSI, the methodologies established in accordance with the requirements of §§ 435.121 and 435.230.

(b) *Basic rule for use of cash assistance methodologies.* Except as specified in paragraphs (c) and (d) of this section or in § 435.121 in determining financial eligibility of individuals as categorically and medically needy, the agency must apply the financial methodologies and requirements of the cash assistance program that is most closely categorically related to the individual's status.

(c) *Financial responsibility of relatives.* The agency must use the requirements for financial responsibility of relatives specified in § 435.602.

(d) *Use of less restrictive methodologies than those under cash assistance programs.* (1) At State option, and subject to the conditions of paragraphs (d)(2) through (d)(5) of this section, the agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies in determining eligibility of the following groups:

(i) Qualified pregnant women and children under the mandatory categorically needy group under § 435.116;

(ii) Low-income pregnant women, infants, and children specified in section 1902(a)(10)(i)(IV), 1902(a)(10)(A)(i)(VI), and 1902(a)(10)(A)(i)(VII) of the Act;

(iii) Qualified Medicare beneficiaries specified in sections 1902(a)(10)(E) and 1905(p) of the Act;

(iv) Optional categorically needy individuals under groups established under subpart C of this part and section 1902(a)(10)(A)(ii) of the Act;

(v) Medically needy individuals under groups established under subpart D of

this part and section 1902(a)(10)(C)(i)(III) of the Act; and

(vi) Aged, blind, and disabled individuals in States using more restrictive eligibility requirements than SSI under groups established under §§ 435.121 and 435.230.

(2) The income and resource methodologies that an agency elects to apply to groups of individuals described in paragraph (d)(1) of this section may be less restrictive, but no more restrictive (except in States using more restrictive requirements than SSI), than:

(i) For groups of aged, blind, and disabled individuals, the SSI methodologies; or

(ii) For all other groups, the methodologies under the State plan most closely categorically related to the individual's status.

(3) A financial methodology is considered to be no more restrictive if, by using the methodology, additional individuals may be eligible for Medicaid and no individuals who are otherwise eligible are by use of that methodology made ineligible for Medicaid.

(4) The less restrictive methodology applied under this section must be comparable for all persons within each category of assistance (aged, or blind, or disabled, or AFDC related) within an eligibility group. For example, if the agency chooses to apply less restrictive income or resource methodology to an eligibility group of aged individuals, it must apply that methodology to all aged individuals within the selected group.

(5) The application of the less restrictive income and resource methodologies permitted under this section must be consistent with the limitations and conditions on FFP specified in subpart K of this part.

(e) [Reserved]

(f) *State plan requirements.* (1) The State plan must specify that, except to the extent precluded in § 435.602, in determining financial eligibility of individuals, the agency will apply the cash assistance financial methodologies and requirements, unless the agency chooses to apply less restrictive income and resource methodologies in accordance with paragraph (d) of this section.

(2) If the agency chooses to apply less restrictive income and resource methodologies, the State plan must specify:

(i) The less restrictive methodologies that will be used; and

(ii) The eligibility group or groups to which the less restrictive methodologies will be applied.

[58 FR 4929, Jan. 19, 1993, as amended at 59 FR 43052, Aug. 22, 1994]

§ 435.602 Financial responsibility of relatives and other individuals.

(a) *Basic requirements.* Subject to the provisions of paragraphs (b) and (c) of this section, in determining financial responsibility of relatives and other persons for individuals under Medicaid, the agency must apply the following requirements and methodologies:

(1) Except for a spouse of an individual or a parent for a child who is under age 21 or blind or disabled, the agency must not consider income and resources of any relative as available to an individual.

(2) In relation to individuals under age 21 (as described in section 1905(a)(i) of the Act), the financial responsibility requirements and methodologies that apply include considering the income and resources of parents or spouses whose income and resources would be considered if the individual under age 21 were dependent under the State's approved AFDC plan, whether or not they are actually contributed, except as specified under paragraphs (c) and (d) of this section. These requirements and methodologies must be applied in accordance with the provisions of the State's approved AFDC plan.

(3) When a couple ceases to live together, the agency must count only the income of the individual spouse in determining his or her eligibility, beginning the first month following the month the couple ceases to live together.

(4) In the case of eligible institutionalized spouses who are aged, blind, and disabled and who have shared the same room in a title XIX Medicaid institution, the agency has the option of considering these couples as eligible couples for purposes of counting income and resources or as eligible individuals, whichever is more advantageous to the couple.

(b) *Requirements for States using more restrictive requirements.* Subject to the provisions of paragraph (c) of this section, in determining financial eligibility of aged, blind, or disabled individuals in States that apply eligibility requirements more restrictive than those used under SSI, the agency must apply:

(1) The requirements and methodologies for financial responsibility of relatives used under the SSI program; or

(2) More extensive requirements for relative responsibility than specified in § 435.602(a) but no more extensive than the requirements under the Medicaid plan in effect on January 1, 1972.

(c) *Use of less restrictive methodologies.* The agency may apply income and resources methodologies that are less restrictive than those used under the cash assistance programs as specified in the State Medicaid plan in accordance with § 435.601(d).

(d) [Reserved]

[58 FR 4930, Jan. 19, 1993, as amended at 59 FR 43052, Aug. 22, 1994]

§ 435.604 [Reserved]

§ 435.606 [Reserved]

§ 435.608 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, retirement, and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

[43 FR 45204, Sept. 29, 1978. Redesignated at 58 FR 4931, Jan. 19, 1993]

§ 435.610 Assignment of rights to benefits.

(a) As a condition of eligibility, the agency must require legally able applicants and recipients to:

(1) Assign rights to the Medicaid agency to medical support and to payment for medical care from any third party;

(2) Cooperate with the agency in establishing paternity and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in section 1902 (1)(1)(A) of the Act (poverty level pregnant women), who are exempt from cooperating in establishing paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(3) Cooperate in identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan, unless the individual establishes good cause for not cooperating.

(b) The requirements for assignment of rights must be applied uniformly for all groups covered under the plan.

(c) The requirements of paragraph (a) of this section for the assignment of rights to medical support and other payments and cooperation in obtaining medical support and payments are effective for medical assistance furnished on or after October 1, 1984. The requirement for cooperation in identifying and providing information for pursuing liable third parties is effective for medical assistance furnished on or after July 1, 1988.

[55 FR 48609, Nov. 21, 1990, as amended at 58 FR 4907, Jan. 19, 1993. Redesignated at 58 FR 4931, Jan. 19, 1993]

§ 435.622 Individuals in institutions who are eligible under a special income level.

(a) If an agency, under § 435.231, provides Medicaid to individuals in medical institutions, nursing facilities, and intermediate care facilities for the mentally retarded who would not be eligible for SSI or State supplements if they were not institutionalized, the agency must use income standards based on the greater need for financial assistance that the individuals would have if they were not in the institution. The standards may vary by the level of institutional care needed by the individual (hospital, nursing facility, or intermediate level care for the mentally retarded), or by other factors related to individual needs. (See § 435.1005 for FFP limits on income

standards established under this section.)

(b) In determining the eligibility of individuals under the income standards established under this section, the agency must not take into account income that would be disregarded in determining eligibility for SSI or for an optional State supplement.

(c) The agency must apply the income standards established under this section effective with the first day of a period of not less than 30 consecutive days of institutionalization.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980; 53 FR 3595, Feb. 8, 1988. Redesignated and amended at 58 FR 4932, Jan. 19, 1993]

§ 435.631 General requirements for determining income eligibility in States using more restrictive requirements for Medicaid than SSI.

(a) *Income eligibility methods.* In determining income eligibility of aged, blind, and disabled individuals in a State using more restrictive eligibility requirements than SSI, the agency must use the methods for treating income elected under §§ 435.121 and 435.230, under § 435.601. The methods used must be comparable for all individuals within each category of individuals under § 435.121 and each category of individuals within each optional categorically needy group included under § 435.230 and for each category of individuals under the medically needy option described under § 435.800.

(b) *Categorically needy versus medically needy eligibility.* (1) Individuals who have income equal to, or below, the categorically needy income standards described in §§ 435.121 and 435.230 are categorically needy in States that include the medically needy under their plans.

(2) Categorically needy eligibility in States that do not include the medically needy is determined in accordance with the provisions of § 435.121 (e)(4) and (e)(5).

[58 FR 4932, Jan. 19, 1993]

§ 435.640 Protected Medicaid eligibility for individuals eligible in December 1973.

In determining whether individuals continue to meet the income requirements used in December 1973, for purposes of determining eligibility under §§ 435.131, 435.132, and 435.133, the agency must deduct increased OASDI payments to the same extent that these deductions were in effect in December 1973. These deductions are required by section 306 of the Social Security Amendments of 1972 (Pub. L. 92–603) and section 1007 of Pub. L. 91–172 (enacted Dec. 30, 1969), modified by section 304 of Pub. L. 92–603.

[43 FR 45204, Sept. 29, 1978. Redesignated at 58 FR 4932, Jan. 19, 1993]

Subpart H—Specific Post-Eligibility Financial Requirements for the Categorically Needy

§ 435.700 Scope.

This subpart prescribes specific financial requirements for determining the post-eligibility treatment of income of categorically needy individuals, including requirements for applying patient income to the cost of care.

[58 FR 4931, Jan. 19, 1993]

§ 435.725 Post-eligibility treatment of income of institutionalized individuals in SSI States: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income,

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) *Applicability.* This section applies to the following individuals in medical institutions and intermediate care facilities.

(1) Individuals receiving cash assistance under SSI or AFDC who are eligible for Medicaid under § 435.110 or § 435.120.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State supplement except for their institutional status and who are eligible for Medicaid under § 435.211.

(3) Aged, blind, and disabled individuals who are eligible for Medicaid, under § 435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(c) *Required deductions.* In reducing its payment to the institution, the agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) *Maintenance needs of spouse.* For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under § 435.811, if the agency provides Medicaid under the medically needy coverage option.

(3) *Maintenance needs of family.* For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under § 435.811, if the agency provides Medicaid under the medically needy coverage option for a family of the same size.

(4) *Expenses not subject to third party payment.* Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(5) *Continued SSI and SSP benefits.* The full amount of SSI and SSP benefits that the individual continues to receive under sections 1611(e)(1) (E) and (G) of the Act.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(3) For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(i) The amount is deducted for not more than a 6-month period; and

(ii) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received, or it may project monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and on medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24884, Apr. 11, 1980; 48 FR 5735, Feb. 8, 1983; 53 FR 3595, Feb. 8, 1988; 55 FR 33705, Aug. 17, 1990; 56 FR 8850, 8854, Mar. 1, 1991; 58 FR 4932, Jan. 19, 1993]

§ 435.726 Post-eligibility treatment of income of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

(a) The agency must reduce its payment for home and community-based services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraph (c) of this section from the individual's income.

(b) This section applies to individuals who are eligible for Medicaid under § 435.217 and are receiving home and community-based services furnished under a waiver of Medicaid requirements specified in part 441, subpart G or H of this subchapter.

(c) In reducing its payment for home and community-based services, the agency must deduct the following amounts, in the following order, from the individual's total income (including amounts disregarded in determining eligibility):

(1) An amount for the maintenance needs of the individual that the State may set at any level, as long as the following conditions are met:

(i) The deduction amount is based on a reasonable assessment of need.

(ii) The State establishes a maximum deduction amount that will not be exceeded for any individual under the waiver.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides Medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under §§ 435.811 and 435.814, if the agency provides Medicaid under the medically needy coverage option.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's AFDC plan or the medically needy income standard established under § 435.811 for a family of the same size.

(4) Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

[46 FR 48539, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985; 57 FR 29155, June 30, 1992; 58 FR 4932, Jan. 19, 1993; 59 FR 37715, July 25, 1994]

§ 435.733 Post-eligibility treatment of income of institutionalized individuals in States using more restrictive requirements than SSI: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) *Applicability.* This section applies to the following individuals in medical institutions and intermediate care facilities:

(1) Individuals receiving cash assistance under AFDC who are eligible for Medicaid under § 435.110 and individuals eligible under § 435.121.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State supplement except for their institutional status and who are eligible for Medicaid under § 435.211.

(3) Aged, blind, and disabled individuals who are eligible for Medicaid, under § 435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(c) *Required deductions.* The agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) *Maintenance needs of spouse.* For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The more restrictive income standard established under § 435.121; or

(ii) The amount of the medically needy income standard for one person

established under § 435.811, if the agency provides Medicaid under the medically needy coverage option.

(3) *Maintenance needs of family.* For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under § 435.811, if the agency provides Medicaid under the medically needy coverage option for a family of the same size.

(4) *Expenses not subject to third party payment.* Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance permiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(5) *Continued SSI and SSP benefits.* The full amount of SSI and SSP benefits that the individual continues to receive under sections 1611(e)(1) (E) and (G) of the Act.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received, or it may project total monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses that may be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24884, Apr. 11, 1980, as amended at 48 FR 5735, Feb. 8, 1983; 53 FR 3596, Feb. 8, 1988; 55 FR 33705, Aug. 17, 1990; 56 FR 8850, 8854, Mar. 1, 1991; 58 FR 4932, Jan. 19, 1993]

§ 435.735 Post-eligibility treatment of income and resources of individuals receiving home and community-based services furnished under a waiver: Application of patient income to the cost of care.

(a) The agency must reduce its payment for home and community-based services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraph (c) of this section from the individual's income.

(b) This section applies to individuals who are eligible for Medicaid under § 435.217, and are eligible for home and community-based services furnished under a waiver of State plan requirements specified in part 441, subpart G or H of this subchapter.

(c) In reducing its payment for home and community-based services, the

agency must deduct the following amounts, in the following order, from the individual's total income (including amounts disregarded in determining eligibility):

(1) An amount for the maintenance needs of the individual that the State may set at any level, as long as the following conditions are met:

(i) The deduction amount is based on a reasonable assessment of need.

(ii) The State establishes a maximum deduction amount that will not be exceeded for any individual under the waiver.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The more restrictive income standard established under § 435.121; or

(ii) The medically needy standard for an individual.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's approved AFDC plan or the medically needy income standard established under § 435.811 for a family of the same size.

(4) Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

[46 FR 48540, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985; 57 FR 29155, June 30, 1992; 58 FR 4932, Jan. 19, 1993; 59 FR 37716, July 25, 1994]

Subpart I—Specific Eligibility and Post-Eligibility Financial Requirements for the Medically Needy

§ 435.800 Scope.

This subpart prescribes specific financial requirements for determining the eligibility of medically needy individuals under subpart D of this part.

[58 FR 4932, Jan. 19, 1993]

MEDICALLY NEEDY INCOME STANDARD

§ 435.811 Medically needy income standard: General requirements.

(a) Except as provided in paragraph (d)(2) of this section, to determine eligibility of medically needy individuals, a Medicaid agency must use a single income standard under this subpart that meets the requirements of this section.

(b) The income standard must take into account the number of persons in the assistance unit. Subject to the limitations specified in paragraph (e) of this section. The standard may not diminish by an increase in the number of persons in the assistance unit. For example, if the income level in the standard for an assistance unit of two is set at $400, the income level in the standard for an assistance unit of three may not be less than $400.

(c) In States that do not use more restrictive requirements than SSI, the income standard must be set at an amount that is no lower than the lowest income standards used under the cash assistance programs that are related to the State's covered medically needy eligibility group or groups of individuals under § 435.301. The amount of the income standard is subject to the limitations specified in paragraph (e) of this section.

(d) In States that use more restrictive requirements for aged, blind, and disabled individuals than SSI:

(1) For all individuals except aged, blind, and disabled individuals, the income standard must be set in accordance with paragraph (c) of this section; and

(2) For all aged, blind, and disabled individuals or any combination of these groups of individuals, the agency

may establish a separate single medically needy income standard that is more restrictive than the single income standard set under paragraph (c) of this section. However, the amount of the more restrictive separate standard for aged, blind, or disabled individuals must be no lower than the higher of the lowest categorically needy income standard currently applied under the State's more restrictive criteria under § 435.121 or the medically needy income standard in effect under the State's Medicaid plan on January 1, 1972. The amount of the income standard is subject to the limitations specified in paragraph (e) of this section.

(e) The income standards specified in paragraphs (c) and (d) of this section must not exceed the maximum dollar amount of income allowed for purposes of FFP under § 435.1007.

(f) The income standard may vary based on the variations between shelter costs in urban areas and rural areas.

[58 FR 4932, Jan. 19, 1993]

§ 435.814 Medically needy income standard: State plan requirements.

The State plan must specify the income standard for the covered medically needy groups.

[58 FR 4933, Jan. 19, 1993]

MEDICALLY NEEDY INCOME ELIGIBILITY

§ 435.831 Income eligibility.

The agency must determine income eligibility of medically needy individuals in accordance with this section.

(a) *Budget periods.* (1) The agency must use budget periods of not more than 6 months to compute income. The agency may use more than one budget period.

(2) The agency may include in the budget period in which income is computed all or part of the 3-month retroactive period specified in § 435.914. The budget period can begin no earlier than the first month in the retroactive period in which the individual received covered services. This provision applies to all medically needy individuals except in groups for whom criteria more restrictive than that used in the SSI program apply.

(3) If the agency elects to begin the first budget period for the medically needy in any month of the 3-month period prior to the date of the application in which the applicant received covered services, this election applies to all medically needy groups.

(b) *Determining countable income.* The agency must deduct the following amounts from income to determine the individual's countable income.

(1) For individuals under age 21 and caretaker relatives, the agency must deduct amounts that would be deducted in determining eligibility under the State's AFDC plan.

(2) For aged, blind, or disabled individuals in States covering all SSI recipients, the agency must deduct amounts that would be deducted in determining eligibility under SSI. However, the agency must also deduct the highest amounts from income that would be deducted in determining eligibility for optional State supplements if these supplements are paid to all individuals who are receiving SSI or would be eligible for SSI except for their income.

(3) For aged, blind, or disabled individuals in States using income requirements more restrictive than SSI, the agency must deduct amounts that are no more restrictive than those used under the Medicaid plan on January 1, 1972 and no more liberal than those used in determining eligibility under SSI or an optional State supplement. However, the amounts must be at least the same as those that would be deducted in determining eligibility, under § 435.121, of the categorically needy.

(c) *Eligibility based on countable income.* If countable income determined under paragraph (b) of this section is equal to or less than the applicable income standard under § 435.814, the individual or family is eligible for Medicaid.

(d) *Deduction of incurred medical expenses.* If countable income exceeds the income standard, the agency must deduct from income medical expenses incurred by the individual or family or financially responsible relatives that are not subject to payment by a third party. An expense is incurred on the date liability for the expense arises.

The agency must determine deductible incurred expenses in accordance with paragraphs (e), (f), and (g) of this section and deduct those expenses in accordance with paragraph (h) of this section.

(e) *Determination of deductible incurred expenses: Required deductions based on kinds of services.* Subject to the provisions of paragraph (g), in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) Expenses for Medicare and other health insurance premiums, and deductibles or coinsurance charges, including enrollment fees, copayments, or deductibles imposed under § 447.51 or § 447.53 of this subchapter;

(2) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan;

(3) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan, including those that exceed agency limitations on amount, duration, or scope of services.

(f) *Determination of deductible incurred expenses: Required deductions based on the age of bills.* Subject to the provisions of paragraph (g), in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) For the first budget period or periods that include only months before the month of application for medical assistance, expenses incurred during such period or periods, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(2) For the first prospective budget period that also includes any of the 3 months before the month of application for medical assistance, expenses incurred during such budget period, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(3) For the first prospective budget period that includes none of the months preceding the month of application, expenses incurred during such budget period and any of the 3 preceding months, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(4) For any of the 3 months preceding the month of application that are not includable under paragraph (f)(2) of this section, expenses incurred in the 3-month period that were a current liability of the individual in any such month for which a spenddown calculation is made and that had not been previously deducted from income in establishing eligibility for medical assistance;

(5) Current payments (that is, payments made in the current budget period) on other expenses incurred before the current budget period and not previously deducted from income in any budget period in establishing eligibility for such period; and

(6) If the individual's eligibility for medical assistance was established in each such preceding period, expenses incurred before the current budget period but not previously deducted from income in establishing eligibility, to the extent that such expenses are unpaid and are:

(i) Described in paragraphs (e)(1) through (e)(3) of this section; and

(ii) Carried over from the preceding budget period or periods because the individual had a spenddown liability in each such preceding period that was met without deducting all such incurred, unpaid expenses.

(g) *Determination of deductible incurred medical expenses: Optional deductions.* In determining incurred medical expenses to be deducted from income, the agency—

(1) May include medical institutional expenses (other than expenses in acute care facilities) projected to the end of the budget period at the Medicaid reimbursement rate;

(2) May, to the extent determined by the State and specified in its approved plan, include expenses incurred earlier than the third month before the month of application (except States using more restrictive eligibility criteria under the option in section 1902(f) of the Act must deduct incurred expenses

regardless of when the expenses were incurred); and

(3) May set reasonable limits on the amount to be deducted for expenses specified in paragraphs (e)(1), (e)(2), and (g)(2) of this section.

(h) *Order of deduction.* The agency must deduct incurred medical expenses that are deductible under paragraphs (e), (f), and (g) of this section in the order prescribed under one of the following three options:

(1) *Type of service.* Under this option, the agency deducts expenses in the following order based on type of expense or service:

(i) Cost-sharing expenses as specified in paragraph (e)(1) of this section.

(ii) Services not included in the State plan as specified in paragraph (e)(2) of this section.

(iii) Services included in the State plan as specified in paragraph (e)(3) of this section but that exceed limitations on amounts, duration, or scope of services.

(iv) Services included in the State plan as specified in paragraph (e)(3) of this section but that are within agency limitations on amount, duration, or scope of services.

(2) *Chronological order by service date.* Under this option, the agency deducts expenses in chronological order by the date each service is furnished, or in the case of insurance premiums, coinsurance or deductible charges, the date such amounts are due. Expenses for services furnished on the same day may be deducted in any reasonable order established by the State.

(3) *Chronological order by bill submission date.* Under this option, the agency deducts expenses in chronological order by the date each bill is submitted to the agency by the individual. If more than one bill is submitted at one time, the agency must deduct the bills from income in the order prescribed in either paragraph (h)(1) or (h)(2) of this section.

(i) *Eligibility based on incurred medical expenses.* (1) Whether a State elects partial or full month coverage, an individual who is expected to contribute a portion of his or her income toward the costs of institutional care or home and community-based services under §§ 435.725, 435.726, 435.733, 435.735 or 435.832 is eligible on the first day of the applicable budget (spenddown) period—

(i) If his or her spenddown liability is met after the first day of the budget period; and

(ii) If beginning eligibility after the first day of the budget period makes the individual's share of health care expenses under §§ 435.725, 435.726, 435.733, 435.735 or 435.832 greater than the individual's contributable income determined under these sections.

(2) At the end of the prospective period specified in paragraphs (f)(2) and (f)(3) of this section, and any subsequent prospective period or, if earlier, when any significant change occurs, the agency must reconcile the projected amounts with the actual amounts incurred, or with changes in circumstances, to determine if the adjusted deduction of incurred expenses reduces income to the income standard.

(3) Except as provided in paragraph (i)(1) of this section, in States that elect partial month coverage, an individual is eligible for Medicaid on the day that the deduction of incurred health care expenses (and of projected institutional expenses if the agency elects the option under paragraph (g)(1) of this section) reduces income to the income standard.

(4) Except as provided in paragraph (i)(1) of this section, in States that elect full month coverage, an individual is eligible on the first day of the month in which spenddown liability is met.

(5) Expenses used to meet spenddown liability are not reimbursable under Medicaid. To the extent necessary to prevent the transfer of an individual's spenddown liability to the Medicaid program, States must reduce the amount of provider charges that would otherwise be reimbursable under Medicaid.

[59 FR 1672, Jan. 12, 1994]

§ 435.832 Post-eligibility treatment of income of institutionalized individuals: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution, for services provided to an individual

specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section, from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) *Applicability.* This section applies to medically needy individuals in medical institutions and intermediate care facilities.

(c) *Required deductions.* The agency must deduct the following amounts, in the following order, from the individual's total income, as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) *Personal needs allowance.* A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or diability.

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

(2) *Maintenance needs of spouse.* For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides Medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under § 435.811.

(3) *Maintenance needs of family.* For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the highest of the following need standards for a family of the same size:

(A) The standard used to determine eligibility under the State's approved AFDC plan.

(B) The medically needy income standard established under § 435.811.

(4) Expenses not subject to third party payment. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance permiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) *Optional deduction: Allowance for home maintenance.* For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option.* In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received or it may project total monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection*. The agency must base the projection on income received in the preceding period, not to exceed 6 months, and on income expected to be received.

(3) *Adjustments*. At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option*. In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection*. The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments*. At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24886, Apr. 11, 1980, as amended at 46 FR 47988, Sept. 30, 1981; 48 FR 5735, Feb. 8, 1983; 53 FR 3596, Feb. 8, 1988; 53 FR 5344, Feb. 23, 1988; 56 FR 8850, 8854, Mar. 1, 1991; 58 FR 4933, Jan. 19, 1993]

MEDICALLY NEEDY RESOURCE STANDARD

§ 435.840 Medically needy resource standard: General requirements.

(a) To determine eligibility of medically needy individuals, a Medicaid agency must use a single resource standard that meets the requirements of this section.

(b) In States that do not use more restrictive criteria than SSI for aged, blind, and disabled individuals, the resource standard must be established at an amount that is no lower than the lowest resource standard used under the cash assistance programs that relate to the State's covered medically needy eligibility group or groups of individuals under § 435.301.

(c) In States using more restrictive requirements than SSI:

(1) For all individuals except aged, blind, and disabled individuals, the resource standard must be set in accordance with paragraph (b) of this section; and

(2) For all aged, blind, and disabled individuals or any combination of these groups of individuals, the agency may establish a separate single medically needy resource standard that is more restrictive than the single resource standard set under paragraph (b) of this section. However, the amount of the more restrictive separate standard for aged, blind, or disabled individuals must be no lower than the higher of the lowest categorically needy resource standard currently applied under the State's more restrictive criteria under § 435.121 or the medically needy resource standard in effect under the State's Medicaid plan on January 1, 1972.

(d) The resource standard established under paragraph (a) of this section may not diminish by an increase in the number of persons in the assistance unit. For example, the resource standard for an assistance unit of three may not be less than that set for a unit of two.

[58 FR 4933, Jan. 19, 1993]

§ 435.843 Medically needy resource standard: State plan requirements.

The State plan must specify the resource standard for the covered medically needy groups.

[58 FR 4933, Jan. 19, 1993]

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

§ 435.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must:

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives in § 435.602.

(b) Deduct the amounts that would be deducted in determining resource eligibility for the medically needy group as provided for in § 435.601 or under the criteria of States using more restrictive criteria than SSI as provided for in § 435.121. In determining the amount of an individual's resources for

Medicaid eligibility, States must count amounts of resources that otherwise would not be counted under the conditional eligibility provisions of the SSI or AFDC programs.

(c) Apply the resource standard specified under § 435.840.

[58 FR 4933, Jan. 19, 1993]

§§ 435.850–435.852 [Reserved]

Subpart J—Eligibility in the States and District of Columbia

SOURCE: 44 FR 17937, Mar. 23, 1979, unless otherwise noted.

§ 435.900 Scope.

This subpart sets forth requirements for processing applications, determining eligibility, and furnishing Medicaid.

GENERAL METHODS OF ADMINISTRATION

§ 435.901 Consistency with objectives and statutes.

The Medicaid agency's standards and methods for determining eligibility must be consistent with the objectives of the program and with the rights of individuals under the United States Constitution, the Social Security Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and all other relevant provisions of Federal and State laws.

[44 FR 17937, Mar. 23, 1979. Redesignated at 59 FR 48809, Sept. 23, 1994]

§ 435.902 Simplicity of administration.

The agency's policies and procedures must ensure that eligibility is determined in a manner consistent with simplicity of administration and the best interests of the applicant or recipient.

[44 FR 17937, Mar. 23, 1979. Redesignated at 59 FR 48809, Sept. 23, 1994]

§ 435.903 Adherence of local agencies to State plan requirements.

The agency must—

(a) Have methods to keep itself currently informed of the adherence of local agencies to the State plan provisions and the agency's procedures for determining eligibility; and

(b) Take corrective action to ensure their adherence.

[44 FR 17937, Mar. 23, 1979. Redesignated at 59 FR 48809, Sept. 23, 1994]

§ 435.904 Establishment of outstation locations to process applications for certain low-income eligibility groups.

(a) *State plan requirements.* The Medicaid State plan must specify that the requirements of this section are met.

(b) *Opportunity to apply.* The agency must provide an opportunity for the following groups of low-income pregnant women, infants, and children under age 19 to apply for Medicaid at outstation locations other than AFDC offices:

(1) The groups of pregnant women or infants with incomes up to 133 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(IV) of the Act;

(2) The group of children age 1 up to age 6 with incomes at 133 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(VI) of the Act;

(3) The group of children age 6 up to age 19 born after September 30, 1983, with incomes up to 100 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(i)(VII) of the Act; and

(4) The groups of pregnant women or infants, children age 1 up to age 6, and children age 6 up to age 19, who are not eligible as a mandatory group, with incomes up to 185 percent of the Federal poverty level as specified under section 1902(a)(10)(A)(ii)(IX) of the Act.

(c) *Outstation locations: general requirements.* (1) The agency must establish either—

(i) Outstation locations at each disproportionate share hospital, as defined in section 1923(a)(1)(A) of the Act, and each Federally-qualified health center, as defined in section 1905(1)(2)(B) of the Act, participating in the Medicaid program and providing services to Medicaid-eligible pregnant women and children; or

(ii) Other outstation locations, which include at least some, disproportionate share hospitals and federally-qualified health centers, as specified under an alternative State plan that is submitted

to and approved by CMS if the following conditions are met:

(A) The State must demonstrate that the alternative plan for outstationing is equally effective as, or more effective than, a plan that would meet the requirements of paragraph (c)(1)(i) of this section in enabling the individuals described in paragraph (b) of this section to apply for and receive Medicaid; and

(B) The State must provide assurances that the level of staffing and funding committed by the State under the alternative plan equals or exceeds the level of staffing and funding under a plan that would meet the requirements of establishing the outstation locations at the sites specified in paragraph (c)(1)(i) of this section.

(2) The agency must establish outstation locations at Indian health clinics operated by a tribe or tribal organization as these clinics are specifically included in the definition of Federally-qualified health centers under section 1905(l)(2)(B) of the Act and are also included in the definition of rural health clinics under part 491, subpart A of this chapter.

(3) The agency may establish additional outstation locations at any other site where potentially eligible pregnant women or children receive services—for example, at school-linked service centers and family support centers. These additional sites may also include sites other than the main outstation location of those Federally-qualified health centers or disproportionate share hospitals providing services to Medicaid-eligible pregnant women and to children and that operate more than one site.

(4) The agency may, at its option, enter into reciprocal agreements with neighboring States to ensure that the groups described in paragraph (b) of this section who customarily receive services in a neighboring State have the opportunity to apply at outstation locations specified in paragraphs (c)(l) and (2) of this section.

(d) *Outstation functions.* (1) The agency must provide for the receipt and initial processing of Medicaid applications from the designated eligibility groups at each outstation location.

(2) ''Initial processing'' means taking applications, assisting applicants in completing the application, providing information and referrals, obtaining required documentation to complete processing of the application, assuring that the information contained on the application form is complete, and conducting any necessary interviews. It does not include evaluating the information contained on the application and the supporting documentation nor making a determination of eligibility or ineligibility.

(3) The agency may, at its option, allow appropriate State eligibility workers assigned to outstation locations to evaluate the information contained on the application and the supporting documentation and make a determination of eligibility if the workers are authorized to determine eligibility for the agency which determines Medicaid eligibility under §431.10 of this subchapter.

(e) *Staffing.* (1) Except for outstation locations that are infrequently used by the low-income eligibility groups, the State agency must have staff available at each outstation location during the regular office operating hours of the State Medicaid agency to accept applications and to assist applicants with the application process.

(2) The agency may station staff at one outstation location or rotate staff among several locations as workload and staffing availability dictate.

(3) The agency may use State employees, provider or contractor employees, or volunteers who have been properly trained to staff outstation locations under the following conditions:

(i) State outstation intake staff may perform all eligibility processing functions, including the eligibility determination, if the staff is authorized to do so at the regular Medicaid intake office.

(ii) Provider or contractor employees and volunteers may perform only initial processing functions as defined in paragraph (d)(2) of this section.

(4) Provider and contractor employees and volunteers are subject to the confidentiality of information rules specified in part 431, subpart F, of this subchapter, to the prohibition against

reassignment of provider claims specified in § 447.10 of this subchapter, and to all other State or Federal laws concerning conflicts of interest.

(5) At locations that are infrequently used by the designated low-income eligibility groups, the State agency may use volunteers, provider or contractor employees, or its own eligibility staff, or telephone assistance.

(i) The agency must display a notice in a prominent place at the outstation location advising potential applicants of when outstation intake workers will be available.

(ii) The notice must include a telephone number that applicants may call for assistance.

(iii) The agency must comply with Federal and State laws and regulations governing the provision of adequate notice to persons who are blind or deaf or who are unable to read or understand the English language.

[59 FR 48809, Sept. 23, 1994]

APPLICATIONS

§ 435.905 Availability of program information.

(a) The agency must furnish the following information in written form, and orally as appropriate, to all applicants and to all other individuals who request it:

(1) The eligibility requirements.

(2) Available Medicaid services.

(3) The rights and responsibilities of applicants and recipients.

(b) The agency must publish in quantity and make available bulletins or pamphlets that explain the rules governing eligibility and appeals in simple and understandable terms.

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980]

§ 435.906 Opportunity to apply.

The agency must afford an individual wishing to do so the opportunity to apply for Medicaid without delay.

§ 435.907 Written application.

(a) The agency must require a written application from the applicant, an authorized representative, or, if the applicant is incompetent or incapacitated, someone acting responsibly for the applicant.

(b) Subject to the conditions specified in paragraph (c) of this section, the application must be on a form prescribed by the agency and signed under a penalty of perjury.

(c) The application form used at outstation locations for low-income pregnant women, infants, and children specified in § 435.904 must not be the application form used to apply for AFDC. The application form (including any computerized application form) for these designated eligibility groups may be—

(1) A Medicaid-only form prescribed by the agency specifically for the designated eligibility groups;

(2) An existing Medicaid-only application; or

(3) A multiple-program application that contains clearly identifiable Medicaid-only sections or parts.

[59 FR 48810, Sept. 23, 1994]

§ 435.908 Assistance with application.

The agency must allow an individual or individuals of the applicant's choice to accompany, assist, and represent the applicant in the application process or a redetermination of eligibility.

§ 435.909 Automatic entitlement to Medicaid following a determination of eligibility under other programs.

The agency must not require a separate application for Medicaid from an individual, if—

(a) The individual receives AFDC; or

(b) The agency has an agreement with the Social Security Administration (SSA) under section 1634 of the Act for determining Medicaid eligibility; and—

(1) The individual receives SSI;

(2) The individual receives a mandatory State supplement under either a federally-administered or State-administered program; or

(3) The individual receives an optional State supplement and the agency provides Medicaid to recipients of optional supplements under § 435.230.

§ 435.910 Use of social security number.

(a) The agency must require, as a condition of eligibility, that each individual (including children) requesting

Medicaid services furnish each of his or her social security numbers (SSNs).

(b) The agency must advise the applicant of—

(1) [Reserved]

(2) The statute or other authority under which the agency is requesting the applicant's SSN; and

(3) The uses the agency will make of each SSN, including its use for verifying income, eligibility, and amount of medical assistance payments under §§ 435.940 through 435.960.

(c)–(d) [Reserved]

(e) If an applicant cannot recall his SSN or SSNs or has not been issued a SSN the agency must—

(1) Assist the applicant in completing an application for an SSN;

(2) Obtain evidence required under SSA regulations to establish the age, the citizenship or alien status, and the true identity of the applicant; and

(3) Either send the application to SSA or, if there is evidence that the applicant has previously been issued a SSN, request SSA to furnish the number.

(f) The agency must not deny or delay services to an otherwise eligible applicant pending issuance or verification of the individual's SSN by SSA.

(g) The agency must verify each SSN of each applicant and recipient with SSA, as prescribed by the Commissioner, to insure that each SSN furnished was issued to that individual, and to determine whether any others were issued.

(h) *Exception.* (1) A State may give a Medicaid identification number to an applicant who, because of well established religious objections, refuses to obtain a Social Security Number (SSN). The identification number may be either an SSN obtained by the State on the applicant's behalf or another unique identifier.

(2) The term *well established religious objections* means that the applicant—

(i) Is a member of a recognized religious sect or division of the sect; and

(ii) Adheres to the tenets or teachings of the sect or division of the sect and for that reason is conscientiously opposed to applying for or using a national identification number.

(3) A State may use the Medicaid identification number established by the State to the same extent as an SSN is used for purposes described in paragraph (b)(3) of this section.

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986; 66 FR 2667, Jan. 11, 2001]

Determination of Medicaid Eligibility

§ 435.911 Timely determination of eligibility.

(a) The agency must establish time standards for determining eligibility and inform the applicant of what they are. These standards may not exceed—

(1) Ninety days for applicants who apply for Medicaid on the basis of disability; and

(2) Forty-five days for all other applicants.

(b) The time standards must cover the period from the date of application to the date the agency mails notice of its decision to the applicant.

(c) The agency must determine eligibility within the standards except in unusual circumstances, for example—

(1) When the agency cannot reach a decision because the applicant or an examining physician delays or fails to take a required action, or

(2) When there is an administrative or other emergency beyond the agency's control.

(d) The agency must document the reasons for delay in the applicant's case record.

(e) The agency must not use the time standards—

(1) As a waiting period before determining eligibility; or

(2) As a reason for denying eligibility (because it has not determined eligibility within the time standards).

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980; 54 FR 50762, Dec. 11, 1989]

§ 435.912 Notice of agency's decision concerning eligibility.

The agency must send each applicant a written notice of the agency's decision on his application, and, if eligibility is denied, the reasons for the action, the specific regulation supporting the action, and an explanation of his

right to request a hearing. (See subpart E of part 431 of this subchapter for rules on hearings.)

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986]

§ 435.913 Case documentation.

(a) The agency must include in each applicant's case record facts to support the agency's decision on his application.

(b) The agency must dispose of each application by a finding of eligibility or ineligibility, unless—

(1) There is an entry in the case record that the applicant voluntarily withdrew the application, and that the agency sent a notice confirming his decision;

(2) There is a supporting entry in the case record that the applicant has died; or

(3) There is a supporting entry in the case record that the applicant cannot be located.

§ 435.914 Effective date.

(a) The agency must make eligibility for Medicaid effective no later than the third month before the month of application if the individual—

(1) Received Medicaid services, at any time during that period, of a type covered under the plan; and

(2) Would have been eligible for Medicaid at the time he received the services if he had applied (or someone had applied for him), regardless of whether the individual is alive when application for Medicaid is made.

(b) The agency may make eligiblity for Medicaid effective on the first day of a month if an individual was eligible at any time during that month.

(c) The State plan must specify the date on which eligibility will be made effective.

REDETERMINATIONS OF MEDICAID ELIGIBILITY

§ 435.916 Periodic redeterminations of Medicaid eligibility.

(a) The agency must redetermine the eligibility of Medicaid recipients, with respect to circumstances that may change, at least every 12 months, however—

(1) The agency may consider blindness as continuing until the review physician under § 435.531 determines that a recipient's vision has improved beyond the definition of blindness contained in the plan; and

(2) The agency may consider disability as continuing until the review team under § 435.541 determines that a recipient's disability no longer meets the definition of disability contained in the plan.

(b) *Procedures for reporting changes.* The agency must have procedures designed to ensure that recipients make timely and accurate reports of any change in circumstances that may affect their eligibility.

(c) *Agency action on information about changes.* (1) The agency must promptly redetermine eligibility when it receives information about changes in a recipient's circumstances that may affect his eligibility.

(2) If the agency has information about anticipated changes in a recipient's circumstances, it must redetermine eligibility at the appropriate time based on those changes.

§ 435.919 Timely and adequate notice concerning adverse actions.

(a) The agency must give recipients timely and adequate notice of proposed action to terminate, discontinue, or suspend their eligibility or to reduce or discontinue services they may receive under Medicaid.

(b) The notice must meet the requirements of subpart E of part 431 of this subchapter.

[44 FR 17937, Mar. 23, 1979, as amended at 45 FR 24887, Apr. 11, 1980; 51 FR 7211, Feb. 28, 1986]

§ 435.920 Verification of SSNs.

(a) In redetermining eligibility, the agency must review case records to determine whether they contain the recipient's SSN or, in the case of families, each family member's SSN.

(b) If the case record does not contain the required SSNs, the agency must require the recipient to furnish them and meet other requirements of § 435.910.

(c) For any recipient whose SSN was established as part of the case record without evidence required under the SSA regulations as to age, citizenship,

alien status, or true identity, the agency must obtain verification of these factors in accordance with § 435.910.

[44 FR 17937, Mar. 23, 1979, as amended at 51 FR 7211, Feb. 28, 1986]

FURNISHING MEDICAID

§ 435.930 Furnishing Medicaid.

The agency must—

(a) Furnish Medicaid promptly to recipients without any delay caused by the agency's administrative procedures;

(b) Continue to furnish Medicaid regularly to all eligible individuals until they are found to be ineligible; and

(c) Make arrangements to assist applicants and recipients to get emergency medical care whenever needed, 24 hours a day and 7 days a week.

INCOME AND ELIGIBILITY VERIFICATION REQUIREMENTS

SOURCE: Sections 435.940 through 935.965 appear at 51 FR 7211, Feb. 28, 1986, unless otherwise noted.

§ 435.940 Basis and scope.

(a) Section 1137 of the Act requires certain Federally-funded, State-administered public assistance programs to establish procedures for obtaining, using and verifying information relevant to determinations as to eligibility and the amount of assistance. Section 1902(a)(4) of the Act allows the Secretary to prescribe methods of administration found necessary for the proper and efficient operation of a State's Medicaid plan.

(b) The agency must maintain information, as enumerated in § 435.960, to exchange for the purpose of enabling any agency or program referenced in § 435.945(b) to verify income, eligibility of, and the amount of assistance for its applicants and recipients.

§ 435.945 General requirements.

(a) The agency must request and use information timely in accordance with §§ 435.948, 435.952, and 435.953 of this subpart for verifying Medicaid eligibility and the amount of medical assistance payments.

(b) The agency must furnish timely to other agencies in the State and in other States and to Federal programs income, eligibility and medical assistance payment information for verifying eligibility or benefit amounts for the programs listed in § 435.948(a)(6) of this subpart. In addition, the agency must furnish income and eligibility information to—

(1) The child support enforcement program under part D of title IV of the Act; and

(2) SSA for old age, survivors and disability benefits under title II and for SSI benefits under title XVI of the Act.

(c) The agency must, upon request, reimburse another agency listed in § 435.948(a)(6) of this subpart or paragraph (b) of this section for reasonable costs incurred in furnishing information, including new developmental costs associated with furnishing the information to another agency.

(d) The agency must inform all applicants in writing at the time of application that the agency will obtain and use information available to it under section 1137 of the Act to verify income, eligibility and the correct amount of medical assistance payments. The agency must give each recipient the same notice when it redetermines eligibility. The requirements in this paragraph do not apply in the case of applicants or recipients whose eligibility is determined by AFDC or by SSA under section 1634 of the Act.

(e) The agency must report as the Secretary prescribes for the purposes of determining compliance with §§ 431.305, 431.800, 435.910, 435.919 and 435.940 through 435.965 of this chapter and of evaluating the effectiveness of the income and eligibility verification system.

(f) The agency must execute written agreements with other agencies before releasing data to or requesting data from, those agencies. The agreements, at a minimum, must specify:

(1) The information to be exchanged;

(2) The titles of all agency officials with the authority to request income and eligibility information;

(3) The methods, including the formats to be used, and the timing for requesting and providing the information (see also paragraph (f)(6) of this section);

(4) The safeguards limiting the use and disclosure of the information as required by Federal or State law or regulations;

(5) The method, if any, the agency will use to reimburse reasonable costs of furnishing the information; and

(6) In the case of an agreement between a SWICA or a UC agency and the Medicaid agency, that the Medicaid agency will obtain information on applicants at least twice monthly; and

(7) In the case of an agreement between any Federal agency and the Medicaid agency for data on individuals, provisions relating to—

(i) Purpose and legal authority;

(ii) Justification and expected results;

(iii) Records description (including specific identification of the system of records, the number of records, what data elements will be included in the match, and projected starting and completion dates);

(iv) Notice procedures;

(v) Verification procedures;

(vi) Disposition of matched items;

(vii) Security procedures;

(viii) Records usage, duplication and redisclosure restrictions;

(ix) Records accuracy assessments; and

(x) Access by the Comptroller General.

(g) SWICA that does not use the quarterly wages reported by employers as required by Section 1137 of the Act of unemployment insurance benefit calculations must maintain wage information that:

(1) Contains the SSN, full name, wages earned for the period of the report, and an identifier of the employer;

(2) Includes all employers covered by the States' UC law;

(3) Accumulates earnings reported by employers for no longer periods than calendar quarters;

(4) Is reported to the SWICA within 30 days after the end of the quarter;

(5) Is machine readable; and

(6) Is accessible to agencies in other States that have executed agreements as required in § 435.945(f) of this chapter and to SSA for use in making eligibility or benefit determinations under Title II or XVI of the Act.

[51 FR 7211, Feb. 28, 1986, as amended at 52 FR 5977, Feb. 27, 1987; 54 FR 8741, Mar. 2, 1989; 57 FR 46097, Oct. 7, 1992; 59 FR 4254, Jan. 31, 1994]

§ 435.948 Requesting information.

(a) Except as provided in paragraphs (d), (e), and (f) of this section, the agency must request information from the sources specified in this paragraph for verifying Medicaid eligibility and the correct amount of medical assistance payments for each applicant (unless obviously ineligible on the face of his or her application) and recipient. The agency must request—

(1) State wage information maintained by the SWICA during the application period and at least on a quarterly basis;

(2) Information about net earnings from self-employment, wage and payment of retirement income, maintained by SSA and available under Section 6103(l)(7)(A) of the Internal Revenue Code of 1954, for applicants during the application period and for recipients for whom the information has not previously been requested;

(3) Information about benefit and other eligibility related information available from SSA under titles II and XVI of the Social Security Act for applicants during the application period and for recipients for whom the information has not previously been requested;

(4) Unearned income information from the Internal Revenue Service available under Section 6103(l)(7)(B) of the Internal Revenue Code of 1954, during the application period and at least yearly;

(5) Unemployment compensation information maintained by the agency administering State unemployment compensation laws (under the provisions of section 3304 of the Internal Revenue Code and section 303 of the Act) as follows:

(i) For an applicant, during the application period and at least for each of the three subsequent months;

(ii) For a recipient that reports a loss of employment, at the time the recipient reports that loss and for at least each of the three subsequent months.

(iii) For an applicant or a recipient who is found to be receiving unemployment compensation benefits, at least for each month until the benefits are reported to be exhausted.

(6) Any additional income, resource, or eligibility information relevant to determinations concerning eligibility or correct amount of medical assistance payments available from agencies in the State or other States administering the following programs as provided in the agency's State plan:

(i) AFDC;

(ii) Medicaid;

(iii) State-administered supplementary payment programs under Section 1616(a) of the Act;

(iv) SWICA;

(v) Unemployment compensation;

(vi) Food stamps; and

(vii) Any State program administered under a plan approved under Title I (assistance to the aged), X (aid to the blind), XIV (aid to the permanently and totally disabled), or XVI (aid to the aged, blind, and disabled in Puerto Rico, Guam, and the Virgin Islands) of the Act.

(b) The agency must request information on applicants from the sources listed in paragraph (a)(1) through (a)(5) of this section at the first opportunity provided by these sources following the receipt of the application. If an applicant cannot provide an SSN at application, the agency must request the information at the next available opportunity after receiving the SSN.

(c) The agency must request the information required in paragraph (a) of this section by SSN, using each SSN furnished by the individual or received through verification.

(d) *Exception:* In cases where the individual is institutionalized, the agency needs to obtain and use information from SWICA only during the application period and on a yearly basis, and from unemployment compensation agencies only during the application period. An individual is institutionalized for purposes of this section when he or she is required to apply his or her income to the cost of medical care as required by §§ 435.725, 435.733, and 435.832.

(e) *Exception: Alternate sources.* (1) The Secretary may, upon application from a State agency, permit an agency to request and use income information from a source or sources alternative to those listed in paragraph (a) of this section. The agency must demonstrate to the Secretary that the alternative source(s) is as timely, complete and useful for verifying eligibility and benefit amounts. The Secretary will consult with the Secretary of Agriculture and the Secretary of Labor before determining whether an agency may use an alternate source.

(2) The agency must continue to meet the requirements of this section unless the Secretary has approved the request.

(f) *Exception:* If the agency administering the AFDC program, or SSA under section 1634 of the Act, determines the eligibility of an applicant or recipient, the requirements of this section do not apply to that applicant or recipient.

§ 435.952 Use of information.

(a) Except as provided under § 435.953, the agency must review and compare against the case file all information received under §§ 435.940 through 435.960 to determine whether it affects the applicant's or recipient's eligibility or amount of medical assistance payment. The agency also must independently verify the information if required by § 435.955 or if determined appropriate by agency experience.

(b) For applicants, if the information is received during the application period, it must be used, to the extent possible, making eligibility determinations. If it is received after the eligibility determination, it must be used as specified for recipients in paragraphs (c) and (d) of this section.

(c) Except as specified in § 435.953 of this subpart and paragraph (d) of this section, for recipients, the agency must, within 45 days of receipt of an item of information, request verification (if appropriate), determine whether the information affects eligibility or the amount of medical assistance payment, and either initiate a notice of case action to advise the recipient of any adverse action the agency intends to take or make an entry in the casefile that no further action is necessary.

(d) Subject to paragraph (e) of this section, if the agency does not receive requested third party verification within the 45-day period after receipt of information, the agency may determine whether the information affects eligibility or correct amount of medical assistance payment after the 45-day period. However, the agency must make any delayed determinations permitted under this paragraph—

(1) Promptly, as required by § 435.916, if the verification is received before the next redetermination; or

(2) In conjunction with the next redetermination if no verification is received before that redetermination.

(e) The number of determinations delayed beyond 45 days from receipt of an item of information (as permitted by paragraph (d) of this section) must not exceed twenty percent of the number of items of information for which verification was requested.

(f) The agency must use appropriate procedures to monitor the timeliness requirements of this section.

(g) The requirements of this section do not relieve the agency of its responsibility for determinations of erroneous payments or the agency's liability for those erroneous payments, as defined in subpart P of part 431 of this chapter.

[51 FR 7211, Feb. 28, 1986, as amended at 53 FR 6648, March 2, 1988; 54 FR 8741, Mar. 2, 1989; 59 FR 4255, Jan. 31, 1994]

§ 435.953 Identifying items of information to use.

(a) With respect to information received on recipients under §§ 435.940 through 435.960, the agency may either review and compare against the case file all items of information received or it may identify (target) separately for each data source the information items that are most likely to be most productive in identifying and preventing ineligibility and incorrect payments.

(b) An agency that wishes to exclude categories of information items must submit for the Secretary's approval a follow-up plan describing the categories that it proposes to exclude. For each category, the agency must provide a reasonable justification that follow-up is not cost-effective; a formal cost/benefit analysis is not required.

(c) If an agency receives an item of unemployment compensation information from the Internal Revenue Service or earnings information from SSA that duplicates an item of information previously received from another source and followed up, the agency may exclude that information item without justification.

(d) An agency may submit a follow-up plan or alter its plan at any time by notifying the Secretary and submitting the necessary justification. The Secretary approves or disapproves categories of items to be excluded under the plan within 60 days of its submission. The categories approved by the Secretary constitute an approved agency follow-up plan for IEVS.

[54 FR 8742, Mar. 2, 1989]

§ 435.955 Additional requirements regarding information released by a Federal agency.

(a) Unless waived under paragraph (d) of this section, based on information received from a computerized data match in which information on an individual is provided to the agency by a Federal agency, the agency may not terminate, deny, suspend, or reduce medical assistance to that individual until it has taken appropriate steps to verify the information independently. The agency must independently verify information relating to—

(1) The amount of the income and resource that generated the income involved;

(2) Whether the applicant or recipient actually has (or had) access to the resource or income (or both) for his or her own use;

(3) The period or periods when the individual actually has (or had) access to the resource or income or both.

(b) The agency must verify the information by either

(1) Requesting the entity from which the information originally came to verify the fact and amount of income or resource; or

(2) Sending the applicant or recipient a letter informing that individual of the information received and asking him or her to respond within a specified period. The letter must clearly explain the information the agency has

and its possible relevance to the individual's past or future eligibility, and be as neutral in tone as possible.

(c)(1) If the original source of the income or resource or the applicant or recipient verifies the information, and the agency intends to reduce, suspend, terminate or deny medical assistance based on the information, the agency must send the applicant or recipient a notice of the action to be taken and include information on the right to appeal and opportunity for a hearing under §§ 431.200 through 431.246 of this chapter (see also § 435.912 and § 435.919).

(2) If the applicant or recipient fails to respond after reasonable attempts to contact him or her, the agency must proceed to deny, terminate, reduce or suspend medical assistance based on the applicant's or recipient's failure to cooperate.

(3) If the applicant or recipient disputes the information, the agency must obtain evidence (from the source of the data, applicant, recipient, or otherwise) to substantiate any negative case action it may take.

(d) The independent verification requirement concerning a category of data received from a Federal benefit agency may be waived if the Federal agency's Data Integrity Board approves the waiver. The Federal benefit agency involved in the data exchange will develop the request by petitioning its Data Integrity Board for a waiver of independent verification by a Medicaid State agency. The State agency must furnish the Federal agency with any information it needs to seek the Data Integrity Board's approval of the waiver.

(e) In accordance with the Federal agency's procedures, the agency must provide data on the costs and benefits of the matching program to the Federal agency from which it receives information on individuals.

(f) In accordance with the Federal agency's procedures, the agency must certify to the Federal agency that it will not take adverse action against an individual until the information has been independently verified and until 10 days (or sooner if permitted by § 431.213 or § 431.214) after the individual has been notified of the findings and given an opportunity to contest.

(g) In accordance with the Federal agency's procedures for renewals of matching programs, the agency must certify to the Federal agency that the terms of the agreement have been followed.

[59 FR 4255, Jan. 31, 1994]

§ 435.960 Standardized formats for furnishing and obtaining information to verifying income and eligibility.

(a) The agency must maintain for all applicants and recipients within an agency file the SSN, surname and other data elements in a format that at a minimum allows the agency to furnish and to obtain eligibility and income information from the agencies or programs referenced in § 435.945(b) and § 435.948(a).

(b) The format to be used will be prescribed by—

(1) CMS when the agency furnishes information to, or requests information from, any Federal or State agency, except SSA and the Internal Revenue Service as specified in paragraphs (b) (2) and (3), respectively;

(2) The Commissioner of Social Security when the agency requests information from SSA; and

(3) The Commissioner of Internal Revenue when the agency requests information from the Internal Revenue Service.

[52 FR 5977, Feb. 27, 1987]

§ 435.965 Delay of effective date.

(a) If the agency submits, by May 29, 1986, a plan describing a good faith effort to come into compliance with the requirements of section 1137 of the Act and of §§ 435.910 and 435.940 through 435.960 of this subpart, the Secretary may, after consultation with the Secretary of Agriculture and the Secretary of Labor, grant a delay in the effective date of §§ 435.910 and 435.940 through 435.960, but not beyond September 30, 1986.

(b) The Secretary may not grant a delay of the effective date of section 1137(c) of the Act, which is implemented by § 435.955 (a) and (c). (The provisions of these statutory and regulation sections require the agency to follow certain procedures before taking

any adverse actions based on information from the Internal Revenue Service concerning unearned income.)

Subpart K—Federal Financial Participation

§ 435.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP IN EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§ 435.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in—

(1) Determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals; and

(2) Determining presumptive eligibility for children and providing services to presumptively eligible children.

(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

[43 FR 45204, Sept. 29, 1978, as amended at 66 FR 2667, Jan. 11, 2001]

§ 435.1002 FFP for services.

(a) Except for the limitations and conditions specified in §§ 435.1007, 35.1008, 435.1009, and 438.814 of this chapter, FFP is available in expenditures for Medicaid services for all recipients whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to recipients who were eligible for Medicaid in the month in which the medical care or services were provided except that, for recipients who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient's liability. (See §§ 435.914 and 436.901 of this subchapter for regulations on retroactive eligibility for Medicaid.)

(c) FFP is available in expenditures for services covered under the plan that are furnished—

(1) To children who are determined by a qualified entity to be presumptively eligible;

(2) During a period of presumptive eligibility;

(3) By a provider that is eligible for payment under the plan; and

(4) Regardless of whether the children are determined eligible for Medicaid following the period of presumptive eligibility.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979; 66 FR 2667, Jan. 11, 2001; 67 FR 41095, June 14, 2002; 71 FR 39225, July 12, 2006]

§ 435.1003 FFP for redeterminations.

(a) If the Social Security Administration (SSA) notifies an agency that a recipient has been determined ineligible for SSI, FFP is available in Medicaid expenditures for services to the recipient as follows:

(1) If the agency receives the SSA notice by the 10th day of the month, FFP is available under this section only through the end of the month unless the recipient requests a hearing under subpart E, part 431 of this subchapter.

(2) If the agency receives the SSA notice after the 10th day of the month, FFP is available only through the end of the following month, unless the recipient requests a hearing under subpart E, part 431 of this subchapter.

(3) If a recipient requests a hearing, FFP is available as specified in subpart E, part 431 of this subchapter.

(b) The agency must take prompt action to determine eligibility after receiving the SSA notice.

(c) When a change in Federal law affects the eligibility of substantial numbers of Medicaid recipients, the Secretary may waive the otherwise applicable FFP requirements and redetermination time limits of this section, in order to provide a reasonable time to complete such redeterminations. The Secretary will designate an additional amount of time beyond that allowed

under paragraphs (a) and (b) of this section, within which FFP will be available, to perform large numbers of redeterminations arising from a change in Federal law.

[43 FR 45204, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979; 62 FR 1685, Jan. 13, 1997]

§ 435.1004 Recipients overcoming certain conditions of eligibility.

(a) FFP is available, as specified in paragraph (b) of this section, in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a parent.

(b) FFP is available for a period not to exceed—

(1) The period during which a recipient of AFDC, SSI or an optional State supplement continues to receive cash payments while these conditions are being overcome; or

(2) For recipients eligible for Medicaid only and recipients of AFDC, SSI or an optional State supplement who do not continue to receive cash payments, the second month following the month in which the recipient's Medicaid eligibility would have been terminated.

[43 FR 45204, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980]

LIMITATIONS ON FFP

§ 435.1005 Recipients in institutions eligible under a special income standard.

For recipients in institutions whose Medicaid eligibility is based on a special income standard established under § 435.236, FFP is available in expenditures for services provided to those individuals only if their income before deductions, as determined by SSI budget methodology, does not exceed 300 percent of the SSI benefit amount payable under section 1611(b)(1) of the Act to an individual in his own home who has no income or resources.

[58 FR 4933, Jan. 19, 1993]

§ 435.1006 Recipients of optional State supplements only.

FFP is available in expenditures for services provided to individuals receiving optional State supplements but not receiving SSI, if their income before deductions, as determined by SSI budget methodology, does not exceed 300 percent of the SSI benefit amount payable under section 1611(b)(1) of the Act to an individual who has no income and resources.

[45 FR 24887, Apr. 11, 1980]

§ 435.1007 Categorically needy, medically needy, and qualified Medicare beneficiaries.

(a) FFP is available in expenditures for covered services provided to categorically needy recipients, medically needy recipients, and qualified Medicare beneficiaries, subject to the restrictions contained in subpart K of this part and as provided in paragraphs (b) and (e) of this section. However, the restrictions listed in paragraphs (b) and (e) of this section do not apply to expenditures for medical assistance made on behalf of qualified Medicare beneficiaries under section 1905(p) of the Act; individuals receiving Medicaid as categorically needy under section 1902(a)(10)(A)(i) (I), (II), (III), (IV), (V), (VI), or (VII) and section 1902(a)(10)(A)(ii) (I), (IX), or (X) and section 1905(u) of the Act; individuals who are eligible to receive benefits (or would be eligible for those benefits if they were not in a medical institution); and any individuals deemed to be members of the groups identified in this sentence.

(b) Except as provided in paragraphs (c) and (d) of this section, FFP is not available in State expenditures for individuals (including the medically needy) whose annual income after deductions specified in § 435.831(a) and (c) exceeds the following amounts, rounded to the next higher multiple of $100.

(c) In the case of a family consisting only of two individuals, both of whom are adults and at least one of whom is aged, blind, or disabled, the State of California may use the amount of the AFDC payment most frequently made to a family of one adult and two children for purposes of computing the

133⅓ percent limitation (under the authority of section 4106 of Public Law 100–230).

(d) For purposes of paragraph (b)(1) of this section, a State that as of June 1, 1989, has in its State plan (as defined in section 2373(c)(5) of Public Law 98–369 as amended by section 9 of Public Law 100–93) an amount for individuals that was reasonably related to 133⅓ percent of the highest amount of AFDC which would ordinarily be paid to a family of two without income or resources may use an amount based upon a reasonable relationship to such an AFDC standard for a family of two.

(e) FFP is not available in expenditures for services provided to categorically needy and medically needy recipients subject to the FFP limits if their annual income, after the cash assistance income deductions and any income disregards in the State plan authorized under section 1902(r)(2) of the Act are applied, exceeds the 133⅓ percent limitation described under paragraphs (b), (c), and (d) of this section.

(f) A State may use the less restrictive income methodologies included under its State plan as authorized under § 435.601 in determining whether a family's income exceeds the limitation described in paragraph (b) of this section.

[58 FR 4933, Jan. 19, 1993, as amended at 66 FR 2321, 2667, Jan. 11, 2001]

§ 435.1008 FFP in expenditures for medical assistance for individuals who have declared United States citizenship or nationality under section 1137(d) of the Act and with respect to whom the State has not documented citizenship and identity.

FFP will not be available to a State with respect to expenditures for medical assistance furnished to individuals unless the State has obtained satisfactory documentary evidence of citizenship or national status, as described in § 435.407 that complies with the requirements of section 1903(x) of the Act. This requirement does not apply with respect to individuals declaring themselves to be citizens or nationals who are eligible for medical assistance and who are either entitled to benefits or enrolled in any parts of the Medicare program under title XVIII of the Social Security Act, or on the basis of receiving supplemental security income benefits under title XVI of the Act.

[71 FR 39225, July 12, 2006]

§ 435.1009 Institutionalized individuals.

(a) FFP is not available in expenditures for services provided to—

(1) Individuals who are inmates of public institutions as defined in § 435.1010; or

(2) Individuals under age 65 who are patients in an institution for mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) The exclusion of FFP described in paragraph (a) of this section does not apply during that part of the month in which the individual is not an inmate of a public institution or a patient in an institution for tuberculosis or mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient psychiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

[43 FR 45204, Sept. 29, 1978, as amended at 50 FR 13199, Apr. 3, 1985; 50 FR 38811, Sept. 25, 1985. Redesignated and amended at 71 FR 39225, July 12, 2006]

§ 435.1010 Definitions relating to institutional status.

For purposes of FFP, the following definitions apply:

Active treatment in intermediate care facilities for the mentally retarded means treatment that meets the requirements specified in the standard concerning active treatment for intermediate care facilities for persons with mental retardation under § 483.440(a) of this subchapter.

Child-care institution means a nonprofit private child-care institution, or a public child-care institution that accommodates no more than twenty-five children, which is licensed by the State

in which it is situated, or has been approved by the agency of the State responsible for licensing or approval of institutions of this type, as meeting the standards established for licensing. The term does not include detention facilities, forestry camps, training schools or any other facility operated primarily for the detention of children who are determined to be delinquent.

In an institution refers to an individual who is admitted to live there and receive treatment or services provided there that are appropriate to his requirements.

Inmate of a public institution means a person who is living in a public institution. An individual is not considered an inmate if—

(a) He is in a public educational or vocational training institution for purposes of securing education or vocational training; or

(b) He is in a public institution for a temporary period pending other arrangements appropriate to his needs.

Inpatient means a patient who has been admitted to a medical institution as an inpatient on recommendation of a physician or dentist and who—

(1) Receives room, board and professional services in the institution for a 24 hour period or longer, or

(2) Is expected by the institution to receive room, board and professional services in the institution for a 24 hour period or longer even though it later develops that the patient dies, is discharged or is transferred to another facility and does not actually stay in the institution for 24 hours.

Institution means an establishment that furnishes (in single or multiple facilities) food, shelter, and some treatment or services to four or more persons unrelated to the proprietor.

Institution for mental diseases means a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases, including medical attention, nursing care and related services. Whether an institution is an institution for mental diseases is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of individuals with mental diseases, whether or not it is licensed as such. An institution for the mentally retarded is not an institution for mental diseases.

Institution for the mentally retarded or persons with related conditions means an institution (or distinct part of an institution) that—

(a) Is primarily for the diagnosis, treatment, or rehabilitation of the mentally retarded or persons with related conditions; and

(b) Provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration of health or rehabilitative services to help each individual function at his greatest ability.

Institution for tuberculosis means an institution that is primarily engaged in providing diagnosis, treatment, or care of persons with tuberculosis, including medical attention, nursing care, and related services. Whether an institution is an institution for tuberculosis is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of tuberculosis, whether or not it is licensed as such.

Medical institution means an institution that—

(a) Is organized to provide medical care, including nursing and convalescent care;

(b) Has the necessary professional personnel, equipment, and facilities to manage the medical, nursing, and other health needs of patients on a continuing basis in accordance with accepted standards;

(c) Is authorized under State law to provide medical care; and

(d) Is staffed by professional personnel who are responsible to the institution for professional medical and nursing services. The services must include adequate and continual medical care and supervision by a physician; registered nurse or licensed practical nurse supervision and services and nurses' aid services, sufficient to meet nursing care needs; and a physician's guidance on the professional aspects of operating the institution.

Outpatient means a patient of an organized medical facility or distinct part of that facility who is expected by

the facility to receive, and who does receive, professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used or whether or not the patient remains in the facility past midnight.

Patient means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward maintenance, improvement, or protection of health, or lessening of illness, disability, or pain.

Persons with related conditions means individuals who have a severe, chronic disability that meets all of the following conditions:

(a) It is attributable to—

(1) Cerebral palsy or epilepsy; or

(2) Any other condition, other than mental illness, found to be closely related to mental retardation because this condition results in impairment of general intellectual functioning or adaptive behavior similar to that of mentally retarded persons, and requires treatment or services similar to those required for these persons.

(b) It is manifested before the person reaches age 22.

(c) It is likely to continue indefinitely.

(d) It results in substantial functional limitations in three or more of the following areas of major life activity:

(1) Self-care.

(2) Understanding and use of language.

(3) Learning.

(4) Mobility.

(5) Self-direction.

(6) Capacity for independent living.

Public institution means an institution that is the responsibility of a governmental unit or over which a governmental unit exercises administrative control. The term ''public institution'' does not include—

(a) A medical institution as defined in this section;

(b) An intermediate care facility as defined in §§ 440.140 and 440.150 of this chapter;

(c) A publicly operated community residence that serves no more than 16 residents, as defined in this section; or

(d) A child-care institution as defined in this section with respect to—

(1) Children for whom foster care maintenance payments are made under title IV-E of the Act; and

(2) Children receiving AFDC—foster care under title IV-A of the Act.

Publicly operated community residence that serves no more than 16 residents is defined in 20 CFR 416.231(b)(6)(i). A summary of that definition is repeated here for the information of readers.

(a) In general, a publicly operated community residence means—

(1) It is publicly operated as defined in 20 CFR 416.231(b)(2).

(2) It is designed or has been changed to serve no more than 16 residents and it is serving no more than 16; and

(3) It provides some services beyond food and shelter such as social services, help with personal living activities, or training in socialization and life skills. Occasional medical or remedial care may also be provided as defined in 45 CFR 228.1; and

(b) A publicly operated community residence does not include the following facilities, even though they accommodate 16 or fewer residents:

(1) Residential facilities located on the grounds of, or immediately adjacent to, any large institution or multiple purpose complex.

(2) Educational or vocational training institutions that primarily provide an approved, accredited, or recognized program to individuals residing there.

(3) Correctional or holding facilities for individuals who are prisoners, have been arrested or detained pending disposition of charges, or are held under court order as material witnesses or juveniles.

(4) Hospitals, nursing facilities, and intermediate care facilities for the mentally retarded.

[43 FR 45204, Sept. 29, 1978, as amended at 47 FR 28655, July 1, 1982; 47 FR 31532, July 20, 1982; 51 FR 19181, May 28, 1986; 52 FR 47934, Dec. 17, 1987; 53 FR 657, Jan. 11, 1988; 53 FR 20495, June 3, 1988; 56 FR 8854, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 56233, Nov. 10, 1994. Redesignated at 71 FR 39225, July 12, 2006]

REQUIREMENTS FOR STATE SUPPLEMENTS

§435.1011 Requirement for mandatory State supplements.

(a) Except as specified in paragraph (b) of this section, FFP is not available in Medicaid expenditures in any quarter in which the State does not have in effect an agreement with the Secretary under section 212 of Pub. L. 93–66 (July 9, 1973) for minimum mandatory State supplements of the basic SSI benefit.

(b) This section does not apply to any State that meets the conditions of section 212(f) of Pub. L. 93–66.

[43 FR 45204, Sept. 29, 1978. Redesignated at 71 FR 39225, July 12, 2006]

§435.1012 Requirement for maintenance of optional State supplement expenditures.

(a) This section applies to States that make optional State supplement payments under section 1616(a) of the Act and mandatory supplement payments under section 212(a) of Pub. L. 93–66.

(b) FFP in Medicaid expenditures is not available during any period in which the State does not have in effect an agreement with the Secretary under section 1618 of the Act to maintain its supplementary payments.

[43 FR 45204, Sept. 29, 1978, as amended at 55 FR 48609, Nov. 21, 1990. Redesignated at 71 FR 39225, July 12, 2006]

Subpart L—Option for Coverage of Special Groups

SOURCE: 66 FR 2667, Jan. 11, 2001, unless otherwise noted.

§435.1100 Basis and scope.

(a) *Statutory basis.* Section 1920A of the Act allows States to provide Medicaid services to children under age 19 during a period of presumptive eligibility, prior to a formal determination of Medicaid eligibility.

(b) Scope. This subpart prescribes the requirements for providing medical assistance to special groups who are not eligible for Medicaid as categorically or medically needy.

PRESUMPTIVE ELIGIBILITY FOR CHILDREN

§435.1101 Definitions related to presumptive eligibility for children.

Application form means at a minimum the form used to apply for Medicaid under the poverty-level-related eligibility groups described in section 1902(l) of the Act or a joint form for children to apply for the State Children's Health Insurance Program and Medicaid.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a Medicaid application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf a Medicaid application has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish the regular Medicaid eligibility of a child of the age involved.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is authorized to determine eligibility of a child for medical assistance

under the Medicaid State plan, or eligibility of a child for child health assistance under the State Children's Health Insurance Program;

(6) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(7) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(8) Is a State or Tribal child support enforcement agency;

(9) Is an organization that—

(i) Provides emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(ii) Is a State or Tribal office or entity involved in enrollment in the program under title XIX, Part A of title IV, or title XXI; or

(iii) Determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); and

(10) Any other entity the State so deems, as approved by the Secretary.

Services means all services covered under the plan including EPSDT (see part 440 of this chapter).

[66 FR 2667, Jan. 11, 2001, as amended at 66 FR 33822, June 25, 2001]

§ 435.1102 General rules.

(a) The agency may provide services to children under age 19 during one or more periods of presumptive eligibility following a determination by a qualified entity that the child's estimated gross family income or, at the State's option, the child's estimated family income after applying simple disregards, does not exceed the applicable income standard.

(b) If the agency elects to provide services to children during a period of presumptive eligibility, the agency must—

(1) Provide qualified entities with application forms for Medicaid and information on how to assist parents, caretakers and other persons in completing and filing such forms;

(2) Establish procedures to ensure that qualified entities—

(i) Notify the parent or caretaker of the child at the time a determination regarding presumptive eligibility is made, in writing and orally if appropriate, of such determination;

(ii) Provide the parent or caretaker of the child with a regular Medicaid application form;

(iii) Within five working days after the date that the determination is made, notify the agency that a child is presumptively eligible;

(iv) For children determined to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate, that—

(A) If a Medicaid application on behalf of the child is not filed by the last day of the following month, the child's presumptive eligibility will end on that last day; and

(B) If a Medicaid application on behalf of the child is filed by the last day of the following month, the child's presumptive eligibility will end on the day that a decision is made on the Medicaid application; and

(v) For children determined not to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate—

(A) Of the reason for the determination; and

(B) That he or she may file an application for Medicaid on the child's behalf with the Medicaid agency;

(3) Provide all services covered under the plan, including EPSDT; and

(4) Allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

(c) The agency must adopt reasonable standards regarding the number of periods of presumptive eligibility that will be authorized for a child in a given time frame.

PART 436—ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45218, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions and Definitions

§ 436.1 Purpose and applicability.

This part sets forth, for Guam, Puerto Rico, and the Virgin Islands—

(a) The eligibility provisions that a State plan must contain;

(b) The mandatory and optional groups of individuals to whom Medicaid is provided under a State plan;

(c) The eligibility requirements and procedures that a Medicaid agency must use in determining and redetermining eligibility, and requirements it may not use; and

(d) The availability of FFP for providing Medicaid and for administering the eligibility provisions of the plan.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

§ 436.2 Basis.

This part implements the following sections of the Act and public laws that state requirements and standards for eligibility:

402(a)(22) Eligibility of deemed recipients of AFDC who receive zero payments because of recoupment of overpayments.
402(a)(37) Eligibility of individuals who lose AFDC eligibility due to increased earnings.
414(g) Eligibility of certain individuals participating in work supplementation programs.

473(b) Eligibility of children in foster care and adopted children who are deemed AFDC recipients.
1902(a)(8) Opportunity to apply; assistance must be furnished promptly.
1902(a)(10) Required and optional groups.
1902(a)(12) Determination of blindness.
1902(a)(16) Out-of-State care for State residents.
1902(a)(17) Standards for determining eligibility; flexibility in the application of income eligibility standards.
1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.
1902(a)(34) Three-month retroactive eligibility.
1902(a) (second paragraph after (47)) Eligibility despite increased monthly insurance benefits under title II.
1902(a)(55) Mandatory use of outstation locations other than welfare offices to receive and initially process applications of certain low-income pregnant women, infants, and children under age 19.
1902(b) Prohibited conditions for eligibility: Age requirements of more than 65 years; State residence requirements excluding individuals who reside in the State; and Citizenship requirement excluding United States citizens.
1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.
1902(e)(2) Minimum eligibility period for recipients enrolled in HMO.
1902(e)(3) Optional coverage of certain disabled children at home.
1902(e)(4) Eligibility of newborn children of Medicaid-eligible women.
1902(e)(5) Eligibility of pregnant women for extended coverage for a specified period after pregnancy ends.
1903(v) Payment for emergency services under Medicaid provided to aliens.
1905(a) (i)-(viii) List of eligible individuals.
1905(a) (clause following (21)) Prohibitions against providing Medicaid to certain institutionalized individuals.
1905(a) (second sentence) Definition f essential person.
1905(d)(2) Definition of resident of an intermediate care facility for the mentally retarded.
1905(n) Definition of qualified pregnant woman and child.
1912(a) Conditions of eligibility.
1915(c) Home or community based services.
1915(d) Home and community-based services for individuals age 65 or older.
412(e)(5) of Immigration and Nationality Act-Eligibility of certain refugees.
Pub. L. 93–66, section 230 Deemed eligibility of certain essential persons.
Pub. L. 93–66, section 231 Deemed eligibility of certain persons in medical institutions.
Pub. L. 93–66, section 232 Deemed eligibility of certain blind and disabled medically indigent persons.
Pub. L. 96–272, section 310(b)(1) Continued eligibility of certain recipients of Veterans Administration pensions.
Pub. L. 99–509, section 9406 Payment for emergency medical services provided to aliens.
Pub. L. 99–603, section 201 Aliens granted legalized status under section 245A of the Immigration and Nationality Act (8 U.S.C. 1255a) may under certain circumstances be eligible for Medicaid.
Pub. L. 99–603, section 302 Aliens granted legalized status under section 210 of the Immigration and Nationality Act may under certain circumstances be eligible for Medicaid (8 U.S.C. 1160).
Pub. L. 99–603, section 303 Aliens granted legal status under section 210A of the Immigration and Nationality Act may under certain circumstances be eligible for Medicaid (8 U.S.C. 1161).

[52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987, as amended at 55 FR 36820, Sept. 7, 1990; 55 FR 48609, Nov. 21, 1990; 57 FR 29155, June 30, 1992; 59 FR 48811, Sept. 23, 1994]

§ 436.3 Definitions and use of terms.

As used in this part—

AABD means aid to the aged, blind, and disabled under title XVI of the Act;

AB means aid to the blind under title X of the Act;

AFDC means aid to families with dependent children under title IV-A of the Act;

APTD means aid to the permanently and totally disabled under title XIV of the Act;

Categorically needy refers to families and children, aged, blind or disabled individuals, and pregnant women listed under subparts B and C of this part who are eligible for Medicaid. Subpart B of this part describes the mandatory eligibility groups who, generally, are receiving or deemed to be receiving cash assistance under the Act. These mandatory groups are specified in sections 1902(a)(10)(A)(i) and 1902(e) of the Act. Subpart C of this part describes the optional eligibility groups of individuals who, generally, meet the categorical requirements that are the same as or less restrictive than those of the cash assistance programs but are not receiving cash payments. These optional groups are specified in sections 1902(a)(10)(A)(ii) and 1902(e) of the Act.

Families and children refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90; 233.100). In addition, this group includes individuals under age 21 who are not deprived of parental support or care but who are financially eligible under AFDC or medically needy rules (see optional coverage group, § 436.222);

Medically needy means families, children, aged, blind, or disabled individuals, and pregnant women listed in subpart D of this part who are not listed in subparts B and C of this part as categorically needy but who may be eligible for Medicaid under this part because their income and resources are within limits set by the State under its Medicaid plan (including persons whose income and resources fall within these limits after their incurred expenses for medical or remedial care are deducted). (Specific financial requirements for determining eligibility of the medically needy appear in subpart I of this part.)

OAA means old age assistance under title I of the Act;

OASDI means old age, survivors, and disability insurance under Title II of the Act.

Optional targeted low-income child means a child under age 19 who meets the financial and categorical standards described below.

(1) *Financial need.* An optional targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved;

(ii) Resides in a State with no Medicaid applicable income level (as defined in § 457.10 of this chapter); or,

(iii) Resides in a State that has a Medicaid applicable income level (as defined in § 457.10) and has family income that either:

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points (expressed as a percentage of the Federal poverty line); or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under the policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage and State maintenance of effort.* An optional targeted low-income child is not covered under a group health plan or health insurance coverage, or would not be eligible for Medicaid under the policies of the State plan in effect on March 31, 1997; except that, for purposes of this standard—

(i) A child shall not be considered to be covered by health insurance coverage based on coverage offered by the State under a program in operation prior to July 1, 1997 if that program received no Federal financial participation;

(ii) A child shall not be considered to be covered under a group health plan or health insurance coverage if the child did not have reasonable geographic access to care under that coverage.

(3) For purposes of this section, policies of the State plan under title XIX plan include policies under a Statewide demonstration project under section 1115(a) of the Act other than a demonstration project that covered an expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980; 46 FR 47989, Sept. 30, 1981; 58 FR 4934, Jan. 19, 1993; 66 FR 2668, Jan. 11, 2001]

§ 436.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom Medicaid is provided, as specified in subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§ 436.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

§ 436.110 Individuals receiving cash assistance.

(a) A Medicaid agency must provide Medicaid to individuals receiving cash assistance under OAA, AFDC, AB, APTD, or AABD.

(b) For purposes of this section, an individual is receiving cash assistance if his needs are considered in determining the amount of the payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient under the State's plan for OAA, AFDC, AB, APTD, or AABD if that plan were as broad as allowed under the Act for FFP.

§ 436.111 Individuals who are not eligible for cash assistance because of a requirement not applicable under Medicaid.

(a) The agency must provide Medicaid to individuals who would be eligible for OAA, AB, APTD, or AABD except for an eligibility requirement used in those programs that is specifically prohibited under title XIX of the Act.

(b) The agency also must provide Medicaid to:

(1) Individuals denied AFDC solely because of policies requiring the deeming of income and resources of the following individuals who are not included as financially responsible relatives under section 1902(a)(17)(D) of the Act:

(i) Stepparents who are not legally liable for support of stepchildren under a State law of general applicability;

(ii) Grandparents

(iii) Legal guardians;

(iv) Aliens sponsors who are not organizations; and

(v) Siblings.

(2) [Reserved]

[58 FR 4934, Jan. 19, 1993, as amended at 59 FR 43053, Aug. 22, 1994]

§ 436.112 Individuals who would be eligible for cash assistance except for increased OASDI under Pub. L. 92–336 (July 1, 1972).

The agency must provide Medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving cash assistance; or

(2) He would have been eligible for cash assistance if he had applied, and the Medicaid plan covered this optional group; or

(3) He would have been eligible for cash assistance if he were not in a medical institution or intermediate care facility, and the Medicaid plan covered this optional group.

(b) The individual would currently be eligible for cash assistance except that the increase in OASDI under Pub. L. 92–336 raised his income over the limit allowed under the cash assistance program. This includes an individual who—

(1) Meets all current requirements for cash assistance except for the requirement to file an application; or

(2) Would meet all current requirements for cash assistance if he were not in a medical institution or intermediate care facility, and the Medicaid plan covers this optional group.

§ 436.114 Individuals deemed to be receiving AFDC.

(a) The Medicaid agency must provide Medicaid to individuals deemed to be receiving AFDC, as specified in this section.

(b) The State must deem individuals to be receiving AFDC who are denied a cash payment from the title IV-A State agency solely because the amount of the AFDC payment would be less than $10.

(c) The State may deem participants in a work supplementation program to be receiving AFDC under section 414(g) of the Act. This section permits States, for purposes of title XIX, to deem an individual and any child or relative of the individual (or other individual living in the same household) to be receiving AFDC, if the individual—

(1) Participates in a State-operated work supplementation program under section 414 of the Act; and

(2) Would be eligible for an AFDC cash payment if the individual were not participating in the work supplementation program.

(d) The State must deem to be receiving AFDC those individuals who are denied AFDC payments from the title IV-A State agency solely because that agency is recovering an overpayment.

(e) The State must deem to be receiving AFDC individuals described in section 473(a)(1) of the Act—

(1) For whom an adoption assistance agreement is in effect under title IV-E of the Act, whether or not adoption assistance is being provided or an interlocutory or other judicial decree of adoption has been issued; or

(2) For whom foster care maintenance payments are made under title IV-E of the Act.

(f) The State must deem an individual to be receiving AFDC if a new collection or increased collection of child or spousal support under title IV-D of the Social Security Act results in the termination of AFDC eligibility in accordance with section 406(h) of the Social Security Act. States must continue to provide Medicaid for four consecutive calendar months, beginning with the first month of AFDC ineligibility, to each dependent child and each relative with whom such a child is living (including the eligible spouse of such relative as described in section 406(b) of the Social Security Act) who:

(1) Becomes ineligible for AFDC on or after August 16, 1984; and

(2) Has received AFDC for at least three of the six months immediately preceding the month in which the individual becomes ineligible for AFDC; and

(3) Becomes ineligible for AFDC wholly or partly as a result of the initiation of or an increase in the amount of a child or spousal support collection under title IV-D.

(g)(1) Except as provided in paragraph (g)(2) of this section, individuals who are eligible for extended Medicaid lose this coverage if they move to another State during the 4-month period. However, if they move back to and reestablish residence in the State in which they have extended coverage, they are eligible for any of the months remaining in the 4-month period in which they are residents of the State.

(2) If a State has chosen in its State plan to provide Medicaid to non-residents, the State may continue to provide the 4-month extended benefits to individuals who have moved to another State.

(h) For purposes of paragraph (f) of this section:

(1) The new collection or increased collection of child or spousal support results in the termination of AFDC eligibility when it actively causes or contributes to the termination. This occurs when:

(i) The change in support collection in and of itself is sufficient to cause ineligibility. This rule applies even if the support collection must be added to other, stable income. It also applies even if other independent factors, alone or in combination with each other, might simultaneously cause ineligibility; or

(ii) The change in support contributes to ineligibility but does not by itself cause ineligibility. Ineligibility must result when the change in support is combined with other changes in income or changes in other circumstances and the other changes in income or circumstances cannot alone or in combination result in termination without the change in support.

(2) In cases of increases in the amounts of both the support collections and earned income, eligibility under this section does not preclude eligibility under 45 CFR 233.20(a)(14) or section 1925 of the Social Security Act (which was added by section 303(a) of the Family Support Act of 1988 (42 U.S.C. 1396r–6)). Extended periods resulting from both an increase in the amount of the support collection and from an increase in earned income must run concurrently.

[46 FR 47989, Sept. 30, 1981, as amended at 52 FR 43072, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987; 55 FR 48610, Nov. 21, 1990; 59 FR 59377, Nov. 17, 1994]

§ 436.116 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide Medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4 calendar month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4 calendar month period also begins retroactively with the first month in which AFDC was erroneously paid.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980]

§ 436.118 Children for whom adoption assistance or foster care maintenance payments are made.

The agency must provide Medicaid to children for whom adoption assistance or foster care maintenance payments are made under title IV-E of the Act.

[47 FR 28656, July 1, 1982]

§ 436.120 Qualified pregnant women and children who are not qualified family members.

(a) The Medicaid agency must provide Medicaid to a pregnant woman whose pregnancy has been medically verified and who—

(1) Would be eligible for an AFDC cash payment (or would be eligible for an AFDC cash payment if coverage under the State's AFDC plan included the AFDC-unemployed parents program) if her child had been born and was living with her in the month of payment;

(2) Is a member of a family that would be eligible for an AFDC cash payment if the State's AFDC plan included an AFDC-unemployed parents program; or

(3) Meets the income and resource requirements of the State's approved AFDC plan. In determining whether the woman meets the AFDC income and resource requirements, the unborn child or children are considered members of the household, and the woman's family is treated as though deprivation exists.

(b) The provisions of paragraphs (a)(1) and (2) of this section are effective October 1, 1984. The provisions of paragraph (a)(3) of this section are effective July 1, 1986.

(c) The agency must provide Medicaid to children who meet all of the following criteria:

(1) They are born after September 30, 1983;

(2) Effective October 1, 1988, they are under age 6 (or if designated by the State, any age that exceeds age 6 but does not exceed age 8), and effective October 1, 1989 they are under age 7 (or if designated by the State, any age that exceeds age 7 but does not exceed age 8); and

(3) They meet the income and resource requirements of the State's approved AFDC plan.

[52 FR 43072, Nov. 9, 1987, as amended at 55 FR 48610, Nov. 21, 1990; 58 FR 48614, Sept. 17, 1993]

§ 436.121 Qualified family members.

(a) *Definition.* A *qualified family member* is any member of a family, including pregnant women and children eligible for Medicaid under § 436.120 of this subpart, who would be receiving AFDC cash benefits on the basis of the unemployment of the principal wage earner under section 407 of the Act had the State not chosen to place time limits on those benefits as permitted under section 407(b)(2)(B)(i) of the Act.

(b) *State plan requirement.* The State plan must provide that the State makes Medicaid available to any individual who meets the definition of ''qualified family member'' as specified in paragraph (a) of this section.

(c) *Applicability.* The provisions in this section are applicable from October 1, 1992, through September 30, 1998.

[58 FR 48614, Sept. 17, 1993]

§ 436.122 Pregnant women eligible for extended coverage.

(a) The Medicaid agency must provide categorically needy Medicaid eligibility for an extended period following termination of pregnancy to women who, while pregnant, applied for, were eligible for, and received Medicaid services on the day that their pregnancy ends. This period extends from the last day of pregnancy through the end of the month in which a 60-day period, beginning on the last day of the pregnancy, ends. Eligibility must be provided, regardless of changes in the woman's financial circumstances that may occur within this extended period. These pregnant women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(b) The provisions of paragraph (a) of this section apply to Medicaid furnished on or after April 7, 1986.

[55 FR 48610, Nov. 21, 1990]

§ 436.124 Newborn children.

(a) The Medicaid agency must provide categorically needy Medicaid eligibility to a child born to a woman who is eligible for and receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as categorically needy for one year so long as the woman remains eligible and the child is a member of the woman's household. If the mother's basis of eligibility changes to medically needy, the child is eligible as medically needy under § 436.301(b)(1)(iii).

(b) The requirements under paragraph (a) of this section apply to children born on or after October 1, 1984.

[52 FR 43073, Nov. 9, 1987; 52 FR 48438, Dec. 22, 1987]

§ 436.128 Coverage for certain qualified aliens.

The agency must provide the services necessary for the treatment of an emergency medical condition as defined in § 440.255(c) of this chapter to those aliens described in § 436.406(c) of this subpart.

[55 FR 36820, Sept. 7, 1990]

Subpart C—Options for Coverage as Categorically Needy

§ 436.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 436.201 Individuals included in optional groups.

(a) The agency may choose to cover as optional categorically needy any group or groups of the following individuals who are not receiving cash assistance and who meet the appropriate eligibility criteria for groups specified in the separate sections of this subpart:

(1) Aged individuals (65 years of age or older);

(2) Blind individuals (as defined in § 436.530);

(3) Disabled individuals (as defined in § 436.541);

(4) Individuals under age 21 (or, at State option), under age 20, 19, or 18) or reasonable classifications of these individuals;

(5) Specified relatives under section 406(b)(1) of the Act who have in their care an individual who is determined to be dependent) as specified in § 436.510;

(6) Pregnant women; and

(7) Essential spouses specified under § 436.230.

(b) If the agency provides Medicaid to any individual in an optional group specified in paragraph (a) of this section, the agency must provide Medicaid to all individuals who apply and are found eligible to be members of that group.

[58 FR 4934, Jan. 19, 1993]

Options for Coverage of Families and Children and Aged, Blind, and Disabled Individuals, Including Pregnant Women

§ 436.210 Individuals who meet the income and resource requirements of the cash assistance programs.

The agency may provide Medicaid to any group or groups of individuals specified under § 436.201(a)(1), (a)(2), (a)(3), (a)(5), and (a)(6) who are not mandatory categorically needy and

who meet the income and resource requirements of the appropriate cash assistance program for their status (that is, OAA, AFDC, AB, APTD, or AABD).

[58 FR 4935, Jan. 19, 1993]

§ 436.211 Individuals who would be eligible for cash assistance if they were not in medical institutions.

The agency may provide Medicaid to any group or groups of individuals specified in § 436.201(a) who are in title XIX reimbursable medical institutions and who:

(a) Are ineligible for the cash assistance program appropriate for their status (that is, OAA, AFDC, AB, APTD, or AABD) because of lower income standards used under the program to determine eligibility for institutionalized individuals; but

(b) Would be eligible for aid or assistance under the State's approved plan under OAA, AFDC, AB, APTD, or AABD if they were not institutionalized.

[58 FR 4935, Jan. 19, 1993]

§ 436.212 Individuals who would be eligible for cash assistance if the State plan for OAA, AFDC, AB, APTD, or AABD were as broad as allowed under the Act.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 436.201(a) who:

(1) Would be eligible for OAA, AFDC, AB, APTD, or AABD if the State's plan under those programs included individuals whose coverage under title I, IV-A, X, XIV, or XVI of the Act is optional (for example, the agency may provide Medicaid to individuals who are 18 years of age and who are attending secondary school full-time and are expected to complete their education before age 19, even though the State's AFDC plan does not include them); or

(2) Would qualify for OAA, AFDC, AB, APTD, or AABD if the State's plan under those programs did not contain eligibility requirements more restrictive than, or in addition to, those required under the appropriate title of the Act. (For example, the agency may provide Medicaid to individuals who would meet the Federal definition of disability, 45 CFR 233.80, but who do not meet the State's more restrictive definitions.)

(b) The agency may cover one or more optional groups under any of the titles of the Act without covering all such groups.

[43 FR 45218, Sept. 29, 1978, as amended at 45 FR 24887, Apr. 11, 1980; 46 FR 47990, Sept. 30, 1981; 58 FR 4935, Jan. 19, 1993]

§ 436.217 Individuals receiving home and community-based services.

The agency may provide Medicaid to any group or groups of individuals in the community who meet the following requirements:

(a) The group would be eligible for Medicaid if institutionalized.

(b) In the absence of home and community-based services under a waiver granted under part 441—

(1) Subpart G of this subchapter, the group would otherwise require the level of care furnished in a hospital, NF, or an ICF/MR; or

(2) Subpart H of this subchapter, the group would otherwise require the level of care furnished in a NF and are age 65 or older.

(c) The group receives the waivered services.

[57 FR 29155, June 30, 1992]

§ 436.220 Individuals who would meet the income and resource requirements under AFDC if child care costs were paid from earnings.

(a) The agency may provide Medicaid to any group or groups of individuals specified under § 436.201(a)(4), (a)(5), and (a)(6) who would meet the income and resource requirements under the State's AFDC plan if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State's AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.

[43 FR 45218, Sept. 29, 1978, as amended at 58 FR 4935, Jan. 19, 1993]

§ 436.222 Individuals under age 21 who meet the income and resource requirements of AFDC.

(a) The agency may provide Medicaid to individuals under age 21 (or at State

option, under age 20, 19, or 18) or reasonable categories of these individuals as specified in paragraph (b) of this section, who are not receiving cash assistance but who meet the income and resource requirements of the State's approved AFDC plan.

(b) The agency may cover all individuals described in paragraph (a) of this section or reasonable classifications of those individuals. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals of the same age in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. If the agency covers these individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47990, Sept. 30, 1981, as amended at 58 FR 4935, Jan. 19, 1993]

§ 436.224 Individuals under age 21 who are under State adoption assistance agreements.

(a) The agency may provide Medicaid to individuals under the age of 21 (or, at State option, age 20, 19, or 18)—

(1) For whom an adoption agreement (other than an agreement under title IV-E) between the State and adoptive parent(s) is in effect;

(2) Who, the State agency responsible for adoption assistance has determined, cannot be placed with adoptive parents without Medicaid because the child has special needs for medical or rehabilitative care; and

(3) Who meet either of the following:

(i) Were eligible for Medicaid under the State plan before the adoption agreement was entered into; or

(ii) Would have been eligible for Medicaid before the adoption agreement was entered into, if the eligibility standards and methodologies of the foster care program were used without employing the threshold title IV-A eligibility determination.

(b) For adoption assistance agreements entered into before April 7, 1986—

(1) The agency must deem the requirements of paragraph (a)(1) and (2) of this section to be met if the State adoption assistance agency determines that—

(i) At the time of the adoption placement, the child had special needs for medical or rehabilitative care that made the child difficult to place; and

(ii) There is in effect an adoption assistance agreement between the State and the adoptive parent(s).

(2) The agency must deem the requirements of paragraph (a)(3) of this section to be met if the child was found by the State to be eligible for Medicaid before the adoption assistance agreement was entered into.

[55 FR 48610, Nov. 21, 1990]

§ 436.229 Optional targeted low-income children.

The agency may provide Medicaid to—

(a) All individuals under age 19 who are optional targeted low-income children as defined in § 436.3; or

(b) Reasonable categories of these individuals.

[66 FR 2668, Jan. 11, 2001]

OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 436.230 Essential spouses of aged, blind, or disabled individuals receiving cash assistance.

The agency may provide Medicaid to the spouse of an individual receiving OAA, AB, APTD, or AABD, if—

(a) The spouse is living with the individual receiving cash assistance;

(b) The cash assistance agency has determined that the spouse is essential to the well-being of the individual and

has considered the spouse's needs in determining the amount of cash assistance provided to the individual.

Subpart D—Optional Coverage of the Medically Needy

§ 436.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§ 436.301 General rules.

(a) A Medicaid agency may provide Medicaid to individuals specified in this subpart who:

(1) Either:

(i) Have income that meets the standard in § 436.811; or

(ii) If their income is more than allowed under the standard, have incurred medical expenses at least equal to the difference between their income and the applicable income standards; and

(2) Have resources that meet the standard in §§ 436.840 and 436.843.

(b) If the agency chooses this option, the following provisions apply:

(1) The agency must provide Medicaid to the following individuals who meet the requirements of paragraph (a) of this section:

(i) All pregnant women during the course of their pregnancy who, except for income and resources, would be eligible for Medicaid as mandatory or optional categorically needy under subparts B and C of this part;

(ii) All individuals under 18 years of age who, except for income and resources, would be eligible for Medicaid as mandatory categorically needy under subpart B of this part;

(iii) All newborn children born on or after October 1, 1984, to a woman who is eligible as medically needy and receiving Medicaid on the date of the child's birth. The child is deemed to have applied and been found eligible for Medicaid on the date of birth and remains eligible as medically needy for ne year so long as the woman remains eligible and the child is a member of the woman's household. If the woman's basis of eligibility changes to categorically needy, the child is eligible as categorically needy under § 436.124. The woman is considered to remain eligible if she meets the spend-down requirements in any consecutive budget period following the birth of the child.

(iv) Women who, while pregnant, applied for, were eligible for, and received Medicaid services as medically needed on the day that their pregnancy ends. The agency must provide medically needy eligibility to these women for an extended period following termination of pregnancy. This period begins on the last day of the pregnancy and extends through the end of the month in which a 60-day period following termination of pregnancy ends. Eligibility must be provided, regardless of changes in the women's financial circumstances that may occur within this extended period. These women are eligible for the extended period for all services under the plan that are pregnancy-related (as defined in § 440.210(c)(1) of this subchapter).

(2) The agency may provide Medicaid to any or all of the following groups of individuals:

(i) Individuals under age 21 (§ 436.308).

(ii) Specified relatives (§ 436.310).

(iii) Aged (§ 436.320).

(iv) Blind (§ 436.321).

(v) Disabled (§ 436.322).

(3) If the agency provides Medicaid to any individual in a group specified in paragraph (b)(2) of this section, the agency must provide Medicaid to all individuals eligible to be members of that group.

[46 FR 47990, Sept. 30, 1981; 46 FR 54743, Nov. 4, 1981, as amended at 52 FR 43073, Nov. 9, 1987; 55 FR 48610, Nov. 21, 1990; 58 FR 4935, Jan. 19, 1993]

§ 436.308 Medically needy coverage of individuals under age 21.

(a) If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals under age 21 (or at State option, under age 20, 19, or 18) as specified in paragraph (b) of this section:

(1) Who would not be covered under the mandatory medically needy group of individuals under 18 under § 436.301(b)(1)(ii); and

(2) Who meet the income and resource requirements of subpart I of this part.

(b) The agency may cover all individuals in paragraph (a) of this section or

individuals in reasonable classifications. Examples of reasonable classifications are as follows:

(1) Individuals in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide Medicaid to individuals placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals in adoptions subsidized in full or in part by a public agency.

(3) Individuals in nursing facilities when nursing facility services are provided under the plan to individuals within the age group selected under this provision. When the agency covers such individuals, it may also provide Medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

[46 FR 47990, Sept. 30, 1981, as amended at 58 FR 4935, Jan. 19, 1993]

§ 436.310 Medically needy coverage of specified relatives.

(a) If the agency provides for the medically needy, it may provide Medicaid to specified relatives, defined in paragraph (b) of this section, who meet the income and resource requirements of subpart I of this part.

(b) *Specified relatives* means individuals who:

(1) Are listed under section 406(b)(1) of the Act and in 45 CFR 233.90(c)(1)(v)(A); and

(2) Have in their care an individual who is determined to be (or would, if needy, be) dependent, as specified in § 436.510.

[58 FR 4936, Jan. 19, 1993]

§ 436.320 Medically needy coverage of the aged.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to individuals who—

(a) Are 65 years of age and older, as provided for in § 436.520; and

(b) Meet the income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.321 Medically needy coverage of the blind.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to blind individuals who meet—

(a) The requirements for blindness, as specified in §§ 436.530 and 436.531; and

(b) The income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.322 Medically needy coverage of the disabled.

If the agency provides Medicaid to the medically needy, it may provide Medicaid to disabled individuals who meet—

(a) The requirements for disability, as specified in §§ 436.540 and 436.541; and

(b) The income and resource requirements of subpart I of this part.

[46 FR 47991, Sept. 30, 1981]

§ 436.330 Coverage for certain aliens.

If an agency provides Medicaid to the medically needy, it must provide the services necessary for the treatment of an emergency medical condition, as defined in § 440.255(c) of this chapter to those aliens described in § 436.406(c) of this subpart.

[55 FR 36820, Sept. 7, 1990]

Subpart E—General Eligibility Requirements

§ 436.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of the part.

§ 436.401 General rules.

(a) The agency may not impose any eligibility requirement that is prohibited under title XIX.

(b) The agency must base any optional group covered under subparts B

and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and are consistent with the objectives of title XIX.

(c) The agency must not use requirements for determining eligibility for optional coverage groups that are more restrictive than those used under the State plans for OAA, AFDC, AB, APTD, or AABD.

§ 436.402 [Reserved]

§ 436.403 State residence.

(a) *Requirement.* The agency must provide Medicaid to eligible residents of the State, including residents who are absent from the State. The conditions under which payment for service is provided to out-of-State residents are set forth in § 431.52 of this chapter.

(b) *Definition.* For purposes of this section—*Institution* has the same meaning as *Institution* and *Medical institution*, as defined in § 435.1010 of this chapter. For purposes of State placement, the term also includes ''foster care homes'', licensed as set forth in 45 CFR 1355.20, and providing food, shelter and supportive services to one or more persons unrelated to the proprietor.

(c) *Incapability of indicating intent.* For purposes of this section, an individual is considered incapable of indicating intent if the individual—

(1) Has an I.Q. of 49 or less or has a mental age of 7 or less, based on tests acceptable to the mental retardation agency in the State;

(2) Is judged legally incompetent; or

(3) Is found incapable of indicating intent based on medical documentation obtained from a physician, psychologist, or other person licensed by the State in the field of mental retardation.

(d) *Who is a State resident.* A resident of a State is any individual who:

(1) Meets the conditions in paragraphs (e) through (h) of this section; or

(2) Meets the criteria specified in an interstate agreement under paragraph (j) of this section.

(e) *Placement by a State in an out-of-state institution*—(1) *General rule.* Any agency of the State, including an entity recognized under State law as being under contract with the State for such purposes, that arranges for an individual to be placed in an institution located in another State, is recognized as acting on behalf of the State in making a placement. The State arranging or actually making the placement is considered as the individual's State of residence.

(2) Any action beyond providing information to the individual and the individual's family would constitute arranging or making a State placement. However, the following actions do not constitute State placement:

(i) Providing basic information to individuals about another State's Medicaid program, and information about the availability of health care services and facilities in another State.

(ii) Assisting an individual in locating an institution in another State provided the individual is capable of indicating intent and independently decides to move.

(3) When a competent individual leaves the facility in which the individual is placed by a State, that individual's State of residency for Medicaid purposes is the State where the individual is physically located.

(4) Where placement is initiated by a State because the State lacks a sufficient number of appropriate facilities to provide services to its residents, the State making the placement is the individual's State of residence for Medicaid purposes.

(f) *Individuals receiving title IV-E payments.* For individuals of any age who are receiving Federal payment for foster care and adoption assistance under title IV-E of the Social Security Act, the State of residence is the State where the child lives.

(g) *Individuals under age 21.* (1) For any individual who is emancipated from his or her parents or who is married and capable of indicating intent, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(2) For any individual not residing in an institution as defined in paragraph (b) whose Medicaid eligibility is based on blindness or disability, the State of residence is the State in which the individual is living.

(3) For any other non-institutionalized individual not subject to paragraph (h)(1) or (h)(2) of this section, the State of residence is determined in accordance with 45 CFR 233.40, the rules governing residence under the AFDC program.

(4) For any institutionalized individual who is neither married nor emancipated, the State of residence is—

(i) The parents' or legal guardian's current State of residence at the time of placement; or

(ii) The current State of residence of the parent or legal guardian who files the application, if the individual is institutionalized in that State. If a legal guardian has been appointed and the parental rights are terminated, the State of residence of the guardian is used instead of the parent's.

(iii) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(h) *Individuals age 21 and over.* (1) For any individual not residing in an institution as defined in paragraph (b), the State of residence is the State where the individual is—

(i) Living with the intention to remain there permanently or for an indefinite period (or if incapable of stating intent, where the individual is living); or

(ii) Living and which the individual entered with a job commitment or seeking employment (whether or not currently employed).

(2) For any institutionalized individual who became incapable of indicating intent before age 21, the State of residence is—

(i) That of the parents applying for Medicaid on the individual's behalf, if the parents reside in separate States;

(ii) The parent's or legal guardian's State of residence at the time of placement; or

(iii) The current State of residence of the parent or legal guardian who files the application, if the individual is institutionalized in that State. If a legal guardian has been appointed and parental rights are terminated, the State of residence of the guardian is used instead of the legal parent's.

(iv) The State of residence of the individual or party who files an application is used if the individual has been abandoned by his or her parent(s), does not have a legal guardian and is institutionalized in that State.

(3) For any institutionalized individual who became incapable of indicating intent at or after age 21, the State of residence is the State in which the individual is physically present, except where another State makes a placement.

(4) For any other institutionalized individual, the State of residence is the State where the individual is living with the intention to remain there permanently or for an indefinite period.

(i) *Specific prohibitions.* (1) The agency may not deny Medicaid eligibility because an individual has not resided in the State for a specified period.

(2) The agency may not deny Medicaid eligibility to an individual in an institution, who satisfies the residency rules set forth in this section, on the grounds that the individual did not establish residence in the State before entering the institution.

(3) The agency may not deny or terminate a resident's Medicaid eligibility because of that person's temporary absence from the State if the person intends to return when the purpose of the absence has been accomplished, unless another State has determined that the person is a resident there for purposes of Medicaid.

(j) *Interstate agreements.* A State may have a written agreement with another State setting forth rules and procedures resolving cases of disputed residency. These agreements may establish criteria other than those specified in paragraphs (c) through (h) of this section, but must not include criteria that result in loss of residency in both States or that are prohibited by paragraph (i) of this section. The agreements must contain a procedure for providing Medicaid to individuals pending resolution of the case.

States may use interstate agreements for purposes other than cases of disputed residency to facilitate administration of the program, and to facilitate the placement and adoption of

title IV-E individuals when the child and his or her adoptive parent(s) move into another State.

(k) *Continued Medicaid for institutionalized recipients.* An agency is providing Medicaid to an institutionalized recipient who, as a result of this section, would be considered a resident of a different State—

(1) The agency must continue to provide Medicaid to that recipient from June 24, 1983 until July 5, 1984 unless it makes arrangements with another State of residence to provide Medicaid at an earlier date; and

(2) Those arrangements must not include provisions prohibited by paragraph (g) of this section.

(l) *Cases of disputed residency.* Where two or more States cannot resolve which State is the State of residence, the State where the individual is physically located is the State of residence.

[49 FR 13533, Apr. 5, 1984, as amended at 55 FR 48610, Nov. 21, 1990; 71 FR 39225, July 12, 2006]

§ 436.404 Applicant's choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

§ 436.406 Citizenship and alienage.

(a) The agency must provide Medicaid to otherwise eligible residents of the United States who are—

(1) Citizens: (i) Under a declaration required by section 1137(d) of the Act that the individual is a citizen or national of the United States; and

(ii) The individual has provided satisfactory documentary evidence of citizenship or national status, as described in § 435.407.

(iii) An individual for purposes of the citizenship requirement is a Medicaid applicant or recipient or an individual receiving any services under a section 1115 demonstration for which States receive Federal financial participation in their expenditures as though they were medical assistance, for example, family planning demonstrations or Medicaid demonstrations.

(iv) Individuals must declare their citizenship and the State must document an individual's eligibility file on initial applications and initial redeterminations effective July 1, 2006.

(2) Qualified aliens as described in section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1641) who have provided satisfactory documentary evidence of Qualified Alien status, which status has been verified with the Department of Homeland Security (DHS) under a declaration required by section 1137(d) of the Act that the applicant or recipient is an alien in a satisfactory immigration status.

(b) The agency must provide payment for the services described in § 440.255 to residents of the State who otherwise meet the eligibility requirements of the State plan (except for receipt of AFDC, SSI, or State Supplementary payments and the presentation of a social security number) but who do not meet the requirements of paragraph (a) of this section.

[55 FR 36820, Sept. 7, 1990, as amended at 71 FR 39225, July 12, 2006]

§ 436.407 Types of acceptable documentary evidence of citizenship.

(a) *Primary evidence of citizenship and identity.* The following evidence must be accepted as satisfactory documentary evidence of both identity and citizenship:

(1) *A U.S. passport.* The Department of State issues this. A U.S. passport does not have to be currently valid to be accepted as evidence of U.S. citizenship, as long as it was originally issued without limitation. NOTE: Spouses and children were sometimes included on one passport through 1980. U.S. passports issued after 1980 show only one person. Consequently, the citizenship and identity of the included person can be established when one of these passports is presented. Exception: Do not accept any passport as evidence of U.S. citizenship when it was issued with a limitation. However, such a passport may be used as proof of identity.

(2) *A Certificate of Naturalization (DHS Forms N–550 or N–570.)* Department of Homeland Security issues for naturalization.

(3) *A Certificate of U.S. Citizenship (DHS Forms N–560 or N–561.)* Department of Homeland Security issues certificates of citizenship to individuals

who derive citizenship through a parent.

(4) A valid State-issued driver's license, but only if the State issuing the license requires proof of U.S. citizenship before issuance of such license or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen. (This provision is not effective until such time as a State makes providing evidence of citizenship a condition of issuing a driver's license and evidence that the license holder is a citizen is included on the license or in a system of records available to the Medicaid agency. States must ensure that the process complies with this statutory provision in section 6036 of the Deficit Reduction Act of 2005. CMS will monitor compliance of States implementing this provision.); or

(b) *Secondary evidence of citizenship.* If primary evidence from the list in paragraph (a) of this section is unavailable, an applicant or recipient should provide satisfactory documentary evidence of citizenship from the list specified in this section to establish citizenship and satisfactory documentary evidence from paragraph (e) of this section to establish identity, in accordance with the rules specified in this section.

(1) *A U.S. public birth certificate showing birth in one of the 50 States, the District of Columbia, Puerto Rico (if born on or after January 13, 1941), Guam (on or after April 10, 1899), the Virgin Islands of the U.S. (on or after January 17, 1917), American Samoa, Swain's Island, or the Northern Mariana Islands (after November 4, 1986 (NMI local time)).* A State, at its option, may use a cross match with a State vital statistics agency to document a birth record. The birth record document may be issued by the State, Commonwealth, Territory or local jurisdiction. It must have been issued before the person was 5 years of age. An amended birth record document that is amended after 5 years of age is considered fourth level evidence of citizenship.

NOTE: If the document shows the individual was born in Puerto Rico, the Virgin Islands of the U.S., or the Northern Mariana Islands before these areas became part of the U.S., the individual may be a collectively naturalized citizen. Collective naturalization occurred on certain dates listed for each of the territories. The following will establish U.S. citizenship for collectively naturalized individuals:

(i) *Puerto Rico:*

(A) Evidence of birth in Puerto Rico on or after April 11, 1899 and the applicant's statement that he or she was residing in the U.S., a U.S. possession or Puerto Rico on January 13, 1941; or

(B) Evidence that the applicant was a Puerto Rican citizen and the applicant's statement that he or she was residing in Puerto Rico on March 1, 1917 and that he or she did not take an oath of allegiance to Spain.

(ii) *U.S. Virgin Islands:*

(A) Evidence of birth in the U.S. Virgin Islands, and the applicant's statement of residence in the U.S., a U.S. possession or the U.S. Virgin Islands on February 25, 1927; or

(B) The applicant's statement indicating resident in the U.S. Virgin Islands as a Danish citizen on January 17, 1917 and residence in the U.S., a U.S. possession or the U.S. Virgin Islands on February 25, 1927, and that he or she did not make a declaration to maintain Danish citizenship; or

(C) Evidence of birth in the U.S. Virgin Islands and the applicant's statement indicating residence in the U.S., a U.S. possession or Territory or the Canal Zone on June 28, 1932.

(iii) *Northern Mariana Islands (NMI) (formerly part of the Trust Territory of the Pacific Islands (TTPI)):*

(A) Evidence of birth in the NMI, TTPI citizenship and residence in the NMI, the U.S., or a U.S. Territory or possession on November 3, 1986 NMI local time) and the applicant's statement that he or she did not owe allegiance to a foreign state on November 4, 1986 (NMI local time); or

(B) Evidence of TTPI citizenship, continuous residence in the NMI since before November 3, 1981 (NMI local time), voter registration prior to January 1, 1975 and the applicant's statement that he or she did not owe allegiance to a foreign state on November 4, 1986 (NMI local time); or

(C) Evidence of continuous domicile in the NMI since before January 1, 1974

and the applicant's statement that he or she did not owe allegiance to a foreign state on November 4, 1986 (NMI local time).

(D) NOTE: If a person entered the NMI as a nonimmigrant and lived in the NMI since January 1, 1974, this does not constitute continuous domicile and the individual is not a U.S. citizen.

(2) *A Certification of Report of Birth (DS–1350).* The Department of State issues a DS–1350 to U.S. citizens in the U.S. who were born outside the U.S. and acquired U.S. citizenship at birth, based on the information shown on the FS–240. When the birth was recorded as a Consular Report of Birth (FS–240), certified copies of the Certification of Report of Birth Abroad (DS–1350) can be issued by the Department of State in Washington, DC. The DS–1350 contains the same information as that on the current version of Consular Report of Birth FS–240. The DS–1350 is not issued outside the U.S.

(3) *A Report of Birth Abroad of a U.S. Citizen (Form FS–240).* The Department of State consular office prepares and issues this. A Consular Report of Birth can be prepared only at an American consular office overseas while the child is under the age of 18. Children born outside the U.S. to U.S. military personnel usually have one of these.

(4) *A Certification of birth issued by the Department of State (Form FS–545 or DS–1350).* Before November 1, 1990, Department of State consulates also issued Form FS–545 along with the prior version of the FS–240. In 1990, U.S. consulates ceased to issue Form FS–545. Treat an FS–545 the same as the DS–1350.

(5) *A U.S. Citizen I.D. card.* (This form was issued as Form I–197 until the 1980's by INS. Although no longer issued, holders of this document may still use it consistent with the provisions of section 1903(x) of the Act. Note that section 1903(x) of the Act incorrectly refers to the same document as an I–97.) INS issued the I–179 from 1960 until 1973. It revised the form and renumbered it as Form I–197. INS issued the I–197 from 1973 until April 7, 1983. INS issued Form I–179 and I–197 to naturalized U.S. citizens living near the Canadian or Mexican border who needed it for frequent border crossings. Although neither form is currently issued, either form that was previously issued is still valid.

(6) *A Northern Mariana Identification Card* (I–873). (Issued by the DHS to a collectively naturalized citizen of the United States who was born in the Northern Mariana Islands before November 4, 1986.) The former Immigration and Naturalization Service (INS) issued the I–873 to a collectively naturalized citizen of the U.S. who was born in the NMI before November 4, 1986. The card is no longer issued, but those previously issued are still valid.

(7) *An American Indian Card (I–872) issued by the Department of Homeland Security with the classification code ''KIC.''* (Issued by DHS to identify U.S. citizen members of the Texas Band of Kickapoos living near the United States/Mexican border.) DHS issues this card to identify a member of the Texas Band of Kickapoos living near the U.S./Mexican border. A classification code ''KIC'' and a statement on the back denote U.S. citizenship

(8) *A final adoption decree showing the child's name and U.S. place of birth.* The adoption decree must show the child's name and U.S. place of birth. In situations where an adoption is not finalized and the State in which the child was born will not release a birth certificate prior to final adoption, a statement from a State approved adoption agency that shows the child's name and U.S. place of birth is acceptable. The adoption agency must state in the certification that the source of the place of birth information is an original birth certificate.

(9) *Evidence of U.S. Civil Service employment before June 1, 1976.* The document must show employment by the U.S. government before June 1, 1976. Individuals employed by the U.S. Civil Service prior to June 1, 1976 had to be U.S. citizens.

(10) *U.S. Military Record showing a U.S. place of birth.* T he document must show a U.S. place of birth (for example a DD–214 or similar official document showing a U.S. place of birth.)

(c) *Third level evidence of citizenship.* Third level evidence of U.S. citizenship is documentary evidence of satisfactory reliability that is used when neither primary nor secondary evidence is

available. Third level evidence may be used only when primary evidence cannot be obtained within the State's reasonable opportunity period, secondary evidence does not exist or cannot be obtained, and the applicant or recipient alleges being born in the U.S. A second document from paragraph (e) of this section to establish identity must also be presented:

(1) *Extract of a hospital record on hospital letterhead established at the time of the person's birth that was created 5 years before the initial application date and that indicates a U.S. place of birth.* (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Do not accept a souvenir ''birth certificate'' issued by the hospital.

NOTE: For children under 16 the document must have been created near the time of birth or 5 years before the date of application.

(2) *Life, health, or other insurance record showing a U.S. place of birth that was created at least 5 years before the initial application date that indicates a U.S. place of birth.* Life or health insurance records may show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth.

(d) *Fourth level evidence of citizenship.* Fourth level evidence of citizenship is documentary evidence of the lowest reliability. Fourth level evidence should only be used in the rarest of circumstances. This level of evidence is used only when primary evidence is unavailable, both secondary and third level evidence do not exist or cannot be obtained within the State's reasonable opportunity period, and the applicant alleges a U.S. place of birth. In addition, a second document establishing identity must be presented as described in paragraph (e) of this section.

(1) *Federal or State census record showing U.S. citizenship or a U.S. place of birth.* (Generally for persons born 1900 through 1950.) The census record must also show the applicant's age. NOTE: Census records from 1900 through 1950 contain certain citizenship information. To secure this information the applicant, recipient or State should complete a Form BC–600, Application for Search of Census Records for Proof of Age. Add in the remarks portion ''U.S. citizenship data requested.'' Also add that the purpose is for Medicaid eligibility. This form requires a fee.

(2) *One of the following documents that show a U.S. place of birth and was created at least 5 years before the application for Medicaid.* This document must be one of the following and show a U.S. place of birth:

(i) Seneca Indian tribal census.

(ii) Bureau of Indian Affairs tribal census records of the Navajo Indians.

(iii) U.S. State Vital Statistics official notification of birth registration.

(iv) An amended U.S. public birth record that is amended more than 5 years after the person's birth

(v) Statement signed by the physician or midwife who was in attendance at the time of birth.

(3) *Institutional admission papers from a nursing facility, skilled care facility or other institution.* Admission papers generally show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth.

(4) *Medical (clinic, doctor, or hospital) record created at least 5 years before the initial application date that indicates a U.S. place of birth.* (For children under 16 the document must have been created near the time of birth or 5 years before the date of application.) Medical records generally show biographical information for the person including place of birth; the record can be used to establish U.S. citizenship when it shows a U.S. place of birth. NOTE: An immunization record is not considered a medical record for purposes of establishing U.S. citizenship. NOTE: For children under 16 the document must have been created near the time of birth or 5 years.

(5) *Written affidavit. Affidavits should ONLY be used in rare circumstances.* If the documentation requirement needs to be met through affidavits, the following rules apply:

(i) There must be at least two affidavits by two individuals who have personal knowledge of the event(s) establishing the applicant's or recipient's

claim of citizenship (the two affidavits could be combined in a joint affidavit).

(ii) At least one of the individuals making the affidavit cannot be related to the applicant or recipient. Neither of the two individuals can be the applicant or recipient.

(iii) In order for the affidavit to be acceptable the persons making them must be able to provide proof of their own citizenship and identity.

(iv) If the individual(s) making the affidavit has (have) information which explains why documentary evidence establishing the applicant's claim or citizenship does not exist or cannot be readily obtained, the affidavit should contain this information as well.

(v) The State must obtain a separate affidavit from the applicant/recipient or other knowledgeable individual (guardian or representative) explaining why the evidence does not exist or cannot be obtained.

(vi) The affidavits must be signed under penalty of perjury.

(e) *Evidence of identity.* The following documents may be accepted as proof of identity and must accompany a document establishing citizenship from the groups of documentary evidence of citizenship in the groups in paragraphs (b) through (d) of this section.

(1) *A driver's license issued by a State or Territory either with a photograph of the individual or other identifying information such as name, age, sex, race, height, weight, or eye color.*

(2) *School identification card with a photograph of the individual.*

(3) *U.S. military card or draft record.*

(4) *Identification card issued by the Federal, State, or local government with the same information included on driver's licenses.*

(5) *Military dependent's identification card.*

(6) *Native American Tribal document.*

(7) *U.S. Coast Guard Merchant Mariner card.*

(8) *Identity documents described in 8 CFR 274a.2(b)(1)(v)(B)(1).*

(i) Driver's license issued by State or Territory either with a photograph of the individual or other identifying information of the individual such as name, age, sex, race, height, weight or eye color.

(ii) School identification card with a photograph of the individual.

(iii) U.S. military card or draft record.

(iv) Identification card issued by the Federal, State, or local government with the same information included on driver's licenses.

(v) Military dependent's identification card.

(vi) Native American Tribal document.

(vii) U.S. Coast Guard Merchant Mariner card.

NOTE TO PARAGRAPH (E)(8): Exception: Do not accept a voter's registration card or Canadian driver's license as listed in 8 CFR 274a.2(b)(1)(v)(B)(1). CMS does not view these as reliable for identity.

(9) *Certificate of Degree of Indian Blood, or other U.S. American Indian/Alaska Native Tribal document with a photograph or other personal identifying information relating to the individual.* Acceptable if the document carries a photograph of the applicant or recipient, or has other personal identifying information relating to the individual.

(10) At State option, a State may use a cross match with a Federal or State governmental, public assistance, law enforcement or corrections agency's data system to establish identity if the agency establishes and certifies true identity of individuals. Such agencies may include food stamps, child support, corrections, including juvenile detention, motor vehicle, or child protective services. The State Medicaid Agency is still responsible for assuring the accuracy of the identity determination.

(f) *Special identity rules for children.* For children under 16, school records may include nursery or daycare records. If none of the above documents in the preceding groups are available, an affidavit may be used. An affidavit is only acceptable if it is signed under penalty of perjury by a parent or guardian stating the date and place of the birth of the child and cannot be used if an affidavit for citizenship was provided.

(g) *Special populations needing assistance.* States must assist individuals to secure satisfactory documentary evidence of citizenship when because of

incapacity of mind or body the individual would be unable to comply with the requirement to present satisfactory documentary evidence of citizenship in a timely manner and the individual lacks a representative to assist him or her.

(h) *Documentary evidence.*

(1) All documents must be either originals or copies certified by the issuing agency. Copies or notarized copies may not be accepted.

(2) States must maintain copies of citizenship and identification documents in the case record or electronic data base and make these copies available for compliance audits.

(3) States may permit applicants and recipients to submit such documentary evidence without appearing in person at a Medicaid office. States may accept original documents in person, by mail, or by a guardian or authorized representative.

(4) If documents are determined to be inconsistent with pre-existing information, are counterfeit, or altered, States should investigate for potential fraud and abuse, including but not limited to, referral to the appropriate State and Federal law enforcement agencies.

(5) Presentation of documentary evidence of citizenship is a one time activity; once a person's citizenship is documented and recorded in a State database, subsequent changes in eligibility should not require repeating the documentation of citizenship unless later evidence raises a question of the person's citizenship. The State need only check its databases to verify that the individual already established citizenship.

(6) CMS requires that as a check against fraud, using currently available automated capabilities, States will conduct a match of the applicant's name against the corresponding Social Security number that was provided. In addition, in cooperation with other agencies of the Federal government, CMS encourages States to use automated capabilities to verify citizenship and identity of Medicaid applicants. Automated capabilities may fall within the computer matching provisions of the Privacy Act of 1974, and CMS will explore any implementation issues that may arise with respect to those requirements. When these capabilities become available, States will be required to match files for individuals who used third or fourth tier documents to verify citizenship and documents to verify identity, and CMS will make available to States necessary information in this regard. States must ensure that all case records within this category will be so identified and made available to conduct these automated matches. CMS may also require States to match files for individuals who used first or second level documents to verify citizenship as well. CMS may provide further guidance to States with respect to actions required in a case of a negative match.

(i) *Record retention.* The State must retain documents in accordance with 45 CFR 74.53.

(j) *Reasonable opportunity to present satisfactory documentary evidence of citizenship.* States must give an applicant or recipient a reasonable opportunity to submit satisfactory documentary evidence of citizenship before taking action affecting the individual's eligibility for Medicaid. The time States give for submitting documentation of citizenship should be consistent with the time allowed to submit documentation to establish other facets of eligibility for which documentation is requested. (See §435.930 and §435.911 of this chapter.)

[71 FR 39226, July 12, 2006]

§ 436.408 [Reserved]

Subpart F—Categorical Requirements for Medicaid Eligibility

§ 436.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of this part.

DEPENDENCY

§ 436.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures used under the State's AFDC plan to determine whether—

(a) An individual is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.

[43 FR 45218, Sept. 29, 1978, as amended at 58 FR 4936, Jan. 19, 1993]

AGE

§ 436.520 Age requirements for the aged.

The agency must not impose an age requirement of more than 65 years.

[58 FR 4936, Jan. 19, 1993]

§ 436.522 Determination of age.

(a) In determining age, the agency must use the common law method (under which an age is reached the day before the anniversary of birth) or the popular usage method (under which a specific age is reached on the anniversary of birth), whichever is used under the corresponding State plan for OAA, AFDC, AB, APTD, or AABD.

(b) The agency may use an arbitrary date, such as July 1, for determining an individual's age if the year, but not the month, of his birth is known.

[58 FR 4936, Jan. 19, 1993]

BLINDNESS

§ 436.530 Definition of blindness.

(a) *Definition.* The agency must use the definition of blindness that is used in the State plan for AB or AABD.

(b) *State plan requirement.* The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 436.531 Determination of blindness.

In determining blindness—

(a) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant's eyes are missing;

(b) The examiner must submit a report of examination to the Medicaid agency; and

(c) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—

(1) Whether the individual meets the definition of blindness; and

(2) Whether and when reexaminations are necessary for periodic redeterminations of eligibility, as required under § 435.916 of this subchapter. Blindness is considered to continue until the reviewing physician determines that the recipient's vision no longer meets the definition.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17939, Mar. 23, 1979]

DISABILITY

§ 436.540 Definition of disability.

(a) *Definition.* The agency must use the definition of permanent and total disability that is used in the State plan for APTD or AABD. (See 45 CFR 233.80(a)(1) for the Federal recommended definition of permanent and total disability.)

(b) *State plan requirement.* The State plan must contain the definition of permanent and total disability.

§ 436.541 Determination of disability.

(a) *Basic requirements.* (1) At a minimum, the agency must use the review team, information, and evidence requirements specified in paragraph (b) through (d) of this section in making a determination of disability.

(2) If the requirements or determining disability under the State's APTD or AABD program are more restrictive than the minimum requirements specified in this section, the agency must use the requirements applied under the APTD or AABD program.

(b) The agency must obtain a medical report and a social history for individuals applying for Medicaid on the basis of disability. The medical report must include a diagnosis based on medical evidence. The social history must contain enough information to enable the agency to determine disability.

(c) A physician and social worker, qualified by professional training and experience, must review the medical report and social history and determine on behalf of the agency whether the individual meets the definition of

disability. The physician must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under § 435.916 of this subchapter.

(d) In subsequently determining disability, the physician and social worker must review reexamination reports and the social history and determine whether the individual continues to meet the definition. Disability is considered to continue until this determination is made.

[54 FR 50762, Dec. 11, 1989]

Subpart G—General Financial Eligibility Requirements and Options

§ 436.600 Scope.

This subpart prescribes:

(a) General financial requirements and options for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of this part. Subparts H and I of this part prescribe additional financial requirements.

(b) [Reserved]

[58 FR 4936, Jan. 19, 1993, as amended at 59 FR 43053, Aug. 22, 1994]

§ 436.601 Application of financial eligibility methodologies.

(a) *Definitions.* For purposes of this section, *cash assistance financial methodologies* refers to the income and resources methodologies of the OAA, AFDC, AB, APTD, and AABD programs.

(b) *Basic rule for use of cash assistance methodologies.* Except as specified in paragraphs (c) and (d) of this section, in determining financial eligibility of individuals as categorically and medically needy, the agency must apply the cash assistance financial methodologies and requirements of the cash assistance program that is most closely categorically related to the individual's status.

(c) *Financial responsibility of relatives.* The agency must use the requirements for financial responsibility of relatives specified in § 436.602.

(d) *Use of less restrictive methodologies than under cash assistance program.* (1) At State option, and subject to the conditions of paragraphs (d)(2) through (d)(5) of this section, the agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies in determining financial eligibility of the following groups:

(i) Qualified pregnant women and children under the mandatory categorically needy group under § 436.120;

(ii) Low-income pregnant women, infants, and children specified in section 1902(a)(10)(i) (IV), (VI), and (VII) of the Act;

(iii) Qualified Medicare beneficiaries specified in sections 1902(a)(10)(E) and 1905(p) of the Act;

(iv) Optional categorically needy individuals under groups established under subpart C of this part and section 1902(a)(10)(A)(ii) of the Act; and

(v) Medically needy individuals under groups established under subpart D of this part and section 1902(a)(10)(C)(i)(III) of the Act.

(2) The income and resource methodologies that an agency elects to apply to groups of individuals under paragraph (c)(1) of this section may be less restrictive, but no more restrictive, than:

(i) For groups of aged, blind, and disabled individuals, the SSI methodologies; or

(ii) For all other groups, the methodologies under the State plan most closely categorically related to the individual's status.

(3) A financial methodology is considered to be no more restrictive if, by using the methodology, additional individuals may be eligible for Medicaid and no individuals who are otherwise eligible are by use of that methodology made ineligible for Medicaid.

(4) The less restrictive methodology applied under this section must be comparable for all persons within each category of assistance (aged, or blind, or disabled, or AFDC-related) within each eligibility group. For example, if the agency chooses to apply a less restrictive income or resource methodology to aged individuals, it must apply that methodology to an eligibility group of all aged individuals within the selected group.

(5) The application of the less restrictive income and resource methodologies permitted under this section must be consistent with the limitations and conditions on FFP specified in subpart K of this part.

(e) [Reserved]

(f) *State plan requirements.* (1) The State plan must specify that, except to the extent precluded by § 436.602 in determining financial eligibility of individuals, the agency will apply the cash assistance financial methodologies and requirements, unless the agency chooses to apply less restrictive income and resource methodologies, in accordance with paragraph (d) of this section.

(2) If the agency chooses to apply less restrictive income and resource methodologies, the State plan must specify:

(i) The less restrictive methodologies that will used; and

(ii) The eligibility groups or groups to which the less restrictive methodologies will be applied.

[58 FR 4936, Jan. 19, 1993, as amended at 59 FR 43053, Aug. 22, 1994]

§ 436.602 Financial responsibility of relatives and other individuals.

(a) Subject to the provisions of paragraphs (b) and (c) of this section, in determining financial responsibility of relatives and other persons for individuals under Medicaid, the agency must use the following financial eligibility requirements and methodologies.

(1) Except for a spouse of an individual or a parent for a child who is under age 21 or blind or disabled, the agency must not consider income and resources of any relative as available to an individual.

(2) In relation to individuals under 21 (as described in section 1905(a)(i) of the Act), the financial responsibility requirements and methodologies include considering the income and resources of parents or spouses whose income and resources would be considered if the individual under age 21 were dependent under the State's approved AFDC plan, whether or not they are actually contributed. These requirements and methodologies must be applied in accordance with provisions of the State's approved AFDC plan.

(3) When a couple ceases to live together, the agency must count only the income and resources of the individual in determining his or her eligibility, beginning the first month following the month the couple ceases to live together.

(b) The agency may apply income and resource methodologies that are less restrictive than the cash assistance methodologies as specified in the State plan in accordance with § 436.601(d).

(c) [Reserved]

[58 FR 4936, Jan. 19, 1993, as amended at 59 FR 43053, Aug. 22, 1994]

§ 436.604 [Reserved]

§ 436.606 [Reserved]

§ 436.608 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, and retirement and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, and retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

[43 FR 45218, Sept. 29, 1978. Redesignated at 58 FR 4937, Jan. 19, 1993]

§ 436.610 Assignment of rights to benefits.

(a) As a condition of eligibility, the agency must require legally able applicants and recipients to:

(1) Assign rights to the Medicaid agency to medical support and to payment for medical care from any third party;

(2) Cooperate with the agency in establishing paternity and in obtaining medical support and payments, unless the individual establishes good cause for not cooperating, and except for individuals described in section 1902(l)(1)(A) of the Act (poverty level pregnant women), who are exempt from cooperating in establishing paternity and obtaining medical support and payments from, or derived from, the father of the child born out of wedlock; and

(3) Cooperate in identifying and providing information to assist the Medicaid agency in pursuing third parties who may be liable to pay for care and services under the plan, unless the individual establishes good cause for not cooperating.

(b) The requirements for assignment of rights must be applied uniformly for all groups covered under the plan.

(c) The requirements of paragraph (a) of this section for assignment of rights to medical support and other payments and cooperation in obtaining medical support and payments are effective for medical assistance furnished on or after October 1, 1984. The requirement for cooperation in identifying and providing information for pursuing liable third parties is effective for medical assistance furnished on or after July 1, 1986.

[55 FR 48610, Nov. 21, 1990; 55 FR 52130, Dec. 19, 1990, as amended at 58 FR 4908, Jan. 19, 1993. Redesignated at 58 FR 4937, Jan. 19, 1993]

Subpart H [Reserved]

Subpart I—Financial Requirements for the Medically Needy

§ 436.800 Scope.

This subpart prescribes financial requirements for determining the eligibility of medically needy individuals under subpart D of this part.

MEDICALLY NEEDY INCOME STANDARD

§ 436.811 Medically needy income standard: General requirements.

(a) To determine eligibility of medically needy individuals, the agency must use a single income standard for all covered medically needy groups that meets the requirements of this section.

(b) The income standard must take into account the number of persons in the assistance unit. The standard may not diminish by the number of persons in the unit (for example, if the income level in the standard for an assistance unit of two is set at $400, the income level in the standard for an assistance unit of three may not be less than $400).

(c) The income standard must be set at an amount that is no lower than the lowest income standard used on or after January 1, 1966, to determine eligibility under the cash assistance programs that are related to the State's covered medically needy group or groups of individuals under § 436.301.

(d) The income standard may vary based on the variations between shelter costs in urban areas and rural areas.

[58 FR 4938, Jan. 19, 1993]

§ 436.814 Medically needy income standard: State plan requirements.

The State plan must specify the income standard for the covered medically needy groups.

[58 FR 4938, Jan. 19, 1993]

MEDICALLY NEEDY INCOME ELIGIBILITY AND LIABILITY FOR PAYMENT OF MEDICAL EXPENSES

§ 436.831 Income eligibility.

The agency must determine income eligibility of medically needy individuals in accordance with this section.

(a) *Budget periods.* (1) The agency must use budget periods of not more than 6 months to compute income. The agency may use more than one budget period.

(2) The agency must include in the budget period in which income is computed all or part of the 3-month retroactive period specified in § 435.914. The budget period can begin no earlier then the first month in the retroactive period in which the individual received covered services.

(3) If the agency elects to begin the first budget period for the medically needy in any month of the 3-month period prior to the date of application in which the applicant received covered services, this election applies to all medically needy groups.

(b) *Determining countable income.* The agency must, to determine countable income, deduct amounts that would be deducted in determining eligibility under the State's approved plan for OAA, AFDC, AB, APTD, or AABD.

(c) *Eligibility based on countable income.* If countable income determined under paragraph (b) of this section is

equal to or less than the applicable income standard under §436.814, the individual is eligible for Medicaid.

(d) *Deduction of incurred medical expenses.* If countable income exceeds the income standard, the agency must deduct from income medical expenses incurred by the individual or family or financially responsible relatives that are not subject to payment by a third party. An expense is incurred on the date liability for the expense arises. The agency must determine deductible incurred expenses in accordance with paragraphs (e), (f) and (g) of this section and deduct those expenses in accordance with paragraph (h) of this section.

(e) *Determination of deductible incurred expenses: Required deductions based on kinds of services.* Subject to the provisions of paragraph (g) of this section, in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) Expenses for Medicare and other health insurance premiums, and deductibles or coinsurance charges, including enrollment fees, copayments, or deductibles imposed under §447.51 or §447.53 of this chapter;

(2) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan;

(3) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan, including those that exceed agency limitations on amount, duration or scope of services;

(f) *Determination of deductible incurred expenses: Required deductions based on the age of bills.* Subject to the provisions of paragraph (g) of this section, in determining incurred medical expenses to be deducted from income, the agency must include the following:

(1) For the first budget period or periods that include only months before the month of application for medical assistance, expenses incurred during such period or periods, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(2) For the first prospective budget period that also includes any of the 3 months before the month of application for medical assistance, expenses incurred during such budget period, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(3) For the first prospective budget period that includes none of the months preceding the month of application, expenses incurred during such budget period and any of the 3 preceding months, whether paid or unpaid, to the extent that the expenses have not been deducted previously in establishing eligibility;

(4) For any of the 3 months preceding the month of application that are not includable under paragraph (f)(2) of this section, expenses incurred in the 3-month period that were a current liability of the individual in any such month for which a spenddown calculation is made and that had not been previously deducted from income in establishing eligibility for medical assistance;

(5) Current payments (that is, payments made in the current budget period) on other expenses incurred before the current budget period and not previously deducted from income in any budget period in establishing eligibility for such period; and

(6) If the individual's eligibility for medical assistance was established in each such preceding period, expenses incurred before the current budget period but not previously deducted from income, to the extent that such expenses are unpaid and are:

(i) Described in paragraphs (e)(1) through (e)(3) of this section; and

(ii) Are carried over from the preceding budget period or periods because the individual had a spenddown liability in each such preceding period that was met without deducting all such incurred, unpaid expenses.

(g) *Determination of deductible incurred medical expenses: Optional deductions.* In determining incurred medical expenses to be deducted from income, the agency—

(1) May include medical institutional expenses (other than expenses in acute care facilities) projected to the end of

the budget period at the Medicaid reimbursement rate;

(2) May, to the extent determined by the agency and specified in its approved plan, include expenses incurred earlier than the third month before the month of application; and

(3) May set reasonable limits on the amount to be deducted for expenses specified in paragraphs (e)(1), (e)(2), and (g)(2) of this section.

(h) *Order of deduction.* The agency must deduct incurred medical expenses that are deductible under paragraphs (e), (f), and (g) of this section, in the order prescribed under one of the following three options:

(1) *Type of service.* Under this option, the agency deducts expenses in the following order based on type of service:

(i) Cost-sharing expenses as specified in paragraph (e)(1) of this section.

(ii) Services not included in the State plan as specified in paragraph (e)(2) of this section.

(iii) Services included in the State plan as specified in paragraph (e)(3) of this section but that exceed agency limitations on amount, duration, or scope of services.

(iv) Services included in the State plan as specified in paragraph (e)(3) of this section but that are within agency limitations on amount, duration, or scope of services.

(2) *Chronological order by service date.* Under this option, the agency deducts expenses in chronological order by the date each service is furnished, or in the case of insurance premiums, coinsurance, or deductibles charges the date such amounts are due. Expenses for services furnished on the same day may be deducted in any reasonable order established by the State.

(3) *Chronological order by bill submission date.* Under this option, the agency deducts expenses in chronological order by the date each bill is submitted to the agency by the individual. If more than one bill is submitted at one time, the agency must deduct the bills from income in the order prescribed in either paragraph (h)(1) or (h)(2) of this section.

(i) *Eligibility based on incurred medical expenses.* (1) Whether a State elects partial or full month coverage, an individual who is expected to contribute a portion of his or her income toward the costs of institutional care or home and community-based services under § 436.832 is eligible on the first day of the applicable budget (spenddown) period—

(i) If his or her spenddown liability is met after the first day of the budget period; and

(ii) If beginning eligibility after the first day of the budget period makes the individual's share of health care expenses under § 436.832 greater than the individual's contributable income determined under this section.

(2) At the end of the prospective period specified in paragraph (f)(2) or (f)(3) of this section and any subsequent prospective period or, if earlier, when any significant change occurs, the agency must reconcile the projected amounts with the actual amounts incurred, or with changes in circumstances, to determine if the adjusted deduction of incurred expenses reduces income to the income standard.

(3) Except as provided in paragraph (i)(1) of this section, if agencies elect partial month coverage, an individual is eligible for Medicaid on the day that the deduction of incurred health care expenses (and of projected institutional expenses if the agency elects the option under paragraph (g)(1) of this section) reduces income to the income standard.

(4) Except as provided in paragraph (i)(1) of this section, if agencies elect full month coverage, an individual is eligible on the first day of the month in which spenddown liability is met.

(5) Expenses used to meet spenddown liability are not reimbursable under Medicaid. Therefore, to the extent necessary to prevent the transfer of an individual's spenddown liability to the Medicaid program, States must reduce the amount of provider charges that would otherwise be reimbursable under Medicaid.

[59 FR 1674, Jan. 12, 1994]

§ 436.832 Post-eligibility treatment of income of institutionalized individuals: Application of patient income to the cost of care.

(a) *Basic rules.* (1) The agency must reduce its payment to an institution,

for services provided to an individual specified in paragraph (b) of this section, by the amount that remains after deducting the amounts specified in paragraphs (c) and (d) of this section from the individual's total income.

(2) The individual's income must be determined in accordance with paragraph (e) of this section.

(3) Medical expenses must be determined in accordance with paragraph (f) of this section.

(b) *Applicability*. This section applies to medically needy individuals in medical institutions and intermediate care facilities.

(c) *Required deductions*. The agency must deduct the following amounts, in the following order, from the individual's total income as determined under paragraph (e) of this section. Income that was disregarded in determining eligibility must be considered in this process.

(1) *Personal needs allowance*. A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $30 a month for an aged, blind, or disabled individual, including a child applying for Medicaid on the basis of blindness or disability;

(ii) $60 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, or disabled.

(2) *Maintenance needs of spouse*. For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The amount of the highest need standard for an individual without income and resources under the State's approved plan for OAA, AFDC, AB, APTD, or AABD; or

(ii) The amount of the highest medically needy income standard for one person established under § 436.811.

(3) *Maintenance needs of family*. For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the highest of the following need standards for a family of the same size:

(A) The standard used to determine eligibility under the State's Medicaid plan, as provided for in § 436.811.

(B) The standard used to determine eligibility under the State's approved AFDC plan.

(4) *Expenses not subject to third party payment*. Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's Medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) *Optional deduction: Allowance for home maintenance*. For single individuals and couples, an amount (in addition to the personal needs allowance) for maintenance of the individual's or couple's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that either of the individuals is likely to return to the home within that period.

(e) *Determination of income*—(1) *Option*. In determining the amount of an individual's income to be used to reduce the agency's payment to the institution, the agency may use total income received or it may project total monthly income for a prospective period not to exceed 6 months.

(2) *Basis for projection*. The agency must base the projection on income received in the preceding period, not to

exceed 6 months, and on income expected to be received.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (e)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with income received.

(f) *Determination of medical expenses*—(1) *Option.* In determining the amount of medical expenses to be deducted from an individual's income, the agency may deduct incurred medical expenses, or it may project medical expenses for a prospective period not to exceed 6 months.

(2) *Basis for projection.* The agency must base the estimate on medical expenses incurred in the preceding period, not to exceed 6 months, and medical expenses expected to be incurred.

(3) *Adjustments.* At the end of the prospective period specified in paragraph (f)(1) of this section, or when any significant change occurs, the agency must reconcile estimates with incurred medical expenses.

[45 FR 24888, Apr. 11, 1980, as amended at 46 FR 47991, Sept. 30, 1981; 48 FR 5735, Feb. 8, 1983; 53 FR 3597, Feb. 8, 1988; 56 FR 8851, 8854, Mar. 1, 1991; 58 FR 4938, Jan. 19, 1993]

MEDICALLY NEEDY RESOURCE STANDARD

§ 436.840 Medically needy resource standard: General requirements.

(a) To determine eligibility of medically needy individuals, the Medicaid agency must use a single resource standard that is set at an amount that is no lower than the lowest resource standard used on or after January 1, 1966, to determine eligibility under the cash assistance programs that are related to the State's covered medically needy group or groups of individuals under § 436.301.

(b) The resource standard established under paragraph (a) of this section may not diminish by an increase in the number of persons in the assistance unit. For example, the resource level in the standard for an assistance unit of three may not be less than that set for an assistance unit of two.

[58 FR 4938, Jan. 19, 1993]

§ 436.843 Medically needy resource standard: State plan requirements.

The State plan must specify the resource standard for the covered medically needy groups.

[58 FR 4938, Jan. 19, 1993]

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

§ 436.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must—

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives under § 436.602;

(b) Consider only resources available during the period for which income is computed under § 436.831(a);

(c) Deduct the value of resources that would be deducted in determining eligibility under the State's plan for OAA, AFDC, AB, APTD, or AABD or under the State's less restrictive financial methodology specified in the State Medicaid plan in accordance with § 436.601. In determining the amount of an individual's resources for Medicaid eligibility, States must count amounts of resources that otherwise would not be counted under the conditional eligibility provisions of the AFDC program.

(d) Apply the resource standards established under § 436.840.

[43 FR 45218, Sept. 29, 1978, as amended at 46 FR 47992, Sept. 30, 1981; 58 FR 4938, Jan. 19, 1993]

Subpart J—Eligibility in Guam, Puerto Rico, and the Virgin Islands

SOURCE: 44 FR 17939, Mar. 23, 1979, unless otherwise noted.

§ 436.900 Scope.

This subpart sets forth requirements for processing applications, determining eligibility, and furnishing Medicaid.

§ 436.901 General requirements.

The Medicaid agency must comply with all the requirements of part 435,

subpart J, of this subchapter, except those specified in § 435.909.

§ 436.909 Automatic entitlement to Medicaid following a determination of eligibility under other programs.

The agency may not require a separate application for Medicaid from an individual if the individual receives cash assistance under a State plan for OAA, AFDC, AB, APTD, or AABD.

Subpart K—Federal Financial Participation (FFP)

§ 436.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for Medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP FOR EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§ 436.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in—

(1) Determining and redetermining Medicaid eligibility and in providing Medicaid to eligible individuals; and

(2) Determining presumptive eligibility for children and providing services to presumptively eligible children.

(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

[43 FR 45218, Sept. 29, 1978, as amended at 66 FR 2668, Jan. 11, 2001]

§ 436.1002 FFP for services.

(a) FFP is available in expenditures for Medicaid services for all recipients whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to recipients who were eligible for Medicaid in the month in which the medical care or services were provided, except that, for recipients who establish eligibility for Medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient's liability.

(c) FFP is available in expenditures for services covered under the plan that are furnished—

(1) To children who are determined by a qualified entity to be presumptively eligible;

(2) During a period of presumptive eligibility;

(3) By a provider that is eligible for payment under the plan; and

(4) Regardless of whether the children are determined eligible for Medicaid following the period of presumptive eligibility.

[43 FR 45218, Sept. 29, 1978, as amended at 44 FR 17940, Mar. 23, 1979; 66 FR 2669, Jan. 11, 2001]

§ 436.1003 Recipients overcoming certain conditions of eligibility.

FFP is available for a temporary period specified in the State plan in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a parent.

[45 FR 24888, Apr. 11, 1980]

§ 436.1004 FFP in expenditures for medical assistance for individuals who have declared United States citizenship or nationality under section 1137(d) of the Act and with respect to whom the State has not documented citizenship and identity.

FFP will not be available to a State with respect to expenditures for medical assistance furnished to individuals unless the State has obtained satisfactory documentary evidence of citizenship or national status, as described in § 436.407 that complies with the requirements of section 1903(x) of the Act. This requirement does not apply with respect to individuals declaring themselves to be citizens or nationals who are eligible for medical assistance and who are either entitled to benefits or enrolled in any parts of the Medicare program under title XVIII of the Social Security Act.

[71 FR 39229, July 12, 2006]

§ 436.1005 Institutionalized individuals.

(a) FFP is not available in expenditures for services provided to—

(1) Individuals who are inmates of public institutions as defined in § 435.1010 of this chapter; or

(2) Individuals under age 65 who are patients in an institution for mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) The exclusion of FFP described in paragraph (a) of this section does not apply during that part of the month in which the individual is not an inmate of a public institution or a patient in an institution for mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient pyschiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

[43 FR 45204, Sept. 29, 1978, as amended at 50 FR 13200, Apr. 3, 1985; 50 FR 38811, Sept. 25, 1985. Redesignated and amended at 71 FR 39229, July 12, 2006]

§ 436.1006 Definitions relating to institutional status.

For purposes of FFP, the definitions in § 435.1010 of this chapter apply to this part.

[44 FR 17939, Mar. 23, 1979. Redesignated and amended at 71 FR 39229, July 12, 2006]

Subpart L—Option for Coverage of Special Groups

SOURCE: 66 FR 2669, Jan. 11, 2001, unless otherwise noted.

§ 436.1100 Basis and scope.

(a) *Statutory basis.* Section 1920A of the Act allows States to provide Medicaid services to children under age 19 during a period of presumptive eligibility, prior to a formal determination of Medicaid eligibility.

(b) *Scope.* This subpart prescribes the requirements for providing medical assistance to special groups who are not eligible for Medicaid as categorically or medically needy.

PRESUMPTIVE ELIGIBILITY FOR CHILDREN

§ 436.1101 Definitions related to presumptive eligibility period for children.

Application form means at a minimum the form used to apply for Medicaid under the poverty-level-related eligibility groups described in section 1902(l) of the Act or a joint form for children to apply for the State Children's Health Insurance Program and Medicaid.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a Medicaid application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf a Medicaid application has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish the regular Medicaid eligibility of a child of the age involved.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive

assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is authorized to determine eligibility of a child for medical assistance under the Medicaid State plan, or eligibility of a child for child health assistance under the State Children's Health Insurance Program;

(6) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(7) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(8) Is a State or Tribal child support enforcement agency;

(9) Is an organization that—

(i) Provides emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(ii) Is a State or Tribal office or entity involved in enrollment in the program under this title, Part A of title IV, or title XXI; or

(iii) Determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); and

(10) Any other entity the State so deems, as approved by the Secretary.

Services means all services covered under the plan including EPSDT (see part 440 of this chapter.)

[66 FR 2669, Jan. 11, 2001, as amended at 66 FR 33822, June 25, 2001]

§ 436.1102 General rules.

(a) The agency may provide services to children under age 19 during one or more periods of presumptive eligibility following a determination made by a qualified entity that the child's estimated gross family income or, at the State's option, the child's estimated family income after applying simple disregards, does not exceed the applicable income standard.

(b) If the agency elects to provide services to children during a period of presumptive eligibility, the agency must—

(1) Provide qualified entities with application forms for Medicaid and information on how to assist parents, caretakers and other persons in completing and filing such forms;

(2) Establish procedures to ensure that qualified entities—

(i) Notify the parent or caretaker of the child at the time a determination regarding presumptive eligibility is made, in writing and orally if appropriate, of such determination;

(ii) Provide the parent or caretaker of the child with a Medicaid application form;

(iii) Within 5 working days after the date that the determination is made, notify the agency that a child is presumptively eligible;

(iv) For children determined to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate, that—

(A) If a Medicaid application on behalf of the child is not filed by the last day of the following month, the child's presumptive eligibility will end on that last day; and

(B) If a Medicaid application on behalf of the child is filed by the last day of the following month, the child's presumptive eligibility will end on the day that a decision is made on the Medicaid application; and

(v) For children determined not to be presumptively eligible, notify the child's parent or caretaker at the time the determination is made, in writing and orally if appropriate—

(A) Of the reason for the determination; and

(B) That he or she may file an application for Medicaid on the child's behalf with the Medicaid agency; and

(3) Provide all services covered under the plan, including EPSDT.

(4) Allow determinations of presumptive eligibility to be made by qualified entities on a Statewide basis.

(c) The agency must adopt reasonable standards regarding the number of periods of presumptive eligibility that will be authorized for a child in a given time frame.

PART 438—MANAGED CARE

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 67 FR 41095, June 14, 2002, unless otherwise noted.

Subpart A—General Provisions

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on sections 1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.

(1) Section 1902(a)(4) requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State plan. The application of the requirements of this part to PIHPs and PAHPs that do not meet the statutory definition of an MCO or a PCCM is under the authority in section 1902(a)(4).

(2) Section 1903(m) contains requirements that apply to comprehensive risk contracts.

(3) Section 1903(m)(2)(H) provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(4) Section 1905(t) contains requirements that apply to PCCMs.

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require Medicaid recipients to enroll in MCOs or PCCMs;

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part;

(iii) Establishes protections for enrollees of MCOs and PCCMs;

(iv) Requires States to develop a quality assessment and performance improvement strategy;

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse;

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements; and

(vii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PIHPs, PAHPs, and PCCMs. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Comprehensive risk contract means a risk contract that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) FQHC services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the PHS Act.

Health care professional means a physician or any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speech-language pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

Health insuring organization (*HIO*) means a county operated entity, that in exchange for capitation payments, covers services for recipients—

(1) Through payments to, or arrangements with, providers;

(2) Under a comprehensive risk contract with the State; and

(3) Meets the following criteria—

(i) First became operational prior to January 1, 1986; or

(ii) Is described in section 9517(e)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990).

Managed care organization (*MCO*) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid recipients within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Nonrisk contract means a contract under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;

(2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

(1) Provides medical services to enrollees under contract with the State agency, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates;

(2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, or pediatrician, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which a PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

Primary care case manager (PCCM) means a physician, a physician group practice, an entity that employs or arranges with physicians to furnish primary care case management services or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Risk contract means a contract under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

§ 438.6 Contract requirements.

(a) *Regional office review.* The CMS Regional Office must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806.

(b) *Entities eligible for comprehensive risk contracts.* A State agency may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as added by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payments under risk contracts*—(1) *Terminology.* As used in this paragraph, the following terms have the indicated meanings:

(i) *Actuarially sound capitation rates* means capitation rates that—

(A) Have been developed in accordance with generally accepted actuarial principles and practices;

(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and

(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(ii) *Adjustments to smooth data* means adjustments made, by cost-neutral methods, across rate cells, to compensate for distortions in costs, utilization, or the number of eligibles.

(iii) *Cost neutral* means that the mechanism used to smooth data, share risk, or adjust for risk will recognize both higher and lower expected costs and is not intended to create a net aggregate gain or loss across all payments.

(iv) *Incentive arrangement* means any payment mechanism under which a contractor may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

(v) *Risk corridor* means a risk sharing mechanism in which States and contractors share in both profits and losses under the contract outside of predetermined threshold amount, so that after an initial corridor in which the contractor is responsible for all losses or retains all profits, the State contributes a portion toward any additional losses, and receives a portion of any additional profits.

(2) *Basic requirements.* (i) All payments under risk contracts and all risk-sharing mechanisms in contracts must be actuarially sound.

(ii) The contract must specify the payment rates and any risk-sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.

(3) *Requirements for actuarially sound rates.* In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:

(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.

(ii) Adjustments made to smooth data and adjustments to account for factors such as medical trend inflation, incomplete data, MCO, PIHP, or PAHP administration (subject to the limits in paragraph (c)(4)(ii) of this section), and utilization;

(iii) Rate cells specific to the enrolled population, by—

(A) Eligibility category;

(B) Age;

(C) Gender;

(D) Locality/region; and

(E) Risk adjustments based on diagnosis or health status (if used).

(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost-neutral methods.

(4) *Documentation.* The State must provide the following documentation:

(i) The actuarial certification of the capitation rates.

(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are—

(A) Based only upon services covered under the State plan (or costs directly related to providing these services, for example, MCO, PIHP, or PAHP administration).

(B) Provided under the contract to Medicaid-eligible individuals.

(iii) The State's projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.

(iv) An explanation of any incentive arrangements, or stop-loss, reinsurance, or any other risk-sharing methodologies under the contract.

(5) *Special contract provisions.* (i) Contract provisions for reinsurance, stop-loss limits or other risk-sharing methodologies must be computed on an actuarially sound basis.

(ii) If risk corridor arrangements result in payments that exceed the approved capitation rates, these excess payments will not be considered actuarially sound to the extent that they result in total payments that exceed the amount Medicaid would have paid, on a fee-for-service basis, for the State plan services actually furnished to enrolled individuals, plus an amount for MCO, PIHP, or PAHP administrative costs directly related to the provision of these services.

(iii) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound.

(iv) For all incentive arrangements, the contract must provide that the arrangement is—

(A) For a fixed period of time;

(B) Not to be renewed automatically;

(C) Made available to both public and private contractors;

(D) Not conditioned on intergovernmental transfer agreements; and

(E) Necessary for the specified activities and targets.

(v) If a State makes payments to providers for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, and PCCMs must provide as follows:

(1) The MCO, PIHP, PAHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, or PCCM will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO, PIHP, or PAHP contract may cover, for enrollees, services that are in addition to those covered under the State plan, although the cost of these

services cannot be included when determining the payment rates under § 438.6(c).

(f) *Compliance with contracting rules.* All contracts under this subpart must:

(1) Comply with all applicable Federal and State laws and regulations including title VI of the Civil Rights Act of 1964; title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; and the Americans with Disabilities Act; and

(2) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

(h) *Physician incentive plans.* (1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210 of this chapter, references to ''M+C organization'', ''CMS'', and ''Medicare beneficiaries'' must be read as references to ''MCO, PIHP, or PAHP'', ''State agency'' and ''Medicaid recipients'', respectively.

(i) *Advance directives.* (1) All MCO and PIHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to this requirement must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(j) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (a) of this section.

(k) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the recipient's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll from their PCCM in accordance with § 438.56(c).

(l) *Subcontracts.* All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(m) *Choice of health professional.* The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

§ 438.8 Provisions that apply to PIHPs and PAHPs.

(a) The following requirements and options apply to PIHPs, PIHP contracts, and States with respect to PIHPs, to the same extent that they apply to MCOs, MCO contracts, and States for MCOs.

(1) The contract requirements of § 438.6, except for requirements that pertain to HIOs.

(2) The information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The enrollee rights and protection provisions in subpart C of this part.

(6) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PIHP.

(7) The grievance system provisions in subpart F of this part.

(8) The certification and program integrity protection provisions set forth in subpart H of this part.

(b) The following requirements and options for PAHPs apply to PAHPs, PAHP contracts, and States.

(1) The contract requirements of § 438.6, except requirements for—

(i) HIOs.

(ii) Advance directives (unless the PAHP includes any of the providers listed in § 489.102) of this chapter.

(2) All applicable portions of the information requirements in § 438.10.

(3) The provision against provider discrimination in § 438.12.

(4) The State responsibility provisions of subpart B of this part except § 438.50.

(5) The provisions on enrollee rights and protections in subpart C of this part.

(6) Designated portions of subpart D of this part.

(7) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

(8) Prohibitions against affiliations with individuals debarred by Federal agencies in § 438.610.

[67 FR 41095, June 14, 2002, as amended at 67 FR 65505, Oct. 25, 2002]

§ 438.10 Information requirements.

(a) *Terminology.* As used in this section, the following terms have the indicated meanings:

Enrollee means a Medicaid recipient who is currently enrolled in an MCO, PIHP, PAHP, or PCCM in a given managed care program.

Potential enrollee means a Medicaid recipient who is subject to mandatory enrollment or may voluntarily elect to enroll in a given managed care program, but is not yet an enrollee of a specific MCO, PIHP, PAHP, or PCCM.

(b) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, and PCCM must provide all enrollment notices, informational materials, and instructional materials relating to enrollees and potential enrollees in a manner and format that may be easily understood.

(2) The State must have in place a mechanism to help enrollees and potential enrollees understand the State's managed care program.

(3) Each MCO and PIHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(c) *Language.* The State must do the following:

(1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. ''Prevalent'' means a non-English language spoken by a significant number or percentage of potential enrollees and enrollees in the State.

(2) Make available written information in each prevalent non-English language.

(3) Require each MCO, PIHP, PAHP, and PCCM to make its written information available in the prevalent non-English languages in its particular service area.

(4) Make oral interpretation services available and require each MCO, PIHP, PAHP, and PCCM to make those services available free of charge to each potential enrollee and enrollee. This applies to all non-English languages, not just those that the State identifies as prevalent.

(5) Notify enrollees and potential enrollees, and require each MCO, PIHP, PAHP, and PCCM to notify its enrollees—

(i) That oral interpretation is available for any language and written information is available in prevalent languages; and

(ii) How to access those services.

(d) *Format.* (1) Written material must—

(i) Use easily understood language and format; and

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

(2) All enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats.

(e) *Information for potential enrollees.* (1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary program, or is first required to enroll in a mandatory enrollment program.

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, PAHPs, or PCCMs.

(2) The information for potential enrollees must include the following:

(i) General information about—

(A) The basic features of managed care;

(B) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program; and

(C) MCO, PIHP, PAHP, and PCCM responsibilities for coordination of enrollee care;

(ii) Information specific to each MCO, PIHP, PAHP, or PCCM program operating in potential enrollee's service area. A summary of the following information is sufficient, but the State must provide more detailed information upon request:

(A) Benefits covered.

(B) Cost sharing, if any.

(C) Service area.

(D) Names, locations, telephone numbers of, and non-English language spoken by current contracted providers, and including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs, this includes at a minimum information on primary care physicians, specialists, and hospitals.

(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service.

(f) *General information for all enrollees of MCOs, PIHPs, PAHPs, and PCCMs.* Information must be furnished to MCO, PIHP, PAHP, and PCCM enrollees as follows:

(1) The State must notify all enrollees of their disenrollment rights, at a minimum, annually. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 days before the start of each enrollment period.

(2) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must notify all enrollees of their right to request and obtain the information listed in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least once a year.

(3) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must furnish to each of its enrollees the information specified in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, within a reasonable time after the MCO, PIHP, PAHP, or PCCM receives, from the State or its contracted representative, notice of the recipient's enrollment.

(4) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must give each enrollee written notice of any change (that the State defines as ''significant'') in the information specified in paragraphs (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least 30 days before the intended effective date of the change.

(5) The MCO, PIHP, and, when appropriate, the PAHP or PCCM, must make a good faith effort to give written notice of termination of a contracted provider, within 15 days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a

regular basis by, the terminated provider.

(6) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must provide the following information to all enrollees:

(i) Names, locations, telephone numbers of, and non-English languages spoken by current contracted providers in the enrollee's service area, including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists, and hospitals.

(ii) Any restrictions on the enrollee's freedom of choice among network providers.

(iii) Enrollee rights and protections, as specified in § 438.100.

(iv) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in § 438.10(g)(1), and for PAHP enrollees, the information specified in § 438.10(h)(1).

(v) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.

(vi) Procedures for obtaining benefits, including authorization requirements.

(vii) The extent to which, and how, enrollees may obtain benefits, including family planning services, from out-of-network providers.

(viii) The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes emergency medical condition, emergency services, and poststabilization services, with reference to the definitions in § 438.114(a).

(B) The fact that prior authorization is not required for emergency services.

(C) The process and procedures for obtaining emergency services, including use of the 911-telephone system or its local equivalent.

(D) The locations of any emergency settings and other locations at which providers and hospitals furnish emergency services and poststabilization services covered under the contract.

(E) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(ix) The poststabilization care services rules set forth at § 422.113(c) of this chapter.

(x) Policy on referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(xi) Cost sharing, if any.

(xii) How and where to access any benefits that are available under the State plan but are not covered under the contract, including any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM need not furnish information on how and where to obtain the service. The State must provide information on how and where to obtain the service.

(g) *Specific information requirements for enrollees of MCOs and PIHPs.* In addition to the requirements in § 438.10(f), the State, its contracted representative, or the MCO and PIHP must provide the following information to their enrollees:

(1) Grievance, appeal, and fair hearing procedures and timeframes, as provided in §§ 438.400 through 438.424, in a State-developed or State-approved description, that must include the following:

(i) For State fair hearing—

(A) The right to hearing;

(B) The method for obtaining a hearing; and

(C) The rules that govern representation at the hearing.

(ii) The right to file grievances and appeals.

(iii) The requirements and timeframes for filing a grievance or appeal.

(iv) The availability of assistance in the filing process.

(v) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.

(vi) The fact that, when requested by the enrollee—

(A) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and

(B) The enrollee may be required to pay the cost of services furnished while the appeal is pending, if the final decision is adverse to the enrollee.

(vii) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.

(2) Advance directives, as set forth in § 438.6(i)(2).

(3) Additional information that is available upon request, including the following:

(i) Information on the structure and operation of the MCO or PIHP.

(ii) Physician incentive plans as set forth in § 438.6(h) of this chapter.

(h) *Specific information for PAHPs.* The State, its contracted representative, or the PAHP must provide the following information to their enrollees:

(1) The right to a State fair hearing, including the following:

(i) The right to a hearing.

(ii) The method for obtaining a hearing.

(iii) The rules that govern representation.

(2) Advance directives, as set forth in § 438.6(i)(2), to the extent that the PAHP includes any of the providers listed in § 489.102(a) of this chapter.

(3) Upon request, physician incentive plans as set forth in § 438.6(h).

(i) *Special rules: States with mandatory enrollment under State plan authority*—(1) *Basic rule.* If the State plan provides for mandatory enrollment under § 438.50, the State or its contracted representative must provide information on MCOs and PCCMs (as specified in paragraph (i)(3) of this section), either directly or through the MCO or PCCM.

(2) *When and how the information must be furnished.* The information must be furnished as follows:

(i) For potential enrollees, within the timeframe specified in § 438.10(e)(1).

(ii) For enrollees, annually and upon request.

(iii) In a comparative, chart-like format.

(3) *Required information.* Some of the information is the same as the information required for potential enrollees under paragraph (e) of this section and for enrollees under paragraph (f) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (i)(2) of this section, and includes the following for each contracting MCO or PCCM in the potential enrollees and enrollee's service area:

(i) The MCO's or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO or PCCM.

(iv) To the extent available, quality and performance indicators, including enrollee satisfaction.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate for the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO, PIHP, or PAHP declines to include individual or groups of providers in its network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with health care professionals, an MCO, PIHP, or PAHP must comply with the requirements specified in § 438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO, PIHP, or PAHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO, PIHP, or PAHP from using different reimbursement amounts for different specialties or for different practitioners in the same specialty; or

(3) Preclude the MCO, PIHP, or PAHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

Subpart B—State Responsibilities

§ 438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid recipients to enroll in

managed care entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115 of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—

(1) The types of entities with which the State contracts;

(2) The payment method it uses (for example, whether fee-for-service or capitation);

(3) Whether it contracts on a comprehensive risk basis; and

(4) The process the State uses to involve the public in both design and initial implementation of the program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following statute and regulations:

(1) Section 1903(m) of the Act, for MCOs and MCO contracts.

(2) Section 1905(t) of the Act, for PCCMs and PCCM contracts.

(3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring recipients to receive their benefits through managed care entities.

(4) This part, for MCOs and PCCMs.

(5) Part 434 of this chapter, for all contracts.

(6) Section 438.6(c), for payments under any risk contracts, and § 447.362 of this chapter for payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO or PCCM:

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCO or PCCM is—

(i) The Indian Health Service; or

(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service.

(3) Children under 19 years of age who are—

(i) Eligible for SSI under title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.

(e) *Priority for enrollment.* The State must have an enrollment system under which recipients already enrolled in an MCO or PCCM are given priority to continue that enrollment if the MCO or PCCM does not have the capacity to accept all those seeking enrollment under the program.

(f) *Enrollment by default.* (1) For recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.

(2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).

(3) An ''existing provider-recipient relationship'' is one in which the provider was the main source of Medicaid services for the recipient during the previous year. This may be established through State records of previous managed care enrollment or fee-for-service experience, or through contact with the recipient.

(4) A provider is considered to have ''traditionally served'' Medicaid recipients if it has experience in serving the Medicaid population.

§ 438.52 Choice of MCOs, PIHPs, PAHPs, and PCCMs.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PIHP, PAHP, or PCCM must give those recipients a choice of at least two entities.

(b) *Exception for rural area residents.* (1) Under any of the following programs, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PIHP, PAHP, or PCCM system:

(i) A program authorized by a plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115 of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) A State that elects the option provided under paragraph (b)(1) of this section, must permit the recipient—

(i) To choose from at least two physicians or case managers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP, PAHP, or PCCM network.

(B) The provider is not part of the network, but is the main source of a service to the recipient, provided that—

(*1*) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, PAHP, or PCCM network as other network providers of that type.

(*2*) If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 days (after being given an opportunity to select a provider who participates).

(C) The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The recipient's primary care provider or other provider determines that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph, ''rural area'' is any area other than an ''urban area'' as defined in § 412.62(f)(1)(ii) of this chapter.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act; and

(2) The recipient who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PIHP, PAHP, or HIO under paragraph (b) or (c) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care arrangements whether enrollment is mandatory or voluntary and whether the contract is with an MCO, a PIHP, a PAHP, or a PCCM.

(b) *Disenrollment requested by the MCO, PIHP, PAHP, or PCCM.* All MCO, PIHP, PAHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PIHP, PAHP, or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PIHP, PAHP, or PCCM may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, or PCCM seriously impairs the entity's ability to furnish

services to either this particular enrollee or other enrollees); and

(3) Specify the methods by which the MCO, PIHP, PAHP, or PCCM assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PIHP, PAHP, and PCCM contracts must provide that a recipient may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the recipient's initial enrollment with the MCO, PIHP, PAHP, or PCCM, or the date the State sends the recipient notice of the enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the recipient to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(3).

(d) *Procedures for disenrollment*—(1) *Request for disenrollment.* The recipient (or his or her representative) must submit an oral or written request—

(i) To the State agency (or its agent); or

(ii) To the MCO, PIHP, PAHP, or PCCM, if the State permits MCOs, PIHP, PAHPs, and PCCMs to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee moves out of the MCO's, PIHP's, PAHP's, or PCCM's service area.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) Other reasons, including but not limited to, poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's health care needs.

(3) *MCO, PIHP, PAHP, or PCCM action on request.* (i) An MCO, PIHP, PAHP, or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the recipient, or one referred by the MCO, PIHP, PAHP, or PCCM, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PIHP, PAHP, or PCCM at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO, PIHP, PAHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PIHP, PAHP, or PCCM's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in § 438.56(e)(1).

(iii) If, as a result of the grievance process, the MCO, PIHP, PAHP, or PCCM approves the disenrollment, the State agency is not required to make a determination.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee or the MCO, PIHP, PAHP, or PCCM files the request.

(2) If the MCO, PIHP, PAHP, or PCCM or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period.

(2) Ensure access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a recipient who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

(a) As a condition for contracting with MCOs, PIHPs, or PAHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or the default enrollment process specified in § 438.50(f).

(b) These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Limit on payment to other providers.

The State agency must ensure that no payment is made to a provider other than the MCO, PIHP, or PAHP for services available under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are provided for in title XIX of the Act, in 42 CFR, or when the State agency has adjusted the capitation rates paid under the contract, in accordance with § 438.6(c)(5)(v), to make payments for graduate medical education.

§ 438.62 Continued services to recipients.

The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, or PCCM whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, or PCCM for any reason other than ineligibility for Medicaid.

§ 438.66 Monitoring procedures.

The State agency must have in effect procedures for monitoring the MCO's, PIHP's, or PAHP's operations, including, at a minimum, operations related to the following:

(a) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

(c) Violations subject to intermediate sanctions, as set forth in subpart I of this part.

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

(e) All other provisions of the contract, as appropriate.

Subpart C—Enrollee Rights and Protections

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that—

(1) Each MCO and PIHP has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PIHP, PAHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take those rights into account when furnishing services to enrollees.

(b) *Specific rights*—(1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (b)(3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, or PCCM has the following rights: The right to—

(i) Receive information in accordance with § 438.10.

(ii) Be treated with respect and with due consideration for his or her dignity and privacy.

(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(f)(6)(xii).)

(iv) Participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR § 164.524 and 164.526.

(3) An enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§ 438.206 through 438.210.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP, PAHP, or PCCM and its providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PIHP, PAHP, and PCCM complies with any other applicable Federal and State laws (such as: title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; and titles II and III of the Americans with Disabilities Act; and other laws regarding privacy and confidentiality).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a health care professional acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs in order to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or nontreatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) Subject to the information requirements of paragraph (b) of this section, an MCO, PIHP, or PAHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds.

(b) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1) An MCO, PIHP, or PAHP that elects the option provided in paragraph (a)(2) of this section must furnish information about the services it does not cover as follows:

(i) To the State—

(A) With its application for a Medicaid contract; and

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment; and

(B) To enrollees, within 90 days after adopting the policy with respect to any particular service. (Although this timeframe would be sufficient to entitle the MCO, PIHP, or PAHP to the option provided in paragraph (a)(2) of this section, the overriding rule in § 438.10(f)(4)

requires the State, its contracted representative, or MCO, PIHP, or PAHP to furnish the information at least 30 days before the effective date of the policy.)

(2) As specified in § 438.10, paragraphs (e) and (f), the information that MCOs, PIHPs, and PAHPs must furnish to enrollees and potential enrollees does not include how and where to obtain the service excluded under paragraph (a)(2) of this section.

(c) *Information requirements: State responsibility*. For each service excluded by an MCO, PIHP, or PAHP under paragraph (a)(2) of this section, the State must provide information on how and where to obtain the service, as specified in § 438.10, paragraphs (e)(2)(ii)(E) and (f)(6)(xii).

(d) *Sanction*. An MCO that violates the prohibition of paragraph (a)(1) of this section is subject to intermediate sanctions under subpart I of this part.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.104 Marketing activities.

(a) *Terminology*. As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PIHP, PAHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

Marketing means any communication, from an MCO, PIHP, PAHP, or PCCM to a Medicaid recipient who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the recipient to enroll in that particular MCO's, PIHP's, PAHP's, or PCCM's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, or PCCM's Medicaid product.

Marketing materials means materials that—

(1) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, or PCCM; and

(2) Can reasonably be interpreted as intended to market to potential enrollees.

MCO, PIHP, PAHP, or PCCM include any of the entity's employees, affiliated providers, agents, or contractors.

(b) *Contract requirements*. Each contract with an MCO, PIHP, PAHP, or PCCM must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval;

(ii) Distributes the materials to its entire service area as indicated in the contract;

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the recipient receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll;

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any private insurance; and

(v) Does not, directly or indirectly, engage in door-to-door, telephone, or other cold-call marketing activities.

(2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients or the State agency. Statements that will be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The recipient must enroll in the MCO, PIHP, PAHP, or PCCM in order to obtain benefits or in order to not lose benefits; or

(ii) The MCO, PIHP, PAHP, or PCCM is endorsed by CMS, the Federal or State government, or similar entity.

(c) *State agency review*. In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO, PIHP, and PAHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's, PIHP's, or PAHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO, PIHP, or PAHP; or

(2) The State, or the MCO, PIHP, or PAHP does not pay the individual or health care provider that furnishes the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO, PIHP, or PAHP provided the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.60 of this chapter.

§ 438.114 Emergency and poststabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(1) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

(2) Serious impairment to bodily functions.

(3) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient and outpatient services that are as follows:

(1) Furnished by a provider that is qualified to furnish these services under this title.

(2) Needed to evaluate or stabilize an emergency medical condition.

Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized in order to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

(b) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and poststabilization care services.

(1) The MCO, PIHP, or PAHP.

(2) The PCCM that has a risk contract that covers these services.

(3) The State, in the case of a PCCM that has a fee-for-service contract.

(c) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (b) of this section—

(i) Must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the MCO, PIHP, PAHP, or PCCM; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1), (2), and (3) of the definition of *emergency medical condition* in paragraph (a) of this section.

(B) A representative of the MCO, PIHP, PAHP, or PCCM instructs the enrollee to seek emergency services.

(2) A PCCM must—

(i) Allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services; and

(ii) Pay for the services if the manager's contract is a risk contract that covers those services.

(d) *Additional rules for emergency services.* (1) The entities specified in paragraph (b) of this section may not—

(i) Limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, PIHP, PAHP or applicable State entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Poststabilization care services.* Poststabilization care services are covered and paid for in accordance with provisions set forth at §422.113(c) of this chapter. In applying those provisions, reference to ''M+C organization'' must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section.

(f) *Applicability to PIHPs and PAHPs.* To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the PIHP or PAHP is responsible, the rules under this section apply.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.116 Solvency standards.

(a) *Requirement for assurances* (1) Each MCO, PIHP, and PAHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's, PIHP's, or PAHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, an MCO or PIHP, must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PIHP, that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

Subpart D—Quality Assessment and Performance Improvement

§ 438.200 Scope.

This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs, PIHPs, and PAHPs. It also establishes standards that States, MCOs, PIHPs, and PAHPs must meet.

§ 438.202 State responsibilities.

Each State contracting with an MCO or PIHP must do the following:

(a) Have a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs.

(b) Obtain the input of recipients and other stakeholders in the development of the strategy and make the strategy available for public comment before adopting it in final.

(c) Ensure that MCOs, PIHPs, and PAHPs comply with standards established by the State, consistent with this subpart.

(d) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy periodically, as needed.

(e) Submit to CMS the following:

(1) A copy of the initial strategy, and a copy of the revised strategy whenever significant changes are made.

(2) Regular reports on the implementation and effectiveness of the strategy.

§ 438.204 Elements of State quality strategies.

At a minimum, State strategies must include the following:

(a) The MCO and PIHP contract provisions that incorporate the standards specified in this subpart.

(b) Procedures that—

(1) Assess the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PIHP contracts, and to individuals with special health care needs.

(2) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PIHP for each Medicaid enrollee at the time of enrollment.

(3) Regularly monitor and evaluate the MCO and PIHP compliance with the standards.

(c) For MCOs and PIHPs, any national performance measures and levels that may be identified and developed by CMS in consultation with States and other relevant stakeholders.

(d) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO and PIHP contract.

(e) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.

(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.

ACCESS STANDARDS

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, and each PIHP and PAHP consistent with the scope of the PIHP's or PAHP's contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract. In establishing and maintaining the network, each MCO, PIHP, and PAHP must consider the following:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services, taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP.

(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.

(iv) The numbers of network providers who are not accepting new Medicaid patients.

(v) The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a qualified health care professional within the network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the network is unable to provide necessary services, covered under the contract, to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP is unable to provide them.

(5) Requires out-of-network providers to coordinate with the MCO or PIHP with respect to payment and ensures that cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its providers are credentialed as required by § 438.214.

(c) *Furnishing of services.* The State must ensure that each MCO, PIHP, and PAHP contract complies with the requirements of this paragraph.

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

(i) Meet and require its providers to meet State standards for timely access to care and services, taking into account the urgency of the need for services.

(ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid fee-for-service, if the provider serves only Medicaid enrollees.

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by providers.

(v) Monitor providers regularly to determine compliance.

(vi) Take corrective action if there is a failure to comply.

(2) *Cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds.

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this subpart.

(b) *Nature of supporting documentation.* Each MCO, PIHP, and PAHP must submit documentation to the State, in a format specified by the State to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of preventive, primary care, and specialty services that is adequate for the anticipated number of enrollees for the service area.

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area.

(c) *Timing of documentation.* Each MCO, PIHP, and PAHP must submit the documentation described in paragraph (b) of this section as specified by the State, but no less frequently than the following:

(1) At the time it enters into a contract with the State.

(2) At any time there has been a significant change (as defined by the State) in the MCO's, PIHP's, or PAHP's operations that would affect adequate capacity and services, including—

(i) Changes in MCO, PIHP, or PAHP services, benefits, geographic service area or payments; or

(ii) Enrollment of a new population in the MCO, PIHP, or PAHP.

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP, the State must certify to CMS that the MCO, PIHP, or PAHP has complied with the State's requirements for availability of services, as set forth in § 438.206.

(e) *CMS' right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP.

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (a)(3) of this section, the State must ensure through its contracts, that each MCO, PIHP, and PAHP complies with the requirements of this section.

(2) *PIHP and PAHP exception.* For PIHPs and PAHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed

care services, whether a particular PIHP or PAHP is required to—

(i) Meet the primary care requirement of paragraph (b)(1) of this section; and

(ii) Implement mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs, as specified in paragraph (c) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For each MCO that serves enrollees who are also enrolled in and receive Medicare benefits from a Medicare+Choice plan, the State determines to what extent the MCO must meet the primary care coordination, identification, assessment, and treatment planning provisions of paragraphs (b) and (c) of this section with respect to dually eligible individuals.

(ii) The State bases its determination on the services it requires the MCO to furnish to dually eligible enrollees.

(b) *Primary care and coordination of health care services for all MCO, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver primary care to and coordinate health care service for all MCO, PIHP, and PAHP enrollees. These procedures must meet State requirements and must do the following:

(1) Ensure that each enrollee has an ongoing source of primary care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the health care services furnished to the enrollee.

(2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee with the services the enrollee receives from any other MCO, PIHP, or PAHP.

(3) Share with other MCOs, PIHPs, and PAHPs serving the enrollee with special health care needs the results of its identification and assessment of that enrollee's needs to prevent duplication of those activities.

(4) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.

(c) *Additional services for enrollees with special health care needs*—(1) *Identification.* The State must implement mechanisms to identify persons with special health care needs to MCOs, PIHPs and PAHPs, as those persons are defined by the State. These identification mechanisms—

(i) Must be specified in the State's quality improvement strategy in § 438.202; and

(ii) May use State staff, the State's enrollment broker, or the State's MCOs,

PIHPs and PAHPs.

(2) *Assessment.* Each MCO, PIHP, and PAHP must implement mechanisms to assess each Medicaid enrollee identified by the State (through the mechanism specified in paragraph (c)(1) of this section) and identified to the MCO, PIHP, and PAHP by the State as having special health care needs in order to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring. The assessment mechanisms must use appropriate health care professionals.

(3) *Treatment plans.* If the State requires MCOs, PIHPs, and PAHPs to produce a treatment plan for enrollees with special health care needs who are determined through assessment to need a course of treatment or regular care monitoring, the treatment plan must be—

(i) Developed by the enrollee's primary care provider with enrollee participation, and in consultation with any specialists caring for the enrollee;

(ii) Approved by the MCO, PIHP, or PAHP in a timely manner, if this approval is required by the MCO, PIHP, or PAHP; and

(iii) In accord with any applicable State quality assurance and utilization review standards.

(4) *Direct access to specialists.* For enrollees with special health care needs determined through an assessment by appropriate health care professionals (consistent with § 438.208(c)(2)) to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a

standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs.

§438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract with an MCO, PIHP, or PAHP must do the following:

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer.

(2) Require that the services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under fee-for-service Medicaid, as set forth in §440.230.

(3) Provide that the MCO, PIHP, or PAHP—

(i) Must ensure that the services are sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are furnished.

(ii) May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary;

(iii) May place appropriate limits on a service—

(A) On the basis of criteria applied under the State plan, such as medical necessity; or

(B) For the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose, as required in paragraph (a)(3)(i) of this section; and

(4) Specify what constitutes ''medically necessary services'' in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; and

(ii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services related to the following:

(A) The prevention, diagnosis, and treatment of health impairments.

(B) The ability to achieve age-appropriate growth and development.

(C) The ability to attain, maintain, or regain functional capacity.

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO, PIHP, or PAHP and its subcontractors have in place, and follow, written policies and procedures.

(2) That the MCO, PIHP, or PAHP—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions; and

(ii) Consult with the requesting provider when appropriate.

(3) That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by a health care professional who has appropriate clinical expertise in treating the enrollee's condition or disease.

(c) *Notice of adverse action.* Each contract must provide for the MCO, PIHP, or PAHP to notify the requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs and PIHPs, the notice must meet the requirements of §438.404, except that the notice to the provider need not be in writing.

(d) *Timeframe for decisions.* Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

(1) *Standard authorization decisions.* For standard authorization decisions, provide notice as expeditiously as the enrollee's health condition requires and within State-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) The MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(2) *Expedited authorization decisions.* (i) For cases in which a provider indicates, or the MCO, PIHP, or PAHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the MCO, PIHP, or PAHP must make an expedited authorization decision and provide notice as expeditiously as the enrollee's health condition requires and no later than 3 working days after receipt of the request for service.

(ii) The MCO, PIHP, or PAHP may extend the 3 working days time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(e) *Compensation for utilization management activities.* Each contract must provide that, consistent with § 438.6(h), and § 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

STRUCTURE AND OPERATION STANDARDS

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of providers and that those policies and procedures include, at a minimum, the requirements of this section.

(b) *Credentialing and recredentialing requirements.* (1) Each State must establish a uniform credentialing and recredentialing policy that each MCO, PIHP, and PAHP must follow.

(2) Each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing of providers who have signed contracts or participation agreements with the MCO, PIHP, or PAHP.

(c) *Nondiscrimination.* MCO, PIHP, and PAHP provider selection policies and procedures, consistent with § 438.12, must not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* MCOs, PIHPs, and PAHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(e) *State requirements.* Each MCO, PIHP, and PAHP must comply with any additional requirements established by the State.

[67 FR 41095, June 14, 2002; 67 FR 54532, Aug. 22, 2002]

§ 438.218 Enrollee information.

The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.

§ 438.224 Confidentiality.

The State must ensure, through its contracts, that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO, PIHP, and PAHP uses and discloses such individually identifiable health information in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.

§ 438.226 Enrollment and disenrollment.

The State must ensure that each MCO, PIHP, and PAHP contract complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.

§ 438.228 Grievance systems.

(a) The State must ensure, through its contracts, that each MCO and PIHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO or PIHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO or PIHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 Subcontractual relationships and delegation.

(a) *General rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP—

(1) Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor; and

(2) Meets the conditions of paragraph (b) of this section.

(b) *Specific conditions.* (1) Before any delegation, each MCO, PIHP, and PAHP evaluates the prospective subcontractor's ability to perform the activities to be delegated.

(2) There is a written agreement that—

(i) Specifies the activities and report responsibilities delegated to the subcontractor; and

(ii) Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.

(3) The MCO, PIHP, or PAHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations.

(4) If any MCO, PIHP, or PAHP identifies deficiencies or areas for improvement, the MCO, PIHP, or PAHP and the subcontractor take corrective action.

Measurement and Improvement Standards

§ 438.236 Practice guidelines.

(a) *Basic rule:* The State must ensure, through its contracts, that each MCO and, when applicable, each PIHP and PAHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and, when applicable, each PIHP and PAHP adopts practice guidelines that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with contracting health care professionals.

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO, PIHP, and PAHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

§ 438.240 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO and PIHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) CMS, in consultation with States and other stakeholders, may specify performance measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs.

(b) *Basic elements of MCO and PIHP quality assessment and performance improvement programs.* At a minimum, the State must require that each MCO and PIHP comply with the following requirements:

(1) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction.

(2) Submit performance measurement data as described in paragraph (c) of this section.

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(c) *Performance measurement.* Annually each MCO and PIHP must—

(1) Measure and report to the State its performance, using standard measures required by the State including those that incorporate the requirements of § 438.204(c) and § 438.240(a)(2);

(2) Submit to the State, data specified by the State, that enables the State to measure the MCO's or PIHP's performance; or

(3) Perform a combination of the activities described in paragraphs (c)(1) and (c)(2) of this section.

(d) *Performance improvement projects.* (1) MCOs and PIHPs must have an ongoing program of performance improvement projects that focus on clinical and nonclinical areas, and that involve the following:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of system interventions to achieve improvement in quality.

(iii) Evaluation of the effectiveness of the interventions.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(2) Each MCO and PIHP must report the status and results of each project to the State as requested, including those that incorporate the requirements of § 438.240(a)(2). Each performance improvement project must be completed in a reasonable time period so as to generally allow information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of each MCO's and PIHP's quality assessment and performance improvement program. The review must include—

(i) The MCO's and PIHP's performance on the standard measures on which it is required to report; and

(ii) The results of each MCO's and PIHP's performance improvement projects.

(2) The State may require that an MCO or PIHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure, through its contracts, that each MCO and PIHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system must provide information on areas including, but not limited to, utilization, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO and PIHP comply with the following:

(1) Collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees through an encounter data system or other methods as may be specified by the State.

(2) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data;

(ii) Screening the data for completeness, logic, and consistency; and

(iii) Collecting service information in standardized formats to the extent feasible and appropriate.

(3) Make all collected data available to the State and upon request to CMS, as required in this subpart.

Subpart E—External Quality Review

SOURCE: 68 FR 3635, Jan. 24, 2003, unless otherwise noted.

§ 438.310 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart is based on sections 1932(c)(2), 1903(a)(3)(C)(ii), and 1902(a)(4) of the Act.

(b) *Scope.* This subpart sets forth requirements for annual external quality reviews of each contracting managed care organization (MCO) and prepaid inpatient health plan (PIHP), including—

(1) Criteria that States must use in selecting entities to perform the reviews;

(2) Specifications for the activities related to external quality review;

(3) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews; and

(4) Standards for making available the results of the reviews.

(c) *Applicability.* The provisions of this subpart apply to MCOs, PIHPs, and to health insuring organizations (HIOs) that began on or after January 1, 1986 that the statute does not explicitly exempt from requirements in section 1903(m) of the Act.

§ 438.320 Definitions.

As used in this subpart—

EQR stands for external quality review.

EQRO stands for external quality review organization.

External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO or PIHP, or their contractors furnish to Medicaid recipients.

External quality review organization means an organization that meets the competence and independence requirements set forth in § 438.354, and performs external quality review, other EQR-related activities as set forth in § 438.358, or both.

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Quality, as it pertains to external quality review, means the degree to which an MCO or PIHP increases the likelihood of desired health outcomes of its enrollees through its structural and operational characteristics and through the provision of health services that are consistent with current professional knowledge.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.350 State responsibilities.

Each State that contracts with MCOs or PIHPs must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each contracting MCO or PIHP;

(b) The EQRO has sufficient information to use in performing the review;

(c) The information used to carry out the review must be obtained from the EQR-related activities described in § 438.358.

(d) For each EQR-related activity, the information must include the elements described in § 438.364(a)(1)(i) through (a)(1)(iv);

(e) The information provided to the EQRO in accordance with paragraph (c) of this section is obtained through methods consistent with the protocols established under § 438.352; and

(f) The results of the reviews are made available as specified in § 438.364.

§ 438.352 External quality review protocols.

Each protocol must specify—

(a) The data to be gathered;

(b) The sources of the data;

(c) The activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) Instructions, guidelines, worksheets, and other documents or tools necessary for implementing the protocol.

§ 438.354 Qualifications of external quality review organizations.

(a) *General rule.* The State must ensure that an EQRO meets the requirements of this section.

(b) *Competence.* The EQRO must have at a minimum the following:

(1) Staff with demonstrated experience and knowledge of—

(i) Medicaid recipients, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement methods; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

(3) Other clinical and nonclinical skills necessary to carry out EQR or EQR-related activities and to oversee the work of any subcontractors.

(c) *Independence.* The EQRO and its subcontractors are independent from the State Medicaid agency and from the MCOs or PIHPs that they review. To qualify as ''independent''—

(1) A State agency, department, university, or other State entity may not have Medicaid purchasing or managed care licensing authority; and

(2) A State agency, department, university, or other State entity must be governed by a Board or similar body the majority of whose members are not government employees.

(3) An EQRO may not—

(i) Review a particular MCO or PIHP if either the EQRO or the MCO or PIHP exerts control over the other (as used in this paragraph, ''control'' has the meaning given the term in 48 CFR 19.101) through—

(A) Stock ownership;

(B) Stock options and convertible debentures;

(C) Voting trusts;

(D) Common management, including interlocking management; and

(E) Contractual relationships.

(ii) Deliver any health care services to Medicaid recipients;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO or PIHP services, except for the related activities specified in § 438.358; or

(iv) Have a present, or known future, direct or indirect financial relationship with an MCO or PIHP that it will review as an EQRO.

§ 438.356 State contract options.

(a) The State—

(1) Must contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities; and

(2) May contract with additional EQROs to conduct EQR-related activities as set forth in § 438.358.

(b) Each EQRO must meet the competence requirements as specified in § 438.354(b).

(c) Each EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each EQRO and its subcontractors performing EQR or EQR-related activities must meet the requirements for independence, as specified in § 438.354(c).

(e) For each contract, the State must follow an open, competitive procurement process that is in accordance with State law and regulations and consistent with 45 CFR part 74 as it applies to State procurement of Medicaid services.

§ 438.358 Activities related to external quality review.

(a) *General rule.* The State, its agent that is not an MCO or PIHP, or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(b) *Mandatory activities.* For each MCO and PIHP, the EQR must use information from the following activities:

(1) Validation of performance improvement projects required by the State to comply with requirements set forth in § 438.240(b)(1) and that were underway during the preceding 12 months.

(2) Validation of MCO or PIHP performance measures reported (as required by the State) or MCO or PIHP performance measure calculated by the State during the preceding 12 months to comply with requirements set forth in § 438.240(b)(2).

(3) A review, conducted within the previous 3-year period, to determine the MCO's or PIHP's compliance with standards (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) established by the State to comply with the requirements of § 438.204(g).

(c) *Optional activities.* The EQR may also use information derived during the

preceding 12 months from the following optional activities:

(1) Validation of encounter data reported by an MCO or PIHP.

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO or PIHP and validated by an EQRO.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO or PIHP and validated by an EQRO.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(d) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs or PIHPs to assist them in conducting activities related to the mandatory and optional activities that provide information for the EQR.

§ 438.360 Nonduplication of mandatory activities.

(a) *General rule.* To avoid duplication, the State may use, in place of a Medicaid review by the State, its agent, or EQRO, information about the MCO or PIHP obtained from a Medicare or private accreditation review to provide information otherwise obtained from the mandatory activities specified in § 438.358 if the conditions of paragraph (b) or paragraph (c) of this section are met.

(b) *MCOs or PIHPs reviewed by Medicare or private accrediting organizations.* For information about an MCO's or PIHP's compliance with one or more standards required under § 438.204(g), (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) the following conditions must be met:

(1) The MCO or PIHP is in compliance with standards established by CMS for Medicare+Choice or a national accrediting organization. The CMS or national accreditation standards are comparable to standards established by the State to comply with § 438.204(g) and the EQR-related activity under § 438.358(b)(3).

(2) Compliance with the standards is determined either by—

(i) CMS or its contractor for Medicare; or

(ii) A private national accrediting organization that CMS has approved as applying standards at least as stringent as Medicare under the procedures in § 422.158.

(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review applicable to the standards provided for in § 438.204(g); and the State provides the information to the EQRO.

(4) In its quality strategy, the State identifies the standards for which the EQR will use information from Medicare or private accreditation reviews, and explains its rationale for why the standards are duplicative.

(c) *Additional provisions for MCOs or PIHPs serving only dually eligibles.* The State may use information obtained from the Medicare program in place of information produced by the State, its agent, or EQRO with respect to the mandatory activities specified in § 438.358 (b)(1) and (b)(2) if the following conditions are met:

(1) The MCO or PIHP serves only individuals who receive both Medicare and Medicaid benefits.

(2) The Medicare review activities are substantially comparable to the State-specified mandatory activities in § 438.358(b)(1) and (b)(2).

(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the Medicare review from the activities specified under § 438.358(b)(1) and (b)(2) and the State provides the information to the EQRO.

(4) In its quality strategy, the State identifies the mandatory activities for which it has exercised this option and explains its rationale for why these activities are duplicative.

§ 438.362 Exemption from external quality review.

(a) *Basis for exemption.* The State may exempt an MCO or PIHP from EQR if the following conditions are met:

(1) The MCO or PIHP has a current Medicare contract under part C of title

XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act.

(2) The two contracts cover all or part of the same geographic area within the State.

(3) The Medicaid contract has been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years the MCO or PIHP has been subject to EQR under this part, and found to be performing acceptably with respect to the quality, timeliness, and access to health care services it provides to Medicaid recipients.

(b) *Information on exempted MCOs or PIHPs.* When the State exercises this option, the State must obtain either of the following:

(1) *Information on Medicare review findings.* Each year, the State must obtain from each MCO or PIHP that it exempts from EQR the most recent Medicare review findings reported on the MCO or PIHP including—

(i) All data, correspondence, information, and findings pertaining to the MCO's or PIHP's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities;

(ii) All measures of the MCO's or PIHP's performance; and

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Medicare information from a private, national accrediting organization that CMS approves and recognizes for Medicare+Choice deeming.* (i) If an exempted MCO or PIHP has been reviewed by a private accrediting organization, the State must require the MCO or PIHP to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

(B) To deem compliance with Medicare requirements, as provided in § 422.156 of this chapter.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

§ 438.364 External quality review results.

(a) *Information that must be produced.* The State must ensure that the EQR produces at least the following information:

(1) A detailed technical report that describes the manner in which the data from all activities conducted in accordance with § 438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO or PIHP. The report must also include the following for each activity conducted in accordance with § 438.358:

(i) Objectives.

(ii) Technical methods of data collection and analysis.

(iii) Description of data obtained.

(iv) Conclusions drawn from the data.

(2) An assessment of each MCO's or PIHP's strengths and weaknesses with respect to the quality, timeliness, and access to health care services furnished to Medicaid recipients.

(3) Recommendations for improving the quality of health care services furnished by each MCO or PIHP.

(4) As the State determines, methodologically appropriate, comparative information about all MCOs and PIHPs.

(5) An assessment of the degree to which each MCO or PIHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) *Availability of information.* The State must provide copies of the information specified in paragraph (a) of this section, upon request, through print or electronic media, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO or PIHP, recipient advocacy groups, and members of the general public. The State must make this information available in alternative formats for persons with sensory impairments, when requested.

(c) *Safeguarding patient identity.* The information released under paragraph

(b) of this section may not disclose the identity of any patient.

§ 438.370 Federal financial participation.

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and EQR-related activities set forth in § 438.358 conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities conducted by any entity that does not qualify as an EQRO.

Subpart F—Grievance System

§ 438.400 Statutory basis and definitions.

(a) *Statutory basis.* This subpart is based on sections 1902(a)(3), 1902(a)(4), and 1932(b)(4) of the Act.

(1) Section 1902(a)(3) requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) requires Medicaid managed care organizations to establish internal grievance procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Action means—

In the case of an MCO or PIHP—

(1) The denial or limited authorization of a requested service, including the type or level of service;

(2) The reduction, suspension, or termination of a previously authorized service;

(3) The denial, in whole or in part, of payment for a service;

(4) The failure to provide services in a timely manner, as defined by the State;

(5) The failure of an MCO or PIHP to act within the timeframes provided in § 438.408(b); or

(6) For a resident of a rural area with only one MCO, the denial of a Medicaid enrollee's request to exercise his or her right, under § 438.52(b)(2)(ii), to obtain services outside the network.

Appeal means a request for review of an action, as ''action'' is defined in this section.

Grievance means an expression of dissatisfaction about any matter other than an action, as ''action'' is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State fair hearing process. (Possible subjects for grievances include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights.)

§ 438.402 General requirements.

(a) *The grievance system.* Each MCO and PIHP must have a system in place for enrollees that includes a grievance process, an appeal process, and access to the State's fair hearing system.

(b) *Filing requirements*—(1) *Authority to file.* (i) An enrollee may file a grievance and an MCO or PIHP level appeal, and may request a State fair hearing.

(ii) A provider, acting on behalf of the enrollee and with the enrollee's written consent, may file an appeal. A provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

(2) *Timing.* The State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PIHP's notice of action. Within that timeframe—

(i) The enrollee or the provider may file an appeal; and

(ii) In a State that does not require exhaustion of MCO and PIHP level appeals, the enrollee may request a State fair hearing.

(3) *Procedures.* (i) The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO or the PIHP.

(ii) The enrollee or the provider may file an appeal either orally or in writing, and unless he or she requests expedited resolution, must follow an oral filing with a written, signed, appeal.

§ 438.404 Notice of action.

(a) *Language and format requirements.* The notice must be in writing and must meet the language and format requirements of § 438.10(c) and (d) to ensure ease of understanding.

(b) *Content of notice.* The notice must explain the following:

(1) The action the MCO or PIHP or its contractor has taken or intends to take.

(2) The reasons for the action.

(3) The enrollee's or the provider's right to file an MCO or PIHP appeal.

(4) If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.

(5) The procedures for exercising the rights specified in this paragraph.

(6) The circumstances under which expedited resolution is available and how to request it.

(7) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice.* The MCO or PIHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)(1).

(4) If the MCO or PIHP extends the timeframe in accordance with § 438.210(d)(1), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse action), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(d).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO and each PIHP must meet the following requirements:

(1) Give enrollees any reasonable assistance in completing forms and taking other procedural steps. This includes, but is not limited to, providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(2) Acknowledge receipt of each grievance and appeal.

(3) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were not involved in any previous level of review or decision-making; and

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(b) *Special requirements for appeals.* The process for appeals must:

(1) Provide that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(2) Provide the enrollee a reasonable opportunity to present evidence, and allegations of fact or law, in person as

well as in writing. (The MCO or PIHP must inform the enrollee of the limited time available for this in the case of expedited resolution.)

(3) Provide the enrollee and his or her representative opportunity, before and during the appeals process, to examine the enrollee's case file, including medical records, and any other documents and records considered during the appeals process.

(4) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* The MCO or PIHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Specific timeframes*—(1) *Standard disposition of grievances.* For standard disposition of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 days from the day the MCO or PIHP receives the grievance.

(2) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 45 days from the day the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(3) *Expedited resolution of appeals.* For expedited resolution of an appeal and notice to affected parties, the State must establish a timeframe that is no longer than 3 working days after the MCO or PIHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) *Extension of timeframes*—(1) The MCO or PIHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO or PIHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO or PIHP extends the timeframes, it must—for any extension not requested by the enrollee, give the enrollee written notice of the reason for the delay.

(d) *Format of notice*—(1) *Grievances.* The State must establish the method MCOs and PIHPs will use to notify an enrollee of the disposition of a grievance.

(2) *Appeals.* (i) For all appeals, the MCO or PIHP must provide written notice of disposition.

(ii) For notice of an expedited resolution, the MCO or PIHP must also make reasonable efforts to provide oral notice.

(e) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The results of the resolution process and the date it was completed.

(2) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State fair hearing, and how to do so;

(ii) The right to request to receive benefits while the hearing is pending, and how to make the request; and

(iii) That the enrollee may be held liable for the cost of those benefits if the hearing decision upholds the MCO's or PIHP's action.

(f) *Requirements for State fair hearings*—(1) *Availability.* The State must permit the enrollee to request a State fair hearing within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days from whichever of the following dates applies—

(i) If the State requires exhaustion of the MCO or PIHP level appeal procedures, from the date of the MCO's or PIHP's notice of resolution; or

(ii) If the State does not require exhaustion of the MCO or PIHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PIHP's notice of action.

(2) *Parties.* The parties to the State fair hearing include the MCO or PIHP as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

§ 438.410 Expedited resolution of appeals.

(a) *General rule.* Each MCO and PIHP must establish and maintain an expedited review process for appeals, when the MCO or PIHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function.

(b) *Punitive action.* The MCO or PIHP must ensure that punitive action is neither taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

(c) *Action following denial of a request for expedited resolution.* If the MCO or PIHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution in accordance with § 438.408(b)(2);

(2) Make reasonable efforts to give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice.

§ 438.414 Information about the grievance system to providers and subcontractors.

The MCO or PIHP must provide the information specified at § 438.10(g)(1) about the grievance system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping and reporting requirements.

The State must require MCOs and PIHPs to maintain records of grievances and appeals and must review the information as part of the State quality strategy.

§ 438.420 Continuation of benefits while the MCO or PIHP appeal and the State fair hearing are pending.

(a) *Terminology.* As used in this section, ''timely'' filing means filing on or before the later of the following:

(1) Within ten days of the MCO or PIHP mailing the notice of action.

(2) The intended effective date of the MCO's or PIHP's proposed action.

(b) *Continuation of benefits.* The MCO or PIHP must continue the enrollee's benefits if—

(1) The enrollee or the provider files the appeal timely;

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;

(3) The services were ordered by an authorized provider;

(4) The original period covered by the original authorization has not expired; and

(5) The enrollee requests extension of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the MCO or PIHP continues or reinstates the enrollee's benefits while the appeal is pending, the benefits must be continued until one of following occurs:

(1) The enrollee withdraws the appeal.

(2) Ten days pass after the MCO or PIHP mails the notice, providing the resolution of the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

(3) A State fair hearing Office issues a hearing decision adverse to the enrollee.

(4) The time period or service limits of a previously authorized service has been met.

(d) *Enrollee responsibility for services furnished while the appeal is pending.* If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's or PIHP's action, the MCO or PIHP may recover the cost of the services furnished to the enrollee while the appeal is pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the

appeal was pending, the MCO or PIHP must authorize or provide the disputed services promptly, and as expeditiously as the enrollee's health condition requires.

(b) *Services furnished while the appeal is pending.* If the MCO or PIHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO or the PIHP or the State must pay for those services, in accordance with State policy and regulations.

Subpart G [Reserved]

Subpart H—Certifications and Program Integrity

§ 438.600 Statutory basis.

This subpart is based on sections 1902(a)(4), 1902(a)(19), 1903(m), and 1932(d)(1) of the Act.

(a) Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) Section 1902(a)(19) requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the recipients.

(c) Section 1903(m) establishes conditions for payments to the State with respect to contracts with MCOs.

(d) Section 1932(d)(1) prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals excluded under Federal regulations from participating in specified activities, or with affiliates of those individuals.

§ 438.602 Basic rule.

As a condition for receiving payment under the Medicaid managed care program, an MCO, PCCM, PIHP, or PAHP must comply with the applicable certification, program integrity and prohibited affiliation requirements of this subpart.

§ 438.604 Data that must be certified.

(a) *Data certifications.* When State payments to an MCO or PIHP are based on data submitted by the MCO or PIHP, the State must require certification of the data as provided in § 438.606. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.

(b) *Additional certifications.* Certification is required, as provided in § 438.606, for all documents specified by the State.

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data specified in § 438.604, the data the MCO or PIHP submits to the State must be certified by one of the following:

(1) The MCO's or PIHP's Chief Executive Officer.

(2) The MCO's or PIHP's Chief Financial Officer.

(3) An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PIHP's Chief Executive Officer or Chief Financial Officer.

(b) *Content of certification.* The certification must attest, based on best knowledge, information, and belief, as follows:

(1) To the accuracy, completeness and truthfulness of the data.

(2) To the accuracy, completeness and truthfulness of the documents specified by the State.

(c) *Timing of certification.* The MCO or PIHP must submit the certification concurrently with the certified data.

§ 438.608 Program integrity requirements.

(a) *General requirement.* The MCO or PIHP must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

(b) *Specific requirements.* The arrangements or procedures must include the following:

(1) Written policies, procedures, and standards of conduct that articulate

the organization's commitment to comply with all applicable Federal and State standards.

(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.

(3) Effective training and education for the compliance officer and the organization's employees.

(4) Effective lines of communication between the compliance officer and the organization's employees.

(5) Enforcement of standards through well-publicized disciplinary guidelines.

(6) Provision for internal monitoring and auditing.

(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PIHP's contract.

§ 438.610 Prohibited affiliations with individuals debarred by Federal agencies.

(a) *General requirement.* An MCO, PCCM, PIHP, or PAHP may not knowingly have a relationship of the type described in paragraph (b) of this section with the following:

(1) An individual who is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual who is an affiliate, as defined in the Federal Acquisition Regulation, of a person described in paragraph (a)(1) of this section.

(b) *Specific requirements.* The relationships described in this paragraph are as follow:

(1) A director, officer, or partner of the MCO, PCCM, PIHP, or PAHP.

(2) A person with beneficial ownership of five percent or more of the MCO's, PCCM's, PIHP's, or PAHP's equity.

(3) A person with an employment, consulting or other arrangement with the MCO, PCCM, PIHP, or PAHP for the provision of items and services that are significant and material to the MCO's, PCCM's, PIHP's, or PAHP's obligations under its contract with the State.

(c) *Effect of Noncompliance.* If a State finds that an MCO, PCCM, PIHP, or PAHP is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PCCM, PIHP, or PAHP unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement.

(d) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (c)(2) or (c)(3) of this section is taken in consultation with the Inspector General.

Subpart I—Sanctions

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM may, establish intermediate sanctions, as specified in § 438.702, that it may impose if it makes any of the determinations specified in paragraphs (b) through (d) of this section. The State may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.

(b) A State determines whether an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a recipient, except as permitted under the Medicaid

program, or any practice that would reasonably be expected to discourage enrollment by recipients whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to CMS or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) A State determines whether an MCO, PIHP, PAHP or PCCM has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) A State determines whether—

(1) An MCO has violated any of the other requirements of sections1903(m) or 1932 of the Act, and any implementing regulations;

(2) A PCCM has violated any of the other applicable requirements of sections 1932 or 1905(t)(3) of the Act and any implementing regulations;

(3) For any of the violations under paragraphs (d)(1) and (d)(2) of this section, only the sanctions specified in § 438.702, paragraphs (a)(3), (a)(4), and (a)(5) may be imposed.

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management for an MCO as provided in § 438.706.

(3) Granting enrollees the right to terminate enrollment without cause and notifying the affected enrollees of their right to disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the effective date of the sanction.

(5) Suspension of payment for recipients enrolled after the effective date of the sanction and until CMS or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties.

(a) *General rule.* The limit on, or the maximum civil money penalty the State may impose varies depending on the nature of the MCO's or PCCM's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under the following paragraphs of § 438.700:

(i) Paragraph (b)(1) (Failure to provide services).

(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers).

(iii) Paragraph (b)(6) (Failure to comply with physician incentive plan requirements).

(iv) Paragraph (c) (Marketing violations).

(2) The limit is $100,000 for each determination under paragraph (b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to CMS or the State) of § 438.700.

(3) The limit is $15,000 for each recipient the State determines was not enrolled because of a discriminatory practice under paragraph (b)(3) of § 438.700. (This is subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the maximum amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* The State may impose temporary management only if it finds (through onsite survey, enrollee complaints, financial audits, or any other means) that—

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act; or

(2) There is substantial risk to enrollees' health; or

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700; or

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in section 1903(m) or section 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3), and must notify the affected enrollees of their right to terminate enrollment.

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO or PCCM contract.

A State has the authority to terminate an MCO or PCCM contract and enroll that entity's enrollees in other MCOs or PCCMs, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO or PCCM has failed to do either of the following:

(a) Carry out the substantive terms of its contract; or

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Due process: Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Except as provided in § 438.706(c), before imposing any of the intermediate sanctions specified in this subpart, the State must give the affected entity timely written notice that explains the following:

(1) The basis and nature of the sanction.

(2) Any other due process protections that the State elects to provide.

(b) *Pre-termination hearing*—(1) *General rule.* Before terminating an MCO or PCCM contract under § 438.708, the State must provide the entity a pre-termination hearing.

(2) *Procedures.* The State must do the following:

(i) Give the MCO or PCCM written notice of its intent to terminate, the reason for termination, and the time and place of the hearing;

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination; and

(iii) For an affirming decision, give enrollees of the MCO or PCCM notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO or PCCM that it intends to terminate the contract, the State may do the following:

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract.

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Notice to CMS.

(a) The State must give the CMS Regional Office written notice whenever it imposes or lifts a sanction for one of the violations listed in § 438.700.

(b) The notice must—

(1) Be given no later than 30 days after the State imposes or lifts a sanction; and

(2) Specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

§ 438.726 State plan requirement.

(a) The State plan must include a plan to monitor for violations that involve the actions and failures to act specified in this part and to implement the provisions of this part.

(b) A contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by CMS under section 438.730(e).

§ 438.730 Sanction by CMS: Special rules for MCOs

(a) *Basis for sanction.* (1) A State agency may recommend that CMS impose the denial of payment sanction specified in paragraph (e) of this section on an MCO with a contract under this part if the agency determines that the MCO acts or fails to act as specified in § 438.700(b)(1) through (b)(6).

(b) *Effect of an Agency Determination.* (1) The State agency's determination becomes CMS's determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the agency decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS's decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless CMS rejects this recommendation within 15 days.

(c) *Notice of sanction.* If the State agency's determination becomes CMS's determination under section (b)(2), the State agency takes the following actions:

(1) Gives the MCO written notice of the nature and basis of the proposed sanction;

(2) Allows the MCO 15 days from the date it receives the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction;

(3) May extend the initial 15-day period for an additional 15 days if—

(i) the MCO submits a written request that includes a credible explanation of why it needs additional time;

(ii) the request is received by CMS before the end of the initial period; and

(iii) CMS has not determined that the MCO's conduct poses a threat to an enrollee's health or safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State agency—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation;

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision; and

(iii) Forwards the decision to CMS.

(2) The agency decision under paragraph (d)(1)(ii) of this section becomes CMS's decision unless CMS reverses or modifies the decision within 15 days from date of receipt by CMS.

(3) If CMS reverses or modifies the State agency decision, the agency sends the MCO a copy of CMS's decision.

(e) *Denial of payment.* (1) CMS, based upon the recommendation of the agency, may deny payment to the State for new enrollees of the HMO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

(i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (b)(6) of § 438.700, is affirmed on review under paragraph (d) of this section.

(ii) If the CMS determination is not timely contested by the MCO under paragraph (c) of this section.

(2) Under § 438.726(b), CMS's denial of payment for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. (A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.)

(f) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date the MCO is notified under paragraph (b) of this section of the decision to impose the sanction.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2)(ii) of this section, the sanction is effective on the date specified in CMS's reconsideration notice.

(ii) If CMS, in consultation with the State agency, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, the sanction may be made effective earlier than the date of the agency's reconsideration decision under paragraph (c)(1)(ii) of this section.

(g) *CMS's role.* (1) CMS retains the right to independently perform the functions assigned to the State agency under paragraphs (a) through (d) of this section.

(2) At the same time that the agency sends notice to the MCO under paragraph (c)(1)(i) of this section, CMS forwards a copy of the notice to the OIG.

(3) CMS conveys the determination described in paragraph (b) of this section to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

(a) Meets the requirements of this part; and

(b) Is in effect.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if—

(1) The Regional Office has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (b)(5) of § 438.6; and

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the implementing regulations in this part.

(b) *MCO contracts.* Prior approval by CMS is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts only if the State excludes from the contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3) of this chapter, either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(ii) Any entity that would provide those services through an excluded individual or entity.

§ 438.810 Expenditures for enrollment broker services.

(a) *Terminology.* As used in this section—

Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PIHP,

PAHP, or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone or in person;

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both, and;

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PIHP, PAHP, PCCM, or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered ''independent'' if it—

(i) Is an MCO, PIHP, PAHP, PCCM or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(3) *Approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by CMS.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible recipients is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

Sec.

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45224, Sept. 29, 1978, unless otherwise noted.

Subpart A—Definitions

§ 440.1 Basis and purpose.

This subpart interprets and implements the following sections of the Act:

1905(a) Services included in the term ''medical assistance.''

1905 (c), (d), (f) through (i), (l), and (m) Definitions of institutions and services that are included in the term ''medical assistance.''

1913 ''Swing-bed'' services. (See §§ 447.280 and 482.66 of this chapter for related provisions on ''swing-bed'' services.)

1915(c) Home and community-based services listed as ''medical assistance'' and furnished under waivers under that section to individuals who would otherwise require the level of care furnished in a hospital, NF, or ICF/MR.

1915(d) Home and community-based services listed as ''medical assistance'' and furnished under waivers under that section to individuals age 65 or older who would otherwise require the level of care furnished in a NF.

[57 FR 29155, June 30, 1992, as amended at 61 FR 38398, July 24, 1996]

§ 440.2 Specific definitions; definitions of services for FFP purposes.

(a) *Specific definitions.*

Inpatient means a patient who has been admitted to a medical institution as an inpatient on recommendation of a physician or dentist and who—

(1) Receives room, board and professional services in the institution for a 24 hour period or longer, or

(2) Is expected by the institution to receive room, board and professional services in the institution for a 24 hour period or longer even though it later develops that the patient dies, is discharged or is transferred to another facility and does not actually stay in the institution for 24 hours.

Outpatient means a patient of an organized medical facility, or distinct part of that facility who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used, or whether or not the patient remains in the facility past midnight.

Patient means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward the maintenance, improvement, or protection of health, or lessening of illness, disability, or pain. (See also § 435.1010 of this chapter for definitions relating to institutional care.)

(b) *Definitions of services for FFP purposes.* Except as limited in part 441, FFP is available in expenditures under the State plan for medical or remedial care and services as defined in this subpart.

[43 FR 45224, Sept. 29, 1978, as amended at 52 FR 47934, Dec. 17, 1987; 71 FR 39229, July 12, 2006]

§ 440.10 Inpatient hospital services, other than services in an institution for mental diseases.

(a) *Inpatient hospital services* means services that—

(1) Are ordinarily furnished in a hospital for the care and treatment of inpatients;

(2) Are furnished under the direction of a physician or dentist; and

(3) Are furnished in an institution that—

(i) Is maintained primarily for the care and treatment of patients with disorders other than mental diseases;

(ii) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting;

(iii) Meets the requirements for participation in Medicare as a hospital; and

(iv) Has in effect a utilization review plan, applicable to all Medicaid patients, that meets the requirements of § 482.30 of this chapter, unless a waiver has been granted by the Secretary.

(b) Inpatient hospital services do not include SNF and ICF services furnished by a hospital with a swing-bed approval.

[47 FR 21050, May 17, 1982, as amended at 47 FR 31532, July 20, 1982; 51 FR 22041, June 17, 1986, 52 FR 47934, Dec. 17, 1987; 60 FR 61486, Nov. 30, 1995]

§ 440.20 Outpatient hospital services and rural health clinic services.

(a) *Outpatient hospital services* means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that—

(1) Are furnished to outpatients;

(2) Are furnished by or under the direction of a physician or dentist; and

(3) Are furnished by an institution that—

(i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and

(ii) Meets the requirements for participation in Medicare as a hospital; and

(4) May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of ''outpatient hospital services'' those types of items and services that are not generally furnished by most hospitals in the State.

(b) *Rural health clinic services.* If nurse practitioners or physician assistants (as defined in § 481.1 of this chapter) are not prohibited by State law from furnishing primary health care, ''rural health clinic services'' means the following services when furnished by a rural health clinic that has been certified in accordance with part 491 of this chapter.

(1) Services furnished by a physician within the scope of practice of his profession under State law, if the physician performs the services in the clinic or the services are furnished away from the clinic and the physician has an agreement with the clinic providing that he will be paid by it for such services.

(2) Services furnished by a physician assistant, nurse practitioner, nurse midwife or other specialized nurse practitioner (as defined in §§ 405.2401 and 491.2 of this chapter) if the services are furnished in accordance with the requirements specified in § 405.2414(a) of this chapter.

(3) Services and supplies that are furnished as an incident to professional services furnished by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner. (See §§ 405.2413 and 405.2415 of this chapter for the criteria for determining whether services and supplies are included under this paragraph.)

(4) Part-time or intermittent visiting nurse care and related medical supplies (other than drugs and biologicals) if:

(i) The clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies (see § 405.2417 of this chapter):

(ii) The services are furnished by a registered nurse or licensed practical nurse or a licensed vocational nurse employed by, or otherwise compensated for the services by, the clinic;

(iii) The services are furnished under a written plan of treatment that is established and reviewed at least every 60 days by a supervising physician of the clinic or that is established by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner and reviewed and

approved at least every 60 days by a supervising physician of the clinic; and

(iv) The services are furnished to a homebound recipient. For purposes of visiting nurse care, a ''homebound'' recipient means one who is permanently or temporarily confined to his place of residence because of a medical or health condition. He may be considered homebound if he leaves the place of residence infrequently. For this purpose, ''place of residence'' does not include a hospital or a skilled nursing facility.

(c) *Other ambulatory services furnished by a rural health clinic.* If the State plan covers rural health clinic services, other ambulatory services means ambulatory services other than rural health clinic services, as defined in paragraph (b) of this section, that are otherwise included in the plan and meet specific State plan requirements for furnishing those services. Other ambulatory services furnishd by a rural health clinic are not subject to the physician supervision requirements specified in §491.8(b) of this chapter, unless required by State law or the State plan.

[43 FR 45224, Sept. 29, 1978, as amended at 47 FR 21050, May 17, 1982; 52 FR 47934, Dec. 17, 1987; 60 FR 61486, Nov. 30, 1995]

§ 440.30 Other laboratory and X-ray services.

Other laboratory and X-ray services means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practioner of the healing arts within the scope of his practice as defined by State law or ordered by a physician but provided by referral laboratory;

(b) Provided in an office or similar facility other than a hospital outpatient department or clinic; and

(c) Furnished by a laboratory that meets the requirements of part 493 of this chapter.

[46 FR 42672, Aug. 24, 1981, as amended at 57 FR 7135, Feb. 28, 1992]

§ 440.40 Nursing facility services for individuals age 21 or older (other than services in an institution for mental disease), EPSDT, and family planning services and supplies.

(a) *Nursing facility services.* (1) ''Nursing facility services for individuals age 21 or older, other than services in an institution for mental diseases'', means services that are—

(i) Needed on a daily basis and required to be provided on an inpatient basis under §§409.31 through 409.35 of this chapter.

(ii) Provided by—

(A) A facility or distinct part (as defined in §483.5(b) of this chapter) that meets the requirements for participation under subpart B of part 483 of this chapter, as evidenced by a valid agreement between the Medicaid agency and the facility for providing nursing facility services and making payments for services under the plan; or

(B) If specified in the State plan, a swing-bed hospital that has an approval from CMS to furnish skilled nursing facility services in the Medicare program; and

(iii) Ordered by and provided under the direction of a physician.

(2) Nursing facility services include services provided by any facility located on an Indian reservation and certified by the Secretary as meeting the requirements of subpart B of part 483 of this chapter.

(b) *EPSDT.* ''Early and periodic screening and diagnosis and treatment'' means—

(1) Screening and diagnostic services to determine physical or mental defects in recipients under age 21; and

(2) Health care, treatment, and other measures to correct or ameliorate any defects and chronic conditions discovered. (See subpart B of part 441 of this chapter.)

(c) *Family planning services and supplies for individuals of child-bearing age.* [Reserved]

[59 FR 56233, Nov. 10, 1994; 60 FR 50117, Sept. 28, 1995, as amended at 61 FR 59198, Nov. 21, 1996; 68 FR 46071, Aug. 4, 2003]

§ 440.50 Physicians' services and medical and surgical services of a dentist.

(a) ''Physicians' services,'' whether furnished in the office, the recipient's home, a hospital, a skilled nursing facility, or elsewhere, means services furnished by a physician—

(1) Within the scope of practice of medicine or osteopathy as defined by State law; and

(2) By or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy.

(b) ''Medical and surgical services of a dentist'' means medical and surgical services furnished, on or after January 1, 1988, by a doctor of dental medicine or dental surgery if the services are services that—

(1) If furnished by a physician, would be considered physician's services.

(2) Under the law of the State where they are furnished, may be furnished either by a physician or by a doctor of dental medicine or dental surgery; and

(3) Are furnished by a doctor of dental medicine or dental surgery who is authorized to furnish those services in the State in which he or she furnished the services.

[56 FR 8851, Mar. 1, 1991]

§ 440.60 Medical or other remedial care provided by licensed practitioners.

(a) ''Medical care or any other type remedial care provided by licensed practitioners'' means any medical or remedial care or services, other than physicians' services, provided by licensed practitioners within the scope of practice as defined under State law.

(b) Chiropractors' services include only services that—

(1) Are provided by a chiropractor who is licensed by the State and meets standards issued by the Secretary under § 405.232(b) of this chapter; and

(2) Consists of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform.

§ 440.70 Home health services.

(a) ''Home health services'' means the services in paragraph (b) of this section that are provided to a recipient—

(1) At his place of residence, as specified in paragraph (c) of this section; and

(2) On his or her physician's orders as part of a written plan of care that the physician reviews every 60 days, except as specified in paragraph (b)(3) of this section.

(b) Home health services include the following services and items. Those listed in paragraphs (b) (1), (2) and (3) of this section are required services; those in paragraph (b)(4) of this section are optional.

(1) Nursing service, as defined in the State Nurse Practice Act, that is provided on a part-time or intermittent basis by a home health agency as defined in paragraph (d) of this section, or if there is no agency in the area, a registered nurse who—

(i) Is currently licensed to practice in the State;

(ii) Receives written orders from the patient's physician;

(iii) Documents the care and services provided; and

(iv) Has had orientation to acceptable clinical and administrative recordkeeping from a health department nurse.

(2) Home health aide service provided by a home health agency,

(3) Medical supplies, equipment, and appliances suitable for use in the home.

(i) A recipient's need for medical supplies, equipment, and appliances must be reviewed by a physician annually.

(ii) Frequency of further physician review of a recipient's continuing need for the items is determined on a case-by-case basis, based on the nature of the item prescribed;

(4) Physical therapy, occupational therapy, or speech pathology and audiology services, provided by a home health agency or by a facility licensed by the State to provide medical rehabilitation services. (See § 441.15 of this subchapter.)

(c) A recipient's place of residence, for home health services, does not include a hospital, nursing facility, or intermediate care facility for the mentally retarded, except for home health services in an intermediate care facility for the mentally retarded that are

not required to be provided by the facility under subpart I of part 483. For example, a registered nurse may provide short-term care for a recipient in an intermediate care facility for the mentally retarded during an acute illness to avoid the recipient's transfer to a nursing facility.

(d) ''Home health agency'' means a public or private agency or organization, or part of an agency or organization, that meets requirements for participation in Medicare, including the capitalization requirements under § 489.28 of this chapter.

(e) A ''facility licensed by the State to provide medical rehabilitation services'' means a facility that—

(1) Provides therapy services for the primary purpose of assisting in the rehabilitation of disabled individuals through an integrated program of—

(i) Medical evaluation and services; and

(ii) Psychological, social, or vocational evaluation and services; and

(2) Is operated under competent medical supervision either—

(i) In connection with a hospital; or

(ii) As a facility in which all medical and related health services are prescribed by or under the direction of individuals licensed to practice medicine or surgery in the State.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980; 62 FR 47902, Sept. 11, 1997; 63 FR 310, Jan. 5, 1998]

§ 440.80 Private duty nursing services.

Private duty nursing services means nursing services for recipients who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of the hospital or skilled nursing facility. These services are provided—

(a) By a registered nurse or a licensed practical nurse;

(b) Under the direction of the recipient's physician; and

(c) To a recipient in one or more of the following locations at the option of the State—

(1) His or her own home;

(2) A hospital; or

(3) A skilled nursing facility.

[52 FR 47934, Dec. 17, 1987]

§ 440.90 Clinic services.

Clinic services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that are furnished by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. The term includes the following services furnished to outpatients:

(a) Services furnished at the clinic by or under the direction of a physician or dentist.

(b) Services furnished outside the clinic, by clinic personnel under the direction of a physician, to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.

[56 FR 8851, Mar. 1, 1991, as amended at 60 FR 61486, Nov. 30, 1995]

§ 440.100 Dental services.

(a) ''Dental services'' means diagnostic, preventive, or corrective procedures provided by or under the supervision of a dentist in the practice of his profession, including treatment of—

(1) The teeth and associated structures of the oral cavity; and

(2) Disease, injury, or impairment that may affect the oral or general health of the recipient.

(b) ''Dentist'' means an individual licensed to practice dentistry or dental surgery.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980]

§ 440.110 Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.

(a) *Physical therapy.* (1) *Physical therapy* means services prescribed by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law and provided to a recipient by or under the direction of a qualified physical therapist. It includes any necessary supplies and equipment.

(2) A ''qualified physical therapist'' is an individual who is—

(i) A graduate of a program of physical therapy approved by both the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Physical

Therapy Association or its equivalent; and

(ii) Where applicable, licensed by the State.

(b) *Occupational therapy.* (1) *Occupational therapy* means services prescribed by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law and provided to a recipient by or under the direction of a qualified occupational therapist. It includes any necessary supplies and equipment.

(2) A ''qualified occupation therapist'' is an individual who is—

(i) Registered by the American Occupational Therapy Association; or

(ii) A graduate of a program in occupational therapy approved by the Committee on Allied Health Education and Accreditation of the American Medical Association and engaged in the supplemental clinical experience required before registration by the American Occupational Therapy Association.

(c) *Services for individuals with speech, hearing, and language disorders.* (1) *Services for individuals with speech, hearing, and language disorders* means diagnostic, screening, preventive, or corrective services provided by or under the direction of a speech pathologist or audiologist, for which a patient is referred by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law. It includes any necessary supplies and equipment.

(2) A ''speech pathologist'' is an individual who meets one of the following conditions:

(i) Has a certificate of clinical competence from the American Speech and Hearing Association.

(ii) Has completed the equivalent educational requirements and work experience necessary for the certificate.

(iii) Has completed the academic program and is acquiring supervised work experience to qualify for the certificate.

(3) A ''qualified audiologist'' means an individual with a master's or doctoral degree in audiology that maintains documentation to demonstrate that he or she meets one of the following conditions:

(i) The State in which the individual furnishes audiology services meets or exceeds State licensure requirements in paragraph (c)(3)(ii)(A) or (c)(3)(ii)(B) of this section, and the individual is licensed by the State as an audiologist to furnish audiology services.

(ii) In the case of an individual who furnishes audiology services in a State that does not license audiologists, or an individual exempted from State licensure based on practice in a specific institution or setting, the individual must meet one of the following conditions:

(A) Have a Certificate of Clinical Competence in Audiology granted by the American Speech-Language-Hearing Association.

(B) Have successfully completed a minimum of 350 clock-hours of supervised clinical practicum (or is in the process of accumulating that supervised clinical experience under the supervision of a qualified master or doctoral-level audiologist); performed at least 9 months of full-time audiology services under the supervision of a qualified master or doctoral-level audiologist after obtaining a master's or doctoral degree in audiology, or a related field; and successfully completed a national examination in audiology approved by the Secretary.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24888, Apr. 11, 1980; 56 FR 8854, Mar. 1, 1991; 60 FR 19861, Apr. 21, 1995; 69 FR 30587, May 28, 2004]

§ 440.120 Prescribed drugs, dentures, prosthetic devices, and eyeglasses.

(a) ''Prescribed drugs'' means simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are—

(1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law;

(2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and

(3) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records.

(b) ''Dentures'' are artificial structures made by or under the direction of a dentist to replace a full or partial set of teeth.

(c) ''Prosthetic devices'' means replacement, corrective, or supportive devices prescribed by a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law to—

(1) Artificially replace a missing portion of the body;

(2) Prevent or correct physical deformity or malfunction; or

(3) Support a weak or deformed portion of the body.

(d) ''Eyeglasses'' means lenses, including frames, and other aids to vision prescribed by a physician skilled in diseases of the eye or an optometrist.

§ 440.130 Diagnostic, screening, preventive, and rehabilitative services.

(a) ''Diagnostic services,'' except as otherwise provided under this subpart, includes any medical procedures or supplies recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, to enable him to identify the existence, nature, or extent of illness, injury, or other health deviation in a recipient.

(b) ''Screening services'' means the use of standardized tests given under medical direction in the mass examination of a designated population to detect the existence of one or more particular diseases or health deviations or to identify for more definitive studies individuals suspected of having certain diseases.

(c) ''Preventive services'' means services provided by a physician or other licensed practitioner of the healing arts within the scope of his practice under State law to—

(1) Prevent disease, disability, and other health conditions or their progression;

(2) Prolong life; and

(3) Promote physical and mental health and efficiency.

(d) ''Rehabilitative services,'' except as otherwise provided under this subpart, includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level.

§ 440.140 Inpatient hospital services, nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for mental diseases.

(a) *Inpatient hospital services.* ''Inpatient hospital services for individuals age 65 or older in institutions for mental diseases'' means services provided under the direction of a physician for the care and treatment of recipients in an institution for mental diseases that meets the requirements specified in § 482.60(b), (c), and (e) of this chapter and—

(1) Meets the requirements for utilization review in § 482.30(a), (b), (d), and (e) of this chapter; or

(2) Has been granted a waiver of those utilization review requirements under section 1903(i)(4) of the Act and subpart H of part 456 of this chapter.

(b) *Nursing facility services.* ''Nursing facility services for individuals age 65 or older in institutions for mental diseases'' means nursing facility services as defined in § 440.40 and in subpart B of part 483 of this chapter that are provided in institutions for mental diseases, as defined in § 435.1010 of this chapter.

[59 FR 56234, Nov. 10, 1994, as a amended at 71 FR 39229, July 12, 2006]

§ 440.150 Intermediate care facility (ICF/MR) services.

(a) ''ICF/MR services'' means those items and services furnished in an intermediate care facility for the mentally retarded if the following conditions are met:

(1) The facility fully meets the requirements for a State license to provide services that are above the level of room and board;

(2) The primary purpose of the ICF/MR is to furnish health or rehabilitative services to persons with mental retardation or persons with related conditions;

(3) The ICF/MR meets the standards specified in subpart I of part 483 of this chapter.

(4) The recipient with mental retardation for whom payment is requested is receiving active treatment, as specified in § 483.440 of this chapter.

(5) The ICF/MR has been certified to meet the requirements of subpart C of part 442 of this chapter, as evidenced by a valid agreement between the Medicaid agency and the facility for furnishing ICF/MR services and making payments for these services under the plan.

(b) ICF/MR services may be furnished in a distinct part of a facility other than an ICF/MR if the distinct part—

(1) Meets all requirements for an ICF/MR, as specified in subpart I of part 483 of this chapter;

(2) Is clearly an identifiable living unit, such as an entire ward, wing, floor or building;

(3) Consists of all beds and related services in the unit;

(4) Houses all recipients for whom payment is being made for ICF/MR services; and

(5) Is approved in writing by the survey agency.

[59 FR 56234, Nov. 10, 1994]

§ 440.155 Nursing facility services, other than in institutions for mental diseases.

(a) ''Nursing facility services, other than in an institution for mental diseases'' means services provided in a facility that—

(1) Fully meets the requirements for a State license to provide, on a regular basis, health-related services to individuals who do not require hospital care, but whose mental or physical condition requires services that—

(i) Are above the level of room and board; and

(ii) Can be made available only through institutional facilities;

(2) Has been certified to meet the requirements of subpart C of part 442 of this chapter as evidenced by a valid agreement between the Medicaid agency and the facility for providing nursing facility services and making payments for services under the plan; and

(b) ''Nursing facility services'' include services—

(1) Considered appropriate by the State and provided by a religious nonmedical institution as defined in § 440.170(b); or

(2) Provided by a facility located on an Indian reservation that—

(i) Furnishes, on a regular basis, health-related services; and

(ii) Is certified by the Secretary to meet the standards in subpart E of part 442 of this chapter.

(c) ''Nursing facility services'' may include services provided in a distinct part (as defined in § 483.5(b) of this chapter) of a facility other than a nursing facility if the distinct part (as defined in § 483.5(b) of this chapter)—

(1) Meets all requirements for a nursing facility;

(2) Is an identifiable unit, such as an entire ward or contiguous ward, a wing, floor, or building;

(3) Consists of all beds and related facilities in the unit;

(4) Houses all recipients for whom payment is being made for nursing facility services, except as provided in paragraph (d) of this section;

(5) Is clearly identified; and

(6) Is approved in writing by the survey agency.

(d) If a State includes as nursing facility services those services provided by a distinct part of a facility other than a nursing facility, it may not require transfer of a recipient within or between facilities if, in the opinion of the attending physician, it might be harmful to the physical or mental health of the recipient.

(e) Nursing facility services may include services provided in a swing-bed hospital that has an approval to furnish nursing facility services.

[59 FR 56234, Nov. 10, 1994, as amended at 64 FR 67052, Nov. 30, 1999; 68 FR 46071, Aug. 4, 2003]

§ 440.160 Inpatient psychiatric services for individuals under age 21.

''Inpatient psychiatric services for individuals under age 21'' means services that—

(a) Are provided under the direction of a physician;

(b) Are provided by—

(1) A psychiatric hospital or an inpatient psychiatric program in a hospital, accredited by the Joint Commission on Accreditation of Healthcare Organizations, or

(2) A psychiatric facility which is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Council on Accreditation of Services for Families and Children, the Commission on Accreditation of Rehabilitation Facilities, or by any other accrediting organization, with comparable standards, that is recognized by the State.

(c) Meet the requirements in § 441.151 of this subchapter.

[63 FR 64198, Nov. 19, 1998]

§ 440.165 Nurse-midwife service.

(a) ''Nurse-midwife services'' means services that—

(1) Are furnished by a nurse-midwife within the scope of practice authorized by State law or regulation and, in the case of inpatient or outpatient hospital services or clinic services, are furnished by or under the direction of a nurse-midwife to the extent permitted by the facility; and

(2) Unless required by State law or regulations or a facility, are reimbursed without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider. (See § 441.21 of this chapter for provisions on independent provider agreements for nurse-midwives.)

(b) ''Nurse-midwife'' means a registered professional nurse who meets the following requirements:

(1) Is currently licensed to practice in the State as a registered professional nurse.

(2) Is legally authorized under State law or regulations to practice as a nurse-midwife.

(3) Except as provided in paragraph (b)(4) of this section, has completed a program of study and clinical experience for nurse-midwives, as specified by the State.

(4) If the State does not specify a program of study and clinical experience that nurse-midwives must complete to practice in that State, meets one of the following conditions:

(i) Is currently certified as a nurse-midwife by the American College of Nurse-Midwives (ACNM or by the ACNM Certification Council, Inc. (ACC).

(ii) Has satisfactorily completed a formal education program (of at least one academic year) that, upon completion qualifies the nurse to take the certification examination offered by the American College of Nurse-Midwives (ACNM) or by the ACNM Certification Council, Inc. (ACC).

(iii) Has successfully completed a formal educational program for preparing registered nurses to furnish gynecological and obstetrical care to women during pregnancy, delivery, and the postpartum period, and care to normal newborns, and was practicing as a nurse-midwife for a total of 12 months during any 18-month period from August 8, 1976 to July 16, 1982.

[47 FR 21050, May 17, 1982; 47 FR 23448, May 28, 1982, as amended at 55 FR 48611, Nov. 21, 1990; 61 FR 61486, Nov. 30, 1996]

§ 440.166 Nurse practitioner services.

(a) *Definition of nurse practitioner services.* Nurse practitioner services means services that are furnished by a registered professional nurse who meets a State's advanced educational and clinical practice requirements, if any, beyond the 2 to 4 years of basic nursing education required of all registered nurses.

(b) *Requirements for certified pediatric nurse practitioner.* The practitioner must be a registered professional nurse who meets the requirements specified in either paragraphs (b)(1) or (b)(2) of this section.

(1) If the State specifies qualifications for pediatric nurse practitioners, the practitioner must—

(i) Be currently licensed to practice in the State as a registered professional nurse; and

(ii) Meet the State requirements for qualification of pediatric nurse practitioners in the State in which he or she furnishes the services.

(2) If the State does not specify, by specialty, qualifications for pediatric nurse practitioners, but the State does define qualifications for nurses in advanced practice or general nurse practitioners, the practitioner must—

(i) Meet qualifications for nurses in advanced practice or general nurse practitioners as defined by the State; and

(ii) Have a pediatric nurse practice limited to providing primary health care to persons less than 21 years of age.

(c) *Requirements for certified family nurse practitioner.* The practitioner must be a registered professional nurse who meets the requirements specified in either paragraph (c)(1) or (c)(2) of this section.

(1) If the State specifies qualifications for family nurse practitioners, the practitioner must—

(i) Be currently licensed to practice in the State as a registered professional nurse; and

(ii) Meet the State requirements for qualification of family nurse practitioners in the State in which he or she furnishes the services.

(2) If the State does not specify, by specialty, qualifications for family nurse practitioners, but the State does define qualifications for nurses in advanced practice or general nurse practitioners, the practitioner must—

(i) Meet qualifications for nurses in advanced practice or general nurse practitioners as defined by the State; and

(ii) Have a family nurse practice limited to providing primary health care to individuals and families.

(d) *Payment for nurse practitioner services.* The Medicaid agency must reimburse nurse practitioners for their services in accordance with § 441.22(c) of this subchapter.

[60 FR 19861, Apr. 21, 1995]

§ 440.167 Personal care services.

Unless defined differently by a State agency for purposes of a waiver granted under part 441, subpart G of this chapter—

(a) *Personal care services* means services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded, or institution for mental disease that are—

(1) Authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State;

(2) Provided by an individual who is qualified to provide such services and who is not a member of the individual's family; and

(3) Furnished in a home, and at the State's option, in another location.

(b) For purposes of this section, *family member* means a legally responsible relative.

[42 FR 47902, Sept. 11, 1997]

§ 440.168 Primary care case management services.

(a) Primary care case management services means case management related services that—

(1) Include location, coordination, and monitoring of primary health care services; and

(2) Are provided under a contract between the State and either of the following:

(i) A PCCM who is a physician or may, at State option, be a physician assistant, nurse practitioner, or certified nurse-midwife.

(ii) A physician group practice, or an entity that employs or arranges with physicians to furnish the services.

(b) Primary care case management services may be offered by the State—

(1) As a voluntary option under the State plan; or

(2) On a mandatory basis under section 1932 (a)(1) of the Act or under section 1915(b) or section 1115 waiver authority.

[67 FR 41115, June 14, 2002]

§ 440.170 Any other medical care or remedial care recognized under State law and specified by the Secretary.

(a) *Transportation.* (1) ''Transportation'' includes expenses for transportation and other related travel expenses determined to be necessary by the agency to secure medical examinations and treatment for a recipient.

(2) Transportation, as defined in this section, is furnished only by a provider to whom a direct vendor payment can appropriately be made by the agency. If other arrangements are made to assure transportation under § 431.53 of this subchapter, FFP is available as an administrative cost.

(3) ''Travel expenses'' include—

(i) The cost of transportation for the recipient by ambulance, taxicab, common carrier, or other appropriate means;

(ii) The cost of meals and lodging en route to and from medical care, and while receiving medical care; and

(iii) The cost of an attendant to accompany the recipient, if necessary, and the cost of the attendant's transportation, meals, lodging, and, if the attendant is not a member of the recipient's family, salary.

(b) *Services furnished in a religious nonmedical health care institution.* Services furnished in a religious nonmedical health care institution are services furnished in an institution that:

(1) Is an institution that is described in (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under section 501(a) of that section.

(2) Is lawfully operated under all applicable Federal, State, and local laws and regulations.

(3) Furnishes only nonmedical nursing items and services to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs.

(4) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients.

(5) Furnishes these nonmedical items and services to inpatients on a 24-hour basis.

(6) Does not furnish, on the basis of its religious beliefs, through its personnel or otherwise, medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.

(7) Is not owned by, is not under common ownership with, or does not have an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest or 5 percent or more in a provider of medical treatment or services. Permissible affiliations are described in paragraph (c) of this section.

(8) Has in effect a utilization review plan that meets the following criteria:

(i) Provides for the review of admissions to the institution, duration of stays, cases of continuous extended duration, and items and services furnished by the institution.

(ii) Requires that the reviews be made by a committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

(iii) Provides that records be maintained of the meetings, decisions, and actions of the utilization review committee.

(iv) Meets other requirements as CMS finds necessary to establish an effective utilization review plan.

(9) Provides information CMS may require to implement section 1821 of the Act, including information relating to quality of care and coverage determinations.

(10) Meets other requirements as CMS finds necessary in the interest of the health and safety of patients who receive services in the institution. These requirements are the conditions of participation found at part 403, subpart G of this chapter.

(c) *Affiliations.* An affiliation is permissible for purposes of paragraph (b)(7) of this section if it is between one of the following:

(1) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of an RNHCI and a provider of medical treatment or services.

(2) An individual who is a director, trustee, officer, employee, or staff member of an RNHCI and an another individual, with whom he or she has a family relationship, who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(3) The RNHCI and an individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and RNHCIs.

(d) *Skilled nursing facility services for individuals under age 21.* ''Skilled nursing facility services for individuals

under 21'' means those services specified in § 440.40 that are provided to recipients under 21 years of age.

(e) *Emergency hospital services.* ''Emergency hospital services'' means services that—

(1) Are necessary to prevent the death or serious impairment of the health of a recipient; and

(2) Because of the threat to the life or health of the recipient necessitate the use of the most accessible hospital available that is equipped to furnish the services, even if the hospital does not currently meet—

(i) The conditions for participation under Medicare; or

(ii) The definitions of inpatient or outpatient hospital services under §§ 440.10 and 440.20.

(f) [Reserved]

(g) *Critical access hospital (CAH).* (1) CAH services means services that (i) are furnished by a provider that meet the requirements for participation in Medicare as a CAH (see subpart F of part 485 of this chapter), and (ii) are of a type that would be paid for by Medicare when furnished to a Medicare beneficiary.

(2) Inpatient CAH services do not include nursing facility services furnished by a CAH with a swing-bed approval.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 46 FR 48540, Oct. 1, 1981; 58 FR 30671, May 26, 1993; 62 FR 46037, Aug. 29, 1997; 64 FR 67051, Nov. 30, 1999]

§ 440.180 Home or community-based services.

(a) *Description and requirements for services.* ''Home or community-based services'' means services, not otherwise furnished under the State's Medicaid plan, that are furnished under a waiver granted under the provisions of part 441, subpart G of this chapter.

(1) These services may consist of any or all of the services listed in paragraph (b) of this section, as those services are defined by the agency and approved by CMS.

(2) The services must meet the standards specified in § 441.302(a) of this chapter concerning health and welfare assurances.

(3) The services are subject to the limits on FFP described in § 441.310 of this chapter.

(b) *Included services.* Home or community-based services may include the following services, as they are defined by the agency and approved by CMS:

(1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Habilitation services.

(7) Respite care services.

(8) Day treatment or other partial hospitalization services, psychosocial rehabilitation services and clinic services (whether or not furnished in a facility) for individuals with chronic mental illness, subject to the conditions specified in paragraph (d) of this section.

(9) Other services requested by the agency and approved by CMS as cost effective and necessary to avoid institutionalization.

(c) *Expanded habilitation services, effective October 1, 1997*—(1) *General rule.* Expanded habilitation services are those services specified in paragraph (c)(2) of this section.

(2) *Services included.* The agency may include as expanded habilitation services the following services:

(i) Prevocational services, which means services that prepare an individual for paid or unpaid employment and that are not job-task oriented but are, instead, aimed at a generalized result. These services may include, for example, teaching an individual such concepts as compliance, attendance, task completion, problem solving and safety. Prevocational services are distinguishable from noncovered vocational services by the following criteria:

(A) The services are provided to persons who are not expected to be able to join the general work force or participate in a transitional sheltered workshop within one year (excluding supported employment programs).

(B) If the recipients are compensated, they are compensated at less than 50 percent of the minimum wage;

(C) The services include activities which are not primarily directed at

teaching specific job skills but at underlying habilitative goals (for example, attention span, motor skills); and

(D) The services are reflected in a plan of care directed to habilitative rather than explicit employment objectives.

(ii) Educational services, which means special education and related services (as defined in sections 602(16) and (17) of the Education of the Handicapped Act) (20 U.S.C. 1401 (16 and 17)) to the extent they are not prohibited under paragraph (c)(3)(i) of this section.

(iii) Supported employment services, which facilitate paid employment, that are—

(A) Provided to persons for whom competitive employment at or above the minimum wage is unlikely and who, because of their disabilities, need intensive ongoing support to perform in a work setting;

(B) Conducted in a variety of settings, particularly worksites in which persons without disabilities are employed; and

(C) Defined as any combination of special supervisory services, training, transportation, and adaptive equipment that the State demonstrates are essential for persons to engage in paid employment and that are not normally required for nondisabled persons engaged in competitive employment.

(3) *Services not included.* The following services may not be included as habilitation services:

(i) Special education and related services (as defined in sections 602(16) and (17) of the Education of the Handicapped Act) (20 U.S.C. 1401 (16) and (17)) that are otherwise available to the individual through a local educational agency.

(ii) Vocational rehabilitation services that are otherwise available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

(d) *Services for the chronically mentally ill*—(1) *Services included.* Services listed in paragraph (b)(8) of this section include those provided to individuals who have been diagnosed as being chronically mentally ill, for which the agency has requested approval as part of either a new waiver request or a renewal and which have been approved by CMS on or after October 21, 1986.

(2) *Services not included.* Any home and community-based service, including those indicated in paragraph (b)(8) of this section, may not be included in home and community-based service waivers for the following individuals:

(i) For individuals aged 22 through 64 who, absent the waiver, would be institutionalized in an institution for mental diseases (IMD); and, therefore, subject to the limitation on IMDs specified in § 435.1009(a)(2) of this chapter.

(ii) For individuals, not meeting the age requirements described in paragraph (d)(2)(i) of this section, who, absent the waiver, would be placed in an IMD in those States that have not opted to include the benefits defined in § 440.140 or § 440.160.

[59 FR 37716, July 25, 1994, as amended at 65 FR 60107, Oct. 10, 2000; 71 FR 39229, July 12, 2006]

§ 440.181 Home and community-based services for individuals age 65 or older.

(a) *Description of services*— Home and community-based services for individuals age 65 or older means services, not otherwise furnished under the State's Medicaid plan, or services already furnished under the State's Medicaid plan but in expanded amount, duration, or scope, which are furnished to individuals age 65 or older under a waiver granted under the provisions of part 441, subpart H of this subchapter. Except as provided in § 441.310, the services may consist of any of the services listed in paragraph (b) of this section that are requested by the State, approved by CMS, and furnished to eligible recipients. Service definitions for each service in paragraph (b) of this section must be approved by CMS.

(b) *Included services.* (1) Case management services.

(2) Homemaker services.

(3) Home health aide services.

(4) Personal care services.

(5) Adult day health services.

(6) Respite care services.

(7) Other medical and social services requested by the Medicaid agency and approved by CMS, which will contribute to the health and well-being of

individuals and their ability to reside in a community-based care setting.

[57 FR 29156, June 30, 1992]

§ 440.185 Respiratory care for ventilator-dependent individuals.

(a) ''Respiratory care for ventilator-dependent individuals'' means services that are not otherwise available under the State's Medicaid plan, provided on a part-time basis in the recipient's home by a respiratory therapist or other health care professional trained in respiratory therapy (as determined by the State) to an individual who—

(1) Is medically dependent on a ventilator for life support at least 6 hours per day;

(2) Has been so dependent for at least 30 consecutive days (or the maximum number of days authorized under the State plan, whichever is less) as an inpatient in one or more hospitals, NFs, or ICFs/MR;

(3) Except for the availability of respiratory care services, would require respiratory care as an inpatient in a hospital, NF, or ICF/MR and would be eligible to have payment made for inpatient care under the State plan;

(4) Has adequate social support services to be cared for at home;

(5) Wishes to be cared for at home; and

(6) Receives services under the direction of a physician who is familiar with the technical and medical components of home ventilator support, and who has medically determined that in-home care is safe and feasible for the individual.

(b) For purposes of paragraphs (a)(4) and (5) of this section, a recipient's home does not include a hospital, NF, ICF/MR or other institution as defined in § 435.1010 of this chapter.

[59 FR 37717, July 25, 1994, as amended at 71 FR 39229, July 12, 2006]

Subpart B—Requirements and Limits Applicable to All Services

§ 440.200 Basis, purpose, and scope.

(a) This subpart implements the following statutory requirements—

(1) Section 1902(a)(10), regarding comparability of services for groups of recipients, and the amount, duration, and scope of services described in section 1905(a) of the Act that the State plan must provide for recipients;

(2) Section 1902(a)(22)(D), which provides for standards and methods to assure quality of services;

(3) Section 1903(v)(1), which provides that no payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law;

(4) Section 1903(v)(2) which provides that FFP will be available for services necessary to treat an emergency medical condition of an alien not described in paragraph (a)(3) of this section if that alien otherwise meets the eligibility requirements of the State plan;

(5) Section 1907 on observance of religious beliefs;

(6) Section 1915 on exceptions to section 1902(a)(10) and waivers of other requirements of section 1902 of the Act; and

(7) Sections 245A(h), 210 and 210A of the Immigration and Nationality Act which provide that certain aliens who are legalized may be eligible for Medicaid.

(b) The requirements and limits of this subpart apply for all services defined in subpart A of this part.

[55 FR 36822, Sept. 7, 1990]

§ 440.210 Required services for the categorically needy.

(a) A State plan must specify that, at a minimum, categorically needy recipients are furnished the following services:

(1) The services defined in §§ 440.10 through 440.50, 440.70, and (to the extent nurse-midwives and nurse practitioners are authorized to practice under State law or regulation) the services defined in §§ 440.165 and 440.166, respectively.

(2) Pregnancy-related services and services for other conditions that might complicate the pregnancy.

(i) Pregnancy-related services are those services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of the woman having been pregnant. These include, but are not

limited to, prenatal care, delivery, postpartum care, and family planning services.

(ii) Services for other conditions that might complicate the pregnancy include those for diagnoses, illnesses, or medical conditions which might threaten the carrying of the fetus to full term or the safe delivery of the fetus; and

(3) For women who, while pregnant, applied for, were eligible for, and received Medicaid services under the plan, all services under the plan that are pregnancy-related for an extended postpartum period. The postpartum period begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends.

(b) A State plan must specify that eligible aliens as defined in §§ 435.406(a) and 436.406(a) of this subchapter will receive at least the services provided in paragraph (a) of this section.

(c) A State plan must specify that aliens not defined in §§ 435.406(a) and 436.406(a) of this subchapter will only be provided the limited services specified in § 440.255.

[56 FR 24010, May 28, 1991, as amended at 60 FR 19862, Apr. 21, 1995]

§ 440.220 Required services for the medically needy.

(a) A State plan that includes the medically needy must specify that the medically needy are provided, as a minimum, the following services:

(1) Prenatal care and delivery services for pregnant women.

(2) Ambulatory services, as defined in the State plan, for:

(i) Individuals under age 18; and

(ii) Groups of individuals entitled to institutional services.

(3) Home health services (§ 440.70) to any individual entitled to skilled nursing facility services.

(4) If the State plan includes services in an institution for mental diseases (§ 440.140 or § 440.160) or in an intermediate care facility for the mentally retarded (§ 440.150(c)) for any group of medically needy, either of the following sets of services to each of the medically needy groups:

(i) The services contained in §§ 440.10 through 440.50 and (to the extent nurse-midwives are authorized to practice under State law or regulation) § 440.165; or

(ii) The services contained in any seven of the sections in §§ 440.10 through 440.165.

(5) For women who, while pregnant, applied for, were eligible as medically needy for, and received Medicaid services under the plan, services under the plan that are pregnancy-related (as defined in § 440.210(a)(2)(i) of this subpart) for an extended postpartum period. The postpartum period begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends.

(b) A State plan must specify that eligible aliens as defined in §§ 435.406(a) and 436.406(a) of this subchapter will receive at least the services provided in paragraphs (a)(4) (i) and (ii) of this section.

(c) A State plan must specify that aliens defined in §§ 435.406(b), 435.406(c), 436.406(b) and 436.406(c) of this subchapter will only be provided the limited services specified in § 440.255.

[56 FR 24011, May 28, 1991, as amended at 58 FR 4938, Jan. 19, 1993]

§ 440.225 Optional services.

Any of the services defined in subpart A of this part that are not required under §§ 440.210 and 440.220 may be furnished under the State plan at the State's option.

[60 FR 19862, Apr. 21, 1995]

§ 440.230 Sufficiency of amount, duration, and scope.

(a) The plan must specify the amount, duration, and scope of each service that it provides for—

(1) The categorically needy; and

(2) Each covered group of medically needy.

(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of

the diagnosis, type of illness, or condition.

(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.

[46 FR 47993, Sept. 30, 1981]

§ 440.240 Comparability of services for groups.

Except as limited in § 440.250—

(a) The plan must provide that the services available to any categorically needy recipient under the plan are not less in amount, duration, and scope than those services available to a medically needy recipient; and

(b) The plan must provide that the services available to any individual in the following groups are equal in amount, duration, and scope for all recipients within the group:

(1) The categorically needy.

(2) A covered medically needy group.

[46 FR 47993, Sept. 30, 1981]

§ 440.250 Limits on comparability of services.

(a) Skilled nursing facility services (§ 440.40(a)) may be limited to recipients age 21 or older.

(b) Early and periodic screening, diagnosis, and treatment (§ 440.40(b)) must be limited to recipients under age 21.

(c) Family planning services and supplies must be limited to recipients of childbearing age, including minors who can be considered sexually active and who desire the services and supplies.

(d) If covered under the plan, services to recipients in institutions for mental diseases (§ 440.140) must be limited to those age 65 or older.

(e) If covered under the plan, inpatient psychiatric services (§ 440.160) must be limited to recipients under age 22 as specified in § 441.151(c) of this subchapter.

(f) If Medicare benefits under Part B of title XVIII are made available to recipients through a buy-in agreement or payment of premiums, or part or all of the deductibles, cost sharing or similar charges, they may be limited to recipients who are covered by the agreement or payment.

(g) If services in addition to those offered under the plan are made available under a contract between the agency or political subdivision and an organization providing comprehensive health services, those additional services may be limited to recipients who reside in the geographic area served by the contracting organization and who elect to receive services from it.

(h) Ambulatory services for the medically needy (§ 440.220(a)(2)) may be limited to:

(1) Individuals under age 18; and

(2) Groups of individuals entitled to institutional services.

(i) Services provided under an exception to requirements allowed under § 431.54 may be limited as provided under that exception.

(j) If CMS has approved a waiver of Medicaid requirements under § 431.55, services may be limited as provided by the waiver.

(k) If the agency has been granted a waiver of the requirements of § 440.240 (Comparability of services) in order to provide for home or community-based services under §§ 440.180 or 440.181, the services provided under the waiver need not be comparable for all individuals within a group.

(l) If the agency imposes cost sharing on recipients in accordance with 447.53, the imposition of cost sharing on an individual who is not exempted by one of the conditions in section 447.53(b) shall not require the State to impose copayments on an individual who is eligible for such exemption.

(m) Eligible legalized aliens who are not in the exempt groups described in §§ 435.406(a) and 436.406(a), and considered categorically needy or medically needy must be furnished only emergency services (as defined in § 440.255), and services for pregnant women as defined in section 1916(a)(2)(B) of the Social Security Act for 5 years from the date the alien is granted lawful temporary resident status.

(n) Aliens who are not lawful permanent residents, permanently residing in the United States under color of law, or granted lawful status under section 245A, 210 or 210A of the Immigration and Nationality Act, who, otherwise meet the eligibility requirements of the State plan (except for receipt of

AFDC, SSI or a State Supplementary payment) must be furnished only those services necessary to treat an emergency medical condition of the alien as defined in § 440.255(c).

(o) If the agency makes respiratory care services available under § 440.185, the services need not be made available in equal amount, duration, and scope to any individual not eligible for coverage under that section. However, the services must be made available in equal amount, duration, and scope to all individuals eligible for coverage under that section.

(p) A State may provide a greater amount, duration, or scope of services to pregnant women than it provides under its plan to other individuals who are eligible for Medicaid, under the following conditions:

(1) These services must be pregnancy-related or related to any other condition which may complicate pregnancy, as defined in § 440.210(a)(2) of this subpart; and

(2) These services must be provided in equal amount, duration, and scope to all pregnant women covered under the State plan.

[43 FR 45224, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 46 FR 48541, Oct. 1, 1981; 48 FR 5735, Jan. 8, 1983; 51 FR 22041, June 17, 1986; 55 FR 36822, Sept. 7, 1990; 56 FR 24011, May 28, 1991; 57 FR 29156, June 30, 1992; 58 FR 4939, Jan. 19, 1993; 59 FR 37717, July 25, 1994]

§ 440.255 Limited services available to certain aliens.

(a) *FFP for services.* FFP is available for services provided to aliens described in this section which are necessary to treat an emergency medical condition as defined in paragraphs (b)(1) and (c) or services for pregnant women described in paragraph (b)(2).

(b) *Legalized aliens eligible only for emergency services and services for pregnant women.* Aliens granted lawful temporary resident status, or lawful permanent resident status under sections 245A, 210 or 210A of the Immigration and Nationality Act, who are not in one of the exempt groups described in §§ 435.406(a)(3) and 436.406(a)(3) and who meet all other requirements for Medicaid will be eligible for the following services—

(1) Emergency services required after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

(i) Placing the patient's health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part.

(2) Services for pregnant women which are included in the approved State plan. These services include routine prenatal care, labor and delivery, and routine post-partum care. States, at their option, may provide additional plan services for the treatment of conditions which may complicate the pregnancy or delivery.

(c) Effective January 1, 1987, aliens who are not lawfully admitted for permanent residence in the United States or permanently residing in the United States under the color of law must receive the services necessary to treat the condition defined in paragraph (1) of this section if—

(1) The alien has, after sudden onset, a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in:

(i) Placing the patient's health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part, and

(2) The alien otherwise meets the requirements in §§ 435.406(c) and 436.406(c) of this subpart.

[55 FR 36823, Sept. 7, 1990; 56 FR 10807, Mar. 14, 1991]

§ 440.260 Methods and standards to assure quality of services.

The plan must include a description of methods and standards used to assure that services are of high quality.

§ 440.270 Religious objections.

(a) Except as specified in paragraph (b) of this section, the agency may not

require any individual to undergo any medical service, diagnosis, or treatment or to accept any other health service provided under the plan if the individual objects, or in the case of a child, a parent or guardian objects, on religious grounds.

(b) If a physical examination is necessary to establish eligibility based on disability or blindness, the agency may not find an individual eligible for Medicaid unless he undergoes the examination.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45229, Sept. 29, 1978, unless otherwise noted.

§ 441.1 Purpose.

This part sets forth State plan requirements and limits on FFP for specific services defined in part 440 of this subchapter. Standards for payments for services provided in intermediate care facilities and skilled nursing facilities are set forth in part 442 of this subchapter.

Subpart A—General Provisions

§ 441.10 Basis.

This subpart is based on the following sections of the Act which state requirements and limits on the services specified or provide Secretarial authority to prescribe regulations relating to services:

(a) Section 1102 for end-stage renal disease (§ 441.40).

(b) Section 1138(b) for organ procurement organization services (§ 441.13(c)).

(c) Sections 1902(a)(10)(A) and 1905(a)(21) for nurse practitioner services (§ 441.22).

(d) Sections 1902(a)(10)(D) and 1905(a)(7) for home health services (§ 441.15).

(e) Section 1903(i)(1) for organ transplant procedures (§ 441.35).

(f) Section 1903(i)(5) for certain prescribed drugs (§ 441.25).

(g) Section 1903(i)(6) for prohibition (except in emergency situations) of FFP in expenditures for inpatient hospital tests that are not ordered by the attending physician or other licensed practitioner (§ 441.12).

(h) Section 1903(i)(18) for the requirement that each home health agency provide the Medicaid agency with a surety bond (§ 441.16).

(i) Section 1905(a)(4)(C) for family planning (§ 441.20).

(j) Sections 1905 (a)(12) and (e) for optometric services (§ 441.30).

(k) Section 1905(a)(17) for nurse-midwife services (§ 441.21).

(l) Section 1905(a) (following (a)(24)) for prohibition of FFP in expenditures for certain services (§ 441.13).

[60 FR 19862, Apr. 21, 1995, as amended at 63 FR 310, Jan. 5, 1998]

§ 441.11 Continuation of FFP for institutional services.

(a) *Basic conditions for continuation of FFP.* FFP may be continued for up to 30 days after the effective date of termination or expiration of a provider agreement, if the following conditions are met:

(1) The Medicaid payments are for recipients admitted to the facility before the effective date of termination or expiration.

(2) The State agency is making reasonable efforts to transfer those recipients to other facilities or to alternate care.

(b) *When the 30-day period begins.* The 30-day period begins on one of the following:

(1) The effective date of termination of the facility's provider agreement by CMS;

(2) The effective date of termination of the facility's Medicaid provider

agreement by the Medicaid agency on its own volition; or

(3) In the case of an ICF/MR, the later of—

(i) The effective date of termination or nonrenewal of the facility's provider agreement by the Medicaid agency on its own volition; or

(ii) The date of issuance of an administrative hearing decision that upholds the agency's termination or nonrenewal action.

(c) *Services for which FFP may be continued.* FFP may be continued for any of the following services, as defined in subpart A of part 440 of this chapter:

(1) Inpatient hospital services.

(2) Inpatient hospital services for individuals age 65 or older in an institution for mental diseases.

(3) Nursing facility services for individuals age 21 or older.

(4) Nursing facility services for individuals age 65 or older in an institution for mental diseases.

(5) Inpatient psychiatric services for individuals under age 21.

(6) Nursing facility services for individuals under 21.

(7) Intermediate care facility services for the mentally retarded.

[59 FR 56234, Nov. 10, 1994]

§ 441.12 Inpatient hospital tests.

Except in an emergency situation (see § 440.170(e)(1) of this chapter for definition), FFP is not available in expenditures for inpatient hospital tests unless the tests are specifically ordered by the attending physician or other licensed practitioner, acting within the scope of practice as defined under State law, who is responsible for the diagnosis or treatment of a particular patient's condition.

[46 FR 48554, Oct. 1, 1981]

§ 441.13 Prohibitions on FFP: Institutionalized individuals.

(a) FFP is not available in expenditures for services for—

(1) Any individual who is in a public institution, as defined in § 435.1010 of this chapter; or

(2) Any individual who is under age 65 and is in an institution for mental diseases, except an individual who is under age 22 and receiving inpatient psychiatric services under subpart D of this part.

(b) With the exception of active treatment services (as defined in § 483.440(a) of this chapter for residents of ICFs/MR and in § 441.154 for individuals under age 21 receiving inpatient psychiatric services), payments to institutions for the mentally retarded or persons with related conditions and to psychiatric facilities or programs providing inpatient psychiatric services to individuals under age 21 may not include reimbursement for formal educational services or for vocational services. Formal educational services relate to training in traditional academic subjects. Subject matter rather than setting, time of day, or class size determines whether a service is educational. Traditional academic subjects include, but are not limited to, science, history, literature, foreign languages, and mathematics. Vocational services relate to organized programs that are directly related to the preparation of individuals for paid or unpaid employment. An example of vocational services is time-limited vocational training provided as a part of a regularly scheduled class available to the general public.

(c) FFP is not available in expenditures for services furnished by an organ procurement organization on or after April 1, 1988, that does not meet the requirements of part 486 subpart G of this chapter.

[43 FR 45229, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986; 53 FR 6549, Mar. 1, 1988; 57 FR 54709, Nov. 20, 1992; 71 FR 31046, May 31, 2006; 71 FR 39229, July 12, 2006]

§ 441.15 Home health services.

With respect to the services defined in § 440.70 of this subchapter, a State plan must provide that—

(a) Home health services include, as a minimum—

(1) Nursing services;

(2) Home health aide services; and

(3) Medical supplies, equipment, and appliances.

(b) The agency provides home health services to—

(1) Categorically needy recipients age 21 or over;

(2) Categorically needy recipients under age 21, if the plan provides

skilled nursing facility services for them; individuals; and

(3) Medically needy recipients to whom skilled nursing facility services are provided under the plan.

(c) The eligibility of a recipient to receive home health services does not depend on his need for or discharge from institutional care.

(d) The agency providing home health services meets the capitalization requirements included in § 489.28 of this chapter.

[43 FR 45229, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980; 63 FR 310, Jan. 5, 1998]

§ 441.16 Home health agency requirements for surety bonds; Prohibition on FFP.

(a) *Definitions.* As used in this section, unless the context indicates otherwise—

Assets includes but is not limited to any listing that identifies Medicaid recipients to whom home health services were furnished by a participating or formerly participating HHA.

Participating home health agency means a ''home health agency'' (HHA) as that term is defined at § 440.70(d) of this subchapter.

Surety bond means one or more bonds issued by one or more surety companies under 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225, provided the bond otherwise meets the requirements of this section.

Uncollected overpayment means an ''overpayment,'' as that term is defined under § 433.304 of this subchapter, plus accrued interest, for which the HHA is responsible, that has not been recouped by the Medicaid agency within a time period determined by the Medicaid agency.

(b) *Prohibition.* FFP is not available in expenditures for home health services under § 440.70 of this subchapter unless the home health agency furnishing these services meets the surety bond requirements of paragraphs (c) through (l) of this section.

(c) *Basic requirement.* Except as provided in paragraph (d) of this section, each HHA that is a Medicaid participating HHA or that seeks to become a Medicaid participating HHA must—

(1) Obtain a surety bond that meets the requirements of this section and instructions issued by the Medicaid agency; and

(2) Furnish a copy of the surety bond to the Medicaid agency.

(d) *Requirement waived for Government-operated HHAs.* An HHA operated by a Federal, State, local, or tribal government agency is deemed to have provided the Medicaid agency with a comparable surety bond under State law, and is therefore exempt from the requirements of this section if, during the preceding 5 years, the HHA has not had any uncollected overpayments.

(e) *Parties to the bond.* The surety bond must name the HHA as Principal, the Medicaid agency as Obligee, and the surety company (and its heirs, executors, administrators, successors and assignees, jointly and severally) as Surety.

(f) *Authorized Surety and exclusion of surety companies.* An HHA may obtain a surety bond required under this section only from an authorized Surety.

(1) An authorized Surety is a surety company that—

(i) Has been issued a Certificate of Authority by the U.S. Department of the Treasury in accordance with 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225 as an acceptable surety on Federal bonds and the Certificate has neither expired nor been revoked;

(ii) Has not been determined by the Medicaid agency to be an unauthorized Surety for the purpose of an HHA obtaining a surety bond under this section; and

(iii) Meets other conditions, as specified by the Medicaid agency.

(2) The Medicaid agency may determine that a surety company is an unauthorized Surety under this section—

(i) If, upon request by the Medicaid agency, the surety company fails to furnish timely confirmation of the issuance of, and the validity and accuracy of information appearing on, a surety bond that an HHA presents to the Medicaid agency that shows the surety company as Surety on the bond;

(ii) If, upon presentation by the Medicaid agency to the surety company of a request for payment on a surety bond and of sufficient evidence to establish the surety company's liability on the bond, the surety company fails to timely pay the Medicaid agency in full the

amount requested up to the face amount of the bond; or

(iii) For other good cause.

(3) The Medicaid agency must specify the manner by which public notification of a determination under paragraph (f)(2) of this section is given and the effective date of the determination.

(4) A determination by the Medicaid agency that a surety company is an unauthorized Surety under paragraph (f)(2) of this section—

(i) Has effect only within the State; and

(ii) Is not a debarment, suspension, or exclusion for the purposes of Executive Order No. 12549 (3 CFR 1986 Comp., p. 189).

(g) *Amount of the bond*—(1) *Basic rule.* The amount of the surety bond must be $50,000 or 15 percent of the annual Medicaid payments made to the HHA by the Medicaid agency for home health services furnished under this subchapter for which FFP is available, whichever is greater.

(2) *Computation of the 15 percent: Participating HHA.* The 15 percent is computed by the Medicaid agency on the basis of Medicaid payments made to the HHA for the most recent annual period for which information is available as specified by the Medicaid agency.

(3) *Computation of 15 percent: An HHA that seeks to become a participating HHA by obtaining assets or ownership interest.* For an HHA that seeks to become a participating HHA by purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent is computed on the basis of Medicaid payments made by the Medicaid agency to the participating or formerly participating HHA for the most recent annual period as specified by the Medicaid agency.

(4) *Computation of 15 percent: Change of ownership.* For an HHA that undergoes a change of ownership (as ''change of ownership'' is defined by the State Medicaid agency) the 15 percent is computed on the basis of Medicaid payments made by the Medicaid agency to the HHA for the most recent annual period as specified by the Medicaid agency.

(5) *An HHA that seeks to become a participating HHA without obtaining assets or ownership interest.* For an HHA that seeks to become a participating HHA without purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent computation does not apply.

(6) *Exception to the basic rule.* If an HHA's overpayment in the most recent annual period exceeds 15 percent, the State Medicaid agency may require the HHA to secure a bond in an amount up to or equal to the amount of the overpayment, provided the amount of the bond is not less than $50,000.

(7) *Expiration of the 15 percent provision.* For an annual surety bond, or for a rider on a continuous surety bond, that is required to be submitted on or after June 1, 2005, notwithstanding any reference in this section to 15 percent as a basis for determining the amount of the bond, the amount of the bond or rider, as applicable, must be $50,000 or such amount as the Medicaid agency specifies in accordance with paragraph (g)(6) of this section, whichever amount is greater.

(h) *Additional requirements of the surety bond.* The surety bond that an HHA obtains under this section must meet the following additional requirements:

(1) The bond must guarantee that, upon written demand by the Medicaid agency to the Surety for payment under the bond and the Medicaid agency furnishing to the Surety sufficient evidence to establish the Surety's liability under the bond, the Surety will timely pay the Medicaid agency the amount so demanded, up to the stated amount of the bond.

(2) The bond must provide that the Surety is liable for uncollected overpayments, as defined in paragraph (a), provided such uncollected overpayments are determined during the term of the bond and regardless of when the overpayments took place. Further, the bond must provide that the Surety remains liable if the HHA fails to furnish a subsequent annual bond that meets the requirements of this subpart or fails to furnish a rider for a year for which a rider is required to be submitted, or if the HHA's provider agreement terminates and that the Surety's liability shall be based on the last bond or rider in effect for the HHA, which shall then remain in effect for an additional 2-year period.

(3) The bond must provide that the Surety's liability to the Medicaid agency is not extinguished by any of the following:

(i) Any action by the HHA or the Surety to terminate or limit the scope or term of the bond. The Surety's liability may be extinguished, however, when—

(A) The Surety furnishes the Medicaid agency with notice of such action not later than 10 days after receiving notice from the HHA of action by the HHA to terminate or limit the scope of the bond, or not later than 60 days before the effective date of such action by the Surety; or

(B) The HHA furnishes the Medicaid agency with a new bond that meets the requirements of both this section and the Medicaid agency.

(ii) The Surety's failure to continue to meet the requirements of paragraph (f)(1) of this section or the Medicaid agency's determination that the surety company is an unauthorized surety under paragraph (f)(2) of this section.

(iii) Termination of the HHA's provider agreement described under § 431.107 of this subchapter.

(iv) Any action by the Medicaid agency to suspend, offset, or otherwise recover payments to the HHA.

(v) Any action by the HHA to—

(A) Cease operation;

(B) Sell or transfer any assets or ownership interest;

(C) File for bankruptcy; or

(D) Fail to pay the Surety.

(vi) Any fraud, misrepresentation, or negligence by the HHA in obtaining the surety bond or by the Surety (or by the Surety's agent, if any) in issuing the surety bond, except that any fraud, misrepresentation, or negligence by the HHA in identifying to the Surety (or to the Surety's agent) the amount of Medicaid payments upon which the amount of the surety bond is determined shall not cause the Surety's liability to the Medicaid agency to exceed the amount of the bond.

(vii) The HHA's failure to exercise available appeal rights under Medicaid or to assign such rights to the Surety (provided the Medicaid agency permits such rights to be assigned).

(4) The bond must provide that actions under the bond may be brought by the Medicaid agency or by an agent that the Medicaid agency designates.

(i) *Term and type of bond*—(1) *Initial term:* Each participating HHA that is not exempted by paragraph (d) of this section must submit to the State Medicaid agency a surety bond for a term beginning January 1, 1998. If an annual bond is submitted for the initial term it must be effective for an annual period specified by the State Medicaid agency.

(2) *Type of bond.* The type of bond required to be submitted by an HHA, under this section, may be either—

(i) An annual bond (that is, a bond that specifies an effective annual period that corresponds to an annual period specified by the Medicaid agency); or

(ii) A continuous bond (that is, a bond that remains in full force and effect from term to term unless it is terminated or canceled as provided for in the bond or as otherwise provided by law) that is updated by the Surety for a particular period, via the issuance of a ''rider,'' when the bond amount changes. For the purposes of this section, ''Rider'' means a notice issued by a Surety that a change to a bond has occurred or will occur. If the HHA has submitted a continuous bond and there is no increase or decrease in the bond amount, no action is necessary by the HHA to submit a rider as long as the continuous bond remains in full force and effect.

(3) *HHA that seeks to become a participating HHA.* (i) An HHA that seeks to become a participating HHA must submit a surety bond before a provider agreement described under § 431.107 of this subchapter can be entered into.

(ii) An HHA that seeks to become a participating HHA through the purchase or transfer of assets or ownership interest of a participating or formerly participating HHA must also ensure that the surety bond is effective from the date of such purchase or transfer.

(4) *Change of ownership.* An HHA that undergoes a change of ownership (as ''change of ownership'' is defined by the State Medicaid agency) must submit the surety bond to the State Medicaid agency by such time and for such term as is specified in the instructions of the State Medicaid agency.

(5) *Government-operated HHA that loses its waiver.* A government-operated HHA that, as of January 1, 1998, meets the criteria for waiver of the requirements of this section but thereafter is determined by the Medicaid agency to not meet such criteria, must submit a surety bond to the Medicaid agency within 60 days after it receives notice from the Medicaid agency that it does not meet the criteria for waiver.

(6) *Change of Surety.* An HHA that obtains a replacement surety bond from a different Surety to cover the remaining term of a previously obtained bond must submit the new surety bond to the Medicaid agency within 60 days (or such earlier date as the Medicaid agency may specify) of obtaining the bond from the new Surety for a term specified by the Medicaid agency.

(j) *Effect of failure to obtain, maintain, and timely file a surety bond.* (1) The Medicaid agency must terminate the HHA's provider agreement if the HHA fails to obtain, file timely, and maintain a surety bond in accordance with this section and the Medicaid agency's instructions.

(2) The Medicaid agency must refuse to enter into a provider agreement with an HHA if an HHA seeking to become a participating HHA fails to obtain and file timely a surety bond in accordance with this section and instructions issued by the State Medicaid agency.

(k) *Evidence of compliance.* (1) The Medicaid agency may at any time require an HHA to make a specific showing of being in compliance with the requirements of this section and may require the HHA to submit such additional evidence as the Medicaid agency considers sufficient to demonstrate the HHA's compliance.

(2) The Medicaid agency may terminate the HHA's provider agreement or refuse to enter into a provider agreement if an HHA fails to timely furnish sufficient evidence at the Medicaid agency's request to demonstrate compliance with the requirements of this section.

(l) *Surety's standing to appeal Medicaid determinations.* The Medicaid agency must establish procedures for granting appeal rights to Sureties.

(m) *Effect of conditions of payment.* If a Surety has paid the Medicaid agency an amount on the basis of liability incurred under a bond obtained by an HHA under this section, and the Medicaid agency subsequently collects from the HHA, in whole or in part, on such overpayment that was the basis for the Surety's liability, the Medicaid agency must reimburse the Surety such amount as the Medicaid agency collected from the HHA, up to the amount paid by the Surety to the Medicaid agency, provided the Surety has no other liability under the bond.

[63 FR 310, Jan. 5, 1998, as amended at 63 FR 10731, Mar. 4, 1998; 63 FR 29654, June 1, 1998; 63 FR 41170, July 31, 1998]

§ 441.17 Laboratory services.

(a) The plan must provide for payment of laboratory services as defined in § 440.30 of this subchapter if provided by—

(1) An independent laboratory that meets the requirements for participation in the Medicare program found in § 405.1316 of this chapter;

(2) A hospital-based laboratory that meets the requirements for participation in the Medicare program found in § 482.27 of this chapter;

(3) A rural health clinic, as defined in § 491.9 of this chapter; or

(4) A skilled nursing facility—based clinical laboratory, as defined in § 405.1128(a) of this chapter.

(b) Except as provided under paragraph (c), if a laboratory or other entity is requesting payment under Medicaid for testing for the presence of the human immunodeficiency virus (HIV) antibody or for the isolation and identification of the HIV causative agent as described in § 405.1316(f) (2) and (3) of this chapter, the laboratory records must contain the name and other identification of the person from whom the specimen was taken.

(c) An agency may choose to approve the use of alternative identifiers, in place of the requirement for patient's name, in paragraph (b) of this section for HIV antibody or causative agent testing of Medicaid recipients.

[54 FR 48647, Dec. 2, 1988. Redesignated at 63 FR 310, Jan. 5, 1998.]

§ 441.20 Family planning services.

For recipients eligible under the plan for family planning services, the plan must provide that each recipient is free from coercion or mental pressure and free to choose the method of family planning to be used.

§ 441.21 Nurse-midwife services.

If a State plan, under § 440.210 or 440.220 of this subchapter, provides for nurse-midwife services, as defined in § 440.165, the plan must provide that the nurse-midwife may enter into an independent provider agreement, without regard to whether the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider.

[47 FR 21051, May 17, 1982]

§ 441.22 Nurse practitioner services.

With respect to nurse practitioner services that meet the definition of § 440.166(a) and the requirements of either § 440.166(b) or § 440.166(c), the State plan must meet the following requirements:

(a) Provide that nurse practitioner services are furnished to the categorically needy.

(b) Specify whether those services are furnished to the medically needy.

(c) Provide that services furnished by a nurse practitioner, regardless of whether the nurse practitioner is under the supervision of, or associated with, a physician or other health care provider, may—

(1) Be reimbursed by the State Medicaid agency through an independent provider agreement between the State and the nurse practitioner; or

(2) Be paid through the employing provider.

[60 FR 19862, Apr. 21, 1995]

§ 441.25 Prohibition on FFP for certain prescribed drugs.

(a) FFP is not available in expenditures for the purchase or administration of any drug product that meets all of the following conditions:

(1) The drug product was approved by the Food and Drug Administration (FDA) before October 10, 1962.

(2) The drug product is available only through prescription.

(3) The drug product is the subject of a notice of opportunity for hearing issued under section 505(e) of the Federal Food, Drug, and Cosmetic Act and published in the FEDERAL REGISTER on a proposed order of FDA to withdraw its approval for the drug product because it has determined that the product is less than effective for all its labeled indications.

(4) The drug product is presently not subject to a determination by FDA, made under its efficacy review program (see 21 CFR 310.6 for an explanation of this program), that there is a compelling justification of the drug product's medical need.

(b) FFP is not available in expenditures for the purchase or administration of any drug product that is identical, related, or similar, as defined in 21 CFR 310.6, to a drug product that meets the conditions of paragraph (a) of this section.

[46 FR 48554, Oct. 1, 1981]

§ 441.30 Optometric services.

The plan must provide for payment of optometric services as physician services, whether furnished by an optometrist or a physician, if—

(a) The plan does not provide for payment for services provided by an optometrist, except for eligibility determinations under §§ 435.531 and 436.531 of this subchapter, but did provide for those services at an earlier period; and

(b) The plan specifically provides that physicians' services include services an optometrist is legally authorized to perform.

§ 441.35 Organ transplants.

(a) FFP is available in expenditures for services furnished in connection with organ transplant procedures only if the State plan includes written standards for the coverage of those procedures, and those standards provide that—

(1) Similarly situated individuals are treated alike; and

(2) Any restriction on the practitioners or facilities that may provide organ transplant procedures is consistent with the accessibility of high quality care to individuals eligible for the procedures under the plan.

(b) Nothing in paragraph (a) permits a State to provide, under its plan, services that are not reasonable in amount, duration, and scope to achieve their purpose.

[56 FR 8851, Mar. 1, 1991]

§ 441.40 End-stage renal disease.

FFP in expenditures for services described in subpart A of part 440 is available for facility treatment of end-stage renal disease only if the facility has been approved by the Secretary to furnish those services under Medicare. This requirement for approval of the facility does not apply under emergency conditions permitted under Medicare (see § 482.2 of this chapter).

[43 FR 45229, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986]

Subpart B—Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) of Individuals Under Age 21

SOURCE: 49 FR 43666, Oct. 31, 1984, unless otherwise noted.

§ 441.50 Basis and purpose.

This subpart implements sections 1902(a)(43) and 1905(a)(4)(B) of the Social Security Act, by prescribing State plan requirements for providing early and periodic screening and diagnosis of eligible Medicaid recipients under age 21 to ascertain physical and mental defects, and providing treatment to correct or ameliorate defects and chronic conditions found.

§ 441.55 State plan requirements.

A State plan must provide that the Medicaid agency meets the requirements of §§ 441.56–441.62, with respect to EPSDT services, as defined in § 440.40(b) of this subchapter.

§ 441.56 Required activities.

(a) *Informing.* The agency must—

(1) Provide for a combination of written and oral methods designed to inform effectively all EPSDT eligible individuals (or their families) about the EPSDT program.

(2) Using clear and nontechnical language, provide information about the following—

(i) The benefits of preventive health care;

(ii) The services available under the EPSDT program and where and how to obtain those services;

(iii) That the services provided under the EPSDT program are without cost to eligible individuals under 18 years of age, and if the agency chooses, to those 18 or older, up to age 21, except for any enrollment fee, premium, or similar charge that may be imposed on medically needy recipients; and

(iv) That necessary transportation and scheduling assistance described in § 441.62 of this subpart is available to the EPSDT eligible individual upon request.

(3) Effectively inform those individuals who are blind or deaf, or who cannot read or understand the English language.

(4) Provide assurance to CMS that processes are in place to effectively inform individuals as required under this paragraph, generally, within 60 days of the individual's initial Medicaid eligibility determination and in the case of families which have not utilized EPSDT services, annually thereafter.

(b) *Screening.* (1) The agency must provide to eligible EPSDT recipients who request it, screening (periodic comprehensive child health assessments); that is, regularly scheduled examinations and evaluations of the general physical and mental health, growth, development, and nutritional status of infants, children, and youth. (See paragraph (c)(3) of this section for requirements relating to provision of immunization at the time of screening.) As a minimum, these screenings must include, but are not limited to:

(i) Comprehensive health and developmental history.

(ii) Comprehensive unclothed physical examination.

(iii) Appropriate vision testing.

(iv) Appropriate hearing testing.

(v) Appropriate laboratory tests.

(vi) Dental screening services furnished by direct referral to a dentist for children beginning at 3 years of age. An agency may request from CMS an exception from this age requirement

(within an outer limit of age 5) for a two year period and may request additional two year exceptions. If an agency requests an exception, it must demonstrate to CMS's satisfaction that there is a shortage of dentists that prevents the agency from meeting the age 3 requirement.

(2) Screening services in paragraph (b)(1) of this section must be provided in accordance with reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care.

(c) *Diagnosis and treatment.* In addition to any diagnostic and treatment services included in the plan, the agency must provide to eligible EPSDT recipients, the following services, the need for which is indicated by screening, even if the services are not included in the plan—

(1) Diagnosis of and treatment for defects in vision and hearing, including eyeglasses and hearing aids;

(2) Dental care, at as early an age as necessary, needed for relief of pain and infections, restoration of teeth and maintenance of dental health; and

(3) Appropriate immunizations. (If it is determined at the time of screening that immunization is needed and appropriate to provide at the time of screening, then immunization treatment must be provided at that time.)

(d) *Accountability.* The agency must maintain as required by §§ 431.17 and 431.18—

(1) Records and program manuals;

(2) A description of its screening package under paragraph (b) of this section; and

(3) Copies of rules and policies describing the methods used to assure that the informing requirement of paragraph (a)(1) of this section is met.

(e) *Timeliness.* With the exception of the informing requirements specified in paragraph (a) of this section, the agency must set standards for the timely provision of EPSDT services which meet reasonable standards of medical and dental practice, as determined by the agency after consultation with recognized medical and dental organizations involved in child health care, and must employ processes to ensure timely initiation of treatment, if required, generally within an outer limit of 6 months after the request for screening services.

[49 FR 43666, Oct. 31, 1984; 49 FR 45431, Nov. 16, 1984]

§ 441.57 Discretionary services.

Under the EPSDT program, the agency may provide for any other medical or remedial care specified in part 440 of this subchapter, even if the agency does not otherwise provide for these services to other recipients or provides for them in a lesser amount, duration, or scope.

§ 441.58 Periodicity schedule.

The agency must implement a periodicity schedule for screening services that—

(a) Meets reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care;

(b) Specifies screening services applicable at each stage of the recipient's life, beginning with a neonatal examination, up to the age at which an individual is no longer eligible for EPSDT services; and

(c) At the agency's option, provides for needed screening services as determined by the agency, in addition to the otherwise applicable screening services specified under paragraph (b) of this section.

§ 441.59 Treatment of requests for EPSDT screening services.

(a) The agency must provide the screening services described in § 441.56(b) upon the request of an eligible recipient.

(b) To avoid duplicate screening services, the agency need not provide requested screening services to an EPSDT eligible if written verification exists that the most recent age-appropriate screening services, due under the agency's periodicity schedule, have already been provided to the eligible.

§ 441.60 Continuing care.

(a) *Continuing care provider.* For purposes of this subpart, a continuing care provider means a provider who has an

agreement with the Medicaid agency to provide reports as required under paragraph (b) of this section and to provide at least the following services to eligible EPSDT recipients formally enrolled with the provider:

(1) With the exception of dental services required under § 441.56, screening, diagnosis, treatment, and referral for follow-up services as required under this subpart.

(2) Maintenance of the recipient's consolidated health history, including information received from other providers.

(3) Physicians' services as needed by the recipient for acute, episodic or chronic illnesses or conditions.

(4) At the provider's option, provision of dental services required under § 441.56 or direct referral to a dentist to provide dental services required under § 441.56(b)(1)(vi). The provider must specify in the agreement whether dental services or referral for dental services are provided. If the provider does not choose to provide either service, then the provider must refer recipients to the agency to obtain those dental services required under § 441.56.

(5) At the provider's option, provision of all or part of the transportation and scheduling assistance as required under § 441.62. The provider must specify in the agreement the transportation and scheduling assistance to be furnished. If the provider does not choose to provide some or all of the assistance, then the provider must refer recipients to the agency to obtain the transportation and scheduling assistance required under § 441.62.

(b) *Reports.* A continuing care provider must provide to the agency any reports that the agency may reasonably require.

(c) *State monitoring.* If the State plan provides for agreements with continuing care providers, the agency must employ methods described in the State plan to assure the providers' compliance with their agreements.

(d) *Effect of agreement with continuing care providers.* Subject to the requirements of paragraphs (a), (b), and (c) of this section, CMS will deem the agency to meet the requirements of this subpart with respect to all EPSDT eligible recipients formally enrolled with the continuing care provider. To be formally enrolled, a recipient or recipient's family agrees to use one continuing care provider to be a regular source of the described set of services for a stated period of time. Both the recipient and the provider must sign statements that reflect their obligations under the continuing care arrangement.

(e) If the agreement in paragraph (a) of this section does not provide for all or part of the transportation and scheduling assistance required under § 441.62, or for dental service under § 441.56, the agency must provide for those services to the extent they are not provided for in the agreement.

§ 441.61 Utilization of providers and coordination with related programs.

(a) The agency must provide referral assistance for treatment not covered by the plan, but found to be needed as a result of conditions disclosed during screening and diagnosis. This referral assistance must include giving the family or recipient the names, addresses, and telephone numbers of providers who have expressed a willingness to furnish uncovered services at little or no expense to the family.

(b) The agency must make available a variety of individual and group providers qualified and willing to provide EPSDT services.

(c) The agency must make appropriate use of State health agencies, State vocational rehabilitation agencies, and Title V grantees (Maternal and Child Health/Crippled Children's Services). Further, the agency should make use of other public health, mental health, and education programs and related programs, such as Head Start, Title XX (Social Services) programs, and the Special Supplemental Food Program for Women, Infants and Children (WIC), to ensure an effective child health program.

§ 441.62 Transportation and scheduling assistance.

The agency must offer to the family or recipient, and provide if the recipient requests—

(a) Necessary assistance with transportation as required under § 431.53 of this chapter; and

(b) Necessary assistance with scheduling appointments for services.

Subpart C—Medicaid for Individuals Age 65 or Over in Institutions for Mental Diseases

SOURCE: 44 FR 17940, Mar. 23, 1979, unless otherwise noted.

§ 441.100 Basis and purpose.

This subpart implements section 1905(a)(14) of the Act, which authorizes State plans to provide for inpatient hospital services, skilled nursing services, and intermediate care facility services for individuals age 65 or older in an institution for mental diseases, and sections 1902(a)(20)(B) and (C) and 1902(a)(21), which prescribe the conditions a State must meet to offer these services. (See § 431.620 of this subchapter for regulations implementing section 1902(a)(20)(A), which prescribe interagency requirements related to these services.)

§ 441.101 State plan requirements.

A State plan that includes Medicaid for individuals age 65 or older in institutions for mental diseases must provide that the requirements of this subpart are met.

§ 441.102 Plan of care for institutionalized recipients.

(a) The Medicaid agency must provide for a recorded individual plan of treatment and care to ensure that institutional care maintains the recipient at, or restores him to, the greatest possible degree of health and independent functioning.

(b) The plan must include—

(1) An initial review of the recipient's medical, psychiatric, and social needs—

(i) Within 90 days after approval of the State plan provision for services in institutions for mental disease; and

(ii) After that period, within 30 days after the date payments are initiated for services provided a recipient.

(2) Periodic review of the recipient's medical, psychiatric, and social needs;

(3) A determination, at least quarterly, of the recipient's need for continued institutional care and for alternative care arrangements;

(4) Appropriate medical treatment in the institution; and

(5) Appropriate social services.

§ 441.103 Alternate plans of care.

(a) The agency must develop alternate plans of care for each recipient age 65 or older who would otherwise need care in an institution for mental diseases.

(b) These alternate plans of care must—

(1) Make maximum use of available resources to meet the recipient's medical, social, and financial needs; and

(2) In Guam, Puerto Rico, and the Virgin Islands, make available appropriate social services authorized under sections 3(a)(4) (i) and (ii) or 1603(a)(4)(A) (i) and (ii) of the Act.

§ 441.105 Methods of administration.

The agency must have methods of administration to ensure that its responsibilities under this subpart are met.

§ 441.106 Comprehensive mental health program.

(a) If the plan includes services in public institutions for mental diseases, the agency must show that the State is making satisfactory progress in developing and implementing a comprehensive mental health program.

(b) The program must—

(1) Cover all ages;

(2) Use mental health and public welfare resources; including—

(i) Community mental health centers;

(ii) Nursing homes; and

(iii) Other alternatives to public institutional care; and

(3) Include joint planning with State authorities.

(c) The agency must submit annual progress reports within 3 months after the end of each fiscal year in which Medicaid is provided under this subpart.

Subpart D—Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs

§ 441.150 Basis and purpose.

This subpart specifies requirements applicable if a State provides inpatient psychiatric services to individuals under age 21, as defined in § 440.160 of this subchapter and authorized under section 1905 (a)(16) and (h) of the Act.

§ 441.151 General requirements.

(a) Inpatient psychiatric services for individuals under age 21 must be:

(1) Provided under the direction of a physician;

(2) Provided by—

(i) A psychiatric hospital or an inpatient psychiatric program in a hospital, accredited by the Joint Commission on Accreditation of Healthcare Organizations; or

(ii) A psychiatric facility that is not a hospital and is accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children, or by any other accrediting organization with comparable standards that is recognized by the State.

(3) Provided before the individual reaches age 21, or, if the individual was receiving the services immediately before he or she reached age 21, before the earlier of the following—

(i) The date the individual no longer requires the services; or

(ii) The date the individual reaches 22; and

(4) Certified in writing to be necessary in the setting in which the services will be provided (or are being provided in emergency circumstances) in accordance with § 441.152.

(b) Inpatient psychiatric services furnished in a psychiatric residential treatment facility as defined in § 483.352 of this chapter, must satisfy all requirements in subpart G of part 483 of this chapter governing the use of restraint and seclusion.

[66 FR 7160, Jan. 22, 2001]

§ 441.152 Certification of need for services.

(a) A team specified in § 441.154 must certify that—

(1) Ambulatory care resources available in the community do not meet the treatment needs of the recipient;

(2) Proper treatment of the recipient's psychiatric condition requires services on an inpatient basis under the direction of a physician; and

(3) The services can reasonably be expected to improve the recipient's condition or prevent further regression so that the services will no longer be needed.

(b) The certification specified in this section and in § 441.153 satisfies the utilization control requirement for physician certification in §§ 456.60, 456.160, and 456.360 of this subchapter.

[43 FR 45229, Sept. 29, 1978, as amended at 61 FR 38398, July 24, 1996]

§ 441.153 Team certifying need for services.

Certification under § 441.152 must be made by terms specified as follows:

(a) For an individual who is a recipient when admitted to a facility or program, certification must be made by an independent team that—

(1) Includes a physician;

(2) Has competence in diagnosis and treatment of mental illness, preferably in child psychiatry; and

(3) Has knowledge of the individual's situation.

(b) For an individual who applies for Medicaid while in the facility of program, the certification must be—

(1) Made by the team responsible for the plan of care as specified in § 441.156; and

(2) Cover any period before application for which claims are made.

(c) For emergency admissions, the certification must be made by the team responsible for the plan of care (§ 441.156) within 14 days after admission.

§ 441.154 Active treatment.

Inpatient psychiatric services must involve ''active treatment'', which means implementation of a professionally developed and supervised individual plan of care, described in § 441.155 that is—

(a) Developed and implemented no later than 14 days after admission; and

(b) Designed to achieve the recipient's discharge from inpatient status at the earliest possible time.

§ 441.155 Individual plan of care.

(a) ''Individual plan of care'' means a written plan developed for each recipient in accordance with §§ 456.180 and 456.181 of this chapter, to improve his condition to the extent that inpatient care is no longer necessary.

(b) The plan of care must—

(1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral and developmental aspects of the recipient's situation and reflects the need for inpatient psychiatric care;

(2) Be developed by a team of professionals specified under § 441.156 in consultation with the recipient; and his parents, legal guardians, or others in whose care he will be released after discharge;

(3) State treatment objectives;

(4) Prescribe an integrated program of therapies, activities, and experiences designed to meet the objectives; and

(5) Include, at an appropriate time, post-discharge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the recipient's family, school, and community upon discharge.

(c) The plan must be reviewed every 30 days by the team specified in § 441.156 to—

(1) Determine that services being provided are or were required on an inpatient basis, and

(2) Recommend changes in the plan as indicated by the recipient's overall adjustment as an inpatient.

(d) The development and review of the plan of care as specified in this section satisfies the utilization control requirements for—

(1) Recertification under §§ 456.60(b), 456.160(b), and 456.360(b) of this subchapter; and

(2) Establishment and periodic review of the plan of care under §§ 456.80, 456.180, and 456.380 of this subchapter.

[43 FR 45229, Sept. 29, 1978, as amended at 46 FR 48560, Oct. 1, 1981; 61 FR 38398, July 24, 1996]

§ 441.156 Team developing individual plan of care.

(a) The individual plan of care under § 441.155 must be developed by an interdisciplinary team of physicians and other personnel who are employed by, or provide services to patients in, the facility.

(b) Based on education and experience, preferably including competence in child psychiatry, the team must be capable of—

(1) Assessing the recipient's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;

(2) Assessing the potential resources of the recipient's family;

(3) Setting treatment objectives; and

(4) Prescribing therapeutic modalities to achieve the plan's objectives.

(c) The team must include, as a minimum, either—

(1) A Board-eligible or Board-certified psychiatrist;

(2) A clinical psychologist who has a doctoral degree and a physician licensed to practice medicine or osteopathy; or

(3) A physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases, and a psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

(d) The team must also include one of the following:

(1) A psychiatric social worker.

(2) A registered nurse with specialized training or one year's experience in treating mentally ill individuals.

(3) An occupational therapist who is licensed, if required by the State, and who has specialized training or one year of experience in treating mentally ill individuals.

(4) A psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

§ 441.180 Maintenance of effort: General rule.

FFP is available only if the State maintains fiscal effort as prescribed under this subpart.

§ 441.181 Maintenance of effort: Explanation of terms and requirements.

(a) For purposes of § 441.182:

(1) The base year is the 4-quarter period ending December 31, 1971.

(2) Quarterly per capita non-Federal expenditures are expenditures for inpatient psychiatric services determined by reimbursement principles under Medicare. (See part 405, subpart D.)

(3) The number of individuals receiving inpatient psychiatric services in the current quarter means—

(i) The number of individuals receiving services for the full quarter; plus

(ii) The full quarter composite number of individuals receiving services for less than a full quarter.

(4) In determining the per capita expenditures for the base year, the Medicaid agency must compute the number of individuals receiving services in a manner similar to that in paragraph (a)(3) of this section.

(5) Non-Federal expenditures means the total amount of funds expended by the State and its political subdivisions, excluding Federal funds received directly or indirectly from any source.

(6) Expenditures for the current calendar quarter exclude Federal funds received directly or indirectly from any source.

(b) As a basis for determining the correct amount of Federal payments, each State must submit estimated and actual cost data and other information necessary for this purpose in the form and at the times specified in this subchapter and by CMS guidelines.

(c) The agency must have on file adequate records to substantiate compliance with the requirements of § 441.182 and to ensure that all necessary adjustments have been made.

(d) Facilities that did not meet the requirements of §§ 441.151–441.156 in the base year, but are providing inpatient psychiatric services under those sections in the current quarter, must be included in the maintenance of effort computation if, during the base year, they were—

(1) Providing inpatient psychiatric services for individuals under age 21; and

(2) Receiving State aid.

§ 441.182 Maintenance of effort: Computation.

(a) For expenditures for inpatient psychiatric services for individuals under age 21, in any calendar quarter, FFP is available only to the extent that the total State Medicaid expenditures in the current quarter for inpatient psychiatric services and outpatient psychiatric treatment for individuals under age 21 exceed the sum of the following:

(1) The total number of individuals receiving inpatient psychiatric services in the current quarter times the average quarterly per capita non-Federal expenditures for the base year; and

(2) The average non-Federal quarterly expenditures for the base year for outpatient psychiatric services for individuals under age 21.

(b) FFP is available for 100 percent of the increase in expenditures over the base year period, but may not exceed the Federal medical assistance percentage times the expenditures under this subpart for inpatient psychiatric services for individuals under age 21.

Subpart E—Abortions

§ 441.200 Basis and purpose.

This subpart implements section 402 of Pub. L. 97–12, and subsequent laws that appropriate funds for the Medicaid program, including section 204 of Pub. L. 98–619. All of these laws prohibit the use of Federal funds to pay for abortions except when continuation of the pregnancy would endanger the mother's life.

[52 FR 47935, Dec. 17, 1987]

§ 441.201 Definition.

As used in this subpart, ''physician'' means a doctor of medicine or osteopathy who is licensed to practice in the State.

[52 FR 47935, Dec. 17, 1987]

§ 441.202 General rule.

FFP is not available in expenditures for an abortion unless the conditions specified in §§ 441.203 and 441.206 are met.

[52 FR 47935, Dec. 17, 1987]

§ 441.203 Life of the mother would be endangered.

FFP is available in expenditures for an abortion when a physician has found, and certified in writing to the Medicaid agency, that on the basis of his professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

§§ 441.204–441.205 [Reserved]

§ 441.206 Documentation needed by the Medicaid agency.

FFP is not available in any expenditures for abortions or other medical procedures otherwise provided for under § 441.203 if the Medicaid agency has paid without first having received the certifications and documentation specified in that section.

[52 FR 47935, Dec. 17, 1987]

§ 441.207 Drugs and devices and termination of ectopic pregnancies.

FFP is available in expenditures for drugs or devices to prevent implantation of the fertilized ovum and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 441.208 Recordkeeping requirements.

Medicaid agencies must maintain copies of the certifications and documentation specified in § 441.203 for 3 years under the recordkeeping requirements at 45 CFR 74.20.

[52 FR 47935, Dec. 17, 1987]

Subpart F—Sterilizations

SOURCE: 43 FR 52171, Nov. 8, 1978, unless otherwise noted.

§ 441.250 Applicability.

This subpart applies to sterilizations and hysterectomies reimbursed under Medicaid.

§ 441.251 Definitions.

As used in this subpart:

Hysterectomy means a medical procedure or operation for the purpose of removing the uterus.

Institutionalized individual means an individual who is (a) involuntarily confined or detained, under a civil or criminal statute, in a correctional or rehabilitative facility, including a mental hospital or other facility for the care and treatment of mental illness; or (b) confined, under a voluntary commitment, in a mental hospital or other facility for the care and treatment of mental illness.

Mentally incompetent individual means an individual who has been declared mentally incompetent by a Federal, State, or local court of competent jurisdiction for any purpose, unless the individual has been declared competent for purposes which include the ability to consent to sterilization.

Sterilization means any medical procedure, treatment, or operation for the purpose of rendering an individual permanently incapable of reproducing.

§ 441.252 State plan requirements.

A State plan must provide that the Medicaid agency will make payment under the plan for sterilization procedures and hysterectomies only if all the requirements of this subpart were met.

§ 441.253 Sterilization of a mentally competent individual aged 21 or older.

FFP is available in expenditures for the sterilization of an individual only if—

(a) The individual is at least 21 years old at the time consent is obtained;

(b) The individual is not a mentally incompetent individual;

(c) The individual has voluntarily given informed consent in accordance with all the requirements precribed in §§ 441.257 and 441.258; and

(d) At least 30 days, but not more than 180 days, have passed between the date of informed consent and the date of the sterilization, except in the case of premature delivery or emergency abdominal surgery. An individual may consent to be sterilized at the time of a premature delivery or emergency abdominal surgery, if at least 72 hours have passed since he or she gave informed consent for the sterilization. In the case of premature delivery, the informed consent must have been given at least 30 days before the expected date of delivery.

§ 441.254 Mentally incompetent or institutionalized individuals.

FFP is not available for the sterilization of a mentally incompetent or institutionalized individual.

§ 441.255 Sterilization by hysterectomy.

(a) FFP is not available in expenditures for a hysterectomy if—

(1) It was performed solely for the purpose of rendering an individual permanently incapable of reproducing; or

(2) If there was more than one purpose to the procedure, it would not have been performed but for the purpose of rendering the individual permanently incapable of reproducing.

(b) FFP is available in expenditures for a hysterectomy not covered by paragraph (a) of this section only under the conditions specified in paragraph (c), (d), or (e) of this section.

(c) FFP is available if—

(1) The person who secured authorization to perform the hysterectomy has informed the individual and her representative, if any, orally and in writing, that the hysterectomy will make the individual permanently incapable of reproducing; and

(2) The individual or her representative, if any, has signed a written acknowledgment of receipt of that information.

(d) Effective on March 8, 1979 or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available if—

(1) The individual—

(i) Was already sterile before the hysterectomy; or

(ii) Requires a hysterectomy because of a life-threatening emergency situation in which the physician determines that prior acknowledgment is not possible; and

(2) The physician who performs the hysterectomy—

(i) Certifies in writing that the individual was already sterile at the time of the hysterectomy, and states the cause of the sterility; or

(ii) Certifies in writing that the hysterectomy was performed under a life-threatening emergency situation in which he or she determined prior acknowledgment was not possible. He or she must also include a description of the nature of the emergency.

(e) Effective March 8, 1979, or any date thereafter through the date of publication of these regulations at the option of the State, FFP is available for hysterectomies performed during a period of an individual's retroactive Medicaid eligibility if the physician who performed the hysterectomy certifies in writing that—

(1) The individual was informed before the operation that the hysterectomy would make her permanently incapable of reproducing; or

(2) One of the conditions in paragraph (d)(1) of this section was met. The physician must supply the information specified in paragraph (d)(2) of this section.

[47 FR 33702, Aug. 4, 1982]

§ 441.256 Additional condition for Federal financial participation (FFP).

(a) FFP is not available in expenditures for any sterilization or hysterectomy unless the Medicaid agency, before making payment, obtained documentation showing that the requirements of this subpart were met. This documentation must include a consent from, an acknowledgement of receipt of hysterectomy information or a physician's certification under § 441.255(d)(2), as applicable.

(b) With regard to the requirements of § 441.255(d) for hysterectomies performed from March 8, 1979 through November 2, 1982, FFP is available in expenditures for those services if the documentation showing that the requirements of that paragraph were met is obtained by the Medicaid agency before submitting a claim for FFP for that procedure.

[47 FR 33702, Aug. 4, 1982]

§ 441.257 Informed consent.

(a) *Informing the individual.* For purposes of this subpart, an individual has given informed consent only if—

(1) The person who obtained consent for the sterilization procedure offered to answer any questions the individual to be sterilized may have concerning the procedure, provided a copy of the consent form and provided orally all of

the following information or advice to the individual to be sterilized:

(i) Advice that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled.

(ii) A description of available alternative methods of family planning and birth control.

(iii) Advice that the sterilization procedure is considered to be irreversible.

(iv) A thorough explanation of the specific sterilization procedure to be performed.

(v) A full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used.

(vi) A full description of the benefits or advantages that may be expected as a result of the sterilization.

(vii) Advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in § 441.253(c).

(2) Suitable arrangements were made to insure that the information specified in paragraph (a)(1) of this section was effectively communicated to any individual who is blind, deaf, or otherwise handicapped;

(3) An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent;

(4) The individual to be sterilized was permitted to have a witness of his or her choice present when consent was obtained;

(5) The consent form requirements of § 441.258 were met; and

(6) Any additional requirement of State or local law for obtaining consent, except a requirement for spousal consent, was followed.

(b) *When informed consent may not be obtained.* Informed consent may not be obtained while the individual to be sterilized is—

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

§ 441.258 Consent form requirements.

(a) *Content of consent form.* The consent form must be a copy of the form appended to this subpart or another form approved by the Secretary.

(b) *Required signatures.* The consent form must be signed and dated by—

(1) The individual to be sterilized;

(2) The interpreter, if one was provided;

(3) The person who obtained the consent; and

(4) The physician who performed the sterilization procedure.

(c) *Required certifications.* (1) The person securing the consent must certify, by signing the consent form, that

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify, by signing the consent form, that:

(i) Shortly before the performance of sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual appeared mentally competent and knowingly and voluntarily consented to be sterilized.

Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual's signature on the consent form and the date upon which the sterilization was performed.

(3) In the case of premature delivery or emergency abdominal surgery performed within 30 days of consent, the physician must certify that the sterilization was performed less than 30 days, but not less than 72 hours after informed consent was obtained because of premature delivery or emergency abdominal surgery and—

(i) In the case of premature delivery, must state the expected date of delivery; or

(ii) In the case of abdominal surgery, must describe the emergency.

(4) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally and read the consent form and explained its contents to the individual to be sterilized and that, to the best of the interpreter's knowledge and belief, the individual understood what the interpreter told him or her.

§ 441.259 Review of regulations.

The Secretary will request public comment on the operation of this subpart not later than 3 years after its effective date.

APPENDIX TO SUBPART F OF PART 441—REQUIRED CONSENT FORM

NOTICE: Your decision at any time not to be sterilized will not result in the withdrawal or withholding of any benefits provided by programs or projects receiving Federal funds.

CONSENT TO STERILIZATION

I have asked for and received information about sterilization from (doctor or clinic). When I first asked for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I understand that the sterilization must be considered permanent and not reversible. I have decided that I do not want to become pregnant, bear children or father children.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least 30 days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by Federally funded programs.

I am at least 21 years of age and was born on (Day) (Month) (Year).

I, _____, hereby consent of my own free will to be sterilized by _____ by a method called _____. My consent expires 180 days from the date of my signature below.

I also consent to the release of this form and other medical records about the operation to:

Representatives of the Department of Health and Human Services or

Employees of programs or projects funded by that Department but only for determining if Federal laws were observed.

I have received a copy of this form. (Signature) (Date) (Month) (Day) (Year).

You are requested to supply the following information, but it is not required: (Race and ethnicity designation (please check)) Black (not of Hispanic origin); Hispanic; Asian or Pacific Islander; American Indian or Alaskan native; or White (not of Hispanic origin).

INTERPRETER'S STATEMENT

If an interpreter is provided to assist the individual to be sterilized:

I have translated the information and advice presented orally to the individual to be sterilized by the person obtaining this consent. I have also read him/her the consent form in _____ _____ language and explained its contents to him/her. To the best of my knowledge and belief he/she understood this explanation. (Interpreter) (Date).

STATEMENT OF PERSON OBTAINING CONSENT

Before (name of individual) signed the consent form, I explained to him/her the nature of the sterilization operation _____, the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health

services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequence of the procedure. (Signature of person obtaining consent) (Date) (Facility) (Address).

PHYSICIAN'S STATEMENT

Shortly before I performed a sterilization operation upon (Name of individual to be sterilized) on (Date of sterilization) (operation), I explained to him/her the nature of the sterilization operation (specify type of operation), the fact that it is intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appeared to understand the nature and consequences of the procedure.

(*Instructions for use of alternative final paragraphs:* Use the first paragraph below except in the case of premature delivery or emergency abdominal surgery where the sterilization is performed less than 30 days after the date of the individual's signature on the consent form. In those cases, the second paragraph below must be used. Cross out the paragraph which is not used.)

(1) At least 30 days have passed between the date of the individual's signature on this consent form and the date the sterilization was performed.

(2) This sterilization was performed less than 30 days but more than 72 hours after the date of the individual's signature on this consent form because of the following circumstances (check applicable box and fill in information requested): Premature delivery. Individual's expected date of delivery: _____

☐ Emergency abdominal surgery: (describe circumstances):_____ (Physician) (Date).

Subpart G—Home and Community-Based Services: Waiver Requirements

SOURCE: 46 FR 48541, Oct. 1, 1981, unless otherwise noted.

§ 441.300 Basis and purpose.

Section 1915(c) of the Act permits States to offer, under a waiver of statutory requirements, an array of home and community-based services that an individual needs to avoid institutionalization. Those services are defined in § 440.180 of this subchapter. This subpart describes what the Medicaid agency must do to obtain a waiver.

§ 441.301 Contents of request for a waiver.

(a) A request for a waiver under this section must consist of the following:

(1) The assurances required by § 441.302 and the supporting documentation required by § 441.303.

(2) When applicable, requests for waivers of the requirements of section 1902(a)(1), section 1902(a)(10)(B), or section 1902(a)(10)(C)(i)(III) of the Act, which concern respectively, statewide application of Medicaid, comparability of services, and income and resource rules applicable to medically needy individuals living in the community.

(3) A statement explaining whether the agency will refuse to offer home or community-based services to any recipient if the agency can reasonably expect that the cost of the services would exceed the cost of an equivalent level of care provided in—

(i) A hospital (as defined in § 440.10 of this chapter);

(ii) A NF (as defined in section 1919(a) of the Act); or

(iii) An ICF/MR (as defined in § 440.150 of this chapter), if applicable.

(b) If the agency furnishes home and community-based services, as defined in § 440.180 of this subchapter, under a waiver granted under this subpart, the waiver request must—

(1) Provide that the services are furnished—

(i) Under a written plan of care subject to approval by the Medicaid agency;

(ii) Only to recipients who are not inpatients of a hospital, NF, or ICF/MR; and

(iii) Only to recipients who the agency determines would, in the absence of these services, require the Medicaid covered level of care provided in—

(A) A hospital (as defined in § 440.10 of this chapter);

(B) A NF (as defined in section 1919(a) of the Act); or

(C) An ICF/MR (as defined in § 440.150 of this chapter);

(2) Describe the qualifications of the individual or individuals who will be responsible for developing the individual plan of care;

(3) Describe the group or groups of individuals to whom the services will be offered;

(4) Describe the services to be furnished so that each service is separately defined. Multiple services that are generally considered to be separate services may not be consolidated under a single definition. Commonly accepted terms must be used to describe the service and definitions may not be open ended in scope. CMS will, however, allow combined service definitions (bundling) when this will permit more efficient delivery of services and not compromise either a recipient's access to or free choice of providers.

(5) Provide that the documentation requirements regarding individual evaluation, specified in § 441.303(c), will be met; and

(6) Be limited to one of the following target groups or any subgroup thereof that the State may define:

(i) Aged or disabled, or both.

(ii) Mentally retarded or developmentally disabled, or both.

(iii) Mentally ill.

[46 FR 48541, Oct. 1, 1981, as amended at 50 FR 10026, Mar. 13, 1985; 59 FR 37717, July 25, 1994; 65 FR 60107, Oct. 10, 2000]

§ 441.302 State assurances.

Unless the Medicaid agency provides the following satisfactory assurances to CMS, CMS will not grant a waiver under this subpart and may terminate a waiver already granted:

(a) *Health and Welfare*—Assurance that necessary safeguards have been taken to protect the health and welfare of the recipients of the services. Those safeguards must include—

(1) Adequate standards for all types of providers that provide services under the waiver;

(2) Assurance that the standards of any State licensure or certification requirements are met for services or for individuals furnishing services that are provided under the waiver; and

(3) Assurance that all facilities covered by section 1616(e) of the Act, in which home and community-based services will be provided, are in compliance with applicable State standards that meet the requirements of 45 CFR Part 1397 for board and care facilities.

(b) *Financial accountability*— The agency will assure financial accountability for funds expended for home and community-based services, provide for an independent audit of its waiver program (except as CMS may otherwise specify for particular waivers), and it will maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services provided under the waiver, including reports of any independent audits conducted.

(c) *Evaluation of need.* Assurance that the agency will provide for the following:

(1) *Initial evaluation.* An evaluation of the need for the level of care provided in a hospital, a NF, or an ICF/MR when there is a reasonable indication that a recipient might need the services in the near future (that is, a month or less) unless he or she receives home or community-based services. For purposes of this section, ''evaluation'' means a review of an individual recipient's condition to determine—

(i) If the recipient requires the level of care provided in a hospital as defined in § 440.10 of this subchapter, a NF as defined in section 1919(a) of the Act, or an ICF/MR as defined by § 440.150 of this subchapter; and

(ii) That the recipient, but for the provision of waiver services, would otherwise be institutionalized in such a facility.

(2) *Periodic reevaluations.* Reevaluations, at least annually, of each recipient receiving home or community-

based services to determine if the recipient continues to need the level of care provided and would, but for the provision of waiver services, otherwise be institutionalized in one of the following institutions:

(i) A hospital;

(ii) A NF; or

(iii) An ICF/MR.

(d) *Alternatives*—Assurance that when a recipient is determined to be likely to require the level of care provided in a hospital, NF, or ICF/MR, the recipient or his or her legal representative will be—

(1) Informed of any feasible alternatives available under the waiver; and

(2) Given the choice of either institutional or home and community-based services.

(e) *Average per capita expenditures.* Assurance that the average per capita fiscal year expenditures under the waiver will not exceed 100 percent of the average per capita expenditures that would have been made in the fiscal year for the level of care provided in a hospital, NF, or ICF/MR under the State plan had the waiver not been granted.

(1) These expenditures must be reasonably estimated and documented by the agency.

(2) The estimate must be on an annual basis and must cover each year of the waiver period.

(f) *Actual total expenditures.* Assurance that the agency's actual total expenditures for home and community-based and other Medicaid services under the waiver and its claim for FFP in expenditures for the services provided to recipients under the waiver will not, in any year of the waiver period, exceed 100 percent of the amount that would be incurred by the State's Medicaid program for these individuals, absent the waiver, in—

(1) A hospital;

(2) A NF; or

(3) An ICF/MR.

(g) *Institutionalization absent waiver.* Assurance that, absent the waiver, recipients in the waiver would receive the appropriate type of Medicaid-funded institutional care (hospital, NF, or ICF/MR) that they require.

(h) *Reporting.* Assurance that annually, the agency will provide CMS with information on the waiver's impact. The information must be consistent with a data collection plan designed by CMS and must address the waiver's impact on—

(1) The type, amount, and cost of services provided under the State plan; and

(2) The health and welfare of recipients.

(i) *Habilitation services.* Assurance that prevocational, educational, or supported employment services, or a combination of these services, if provided as habilitation services under the waiver, are—

(1) Not otherwise available to the individual through a local educational agency under section 602 (16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401 (16 and 17)) or as services under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730); and

(2) Furnished as part of expanded habilitation services, if the State has requested and received CMS's approval under a waiver or an amendment to a waiver.

(j) *Day treatment or partial hospitalization, psychosocial rehabilitation services, and clinic services for individuals with chronic mental illness.* Assurance that FFP will not be claimed in expenditures for waiver services including, but not limited to, day treatment or partial hospitalization, psychosocial rehabilitation services, and clinic services provided as home and community-based services to individuals with chronic mental illnesses if these individuals, in the absence of a waiver, would be placed in an IMD and are—

(1) Age 22 to 64;

(2) Age 65 and older and the State has not included the optional Medicaid benefit cited in § 440.140; or

(3) Age 21 and under and the State has not included the optional Medicaid benefit cited in § 440.160.

[50 FR 10026, Mar. 13, 1985, as amended at 59 FR 37717, July 25, 1994; 65 FR 60107, Oct. 10, 2000]

§ 441.303 Supporting documentation required.

The agency must furnish CMS with sufficient information to support the assurances required by § 441.302. Except

as CMS may otherwise specify for particular waivers, the information must consist of the following:

(a) A description of the safeguards necessary to protect the health and welfare of recipients. This information must include a copy of the standards established by the State for facilities that are covered by section 1616(e) of the Act.

(b) A description of the records and information that will be maintained to support financial accountability.

(c) A description of the agency's plan for the evaluation and reevaluation of recipients, including—

(1) A description of who will make these evaluations and how they will be made;

(2) A copy of the evaluation form to be used; and if it differs from the form used in placing recipients in hospitals, NFs, or ICFs/MR, a description of how and why it differs and an assurance that the outcome of the new evaluation form is reliable, valid, and fully comparable to the form used for hospital, NF, or ICF/MR placement;

(3) The agency's procedure to ensure the maintenance of written documentation on all evaluations and reevaluations; and

(4) The agency's procedure to ensure reevaluations of need at regular intervals.

(d) A description of the agency's plan for informing eligible recipients of the feasible alternatives available under the waiver and allowing recipients to choose either institutional services or home and community-based services.

(e) An explanation of how the agency will apply the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services who are eligible under a special income level (included in § 435.217 of this chapter).

(f) An explanation with supporting documentation satisfactory to CMS of how the agency estimated the average per capita expenditures for services.

(1) The annual average per capita expenditure estimate of the cost of home and community-based and other Medicaid services under the waiver must not exceed the estimated annual average per capita expenditures of the cost of services in the absence of a waiver. The estimates are to be based on the following equation:

$$D+D' \leq G+G'.$$

The symbol ''≤'' means that the result of the left side of the equation must be less than or *equal* to the result of the right side of the equation.

D = the estimated annual average per capita Medicaid cost for home and community-based services for individuals in the waiver program.

D′ = the estimated annual average per capita Medicaid cost for all other services provided to individuals in the waiver program.

G = the estimated annual average per capita Medicaid cost for hospital, NF, or ICF/MR care that would be incurred for individuals served in the waiver, were the waiver not granted.

G′ = the estimated annual average per capita Medicaid costs for all services other than those included in factor G for individuals served in the waiver, were the waiver not granted.

(2) For purposes of the equation, the prime factors include the average per capita cost for all State plan services and expanded EPSDT services provided that are not accounted for in other formula values.

(3) In making estimates of average per capita expenditures for a waiver that applies only to individuals with a particular illness (for example, acquired immune deficiency syndrome) or condition (for example, chronic mental illness) who are inpatients in or who would require the level of care provided in hospitals as defined by § 440.10, NFs as defined in section 1919(a) of the Act, or ICFs/MR, the agency may determine the average per capita expenditures for these individuals absent the waiver without including expenditures for other individuals in the affected hospitals, NFs, or ICFs/MR.

(4) In making estimates of average per capita expenditures for a separate waiver program that applies only to individuals identified through the preadmission screening annual resident review (PASARR) process who are developmentally disabled, inpatients of a NF, and require the level of care provided in an ICF/MR as determined by the State on the basis of an evaluation under § 441.303(c), the agency may determine the average per capita expenditures that would have been made in a

fiscal year for those individuals based on the average per capita expenditures for inpatients in an ICF/MR. When submitting estimates of institutional costs without the waiver, the agency may use the average per capita costs of ICF/MR care even though the deinstitutionalized developmentally disabled were inpatients of NFs.

(5) For persons diverted rather than deinstitutionalized, the State's evaluation process required by §441.303(c) must provide for a more detailed description of their evaluation and screening procedures for recipients to ensure that waiver services will be limited to persons who would otherwise receive the level of care provided in a hospital, NF, or ICF/MR, as applicable.

(6) The State must indicate the number of unduplicated beneficiaries to which it intends to provide waiver services in each year of its program. This number will constitute a limit on the size of the waiver program unless the State requests and the Secretary approves a greater number of waiver participants in a waiver amendment.

(7) In determining the average per capita expenditures that would have been made in a waiver year, for waiver estimates that apply to persons with mental retardation or related conditions, the agency may include costs of Medicaid residents in ICFs/MR that have been terminated on or after November 5, 1990.

(8) In submitting estimates for waivers that include personal caregivers as a waiver service, the agency may include a portion of the rent and food attributed to the unrelated personal caregiver who resides in the home or residence of the recipient covered under the waiver. The agency must submit to CMS for review and approval the method it uses to apportion the costs of rent and food. The method must be explained fully to CMS. A personal caregiver provides a waiver service to meet the recipient's physical, social, or emotional needs (as opposed to services not directly related to the care of the recipient; that is, housekeeping or chore services). FFP for live-in caregivers is not available if the recipient lives in the caregiver's home or in a residence that is owned or leased by the caregiver.

(9) In submitting estimates for waivers that apply to individuals with mental retardation or a related condition, the agency may adjust its estimate of average per capita expenditures to include increases in expenditures for ICF/MR care resulting from implementation of a PASARR program for making determinations for individuals with mental retardation or related conditions on or after January 1, 1989.

(10) For a State that has CMS approval to bundle waiver services, the State must continue to compute separately the costs and utilization of the component services that make up the bundled service to support the final cost and utilization of the bundled service that will be used in the cost-neutrality formula.

(g) The State, at its option, may provide for an independent assessment of its waiver that evaluates the quality of care provided, access to care, and cost-neutrality. The results of the assessment should be submitted to CMS at least 90 days prior to the expiration date of the approved waiver-period and cover the first 24 or 48 months of the waiver. If a State chooses to provide for an independent assessment, FFP is available for the costs attributable to the independent assessment.

(h) For States offering habilitation services that include prevocational, educational, or supported employment services, or a combination of these services, consistent with the provisions of §440.180(c) of this chapter, an explanation of why these services are not available as special education and related services under sections 602 (16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401 (16 and 17)) or as services under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. section 730);

(i) For States offering home and community-based services for individuals diagnosed as chronically mentally ill, an explanation of why these individuals would not be placed in an institution for mental diseases (IMD) absent the waiver, and the age group of these individuals.

[46 FR 48532, Oct. 1, 1981, as amended at 50 FR 10027, Mar. 13, 1985; 50 FR 25080, June 17, 1985; 59 FR 37718, July 25, 1994]

§ 441.304 Duration of a waiver.

(a) The effective date for a new waiver of Medicaid requirements to provide home and community-based services approved under this subpart is established by CMS prospectively on or after the date of approval and after consultation with the State agency. The initial approved waiver continues for a 3-year period from the effective date. If the agency requests it, the waiver may be extended for additional periods unless—

(1) CMS's review of the prior waiver period shows that the assurances required by § 441.302 were not met; and

(2) CMS is not satisfied with the assurances and documentation provided by the State in regard to the extension period.

(b) CMS will determine whether a request for extension of an existing waiver is actually an extension request or a request for a new waiver. If a State submits an extension request that would add a new group to the existing group of recipients covered under the waiver (as defined under § 441.301(b)(6)), CMS will consider it to be two requests: One as an extension request for the existing group, and the other as a new waiver request for the new group. Waivers may be extended for additional 5-year periods.

(c) CMS *may* grant a State an extension of its existing waiver for up to 90 days to permit the State to document more fully the satisfaction of statutory and regulatory requirements needed to approve a new waiver request. CMS will consider this option when it requests additional information on a new waiver request submitted by a State to extend its existing waiver or when CMS disapproves a State's request for extension.

(d) If CMS finds that an agency is not meeting one or more of the requirements for a waiver contained in this subpart, the agency is given a notice of CMS's findings and an opportunity for a hearing to rebut the findings. If CMS determines that the agency is not in compliance with this subpart after the notice and any hearing, CMS may terminate the waiver. For example, a State submits to CMS a waiver request for home and community-based services that includes an estimate of the expenditures that would be incurred if the services were provided to the covered individuals in a hospital, NF, or ICF/MR in the absence of the waiver. CMS approves the waiver. At the end of the waiver year, the State submits to CMS a report of its actual expenditures under the waiver. CMS finds that the actual expenditures under the waiver exceed 100 percent of the State's approved estimate of expenditures for these individuals in a hospital, NF, or ICF/MR in the absence of the waiver. CMS next requires the State to amend its estimates for subsequent waiver year(s). CMS then compares the revised estimates with the State's actual experience to determine if the revised estimates are reasonable. CMS may terminate the waiver if the revised estimates indicate that the waiver is not cost-neutral or that the revised estimates are unreasonable.

[50 FR 10028, Mar. 13, 1985; 50 FR 25080, June 17, 1985, as amended at 59 FR 37719, July 25, 1994]

§ 441.305 Replacement of recipients in approved waiver programs.

(a) *Regular waivers.* A State's estimate of the number of individuals who may receive home and community-based services must include those who will replace recipients who leave the program for any reason. A State may replace recipients who leave the program due to death or loss of eligibility under the State plan without regard to any federally-imposed limit on utilization, but must maintain a record of recipients replaced on this basis.

(b) *Model waivers.* (1) The number of individuals who may receive home and community-based services under a model waiver may not exceed 200 recipients at any one time.

(2) The agency may replace any individuals who die or become ineligible for State plan services to maintain a count up to the number specified by the State and approved by CMS within the 200-maximum limit.

[59 FR 37719, July 25, 1994]

§ 441.306 Cooperative arrangements with the Maternal and Child Health program.

Whenever appropriate, the State agency administering the plan under

Medicaid may enter into cooperative arrangements with the State agency responsible for administering a program for children with special health care needs under the Maternal and Child Health program (Title V of the Act) in order to ensure improved access to coordinated services to meet the children's needs.

[59 FR 37720, July 25, 1994]

§ 441.307 Notification of a waiver termination.

(a) If a State chooses to terminate its waiver before the initial 3-year period or 5-year renewal period expires, it must notify CMS in writing 30 days before terminating services to recipients.

(b) If CMS or the State terminates the waiver, the State must notify recipients of services under the waiver in accordance with § 431.210 of this subchapter and notify them 30 days before terminating services.

[46 FR 48541, Oct. 1, 1981. Redesignated at 59 FR 37719, July 25, 1994, as amended at 65 FR 60107, Oct. 10, 2000]

§ 441.308 Hearings procedures for waiver terminations.

The procedures specified in subpart D of part 430 of this chapter are applicable to State requests for hearings on terminations.

[50 FR 10028, Mar. 13, 1985. Redesignated at 59 FR 37720, July 25, 1994]

§ 441.310 Limits on Federal financial participation (FFP).

(a) FFP for home and community-based services listed in § 440.180 of this chapter is not available in expenditures for the following:

(1) Services provided in a facility subject to the health and welfare requirements described in § 441.302(a) during any period in which the facility is found not to be in compliance with the applicable State standards described in that section.

(2) The cost of room and board except when provided as—

(i) Part of respite care services in a facility approved by the State that is not a private residence; or

(ii) For waivers that allow personal caregivers as providers of approved waiver services, a portion of the rent and food that may be reasonably attributed to the unrelated caregiver who resides in the same household with the waiver recipient. FFP for a live-in caregiver is not available if the recipient lives in the caregiver's home or in a residence that is owned or leased by the provider of Medicaid services (the caregiver). For purposes of this provision, ''board'' means 3 meals a day or any other full nutritional regimen and does not include meals provided as part of a program of adult day health services as long as the meals provided do not constitute a ''full'' nutritional regimen.

(3) Prevocational, educational, or supported employment services, or any combination of these services, as part of habilitation services that are—

(i) Provided in approved waivers that include a definition of ''habilitation services'' but which have not included prevocational, educational, and supported employment services in that definition; or

(ii) Otherwise available to the recipient under either special education and related services as defined in section 602(16) and (17) of the Education of the Handicapped Act (20 U.S.C. 1401(16) and (17)) or vocational rehabilitation services available to the individual through a program funded under section 110 of the Rehabilitation Act of 1973 (29 U.S.C. 730).

(4) For waiver applications and renewals approved on or after October 21, 1986, home and community-based services provided to individuals aged 22 through 64 diagnosed as chronically mentally ill who would be placed in an institution for mental diseases. FFP is also not available for such services provided to individuals aged 65 and over and 21 and under as an alternative to institutionalization in an IMD if the State does not include the appropriate optional Medicaid benefits specified at §§ 440.140 and 440.160 of this chapter in its State plan.

(b) FFP is available for expenditures for expanded habilitation services, as described in § 440.180 of this chapter, if the services are included under a waiver or waiver amendment approved by CMS.

[59 FR 37720, July 25, 1994, as amended at 65 FR 60107, Oct. 10, 2000]

Subpart H—Home and Community-Based Services Waivers for Individuals Age 65 or Older: Waiver Requirements

SOURCE: 57 FR 29156, June 30, 1992, unless otherwise noted.

§441.350 Basis and purpose.

Section 1915(d) of the Act permits States to offer, under a waiver of statutory requirements, home and community-based services not otherwise available under Medicaid to individuals age 65 or older, in exchange for accepting an aggregate limit on the amount of expenditures for which they claim FFP for certain services furnished to these individuals. The home and community-based services that may be furnished are listed in §440.181 of this subchapter. This subpart describes the procedures the Medicaid agency must follow to request a waiver.

§441.351 Contents of a request for a waiver.

A request for a waiver under this section must meet the following requirements:

(a) *Required signatures.* The request must be signed by the Governor, the Director of the Medicaid agency or the Director of the larger State agency of which the Medicaid agency is a component or any official of the Medicaid agency to whom this authority has been delegated. A request from any other agency of State government will not be accepted.

(b) *Assurances and supporting documentation.* The request must provide the assurances required by §441.352 of this part and the supporting documentation required by §441.353.

(c) *Statement for sections of the Act.* The request must provide a statement as to whether waiver of section 1902(a)(1), 1902(a)(10)(B), or 1902(a)(10)(C)(i)(III) of the Act is requested. If the State requests a waiver of section 1902(a)(1) of the Act, the waiver must clearly specify the geographic areas or political subdivisions in which the services will be offered. The State must indicate whether it is requesting a waiver of one or all of these sections. The State may request a waiver of any one of the sections cited above.

(d) *Identification of services.* The request must identify all services available under the approved State plan, which are also included in the APEL and which are identified under §440.181, and any limitations that the State has imposed on the provision of any service. The request must also identify and describe each service specified in §440.181 of this subchapter to be furnished under the waiver, and any additional services to be furnished under the authority of §440.181(b)(7). Descriptions of additional services must explain how each additional service included under §440.181(b)(7) will contribute to the health and well-being of the recipients and to their ability to reside in a community-based setting.

(e) *Recipients served.* The request must provide that the home and community-based services described in §440.181 of this subchapter, are furnished only to individuals who—

(1) Are age 65 or older;

(2) Are not inpatients of a hospital, NF, or ICF/MR; and

(3) The agency determines would be likely to require the care furnished in a NF under Medicaid.

(f) *Plan of care.* The request must provide that the home and community-based services described in §440.181 of this subchapter, are furnished under a written plan of care based on an assessment of the individual's health and welfare needs and developed by qualified individuals for each recipient under the waiver. The qualifications of the individual or individuals who will be responsible for developing the individual plan of care must be described. Each plan of care must contain, at a minimum, the medical and other services to be provided, their frequency, and the type of provider to furnish them. Plans of care must be subject to the approval of the Medicaid agency.

(g) *Medicaid agency review.* The request must assure that the State agency maintain and exercise its authority to review (at a minimum) a valid statistical sample of each month's plans of care. When the services in a plan do not comport with the stated disabilities and needs of the recipient, the agency must implement immediate

corrective action procedures to ensure that the needs of the recipient are adequately addressed.

(h) *Groups served.* The request must describe the group or groups of individuals to whom the services will be offered.

(i) *Assurances regarding amount expended.* The request must assure that the total amount expended by the State under the plan for individuals age 65 or older during a waiver year for medical assistance with respect to NF, home health, private duty nursing, personal care, and home and community-based services described in §§ 440.180 and 440.181 of this subchapter and furnished as an alternative to NF care will not exceed the aggregate projected expenditure limit (APEL) defined in § 441.354.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.351 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.352 State assurances.

Unless the Medicaid agency provides the following satisfactory assurances to CMS, CMS will not grant a waiver under this subpart and may terminate a waiver already granted.

(a) *Health and welfare.* The agency must assure that necessary safeguards have been taken to protect the health and welfare of the recipients of services by assuring that the following conditions are met:

(1) Adequate standards for all types of providers that furnish services under the waiver are met. (These standards must be reasonably related to the requirements of the waiver service to be furnished.)

(2) The standards of any State licensure or certification requirements are met for services or for individuals furnishing services under the waiver.

(3) All facilities covered by section 1616(e) of the Act, in which home and community-based services are furnished, are in compliance with applicable State standards that meet the requirements of 45 CFR part 1397 for board and care facilities.

(4) Physician reviews of prescribed psychotropic drugs (when prescribed for purposes of behavior control of waiver recipients) occur at least every 30 days.

(b) *Financial accountability.* The agency must assure financial accountability for funds expended for home and community-based services. The State must provide for an independent audit f its waiver program. The performance of a single financial audit, in accordance with the Single Audit Act of 1984 (Pub. L. 98–502, enacted on October 19, 1984), is deemed to satisfy the requirement for an independent audit. The agency must maintain and make available to HHS, the Comptroller General, or other designees, appropriate financial records documenting the cost of services furnished to individuals age 65 or older under the waiver and the State plan, including reports of any independent audits conducted.

(c) *Evaluation of need.* The agency must provide for an initial evaluation (and periodic reevaluations) of the need for the level of care furnished in a NF when there is a reasonable indication that individuals age 65 or older might need those services in the near future, but for the availability of home and community-based services. The procedures used to assess level of care for a potential waiver recipient must be at least as stringent as any existing State procedures applicable to individuals entering a NF. The qualifications of individuals performing the waiver assessment must be as high as those of individuals assessing the need for NF care, and the assessment instrument itself must be the same as any assessment instrument used to establish level of care of prospective inpatients in NFs. A periodic reevaluation of the level of care must be performed. The period of reevaluation of level of care cannot extend beyond 1 year.

(d) *Expenditures.* The agency must assure that the total amount expended by the State for medical assistance with respect to NF, home health, private duty nursing, personal care services, home and community-based services furnished under a section 1915(c) waiver granted under Subpart G of this part to individuals age 65 or older, and the home and community-based services approved and furnished under a section 1915(d) waiver for individuals

age 65 or older during a waiver year will not exceed the APEL, calculated in accordance with § 441.354.

(e) *Reporting.* The agency must assure that it will provide CMS annually with information on the waiver's impact. The information must be consistent with a reasonable data collection plan designed by CMS and must address the waiver's impact on—

(1) The type, amount, and cost of services furnished under the State plan; and

(2) The health and welfare of recipients of the services described in § 440.181 of this chapter.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.352 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.353 Supporting documentation required.

The agency must furnish CMS with sufficient information to support the assurances required under § 441.352, in order to meet the requirement that the assurances are satisfactory. At a minimum, this information must consist of the following:

(a) *Safeguards.* A description of the safeguards necessary to protect the health and welfare of recipients.

This information must include:

(1) A copy of the standards established by the State for facilities (in which services will be furnished) that are covered by section 1616(e) of the Act.

(2) The minimum educational or professional qualifications of the providers of the services.

(3) A description of the administrative oversight mechanisms established by the State to ensure quality of care.

(b) *Records.* A description of the records and information that are maintained by the agency and by providers of services to support financial accountability, information regarding how the State meets the requirement for financial accountability, and an explanation of how the State assures that there is an audit trail for State and Federal funds expended for section 1915(d) home and community-based waiver services. If the State has an approved Medicaid Management Information System (MMIS), this system must be used to process individual claims data and account for funds expended for services furnished under the waiver.

(c) *Evaluation and reevaluation of recipients.* A description of the agency's plan for the evaluation and reevaluation of recipients' level of care, including the following:

(1) A description of who makes these evaluations and how they are made.

(2) A copy of the evaluation instrument.

(3) The agency's procedure to assure the maintenance of written documentation on all evaluations and reevaluations and copies of the forms. In accordance with regulations at 45 CFR part 74, written documentation of all evaluations and reevaluations must be maintained for a minimum period of 3 years.

(4) The agency's procedure to assure reevaluations of need at regular intervals.

(5) The intervals at which reevaluations occur, which may be no less frequent than for institutionalized individuals at comparable levels of care.

(6) The procedures and criteria used for evaluation and reevaluation of waiver recipients must be the same or more stringent than those used for individuals served in NFs.

(d) *Alternatives available.* A description of the agency's plan for informing eligible recipients of the feasible alternatives available under the waiver and allowing recipients to choose either institutional or home and community-based services must be submitted to CMS. A copy of the forms or documentation used by the agency to verify that this choice has been offered and that recipients of waiver services, or their legal representatives, have been given the free choice of the providers of both waiver and State plan services must also be available for CMS review. The Medicaid agency must provide an opportunity for a fair hearing, under 42 CFR part 431, subpart E, to recipients who are not given the choice of home or community-based services as an alternative to institutional care in a NF or who are denied the service(s) or the providers of their choice.

(e) *Post-eligibility of income.* An explanation of how the agency applies the applicable provisions regarding the post-eligibility treatment of income and resources of those individuals receiving home and community-based services who are eligible under a special income level (included in § 435.217 of this subchapter).

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.353 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.354 Aggregate projected expenditure limit (APEL).

(a) *Definitions.* For purposes of this section, the term *base year* means—

(1) Federal fiscal year (FFY) 1987 (that is, October 1, 1986 through September 30, 1987); or

(2) In the case of a State which did not report expenditures on the basis of age categories during FFY 1987, the base year means FFY 1989 (that is, October 1, 1988 through September 30, 1989).

(b) *General.* (1) The total amount expended by the State for medical assistance with respect to NF, home and community-based services under the waiver, home health services, personal care services, private duty nursing services, and services furnished under a waiver under subpart G of this part to individuals age 65 or older furnished as an alternative to care in an SNF or ICF (NF effective October 1, 1990), may not exceed the APEL calculated in accordance with paragraph (c) of this section.

(2) In applying for a waiver under this subpart, the agency must clearly identify the base year it intends to use.

(3) The State may make a preliminary calculation of the expenditure limit at the time of the waiver approval; however, CMS makes final calculations of the aggregate limit after base data have been verified and accepted.

(4) All base year and waiver year data are subject to final cost settlement within 2 years from the end of the base or waiver year involved.

(c) *Formula for calculating APEL.* Except as provided in paragraph (d) of this section, the formula for calculating the APEL follows:

$APEL = P \times (1+Y) + V \times (1+Z)$, where

P=The aggregate amount of the State's medical assistance under title XIX for SNF and ICF (NF effective October 1, 1990) services furnished to individuals who have reached age 65, defined as the total medical assistance payments (Federal and State) reported on line 6 of form CMS 64 (as adjusted) for SNF services, ICF-other services, and mental health facility services for the base year, multiplied by the ratio of expenditures for SNF and ICF-other services for the aged to total expenditures for these services as reported on form CMS 2082 for the base year.

Q=The market basket index for SNF and ICF (NF effective October 1, 1990) services for the waiver year involved, defined as the total SNF Input Price Index used in the Medicare program, identified as the third quarter data available from CMS's Office of National Cost Estimates in August preceding the start of the fiscal year.

R=The SNF Input Price Index for the base year.

S=The number of residents in the State in the waiver year involved who have reached age 65, defined as the number of aged Medicare beneficiaries in the State, equal to the Mid-Period Enrollment in HI or SMI in that State on July 1 preceding the start of the fiscal year.

T=The number of aged Medicare beneficiaries in the State who are enrolled in either the HI or SMI programs in the base year, as defined in S, above.

U=The number of years beginning after the base year and ending on the last day of the waiver year involved.

V=The aggregate amount of the State's medical assistance under title XIX in the base year for home and community-based services for individuals who have reached age 65, defined as the total medical assistance payments (Federal and State) reported on line 6 of form CMS 64 (as adjusted) for home health, personal care, and home and community-based services waivers, which provide services as an alternative to care in a SNF or ICF (NF effective October 1, 1990), increased by an estimate (acceptable to CMS) of expenditures for private duty nursing services, multiplied by the ratio of expenditures for home health services for the aged to total expenditures for home health services, as reported on form CMS 2082, for the base year.

W=The market basket index for home and community-based services for the waiver year involved, defined as the Home Agency Input Price Index, used in the Medicare program identified as the third quarter

data available from CMS's Office of National Cost Estimates in August preceding the start of the fiscal year.

X=The Home Health Agency Input Price Index for the base year.

Y=The greater of—

(U×.07), or (Q/R)-1+(S/T)-1+(U×.02).

Z=The greater of—

(U×.07), or (W/X)-1+(S/T)-1++(U×.02).

(d) *Amendment of the APEL.* The State may request amendment of its APEL to reflect an increase in the aggregate amount of medical assistance for NF services and for services included in the calculation of the APEL as required by paragraph (c) of this section when the increase is directly attributable to legislation enacted on or after December 22, 1987, which amends title XIX of the Act. Costs attributable to laws enacted before December 22, 1987 will not be considered. Because the APEL for each year of the waiver is computed separately from the APEL for any other waiver year, a separate amendment must be submitted for each year in which the State chooses to raise its APEL. Documentation specific to the waiver year involved must be submitted to CMS.

§441.355 Duration, extension, and amendment of a waiver.

(a) *Effective dates and extension periods.* (1) The effective date for a waiver of Medicaid requirements to furnish home and community-based services to individuals age 65 or older under this subpart is established by CMS prospectively on the first day of the FFY following the date on which the waiver is approved.

(2) The initial waiver is approved for a 3-year period from the effective date. Subsequent renewals are approved for 5-year periods.

(3) If the agency requests it, the waiver may be extended for an additional 5-year period if CMS's review of the prior period shows that the assurances required by §441.352 were met.

(4) The agency may request that waiver modifications be made effective retroactive to the first day of the waiver year in which the amendment is submitted, unless the amendment involves substantive change. Substantive changes may include, but are not limited to, addition of services under the waiver, a change in the qualifications of service providers, or a change in the eligible population.

(5) A request for an amendment that involves a substantive change is given a prospective effective date, but this date need not coincide with the start of the next FFY.

(b) *Extension or new waiver request.* CMS determines whether a request for extension of an existing waiver is actually an extension request, or a request for a new waiver. Generally, if a State's extension request proposes a substantive change in services furnished, eligible population, service area, statutory sections waived, or qualifications of service providers, CMS considers it a new waiver request.

(c) *Reconsideration of denial.* A determination of CMS to deny a request for a waiver (or for extension of a waiver) under this subpart may be reconsidered in accordance with §441.357.

(d) *Existing waiver effectiveness after denial.* If CMS denies a request for an extension of an existing waiver under this subpart:

(1) The existing waiver remains in effect for a period of not less than 90 days after the date on which CMS denies the request, or, if the State seeks reconsideration in accordance with §441.357, the date on which a final determination is made with respect to that review.

(2) CMS calculates an APEL for the period for which the waiver remains in effect, and this calculation is used to pro-rate the limit according to the number of days to which it applies.

§441.356 Waiver termination.

(a) *Termination by the State.* If a State chooses to terminate its waiver before an approved program is due to expire, the following conditions apply:

(1) The State must notify CMS in writing at least 30 days before terminating services to recipients.

(2) The State must notify recipients of services under the waiver at least 30 days before terminating services in accordance with §431.210 of this chapter.

(3) CMS continues to apply the APEL described in §441.354 through the end of the waiver year, but this limit is not applied in subsequent years.

(4) The State may not decrease the services available under the approved

State plan to individuals age 65 or older by an amount that violates the comparability of service requirements set forth in § 440.240 of this chapter.

(b) *Termination by CMS.* (1) If CMS finds, during an approved waiver period, that an agency is not meeting one or more of the requirements for a waiver contained in this subpart, CMS notifies the agency in writing of its findings and grants an opportunity for a hearing in accordance with § 441.357. If CMS determines that the agency is not in compliance with this subpart after the notice and any hearing, CMS may terminate the waiver.

(2) If CMS terminates the waiver, the following conditions apply:

(i) The State must notify recipients of services under the waiver at least 30 days before terminating services in accordance with § 431.210 of this chapter.

(ii) CMS continues to apply the APEL in § 441.354 of this subpart, but the limit is prorated according to the number of days in the fiscal year during which waiver services were offered. The limit expires concurrently with the termination of home and community-based services under the waiver.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.356 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 441.357 Hearing procedures for waiver denials.

The procedures specified in § 430.18 of this subchapter apply to State requests for hearings on denials, renewals, or amendments of waivers for home and community-based services for individuals age 65 or older.

§ 441.360 Limits on Federal financial participation (FFP).

FFP for home and community-based services listed in § 440.181 of this subchapter is not available in expenditures for the following:

(a) Services furnished in a facility subject to the health and welfare requirements described in § 441.352(a) during any period in which the facility is found not to be in compliance with the applicable State requirements described in that section.

(b) The cost of room and board except when furnished as part of respite care services in a facility, approved by the State, that is not a private residence. For purposes of this subpart, ''board'' means three meals a day or any other full nutritional regimen. ''Board'' does not include meals, which do not comprise a full nutritional regimen, furnished as part of adult day health services.

(c) The portion of the cost of room and board attributed to unrelated, live-in personal caregivers when the waiver recipient lives in the caregiver's home or a residence owned or leased by the provider of the Medicaid services (the caregiver).

(d) Services that are not included in the approved State plan and not approved as waiver services by CMS.

(e) Services furnished to recipients who are ineligible under the terms of the approved waiver.

(f) Services furnished by a provider when either the services or the provider do not meet the standards that are set by the State and included in the approved waiver.

(g) Services furnished to a recipient by his or her spouse.

§ 441.365 Periodic evaluation, assessment, and review.

(a) *Purpose.* This section prescribes requirements for periodic evaluation, assessment, and review of the care and services furnished to individuals receiving home and community-based waiver services under this subpart.

(b) *Evaluation and assessment review team.* (1) A review team, as described in paragraphs (b)(2) and (c) of this section, must periodically evaluate and assess the care and services furnished to recipients under this subpart. The review team must be created by the State agency directly, or (through interagency agreement) by other departments of State government (such as the Department of Health or the Agency on Aging).

(2) Each review team must consist of at least one physician or registered nurse, and at least one other individual with health and social service credentials who the State believes is qualified to properly evaluate and assess the care and services provided under the

waiver. If there is no physician on the review team, the Medicaid agency must ensure that a physician is available to provide consultation to the review team.

(3) For waiver services furnished to individuals who have been found to be likely to require the level of care furnished in a NF that is also an IMD, each review team must have a psychiatrist or physician and other appropriate mental health or social service personnel who are knowledgeable about geriatric mental illness.

(c) *Financial interests and employment of review team members.* (1) No member of a review team may have a financial interest in or be employed by any entity that furnishes care and services under the waiver to a recipient whose care is under review.

(2) No physician member of a review team may evaluate or assess the care of a recipient for whom he or she is the attending physician.

(3) No individual who serves as case manager, caseworker, benefit authorizer, or any similar position, may serve as member of a review team that evaluates and assesses care furnished to a recipient with whom he or she has had a professional relationship.

(d) *Number and location of review teams.* A sufficient number of teams must be located within the State so that onsite inspections can be made at appropriate intervals at sites where waiver recipients receive care and services.

(e) *Frequency of periodic evaluations and assessments.* Periodic evaluations and assessments must be conducted at least annually for each recipient under the waiver. The review team and the agency have the option to determine the frequency of further periodic evaluations and assessments, based on the quality of services and access to care being furnished under the waiver and the condition of patients receiving care and services.

(f) *Notification before inspection.* No provider of care and services under the waiver may be notified in advance of a periodic evaluation, assessment, and review. However, when a recipient receives services in his own home or the home of a relative, notification must be provided to the residents of the household at least 48 hours in advance. The recipient must have an opportunity to decline access to the home. If the recipient declines access to his or her own home, or the home of a relative, the review is limited solely to the review of the provider's records. If the recipient is incompetent, the head of the household has the authority to decline access to the home.

(g) *Personal contact with and observation of recipients and review of records.* (1) For recipients of care and services under a waiver, the review team's evaluation and assessment must include—

(i) A review of each recipient's medical record, the evaluation and reevaluation required by §441.353(c), and the plan of care under which the waiver and other services are furnished; and

(ii) If the records described in paragraph (g)(1)(i) of this section are inadequate or incomplete, personal contact and observation of each recipient.

(2) The review team may personally contact and observe any recipient whose care the team evaluates and assesses.

(3) The review team may consult with both formal and informal caregivers when the recipient's records are inadequate or incomplete and when any apparent discrepancy exists between services required by the recipient and services furnished under the waiver.

(h) *Determinations by the review team.* The review team must determine in its evaluation and assessment whether—

(1) The services included in the plan of care are adequate to meet the health and welfare needs of each recipient;

(2) The services included in the plan of care have been furnished to the recipient as planned;

(3) It is necessary and in the interest of the recipient to continue receiving services through the waiver program; and

(4) It is feasible to meet the recipient's health and welfare needs through the waiver program.

(i) *Other information considered by review team.* When making determinations, under paragraph (h) of this section, for each recipient, the review team must consider the following information and may consider other information as it deems necessary:

(1) Whether the medical record, the determination of level of care, and the plan of care are consistent, and whether all ordered services have been furnished and properly recorded.

(2) Whether physician review of prescribed psychotropic medications (when required for behavior control) has occurred at least every 30 days.

(3) Whether tests or observations of each recipient indicated by his or her medical record are made at appropriate times and properly recorded.

(4) Whether progress notes entered in the record by formal and informal caregivers are made as required and appear to be consistent with the observed condition of the recipient.

(5) Whether reevaluations of the recipient's level of care have occurred at least as frequently as would be required if that individual were served in a NF.

(6) Whether the recipient receives adequate care and services, based, at a minimum, on the following when observations are necessary (the requirements for the necessity of observations are set forth in new § 441.365(g)(3)):

(i) Cleanliness.

(ii) Absence of bedsores.

(iii) Absence of signs of malnutrition or dehydration.

(7) Whether the recipient needs any service that is not included in the plan of care, or if included, is not being furnished by formal or informal caregivers under the waiver or through arrangements with another public or private source of assistance.

(8) Determination as to whether continued home and community-based services are required by the recipient to avoid the likelihood of placement in a NF.

(j) *Submission of review team's results.* The review team must submit to the Medicaid agency the results of its periodic evaluation, assessment and review of the care of the recipient:

(1) Within 1 month of the completion of the review.

(2) Immediately upon its determination that conditions exist that may constitute a threat to the life or health of a recipient.

(k) *Agency's action.* The Medicaid agency must establish and adhere to procedures for taking appropriate action in response to the findings reported by the review team. These procedures must provide for immediate response to any finding that the life or health of a recipient may be jeopardized.

EFFECTIVE DATE NOTE: At 57 FR 29156, June 30, 1992, § 441.365 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

Subpart I—Community Supported Living Arrangements Services

SOURCE: 56 FR 48114, Sept. 24, 1991, unless otherwise noted.

§ 441.400 Basis and purpose.

This subpart implements section 1905(a)(24) of the Act, which adds community supported living arrangements services to the list of services that States may provide as medical assistance under title XIX (to the extent and as defined in section 1930 of the Act), and section 1930(h)(1)(B) of the Act, which specifies minimum protection requirements that a State which provides community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals must meet to ensure the health, safety and welfare of those individuals.

§ 441.402 State plan requirements.

If a State that is eligible to provide community supported living arrangements services as an optional Medicaid service to developmentally disabled individuals provides such services, the State plan must specify that it complies with the minimum protection requirements in § 441.404.

§ 441.404 Minimum protection requirements.

To be eligible to provide community supported living arrangements services to developmentally disabled individuals, a State must assure, through methods other than reliance on State licensure processes or the State quality assurance programs described under section 1930(d) of the Act, that:

(a) Individuals receiving community supported living arrangements services

are protected from neglect, physical and sexual abuse, and financial exploitation;

(b) Providers of community supported living arrangements services—

(1) Do not use individuals who have been convicted of child or client abuse, neglect, or mistreatment, or of a felony involving physical harm to an individual; and

(2) Take all reasonable steps to determine whether applicants for employment by the provider have histories indicating involvement in child or client abuse, neglect, or mistreatment, or a criminal record involving physical harm to an individual;

(c) Providers of community supported living arrangements services are not unjustly enriched as a result of abusive financial arrangements (such as owner lease-backs) with developmentally disabled clients; and

(d) Providers of community supported living arrangements services, or the relatives of such providers, are not named beneficiaries of life insurance policies purchased by or on behalf of developmentally disabled clients.

PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR THE MENTALLY RETARDED

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Subparts D–F [Reserved]

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

SOURCE: 43 FR 45233, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 442.1 Basis and purpose.

(a) This part states requirements for provider agreements for facility certification relating to the provision of services furnished by nursing facilities and intermediate care facilities for the mentally retarded. This part is based on the following sections of the Act:

Section 1902(a)(4), administrative methods for proper and efficient operation of the State plan;
Section 1902(a)(27), provider agreements;
Section 1902(a)(28), nursing facility standards;
Section 1902(a)(33)(B), State survey agency functions; Section 1902(i), circumstances and procedures for denial of payment and termination of provider agreements in certain cases;
Section 1905(c), definition of nursing facility;
Section 1905(d), definition of intermediate care facility for the mentally retarded;
Section 1905 (f), definition of nursing facility services;
Section 1910, certification and approval of ICFs/MR and of RHCs;
Section 1913, hospital providers of nursing facility services;
Section 1919 (g) and (h), survey, certification and enforcement of nursing facilities; and
Section 1922, correction and reduction plans for intermediate care facilities for the mentally retarded.

(b) Section 431.610 of this subchapter contains requirements for designating the State licensing agency to survey

these facilities and for certain survey agency responsibilities.

[43 FR 45233, Sept. 29, 1978, as amended at 47 FR 31533, July 20, 1982; 59 FR 56235, Nov. 10, 1994]

§ 442.2 Terms.

In this part—

Facility refers to a nursing facility, and an intermediate care facility for the mentally retarded or persons with related conditions (ICF/MR).

Facility, and any specific type of facility referred to, may include a distinct part of a facility as specified in § 440.40 or § 440.150 of this subchapter.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the provider's noncompliance with one or more requirements of participation or conditions of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to an individual receiving care in a facility.

New admission means the admission of a Medicaid recipient who has never been in the facility or, if previously admitted, had been discharged or had voluntarily left the facility. The term does not include the following:

(a) Individuals who were in the facility before the effective date of denial of payment for new admissions, even if they become eligible for Medicaid after that date.

(b) If the approved State plan includes payments for reserved beds, individuals who, after a temporary absence from the facility, are readmitted to beds reserved for them in accordance with § 447.40(a) of this chapter.

[43 FR 45233, Sept. 29, 1978, as amended at 51 FR 24491, July 3, 1986; 53 FR 1993, Jan. 25, 1988; 54 FR 5358, Feb. 2, 1989; 56 FR 48865, Sept. 26, 1991; 59 FR 56235, Nov. 10, 1994]

Subpart B—Provider Agreements

§ 442.10 State plan requirement.

A State plan must provide that requirements of this subpart are met.

§ 442.12 Provider agreement: General requirements.

(a) *Certification and recertification.* Except as provided in paragraph (b) of this section, a Medicaid agency may not execute a provider agreement with a facility for nursing facility services nor make Medicaid payments to a facility for those services unless the Secretary or the State survey agency has certified the facility under this part to provide those services. (See § 442.101 for certification by the Secretary or by the State survey agency).

(b) *Exception.* The certification requirement of paragraph (a) of this section does not apply with respect to religious nonmedical institutions as defined in § 440.170(b) of this chapter.

(c) *Conformance with certification condition.* An agreement must be in accordance with the certification provisions set by the Secretary or the survey agency under subpart C of this part for ICFs/MR or subpart E of part 488 of this chapter for NFs.

(d) *Denial for good cause.* (1) If the Medicaid agency has adequate documentation showing good cause, it may refuse to execute an agreement, or may cancel an agreement, with a certified facility.

(2) A provider agreement is not a valid agreement for purposes of this part even though certified by the State survey agency, if the facility fails to meet the civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

[45 FR 22936, Apr. 4, 1980, as amended at 56 FR 48865, Sept. 26, 1991; 59 FR 56235, Nov. 10, 1994; 64 FR 67052, Nov. 30, 1999]

§ 442.13 Effective date of provider agreement.

The effective date of a provider agreement with an NF or ICF/MR is determined in accordance with the rules set forth in § 431.108.

[62 FR 43936, Aug. 18, 1997]

§ 442.14 Effect of change of ownership.

(a) *Assignment of agreement.* When there is a change of ownership, the Medicaid agency must automatically assign the agreement to the new owner.

(b) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued, including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Any expiration date for ICFs/MR.

(3) Compliance with applicable health and safety requirements.

(4) Compliance with the ownership and financial interest disclosure requirements of §§ 455.104 and 455.105 of this chapter.

(5) Compliance with civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

(6) Compliance with any additional requirements imposed by the Medicaid agency.

[45 FR 22936, Apr. 4, 1980, as amended at 53 FR 20495, June 3, 1988; 59 FR 56235, Nov. 10, 1994]

§ 442.15 Duration of agreement for ICFs/MR.

(a) Except as specified under § 442.16, the duration of an agreement may not exceed 12 months.

(b) The agreement must be for the same duration as the certification period set by the survey agency. However, if the Medicaid agency has adequate documentation showing good cause, it may make an agreement for less than this period.

(c) FFP is available for services provided by a facility for up to 30 days after its agreement expires or terminates under the conditions specified in § 441.11 of this subchapter.

[43 FR 45233, Sept. 29, 1978, as amended at 47 FR 31532, July 20, 1982; 59 FR 56235, Nov. 10, 1994]

§ 442.16 Extension of agreement for ICFs/MR.

A Medicaid agency may extend a provider agreement for a single period of up to 2 months beyond the original expiration date specified in the agreement if it receives written notice from the survey agency, before the expiration date of the agreement, that extension will not jeopardize the patients' health and safety, and—

(a) Is needed to prevent irreparable harm to the facility or hardship to the recipients in the facility; or

(b) Is needed because it is impracticable to determine, before the expiration date, whether the facility meets certification requirements.

[43 FR 45233, Sept. 29, 1978, as amended at 52 FR 32551, Aug. 28, 1987; 53 FR 20495, June 3, 1988; 59 FR 56235, Nov. 10, 1994]

§ 442.30 Agreement as evidence of certification.

(a) Under §§ 440.40(a) and 440.150 of this chapter, FFP is available in expenditures for NF and ICF/MR services only if the facility has been certified as meeting the requirements for Medicaid participation, as evidenced by a provider agreement executed under this part. An agreement is not valid evidence that a facility has met those requirements if CMS determines that—

(1) The survey agency failed to apply the applicable requirements under subpart B of part 483 of this chapter for NFs or subpart I of part 483 of this chapter, which set forth the conditions of participation for ICFs/MR.

(2) The survey agency failed to follow the rules and procedures for certification set forth in subpart C of this part, subpart E of part 488, and § 431.610 of this subchapter;

(3) The survey agency failed to perform any of the functions specified in § 431.610(g) of this subchapter relating to evaluating and acting on information about the facility and inspecting the facility;

(4) The agency failed to use the Federal standards, and the forms, methods and procedures prescribed by CMS as required under § 431.610(f)(1) or § 488.318(b) of this chapter, for determining the qualifications of providers; or

(5) The survey agency failed to adhere to the following principles in determining compliance:

(i) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(ii) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically, surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(iii) Surveyors are professionals who use their judgment, in concert with

Federal forms and procedures, to determine compliance;

(iv) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(v) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(6) The survey agency failed to assess in a systematic manner a facility's actual provision of care and services to residents and effects of that care on residents.

(7) Required elements of the NF survey process fails to include all of the following:

(i) An entrance conference;

(ii) A resident-centered tour of facility;

(iii) An in-depth review of a sample of residents including observation, interview and record review;

(iv) Observation of the preparation and administration of drugs for a sample of residents;

(v) Evaluation of a facility's meals, dining areas and eating assistance procedures;

(vi) Formulation of a deficiency statement based on the incorporation of all appropriate findings onto the survey report form;

(vii) An exit conference; and

(viii) Follow-up surveys as appropriate.

(8) The agreement's terms and conditions do not meet the requirements of this subpart.

(b) The Administrator will make the determination under paragraph (a) of this section through onsite surveys, other Federal reviews, State certification records, or reports he may require from the Medicaid or survey agency.

(c) If the Administrator disallows a State's claim for FFP because of a determination under paragraph (a) of this section, the State is entitled upon request to reconsideration of the disallowance under 45 CFR part 16.

[43 FR 45233, Sept. 29, 1978, as amended at 51 FR 21558, June 13, 1986; 53 FR 20495, June 3, 1988; 53 FR 23101, June 17, 1988; 56 FR 48865, Sept. 26, 1991; 59 FR 56235, Nov. 10, 1994]

§ 442.40 Availability of FFP during appeals for ICFs/MR.

(a) *Definitions.* As used in this section—

Effective date of expiration means the date of expiration originally specified in the provider agreement, or the later date specified if the agreement is extended under § 442.16; and

Effective date of termination means a date earlier than the expiration date, set by the Medicaid agency when continuing participation until the expiration date is not justified, because the facility no longer meets the requirements for participation.

(b) *Scope, applicability, and effective date*—(1) *Scope.* This section sets forth the extent of FFP in State Medicaid payments to an ICF/MR after its provider agreement has been terminated or has expired and not been renewed.

(2) *Applicability.* (i) This section and § 442.42 apply only when the Medicaid agency, of its own volition, terminates or does not a renew a provider agreement, and only when the survey agency certifies that there is no jeopardy to recipient health and safety. When the survey agency certifies that there is jeopardy to recipient health and safety, or when it fails to certify that there is no jeopardy, FFP ends on the effective date of termination or expiration.

(ii) When the State acts under instructions from CMS, FFP ends on the date specified by CMS (CMS instructs the State to terminate the Medicaid provider agreement when CMS in validating a State survey agency certification, determines that an ICF/MR does not meet the requirements for participation.)

(3) *Effective date.* This section and § 442.42 apply to terminations or expirations that are effective on or after September 28, 1987. For terminations or nonrenewals that were effective before that date, FFP may continue for up to 120 days from September 28, 1987, or 12 months from the effective date of termination or nonrenewal, whichever is earlier.

(c) *Basic rules.* (1) Except as provided in paragraphs (d) and (e) of this section, FFP in payments to an ICF/MR

ends on the effective date of termination of the facility's provider agreement, or if the agreement is not terminated, on the effective date of expiration.

(2) If State law, or a Federal or State court order or injunction, requires the agency to extend the provider agreement or continue payments to a facility after the dates specified in paragraph (d) of this section, FFP is not available in those payments.

(d) *Exception: Continuation of FFP after termination or expiration of provider agreement*—(1) *Conditions for continuation.* FFP is available after the effective date of termination or expiration only if—

(i) The evidentiary hearing required under § 431.153 of this chapter is provided by the State agency after the effective date of termination or expiration (or, if begun before termination or expiration, is not completed until after that date); and

(ii) Termination or nonrenewal action is based on a survey agency certification that there is no jeopardy to recipients' health and safety.

(2) *Extent of continuation.* FFP is available only through the earlier of the following:

(i) The date of issuance of an administrative hearing decision that upholds the agency's termination or nonrenewal action.

(ii) The 120th day after the effective date of termination of the facility's provider agreement or, if the agreement is not terminated, the 120th day after the effective date of expiration. (If a hearing decision that upholds the facility is issued after the end of the 120-day period, when FFP has already been discontinued, the rules of § 442.42 on retroactive agreements apply).

(e) *Applicability of § 441.11.* If FFP is continued during appeal under paragraph (d) of this section, the 30-day period provided by § 441.11 of this chapter would not begin to run until issuance of a hearing decision that upholds the agency's termination or nonrenewal action.

[52 FR 32551, Aug. 28, 1987, as amended at 56 FR 48865, Sept. 26, 1991; 59 FR 56236, Nov. 10, 1994]

§ 442.42 FFP under a retroactive provider agreement following appeal.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, if an NF or ICF/MR prevails on appeal from termination or, in the case of an ICF/MR, nonrenewal of a provider agreement, and the State issues a retroactive agreement, FFP is available beginning with the retroactive effective date, which must be determined in accordance with § 442.13.

(b) *Exception.* This rule does not apply if CMS determines, under § 442.30, that the agreement is not valid evidence that the facility meets the requirements for participation. This exclusion applies even if the State issues the new agreement as the result of an administrative hearing decision favorable to the facility or under a Federal or State court order.

[52 FR 32551, Aug. 28, 1987, as amended at 59 FR 56236, Nov. 10, 1994]

Subpart C—Certification of ICFs/MR

§ 442.100 State plan requirements.

A State plan must provide that the requirements of this subpart and part 483 are met.

[53 FR 20495, June 3, 1988]

§ 442.101 Obtaining certification.

(a) This section states the requirements for obtaining notice of an ICF/MR's certification before a Medicaid agency executes a provider agreement under § 442.12.

(b) The agency must obtain notice of certification from the Secretary for an ICF/MR located on an Indian reservation.

(c) The agency must obtain notice of certification from the survey agency for all other ICFs/MR.

(d) The notice must indicate that one of the following provisions pertains to the ICF/MR:

(1) An ICF/MR meets the conditions of participation set forth in subpart I of part 483 of this chapter.

(2) The ICF/MR has been granted a waiver or variance by CMS or the survey agency under subpart I of part 483 of this chapter.

(3) An ICF/MR has been certified with standard-level deficiencies and

(i) All conditions of participation are found met; and

(ii) The facility submits an acceptable plan of correction covering the remaining deficiencies, subject to other limitations specified in § 442.105.

(e) The failure to meet one or more of the applicable conditions of participation is cause for termination or non-renewal of the ICF/MR provider agreement.

[56 FR 48866, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 59 FR 56236, Nov. 10, 1994]

§ 442.105 Certification of ICFs/MR with deficiencies: General provisions.

If a survey agency finds a facility deficient in meeting the standards for ICFs/MR, as specified under subpart I of part 483 of this chapter, the agency may certify the facility for Medicaid purposes under the following conditions:

(a) The agency finds that the facility's deficiencies, individually or in combination, do not jeopardize the patient's health and safety, nor seriously limit the facility's capacity to give adequate care.

(b) The agency finds acceptable the facility's written plan for correcting the deficiencies.

(c) If a facility was previously certified with a deficiency and has a different deficiency at the time of the next survey, the agency documents that the facility—

(1) Was unable to stay in compliance with the standard for ICFs/MR for reasons beyond its control, or despite intensive efforts to comply; and

(2) Is making the best use of its resources to furnish adequate care.

(d) If a facility has the same deficiency it had under the prior certification, the agency documents that the facility—

(1) Did achieve compliance with the standard for ICFs/MR at some time during the prior certification period;

(2) Made a good faith effort, as judged by the survey agency, to stay in compliance; and

(3) Again became out of compliance for reasons beyond its control.

[56 FR 48866, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 57 FR 54712, Nov. 20, 1992; 59 FR 56236, Nov. 10, 1994]

§ 442.109 Certification period for ICFs/MR: General provisions.

(a) A survey agency may certify a facility that fully meets applicable requirements for up to 12 months.

(b) The survey agency may notify the Medicaid agency that the term of a provider agreement may be extended up to 2 months after the expiration date of the agreement under the conditions specified in § 442.16.

[43 FR 45233, Sept. 29, 1978. Redesignated at 53 FR 1993, Jan. 25, 1988, and amended at 59 FR 56236, Nov. 10, 1994]

§ 442.110 Certification period for ICFs/MR with standard-level deficiencies.

(a) Facilities with deficiencies may be certified under § 442.105 for the period specified in either paragraph (b) or (c) of this section.

(b) The survey agency may certify a facility for a period that ends no later than 60 days after the last day specified in the plan for correcting deficiencies. The certification period must not exceed 12 months, including the period allowed for corrections.

(c) The survey agency may certify a facility for up to 12 months with a condition that the certification will be automatically canceled on a specified date within the certification period unless—

(1) The survey agency finds that all deficiencies have been satisfactorily corrected; or

(2) The survey agency finds and notifies the Medicaid agency that the facility has made substantial progress in correcting the deficiencies and has a new plan for correction that is acceptable.

The automatic cancellation date must be no later than 60 days after the last day specified in the plan for correction of deficiencies under § 442.105.

[43 FR 45233, Sept. 29, 1978. Redesignated and amended at 53 FR 1993, Jan. 25, 1988; 59 FR 56236, Nov. 10, 1994]

§ 442.117 Termination of certification for ICFs/MR whose deficiencies pose immediate jeopardy.

(a) A survey agency must terminate a facility's certification if it determines that—

(1) The facility no longer meets conditions of participation for ICFs/MR as specified in subpart I of part 483 of this chapter.

(2) The facility's deficiencies pose immediate jeopardy to residents' health and safety.

(b) Subsequent to a certification of a facility's noncompliance, the Medicaid agency must, in terminating the provider agreement, follow the appeals process specified in part 431, subpart D of this chapter.

[51 FR 24491, July 3, 1986, as amended at 59 FR 56236, Nov. 10, 1994]

§ 442.118 Denial of payments for new admissions to an ICF/MR.

(a) *Basis for denial of payments.* The Medicaid agency may deny payment for new admissions to an ICF/MR that no longer meets the applicable conditions of participation specified under subpart I of part 483 of this chapter.

(b) *Agency procedures.* Before denying payments for new admissions, the Medicaid agency must comply with the following requirements:

(1) Provide the facility up to 60 days to correct the cited deficiencies and comply with conditions of participation for ICFs/MR.

(2) If at the end of the specified period the facility has not achieved compliance, give the facility notice of intent to deny payment for new admissions, and opportunity for an informal hearing.

(3) If the facility requests a hearing, provide an informal hearing that includes—

(i) The opportunity for the facility to present, before a State Medicaid official who was not involved in making the initial determination, evidence or documentation, in writing or in person, to refute the decision that the facility is out of compliance with the conditions of participation for ICFs/MR.

(ii) A written decision setting forth the factual and legal bases pertinent to a resolution of the dispute.

(4) If the decision of the informal hearing is to deny payments for new admissions, provide the facility and the public, at least 15 days before the effective date of the sanction, with a notice that includes the effective date and the reasons for the denial of payments.

[51 FR 24491, July 3, 1986, as amended at 59 FR 56236, Nov. 10, 1994]

§ 442.119 Duration of denial of payments and subsequent termination of an ICF/MR.

(a) *Period of denial.* The denial of payments for new admissions will continue for 11 months after the month it was imposed unless, before the end of that period, the Medicaid agency finds that—

(1) The facility has corrected the deficiencies or is making a good faith effort to achieve compliance with the conditions of participation for ICFs/MR; or

(2) The deficiencies are such that it is necessary to terminate the facility's provider agreement.

(b) *Subsequent termination.* The Medicaid agency must terminate a facility's provider agreement—

(1) Upon the agency's finding that the facility has been unable to achieve compliance with the conditions of participation for ICFs/MR during the period that payments for new admissions have been denied;

(2) Effective the day following the last day of the denial of payments period; and

(3) In accordance with the procedures for appeal of terminations set forth in subpart D of part 431 of this chapter.

[51 FR 24491, July 3, 1986, as amended at 59 FR 56236, Nov. 10, 1994]

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted.

Subpart A—Payments: General Provisions

§ 447.1 Purpose.

This subpart prescribes State plan requirements, FFP limitations and procedures concerning payments made by State Medicaid agencies for Medicaid services.

§ 447.10 Prohibition against reassignment of provider claims.

(a) *Basis and purpose.* This section implements section 1902(a)(32) of the Act which prohibits State payments for Medicaid services to anyone other than a provider or recipient, except in specified circumstances.

(b) *Definitions.* For purposes of this section:

Facility means an institution that furnishes health care services to inpatients.

Factor means an individual or an organization, such as a collection agency or service bureau, that advances money to a provider for accounts receivable that the provider has assigned, sold or transferred to the individual organization for an added fee or a deduction of a portion of the accounts receivable. Factor does not include a business representative as described in paragraph (f) of this section.

Organized health care delivery system means a public or private organization for delivering health services. It includes, but is not limited to, a clinic, a group practice prepaid capitation plan, and a health maintenance organization.

(c) *State plan requirements.* A State plan must provide that the requirements of paragraphs (d) through (h) of this section are met.

(d) *Who may receive payment.* Payment may be made only—

(1) To the provider; or

(2) To the recipient if he is a noncash recipient eligible to receive the payment under § 447.25; or

(3) In accordance with paragraphs (e), (f), and (g) of this section.

(e) *Reassignments.* Payment may be made in accordance with a reassignment from the provider to a government agency or reassignment by a court order.

(f) *Business agents.* Payment may be made to a business agent, such as a billing service or an accounting firm, that furnishes statements and receives payments in the name of the provider, if the agent's compensation for this service is—

(1) Related to the cost of processing the billing;

(2) Not related on a percentage or other basis to the amount that is billed or collected; and

(3) Not dependent upon the collection of the payment.

(g) *Individual practitioners.* Payment may be made to—

(1) The employer of the practitioner, if the practitioner is required as a condition of employment to turn over his fees to the employer;

(2) The facility in which the service is provided, if the practitioner has a contract under which the facility submits the claim; or

(3) A foundation, plan, or similar organization operating an organized health care delivery system, if the practitioner has a contract under which the organization submits the claim.

(h) *Prohibition of payment to factors.* Payment for any service furnished to a recipient by a provider may not be made to or through a factor, either directly or by power of attorney.

[43 FR 45253, Sept. 29, 1978, as amended at 46 FR 42672, Aug. 24, 1981; 61 FR 38398, July 24, 1996]

§ 447.15 Acceptance of State payment as payment in full.

A State plan must provide that the Medicaid agency must limit participation in the Medicaid program to providers who accept, as payment in full, the amounts paid by the agency plus any deductible, coinsurance or copayment required by the plan to be paid by the individual. However, the provider may not deny services to any eligible individual on account of the individual's inability to pay the cost sharing amount imposed by the plan in accordance with § 431.55(g) or § 447.53. The previous sentence does not apply to an individual who is able to pay. An individual's inability to pay does not eliminate his or her liability for the cost sharing charge.

[50 FR 23013, May 30, 1985]

§ 447.20 Provider restrictions: State plan requirements.

A State plan must provide for the following:

(a) In the case of an individual who is eligible for medical assistance under the plan for service(s) for which a third party or parties is liable for payment, if the total amount of the established liability of the third party or parties for the service is—

(1) Equal to or greater than the amount payable under the State plan (which includes, when applicable, cost-sharing payments provided for in §§ 447.53 through 447.56), the provider furnishing the service to the individual may not seek to collect from the individual (or any financially responsible relative or representative of that individual) any payment amount for that service; or

(2) Less than the amount payable under the State plan (including cost sharing payments set forth in §§ 447.53 through 447.56), the provider furnishing the service to that individual may collect from the individual (or any financially responsible relative or representative of the individual) an amount which is the lesser of—

(i) Any cost-sharing payment amount imposed upon the individual under §§ 447.53 through 447.56; or

(ii) An amount which represents the difference between the amount payable under the State plan (which includes, where applicable, cost-sharing payments provided for in §§ 447.53 through 447.56) and the total of the established third party liability for the services.

(b) A provider may not refuse to furnish services covered under the plan to an individual who is eligible for medical assistance under the plan on account of a third party's potential liability for the service(s).

[55 FR 1433, Jan. 16, 1990]

§ 447.21 Reduction of payments to providers.

If a provider seeks to collect from an individual (or any financially responsible relative or representative of that individual) an amount that exceeds an amount specified under § 447.20(a)—

(a) The Medicaid agency may provide for a reduction of any payment amount otherwise due to the provider in addition to any other sanction available to the agency; and

(b) The reduction may be equal to up to three times the amount that the provider sought to collect in violation of § 447.20(a).

[55 FR 1433, Jan. 16, 1990]

§ 447.25 Direct payments to certain recipients for physicians' or dentists' services.

(a) *Basis and purpose.* This section implements section 1905(a) of the Act by prescribing requirements applicable to States making direct payments to certain recipients for physicians' or dentists' services.

(b) *State plan requirements.* Except for groups specified in paragraph (c) of this section, a State may make direct payments to recipients for physicians' or dentists' services. If it does so, the State plan must—

(1) Provide for direct payments; and

(2) Specify the conditions under which payments are made.

(c) *Federal financial participation.* No FFP is available in expenditures for direct payment for physicians' or dentists' services to any recipient—

(1) Who is receiving assistance under the State's approved plan under title I, IV-A, X, XIV or XVI (AABD) of the Act; or

(2) To whom supplemental security benefits are being paid under title XVI of the Act; or

(3) Who is receiving or eligible for a State supplementary payment or would be eligible if he were not in a medical institution, and who is eligible for Medicaid as a categorically needy recipient.

(d) *Federal requirements.* (1) Direct payments to recipients under this section are an alternative to payments directly to providers and are subject to the same conditions; for example, the State's reasonable charge schedules are applicable.

(2) Direct payments must be supported by providers' bills for services.

§ 447.30 Withholding the Federal share of payments to Medicaid providers to recover Medicare overpayments.

(a) *Basis and purpose.* This section implements section 1914 of the Act, which provides for withholding the Federal share of Medicaid payments to a provider if the provider has not arranged to repay Medicare overpayments or has failed to provide information to determine the amount of the overpayments. The intent of the statute and regulations is to facilitate the recovery of Medicare overpayments. The provision enables recovery of overpayments when institutions have reduced participation in Medicare or when physicians and suppliers have submitted few or no claims under Medicare, thus not receiving enough in Medicare reimbursement to permit offset of the overpayment.

(b) *When withholding occurs.* The Federal share of Medicaid payments may be withheld from any provider specified in paragraph (c) of this section to recover Medicare overpayments that CMS has been unable to collect if the provider participates in Medicaid and—

(1) The provider has not made arrangements satisfactory to CMS to repay the Medicare overpayment; or

(2) CMS has been unable to collect information from the provider to determine the existence or amount of Medicare overpayment.

(c) The Federal share of Medicaid payments may be withheld with respect to the following providers:

(1) An institutional provider that has or previously had in effect a Medicare provider agreement under section 1866 of the Act; and

(2) A Medicaid provider who has previously accepted Medicare payment on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act; and during the 12 month period preceding the quarter in which the Federal share is to be withheld for a Medicare overpayment, submitted no claims under Medicare or submitted claims which total less than the amount of overpayment.

(d) *Order to reduce State payment.* (1) CMS may, at its discretion, issue an order to the Medicaid agency of any State that is using the provider's services, to reduce its payment to the provider by the amount specified in paragraph (f) of this section.

(2) The order to reduce payment to the provider will remain in effect until—

(i) The Medicaid agency determines that the overpayment has been completely recovered; or

(ii) CMS terminates the order.

(3) CMS may withhold FFP from any State that does not comply with the order specified in paragraph (d)(1) of this section to reduce payment to the provider and claims FFP for the expenditure on its quarterly expenditure report.

(e) *Notice of withholding.* (1) Before the Federal share of payments may be withheld under this section, CMS will notify the provider and the Medicaid agency of each State that CMS believes may use the overpaid provider's services under Medicaid.

(2) The notice will include the instruction to reduce State payments, as provided under paragraph (d) of this section.

(3) CMS will send the notice referred to in paragraph (e)(1) by certified mail, return receipt requested.

(4) Each Medicaid agency must identify the amount of payment due the provider under Medicaid and give that information to CMS in the next quarterly expenditure report.

(5) The Medicaid agency may appeal any disallowance of FFP resulting from the withholding decision to the

Grant Appeals Board, in accordance with 45 CFR part 16.

(f) Amount to be withheld. CMS may require the Medicaid agency to reduce the Federal share of its payment to the provider by the lesser of the following amounts.

(1) The Federal matching share of payments to the provider, or

(2) The total Medicare overpayment to the provider.

(g) *Effective date of withholding.* Withholding of payment will become effective no less than 60 days after the day on which the agency receives notice of withholding.

(h) *Duration of withholding.* No Federal funds are available in expenditures for services that are furnished by a provider specified in paragraph (c) of this section from the date on which the withholding becomes effective until the termination of withholding under paragraph (i) of this section.

(i) *Termination of withholding.* (1) CMS will terminate the order to reduce State payment if it determines that any of the following has occurred:

(i) The Medicare overpayment is completely recovered:

(ii) The institution or person makes an agreement satisfactory to CMS to repay the overpayment; or

(iii) CMS determines that there is no overpayment based on newly acquired evidence or a subsequent audit.

(2) CMS will notify each State that previously received a notice ordering the withholding that the withholding has been terminated.

(j) *Procedures for restoring excess withholding.* If an amount ultimately determined to be in excess of the Medicare overpayment is withheld, CMS will restore any excess funds withheld.

(k) *Recovery of funds from Medicaid agency.* A provider is not entitled to recover from the Medicaid agency the amount of payment withheld by the agency in accordance with a CMS order issued under paragraph (d) of this section.

[50 FR 19688, May 10, 1985; 50 FR 23307, June 3, 1985]

§ 447.31 Withholding Medicare payments to recover Medicaid overpayments.

(a) *Basis and purpose.* Section 1885 of the Act provides authority for CMS to withhold Medicare payments to a Medicaid provider in order to recover Medicaid overpayments to the provider. Section 405.377 of this chapter sets forth the Medicare rules implementing section 1885, and specifies under what circumstances withholding will occur and the providers that are subject to withholding. This section establishes the procedures that the Medicaid agency must follow when requesting that CMS withhold Medicare payments.

(b) *Agency notice to providers.* (1) Before the agency requests recovery of a Medicaid overpayment through Medicare, the agency must send either or both of the following notices, in addition to that required under paragraph (b)(2) of this section, to the provider.

(i) Notice that—

(A) There has been an overpayment;

(B) Repayment is required; and

(C) The overpayment determination is subject to agency appeal procedures, but we may withhold Medicare payments while an appeal is in progress.

(ii) Notice that—

(A) Information is needed to determine the amount of overpayment if any; and

(B) The provider has at least 30 days in which to supply the information to the agency.

(2) Notice that, 30 days or later from the date of the notice, the agency intends to refer the case to CMS for withholding of Medicare payments.

(3) The agency must send all notices to providers by certified mail, return receipt requested.

(c) *Documentation to be submitted to CMS.* The agency must submit the following information or documentation to CMS (unless otherwise specified) with the request for withholding of Medicare payments.

(1) A statement of the reason that withholding is requested.

(2) The amount of overpayment, type of overpayment, date the overpayment was determined, and the closing date of the pertinent cost reporting period (if applicable).

(3) The quarter in which the overpayment was reported on the quarterly expenditure report (Form CMS 64).

(4) As needed, and upon request from CMS, the names and addresses of the provider's officers and owners for each period that there is an outstanding overpayment.

(5) A statement of assurance that the State agency has met the notice requirements under paragraph (b) of this section.

(6) As needed, and upon request for CMS, copies of notices (under paragraph (b) of this section), and reports of contact or attempted contact with the provider concerning the overpayment, including any reduction or suspension of Medicaid payments made with respect to that overpayment.

(7) A copy of the provider's agreement with the agency under § 431.107 of this chapter.

(d) *Notification to terminate withholding.* (1) If an agency has requested withholding under this section, it must notify CMS if any of the following occurs:

(i) The Medicaid provider makes an agreement satisfactory to the agency to repay the overpayment;

(ii) The Medicaid overpayment is completely recovered; or

(iii) The agency determines that there is no overpayment, based on newly acquired evidence or subsequent audit.

(2) Upon receipt of notification from the State agency, CMS will terminate withholding.

(e) *Accounting for returned overpayment.* The agency must treat as a recovered overpayment the amounts received from CMS to offset Medicaid overpayments.

(f) *Procedures for restoring excess withholding.* The agency must establish procedures satisfactory to CMS to assure the return to the provider of amounts withheld under this section that are ultimately determined to be in excess of overpayments. Those procedures are subject to CMS review.

[50 FR 19689, May 10, 1985, as amended at 61 FR 63749, Dec. 2, 1996]

§ 447.40 Payments for reserving beds in institutions.

(a) The Medicaid agency may make payments to reserve a bed during a recipient's temporary absence from an inpatient facility, if—

(1) The State plan provides for such payments and specifies any limitations on the policy; and

(2) Absences for purposes other than required hospitalization (which cannot be anticipated and planned) are included in the patient's plan of care.

(b) An agency that pays for reserved beds in an inpatient facility may pay less for a reserved bed than an occupied bed if there is a cost differential between the two beds. (Section 1102 of the Act.)

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 24491, July 3, 1986]

§ 447.45 Timely claims payment.

(a) *Basis and purpose.* This section implements section 1902(a)(37) of the Act by specifying—

(1) State plan requirements for—

(i) Timely processing of claims for payment;

(ii) Prepayment and postpayment claims reviews; and

(2) Conditions under which the Administrator may grant waivers of the time requirements.

(b) *Definitions. Claim* means (1) a bill for services, (2) a line item of service, or (3) all services for one recipient within a bill.

Clean claim means one that can be processed without obtaining additional information from the provider of the service or from a third party. It includes a claim with errors originating in a State's claims system. It does not include a claim from a provider who is under investigation for fraud or abuse, or a claim under review for medical necessity.

A *shared health facility* means any arrangement in which—

(1) Two or more health care practitioners practice their professions at a common physical location;

(2) The practitioners share common waiting areas, examining rooms, treatment rooms, or other space, the services of supporting staff, or equipment;

(3) The practitioners have a person (who may himself be a practitioner)—

(i) Who is in charge of, controls, manages, or supervises substantial aspects of the arrangement or operation for the delivery of health or medical services at the common physical location other than the direct furnishing of professional health care services by the practitioners to their patients; or

(ii) Who makes available to the practitioners the services of supporting staff who are not employees of the practitioners; and

(iii) Who is compensated in whole or in part, for the use of the common physical location or related support services, on a basis related to amounts charged or collected for the services rendered or ordered at the location or on any basis clearly unrelated to the value of the services provided by the person; and

(4) At least one of the practitioners received payments on a fee-for-service basis under titles V, XVIII, and XIX in an amount exceeding $5,000 for any one month during the preceding 12 months or in an aggregate amount exceeding $40,000 during the preceding 12 months. The term does not include a provider of services (as specified in § 489.2(b) of this chapter), a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.

Third party is defined in § 433.135 of this chapter.

(c) *State plan requirements.* A State plan must (1) provide that the requirements of paragraphs (d), (e)(2), (f) and (g) of this section are met; and

(2) Specify the definition of a claim, as provided in paragraph (b) of this section, to be used in meeting the requirements for timely claims payment. The definition may vary by type of service (e.g., physician service, hospital service).

(d) *Timely processing of claims.* (1) The Medicaid agency must require providers to submit all claims no later than 12 months from the date of service.

(2) The agency must pay 90 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 30 days of the date of receipt.

(3) The agency must pay 99 percent of all clean claims from practitioners, who are in individual or group practice or who practice in shared health facilities, within 90 days of the date of receipt.

(4) The agency must pay all other claims within 12 months of the date of receipt, except in the following circumstances:

(i) This time limitation does not apply to retroactive adjustments paid to providers who are reimbursed under a retrospective payment system, as defined in § 447.272 of this part.

(ii) If a claim for payment under Medicare has been filed in a timely manner, the agency may pay a Medicaid claim relating to the same services within 6 months after the agency or the provider receives notice of the disposition of the Medicare claim.

(iii) The time limitation does not apply to claims from providers under investigation for fraud or abuse.

(iv) The agency may make payments at any time in accordance with a court order, to carry out hearing decisions or agency corrective actions taken to resolve a dispute, or to extend the benefits of a hearing decision, corrective action, or court order to others in the same situation as those directly affected by it.

(5) The date of receipt is the date the agency receives the claim, as indicated by its date stamp on the claim.

(6) The date of payment is the date of the check or other form of payment.

(e) *Waivers.* (1) The Administrator may waive the requirements of paragraphs (d) (2) and (3) of this section upon request by an agency if he finds that the agency has shown good faith in trying to meet them. In deciding whether the agency has shown good faith, the Administrator will consider whether the agency has received an unusually high volume of claims which are not clean claims, and whether the agency is making diligent efforts to implement an automated claims processing and information retrieval system.

(2) The agency's request for a waiver must contain a written plan of correction specifying all steps it will take to meet the requirements of this section.

(3) The Administrator will review each case and if he approves a waiver, will specify its expiration date, based on the State's capability and efforts to meet the requirements of this section.

(f) *Prepayment and postpayment claims review.* (1) For all claims, the agency must conduct prepayment claims review consisting of—

(i) Verification that the recipient was included in the eligibility file and that the provider was authorized to furnish the service at the time the service was furnished;

(ii) Checks that the number of visits and services delivered are logically consistent with the recipient's characteristics and circumstances, such as type of illness, age, sex, service location;

(iii) Verification that the claim does not duplicate or conflict with one reviewed previously or currently being reviewed;

(iv) Verification that a payment does not exceed any reimbursement rates or limits in the State plan; and

(v) Checks for third party liability within the requirements of § 433.137 of this chapter.

(2) The agency must conduct postpayment claims review that meets the requirements of parts 455 and 456 of this chapter, dealing with fraud and utilization control.

(g) *Reports.* The agency must provide any reports and documentation on compliance with this section that the Administrator may require.

(Secs. 1102 and 1902(a)(37) of the Social Security Act (42 U.S.C. 1302, 1396a(a)(37)))

[44 FR 30344, May 25, 1979, as amended at 55 FR 1434, Jan. 16, 1990]

§ 447.46 Timely claims payment by MCOs.

(a) *Basis and scope.* This section implements section 1932(f) of the Act by specifying the rules and exceptions for prompt payment of claims by MCOs.

(b) *Definitions.* ''Claim'' and ''clean claim'' have the meaning given those terms in § 447.45.

(c) *Contract requirements*—(1) *Basic rule.* A contract with an MCO must provide that the organization will meet the requirements of §§ 447.45(d)(2) and (d)(3), and abide by the specifications of §§ 447.45(d)(5) and (d)(6).

(2) *Exception.* The MCO and its providers may, by mutual agreement, establish an alternative payment schedule.

(3) *Alternative schedule.* Any alternative schedule must be stipulated in the contract.

[67 FR 41115, June 14, 2002]

COST SHARING

§ 447.50 Cost sharing: Basis and purpose.

(a) Section 1902(a)(14) of the Act permits States to require certain recipients to share some of the costs of Medicaid by imposing upon them such payments as enrollment fees, premiums, deductibles, coinsurance, co-payments, or similar cost sharing charges. For States that impose cost sharing payments, §§ 447.51 through 447.59 prescribe State plan requirements and options for cost sharing, specify the standards and conditions under which States may impose cost sharing, set forth minimum amounts and the methods for determining maximum amounts, and prescribe conditions for FFP that relate to cost sharing requirements.

ENROLLMENT FEE, PREMIUM OR SIMILAR COST SHARING CHARGE

§ 447.51 Requirements and options.

(a) The plan must provide that the Medicaid agency does not impose any enrollment fee, premium, or similar charge upon categorically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(b) The plan may impose an enrollment fee, premium, or similar charge on medically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(c) For each charge imposed under paragraph (b) of this section, the plan must specify—

(1) The amount of the charge;

(2) The period of liability for the charge; and

(3) The consequences for an individual who does not pay.

(d) The plan must provide that any charge imposed under paragraph (b) of this section is related to total gross family income as set forth under § 447.52.

§ 447.52 Minimum and maximum income-related charges.

For the purpose of relating the amount of an enrollment fee, premium, or similar charge to total gross family income, as required under § 447.51(d), the following rules apply:

(a) *Minimum charge.* A charge of at least $1.00 per month is imposed on each—

(1) One- or two-person family with monthly gross income of $150 or less;

(2) Three- or four-person family with monthly gross income of $300 or less; and

(3) Five- or more-person family with monthly gross income of $350 or less.

(b) *Maximum charge.* Any charge related to gross family income that is above the minimum listed in paragraph (a) of this section may not exceed the standards shown in the following table:

MAXIMUM MONTHLY CHARGE

Gross family income (per month)	Family size		
	1 or 2	3 or 4	5 or more
$150 or less	$1	$1	$1
$151 or $200	2	1	1
$201 to $250	3	1	1
$251 to $300	4	1	1
$301 to $350	5	2	1
$351 to $400	6	3	2
$401 to $450	7	4	3
$451 to $500	8	5	4
$501 to $550	9	6	5
$551 to $600	10	7	6
$601 to $650	11	8	7
$651 to $700	12	9	8
$701 to $750	13	10	9
$751 to $800	14	11	10
$801 to $850	15	12	11
$851 to $900	16	13	12
$901 to $950	17	14	13
$951 to $1,000	18	15	14
More than $1,000	19	16	15

(c) *Income-related charges.* The agency must impose an appropriately higher charge for each higher level of family income, within the maximum amounts specified in paragraph (b) of this section.

[43 FR 45253, Sept. 29, 1978, as amended at 45 FR 24889, Apr. 11, 1980]

DEDUCTIBLE, COINSURANCE, CO-PAYMENT OR SIMILAR COST-SHARING CHARGE

§ 447.53 Applicability; specification; multiple charges.

(a) *Basic requirements.* Except as specified in paragraph (b) of this section, the plan may impose a nominal deductible, coinsurance, copayment, or similar charge upon categorically and medically needy individuals for any service under the plan.

(b) *Exclusions from cost sharing.* The plan may not provide for impositions of a deductible, coinsurance, copayment, or similar charge upon categorically or medically needy individuals for the following:

(1) *Children.* Services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over but under 21) are excluded from cost sharing.

(2) *Pregnant women.* Services furnished to pregnant women if such services related to the pregnancy, or to any other medical condition which may complicate the pregnancy are excluded from cost sharing obligations. These services include routine prenatal care, labor and delivery, routine postpartum care, family planning services, complications of pregnancy or delivery likely to affect the pregnancy, such as hypertension, diabetes, urinary tract infection, and services furnished during the postpartum period for conditions or complications related to the pregnancy. The postpartum period is the immediate postpartum period which begins on the last day of pregnancy and extends through the end of the month in which the 60-day period following termination of pregnancy ends. States may further exclude from cost sharing all services furnished to pregnant women if they desire.

(3) *Institutionalized individuals.* Services furnished to any individual who is an inpatient in a hospital, long-term

care facility, or other medical institution if the individual is required (pursuant to § 435.725, § 435,733, § 435.832, or § 436.832), as a condition of receiving services in the institution, to spend all but a minimal amount of his income required for personal needs, for medical care costs are excluded from cost sharing.

(4) *Emergency services.* Services provided in a hospital, clinic, office, or other facility that is equipped to furnish the required care, after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in—

(i) Placing the patient's health in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part.

(5) *Family planning.* Family planning services and supplies furnished to individuals of child-bearing age are excluded from cost sharing.

(c) *Prohibition against multiple charges.* For any service, the plan may not impose more than one type of charge referred to in paragraph (a) of this section.

(d) *State plan specifications.* For each charge imposed under this section, the plan must specify—

(1) The service for which the charge is made;

(2) The amount of the charge;

(3) The basis for determining the charge;

(4) The basis for determining whether an individual is unable to pay the charge and the means by which such an individual will be identified to providers; and

(5) The procedures for implementing and enforcing the exclusions from cost sharing found in paragraph (b) of this section.

(e) No provider may deny services, to an individual who is eligible for the services, on account of the individual's inability to pay the cost sharing.

[43 FR 45253, Sept. 29, 1978, as amended at 47 FR 21051, May 17, 1982; 48 FR 5736, Jan. 8, 1983; 50 FR 23013, May 30, 1985; 55 FR 48611, Nov. 21, 1990; 55 FR 52130, Dec. 19, 1990; 67 FR 41116, June 14, 2002]

§ 447.54 Maximum allowable charges.

(a) *Non-institutional services.* Except as specified in paragraph (b), for non-institutional services, the plan must provide that—

(1) Any deductible it imposes does not exceed $2.00 per month per family for each period of Medicaid eligibility. For example, if Medicaid eligibility is certified for a 3-month period, the maximum deductible which may be imposed on a family for that period of eligibility is $6.00;

(2) Any coinsurance rate it imposes does not exceed 5 percent of the payment the agency makes for the services; and

(3) Any co-payments it imposes do not exceed the amounts shown in the following table:

States payment for the service	Maximum copayment chargeable to recipient
$10 or less	$.50
$10.01 to $25	1.00
$25.01 to $50	2.00
$50.01 or more	3.00

(b) *Waiver of the requirement that cost sharing amounts be nominal.* Upon approval from CMS, the requirement that cost sharing charges must be nominal may be waived, in accordance with section 431.55(g) for nonemergency services furnished in a hospital emergency room.

(c) *Institutional services.* For institutional services, the plan must provide that the maximum deductible, coinsurance or co-payment charge for each admission does not exceed 50 percent of the payment the agency makes for the first day of care in the institution.

(d) *Cumulative maximum.* The plan may provide for a cumulative maximum amount for all deductible, coinsurance or co-payment charges that it

imposes on any family during a specified period of time.

[48 FR 5736, Jan. 8, 1983]

§ 447.55 Standard co-payment.

(a) The plan may provide for a standard, or fixed, co-payment amount for any service.

(b) This standard copayment amount for any service may be determined by applying the maximum co-payment amounts specified in § 447.54 (a) and (b) to the agency's average or typical payment for that service. For example, if the agency's typical payment for prescribed drugs is $4 to $5 per prescription, the agency might set a standard copayment of $0.50 per prescription.

§ 447.56 Income-related charges.

Subject to the maximum allowable charges specified in § 447.54 (a) and (b), the plan may provide for income-related deductible, coinsurance or copayment charges. For example, an agency may impose a higher charge on medically needy recipients than it imposes upon categorically needy recipients.

§ 447.57 Restrictions on payments to providers.

(a) The plan must provide that the agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, coinsurance, copayments or similar charges that the provider has waived or are uncollectable, except as permitted under paragraph (b) of this section.

(b) For those providers that the agency reimburses under Medicare reasonable cost reimbursement principles, in accordance with subpart B of this part, an agency may increase its payment to offset uncollected deductible, coinsurance, copayment, or similar charges that are bad debts of providers.

§ 447.58 Payments to prepaid capitation organizations.

If the agency contracts with a prepaid capitation organization that does not impose the agency's deductibles, coinsurance, co-payments or similar charges on its recipient members, the plan must provide that the agency calculates its payments to the organization as if those cost sharing charges were collected.

[48 FR 5736, Jan. 8, 1983, as amended at 67 FR 41116, June 14, 2002]

FEDERAL FINANCIAL PARTICIPATION

§ 447.59 FFP: Conditions relating to cost sharing.

No FFP in the State's expenditures for services is available for—

(a) Any cost sharing amounts that recipients should have paid as enrollment fees, premiums, deductibles, coinsurance, copayments, or similar charges under §§ 447.50 through 447.58 (except for amounts that the agency pays as bad debts of providers under § 447.57); and

(b) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium or enrollment fee.

§ 447.60 Cost-sharing requirements for services furnished by MCOs.

Contracts with MCOs must provide that any cost-sharing charges the MCO imposes on Medicaid enrollees are in accordance with the requirements set forth in §§ 447.50 and 447.53 through 447.58 for cost-sharing charges imposed by the State agency.

[67 FR 41116, June 14, 2002]

§ 447.88 Options for claiming FFP payment for section 1920A presumptive eligibility medical assistance payments.

(a) The FMAP rate for medical assistance payments made available to a child during a presumptive eligibility period under section 1920A of the Act is the regular FMAP under title XIX, based on the category of medical assistance; that is, the enhanced FMAP is not available for section 1920A presumptive eligibility expenditures.

(b) States have the following 3 options for identifying Medicaid section 1920A presumptive eligibility expenditures and the application of payments for those expenditures:

(1) A State may identify Medicaid section 1920A presumptive eligibility expenditures in the quarter expended with no further adjustment based on the results of a subsequent actual eligibility determination (if any).

(2) A State may identify Medicaid section 1920A presumptive eligibility expenditures in the quarter expended but may adjust reported expenditures based on results of the actual eligibility determination (if any) to reflect the actual eligibility status of the individual, if other than presumptively eligible.

(3) A State may elect to delay submission of claims for payments of section 1920A presumptive eligibility expenditures until after the actual eligibility determination (if any) is made and, at that time identify such expenditures based on the actual eligibility status of individuals if other than presumptively eligible. At that time, the State would, as appropriate, recategorize the medical assistance expenditures made during the section 1920A presumptive eligibility period based on the results of the actual eligibility determination, and claim them appropriately.

[65 FR 33622, May 24, 2000]

Subpart B—Payment Methods: General Provisions

§ 447.200 Basis and purpose.

This subpart prescribes State plan requirements for setting payment rates to implement, in part, section 1902(a)(30) of the Act, which requires that payments for services be consistent with efficiency, economy, and quality of care.

[46 FR 48560, Oct. 1, 1981]

§ 447.201 State plan requirements.

(a) A State plan must provide that the requirements in this subpart are met.

(b) The plan must describe the policy and the methods to be used in setting payment rates for each type of service included in the State's Medicaid program.

§ 447.202 Audits.

The Medicaid agency must assure appropriate audit of records if payment is based on costs of services or on a fee plus cost of materials.

§ 447.203 Documentation of payment rates.

(a) The agency must maintain documentation of payment rates and make it available to HHS upon request.

(b) The agency must record, in State manuals or other official files, the following information for increases in payment rates for individual practitioner services:

(1) An estimate of the percentile of the range of customary charges to which the revised payment structure equates and a description of the methods used to make the estimate.

(2) An estimate of the composite average percentage increase of the revised payment rates over the preceding rates.

§ 447.204 Encouragement of provider participation.

The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.

§ 447.205 Public notice of changes in Statewide methods and standards for setting payment rates.

(a) *When notice is required.* Except as specified in paragraph (b) of this section, the agency must provide public notice of any significant proposed change in its methods and standards for setting payment rates for services.

(b) *When notice is not required.* Notice is not required if—

(1) The change is being made to conform to Medicare methods or levels of reimbursement;

(2) The change is required by court order; or

(3) The change is based on changes in wholesalers' or manufacturers' prices of drugs or materials, if the agency's reimbursement system is based on material cost plus a professional fee.

(c) *Content of notice.* The notice must—

(1) Describe the proposed change in methods and standards;

(2) Give an estimate of any expected increase or decrease in annual aggregate expenditures;

(3) Explain why the agency is changing its methods and standards;

(4) Identify a local agency in each county (such as the social services agency or health department) where copies of the proposed changes are available for public review;

(5) Give an address where written comments may be sent and reviewed by the public; and

(6) If there are public hearings, give the location, date and time for hearings or tell how this information may be obtained.

(d) *Publication of notice.* The notice must—

(1) Be published before the proposed effective date of the change; and

(2) Appear as a public announcement in one of the following publications:

(i) A State register similar to the FEDERAL REGISTER.

(ii) The newspaper of widest circulation in each city with a population of 50,000 or more.

(iii) The newspaper of widest circulation in the State, if there is no city with a population of 50,000 or more.

[46 FR 58680, Dec. 3, 1981; 47 FR 8567, Mar. 1, 1982, as amended at 48 FR 56057, Dec. 19, 1983]

Subpart C—Payment for Inpatient Hospital and Long-Term Care Facility Services

SOURCE: 46 FR 47971, Sept. 30, 1981, unless otherwise noted.

§ 447.250 Basis and purpose.

(a) This subpart implements section 1902(a)(13)(A) of the Act, which requires that the State plan provide for payment for hospital and long-term care facility services through the use of rates that the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated facilities to provide services in conformity with State and Federal laws, regulations, and quality and safety standards.

(b) Section 447.253(a)(2) implements section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy, and quality of care;

(c) Sections 447.253 (c) and (d) implement sections 1902(a)(13)(B) and 1902(a)(13)(C) of the Act, which require a State Medicaid agency to make certain assurances to the Secretary regarding increases in payments resulting solely from changes in ownerships of hospitals, NFs, and ICFs/MR.

(d) Section 447.271 implements section 1903(i)(3) of the Act, which requires that payments for inpatient hospital services not exceed the hospital's customary charges.

(e) Section 447.280 implements section 1913(b) of the Act, which concerns reimbursement for long-term care services furnished by swing-bed hospitals.

[48 FR 56057, Dec. 19, 1983, as amended at 57 FR 43921, Sept. 23, 1992]

PAYMENT RATES

§ 447.251 Definitions.

For the purposes of this subpart—

Long-term care facility services means intermediate care facility services for the mentally retarded (ICF/MR) and nursing facility (NF) services.

Provider means an institution that furnishes inpatient hospital services or an institution that furnishes long-term care facility services.

[46 FR 47971, Sept. 30, 1981, as amended at 54 FR 5359, Feb. 2, 1989; 56 FR 48867, Sept. 26, 1991]

§ 447.252 State plan requirements.

(a) The plan must provide that the requirements of this subpart are met.

(b) The plan must specify comprehensively the methods and standards used by the agency to set payment rates in a manner consistent with § 430.10 of this chapter.

(c) If the agency chooses to apply the cost limits established under Medicare (see § 413.30 of this chapter) on an individual provider basis, the plan must specify this requirement.

(Approved by the Office of Management and Budget under control number 0938–0193)

[48 FR 56058, Dec. 19, 1983, as amended at 51 FR 34833, Sept. 30, 1986]

§ 447.253 Other requirements.

(a) *State assurances.* In order to receive CMS approval of a State plan change in payment methods and standards, the Medicaid agency must make assurances satisfactory to CMS that

the requirements set forth in paragraphs (b) through (i) of this section are being met, must submit the related information required by § 447.255 of this subpart, and must comply with all other requirements of this subpart.

(b) *Findings.* Whenever the Medicaid agency makes a change in its methods and standards, but not less often than annually, the agency must make the following findings:

(1) *Payment rates.* (i) The Medicaid agency pays for inpatient hospital services and long-term care facility services through the use of rates that are reasonable and adequate to meet the costs that must be incurred by efficiently and economically operated providers to provide services in conformity with applicable State and Federal laws, regulations, and quality and safety standards.

(ii) With respect to inpatient hospital services—

(A) The methods and standards used to determine payment rates take into account the situation of hospitals which serve a disproportionate number of low income patients with special needs;

(B) If a State elects in its State plan to cover inappropriate level of care services (that is, services furnished to hospital inpatients who require a lower covered level of care such as skilled nursing or intermediate care services) under conditions similar to those described in section 1861(v)(1)(G) of the Act, the methods and standards used to determine payment rates must specify that the payments for this type of care must be made at rates lower than those for inpatient hospital level of care services, reflecting the level of care actually received, in a manner consistent with section 1861(v)(1)(G) of the Act; and

(C) The payment rates are adequate to assure that recipients have reasonable access, taking into account geographic location and reasonable travel time, to inpatient hospital services of adequate quality.

(iii) With respect to nursing facility services—

(A) Except for preadmission screening for individuals with mental illness and mental retardation under § 483.20(f) of this Chapter, the methods and standards used to determine payment rates take into account the costs of complying with the requirements of part 483 subpart B of this chapter;

(B) The methods and standards used to determine payment rates provide for an appropriate reduction to take into account the lower costs (if any) of the facility for nursing care under a waiver of the requirement in § 483.30(c) of this Chapter to provide licensed nurses on a 24-hour basis;

(C) The State establishes procedures under which the data and methodology used in establishing payment rates are made available to the public.

(2) *Upper payment limits.* The agency's proposed payment rate will not exceed the upper payment limits as specified in § 447.272.

(c) *Changes in ownership of hospitals.* In determining payment when there has been a sale or transfer of the assets of a hospital, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate solely as a result of changes of ownership, more than the payments would increase under Medicare under §§ 413.130, 413.134, 413.153, and 413.157 of this chapter, insofar as these sections affect payments for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments were previously made to prior owners, and the recapture of depreciation.

(d) *Changes in ownership of NFs and ICFs/MR.* In determining payment when there has been a sale or transfer of assets of an NF or ICF/MR, the State's methods and standards must provide the following depending upon the date of the transfer.

(1) For transfers on or after July 18, 1984 but before October 1, 1985, the State's methods and standards must provide that payment rates can reasonably be expected not to increase in the aggregate, solely as the result of a change in ownership, more than payments would increase under Medicare under §§ 413.130, 413.134, 413.153 and 413.157 of this chapter, insofar as these sections affect payment for depreciation, interest on capital indebtedness, return on equity capital (if applicable), acquisition costs for which payments

were previously made to prior owners, and the recapture of depreciation.

(2) For transfers on or after October 1, 1985, the State's methods and standards must provide that the valuation of capital assets for purposes of determining payment rates for NFs and ICFs/MR is not to increase (as measured from the date of acquisition by the seller to the date of the change of ownership) solely as a result of a change of ownership, by more than the lesser of—

(i) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership, or, if necessary, as extrapolated retrospectively by the Secretary) in the Dodge construction index applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year; or

(ii) One-half of the percentage increase (as measured from the date of acquisition by the seller to the date of the change of ownership) in the Consumer Price Index for All Urban Consumers (CPI-U) (United States city average) applied in the aggregate with respect to those facilities that have undergone a change of ownership during the fiscal year.

(e) *Provider appeals.* The Medicaid agency must provide an appeals or exception procedure that allows individual providers an opportunity to submit additional evidence and receive prompt administrative review, with respect to such issues as the agency determines appropriate, of payment rates.

(f) *Uniform cost reporting.* The Medicaid agency must provide for the filing of uniform cost reports by each participating provider.

(g) *Audit requirements.* The Medicaid agency must provide for periodic audits of the financial and statistical records of participating providers.

(h) *Public notice.* The Medicaid agency must provide that it has complied with the public notice requirements in § 447.205 of this part when it is proposing significant changes to its methods or standards for setting payment rates for inpatient hospital or LTC facility services.

(i) *Rates paid.* The Medicaid agency must pay for inpatient hospital and long term care services using rates determined in accordance with methods and standards specified in an approved State plan.

[48 FR 56057, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987; 54 FR 5359, Feb. 2, 1989; 57 FR 43921, Sept. 23, 1992]

§ 447.255 Related information.

The Medicaid agency must submit, with the assurances described in § 447.253(a), the following information:

(a) The amount of the estimated average proposed payment rate for each type of provider (hospital, ICF/MR, or nursing facility), and the amount by which that estimated average rate increased or decreased relative to the average payment rate in effect for each type or provider for the immediately preceding rate period;

(b) An estimate of the short-term and, to the extent feasible, long-term effect the change in the estimated average rate will have on—

(1) The availability of services on a Statewide and geographic area basis;

(2) The type of care furnished;

(3) The extent of provider participation; and

(4) The degree to which costs are covered in hospitals that serve a disproportionate number of low income patients with special needs.

[48 FR 56058, Dec. 19, 1983, as amended at 54 FR 5359, Feb. 2, 1989; 56 FR 48867, Sept. 26, 1991; 57 FR 43924, Sept. 23, 1992; 57 FR 46431, Oct. 8, 1992]

§ 447.256 Procedures for CMS action on assurances and State plan amendments.

(a) *Criteria for approval.* (1) CMS approval action on State plans and State plan amendments, is taken in accordance with subpart B of part 430 of this chapter and sections 1116, 1902(b) and 1915(f) of the Act.

(2) In the case of State plan and plan amendment changes in payment methods and standards, CMS bases its approval on the acceptability of the Medicaid agency's assurances that the requirements of § 447.253 have been met, and the State's compliance with the other requirements of this subpart.

(b) *Time limit.* CMS will send a notice to the agency of its determination as to whether the assurances regarding a State plan amendment are acceptable within 90 days of the date CMS receives the assurances described in §447.253, and the related information described in §447.255 of this subpart. If CMS does not send a notice to the agency of its determination within this time limit and the provisions in paragraph (a) of this section are met, the assurances and/or the State plan amendment will be deemed accepted and approved.

(c) *Effective date.* A State plan amendment that is approved will become effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted in accordance with §430.20 of this chapter and 447.253.

[48 FR 56058, Dec. 19, 1983, as amended at 52 FR 28147, July 28, 1987]

FEDERAL FINANCIAL PARTICIPATION

§447.257 FFP: Conditions relating to institutional reimbursement.

FFP is not available for a State's expenditures for hospital inpatient or long-term care facility services that are in excess of the amounts allowable under this subpart.

[52 FR 28147, July 28, 1987]

UPPER LIMITS

§447.271 Upper limits based on customary charges.

(a) Except as provided in paragraph (b) of this section, the agency may not pay a provider more for inpatient hospital services under Medicaid than the provider's customary charges to the general public for the services.

(b) The agency may pay a public provider that provides services free or at a nominal charge at the same rate that would be used if the provider's charges were equal to or greater than its costs.

§447.272 Inpatient services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for inpatient services furnished by hospitals, NFs, and ICFs/MR within one of the following categories:

(1) State government-owned or operated facilities (that is, all facilities that are either owned or operated by the State).

(2) Non-State government-owned or operated facilities (that is, all government facilities that are neither owned nor operated by the State).

(3) Privately-owned and operated facilities.

(b) *General rules.* (1) Upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to a group of facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(c) *Exceptions*—(1) *Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Public Law 93–638).

(2) *Disproportionate share hospitals.* The limitation in paragraph (b) of this section does not apply to payment adjustments made under section 1923 of the Act that are made under a State plan to hospitals found to serve a disproportionate number of low-income patients with special needs as provided in section 1902(a)(13)(A)(iv) of the Act. Disproportionate share hospital (DSH) payments are subject to the following limits:

(i) The aggregate DSH limit using the Federal share of the DSH limit under section 1923(f) of the Act.

(ii) The hospital-specific DSH limit in section 1923(g) of the Act.

(iii) The aggregate DSH limit for institutions for mental disease (IMDs) under section 1923(h) of the Act.

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b)(1) of this section by one of the following dates:

(1) *For non-State government-owned or operated hospitals*—March 19, 2002.

(2) *For all other facilities*—March 13, 2001.

(e) *Transition periods*—(1) *Definitions.* For purposes of this paragraph, the following definitions apply:

(i) *Transition period* refers to the period of time beginning March 13, 2001 through the end of one of the schedules permitted under paragraph (e)(2)(ii) of this section.

(ii) *UPL* stands for the upper payment limit described in paragraph (b)(1) of this section for the referenced year.

(iii) *X* stands for the payments to a specific group of providers described in paragraphs (a)(2) and (a)(3) of this section in State FY 2000 that exceeded the amount that would have been under the upper payment limit described in paragraph (b) of this section if that limit had been applied to that year.

(2) *General rules.* (i) The amount that a State's payment exceeded the upper payment limit described in paragraph (b) of this section must not increase.

(ii) A State with an approved State plan amendment payment provision effective on one of the following dates and that makes payments that exceed the upper payment limit described in paragraph (b) of this section to providers described in paragraphs (a)(2) and (a)(3) of this section may follow the respective transition schedule:

(A) For State plan provisions that are effective after September 30, 1999 and were approved before January 22, 2001, payments may exceed the upper payment limit in paragraph (b) of this section until September 30, 2002.

(B) For approved plan provisions that are effective after October 1, 1992 and before October 1, 1999, payments during the transition period may not exceed the following—

(*1*) For State FY 2003: State FY 2003 UPL + .75X.

(*2*) For State FY 2004: State FY 2004 UPL + .50X.

(*3*) For State FY 2005: State FY 2005 UPL + .25X.

(*4*) For State FY 2006; State FY 2006 UPL.

(C) For approved plan provisions that are effective on or before October 1, 1992, payments during the transition period may not exceed the following:

(*1*) For State FY 2004: State FY 2004 UPL + .85X.

(*2*) For State FY 2005: State FY 2005 UPL + .70X.

(*3*) For State FY 2006: State FY 2006 UPL + .55X.

(*4*) For State FY 2007: State FY 2007 UPL + .40X.

(*5*) For State FY 2008: State FY 2008 UPL + .25X.

(*6*) For the portion of State FY 2009 before October 1, 2008: State FY 2009 UPL + .10X.

(*7*) Beginning October 1, 2008: UPL described in paragraph (b) of this section.

(D) For State plan provisions that were effective after September 30, 1999, submitted to CMS before March 13, 2001, and approved by CMS after January 21, 2001, payments may exceed the limit in paragraph (b) of this section until the later of November 5, 2001, or 1 year from the approved effective date of the State plan provision.

(iii) When State FY 2003 begins after September 30, 2002, the reduction schedule in paragraphs (e)(2)(ii)(C)(*1*) through (e)(2)(ii)(C)(*7*) will begin on State FY 2003.

(iv) If a State meets the criteria in paragraph (e)(2)(ii) of this section and its State plan amendment expires before the end of the applicable transition period, the State may continue making payments that exceed the UPL described in paragraph (b) of this section in accordance with the applicable transition schedule described in paragraph (e)(2)(ii) of this section.

(v) A State with an approved State plan amendment payment provision that makes payments up to 150 percent of the UPL described in paragraph (b)(1) of this section to providers described in paragraph (a)(2) of this section does not qualify for a transition period.

(f) *Reporting requirements for payments during the transition periods.* States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the upper payment limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

[66 FR 3175, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2610, Jan. 18, 2002]

SWING-BED HOSPITALS

§ 447.280 Hospital providers of NF services (swing-bed hospitals).

(a) *General rule.* If the State plan provides for NF services furnished by a swing-bed hospital, as specified in §§ 440.40(a) and 440.150(f) of this chapter, the methods and standards used to determine payment rates for routine NF services must—

(1) Provide for payment at the average rate per patient day paid to NFs, as applicable, for routine services furnished during the previous calendar year; or

(2) Meet the State plan and payment requirements described in this subpart, as applicable.

(b) *Application of the rule.* The payment methodology used by a State to set payment rates for routine NF services must apply to all swing-bed hospitals in the State.

[59 FR 56237, Nov. 10, 1994]

Subpart D [Reserved]

Subpart E—Payment Adjustments for Hospitals That Serve a Disproportionate Number of Low-Income Patients

SOURCE: 57 FR 55143, Nov. 24, 1992, unless otherwise noted.

§ 447.296 Limitations on aggregate payments for disproportionate share hospitals for the period January 1, 1992 through September 30, 1992.

(a) The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) For the period January 1, 1992 through September 30, 1992, FFP is available for aggregate payments to hospitals that serve a disproprotionate number of low-income patients with special needs only if the payments are made in accordance with sections 1902(a)(13)(A) and 1923 of the Act, and with one of the following:

(1) An approved State plan in effect as of September 30, 1991.

(2) A State plan amendment submitted to CMS by September 30, 1991.

(3) A State plan amendment, or modification thereof, submitted to CMS between October 1, 1991 and November 26, 1991, if the amendment, or modification thereof, was intended to limit the State's definition of disproportionate share hospitals to those hospitals with Medicaid inpatient utilization rates or low-income utilization rates (as defined in section 1923 (b) of the Act) at or above the statewide arithmetic mean.

(4) A methodology for disproportionate share hospital payments that was established and in effect as of September 30, 1991, or in accordance with a State law enacted or State regulation adopted as of September 30, 1991.

(5) A State plan amendment submitted to CMS by September 30, 1992 that increases aggregate disproportionate share hospitals payments in order to meet the minimum payment adjustments required by section 1923(c)(1) of the Act. The minimum payment adjustment is the amount required by the Medicare methodology described in section 1923(c)(1) of the Act for those hospitals that satisfy the minimum Federal definition of a disproportionate share hospital in section 1923(b) of the Act.

(6) A State plan amendment submitted to CMS by September 30, 1992 that provides for a redistribution of disproportionate share hospital payments within the State without raising total payments compared to the previously approved State plan. CMS will approve the amendment only if the State submits written documentation that demonstrates to CMS that the aggregate payments that will be made after the redistribution are no greater

than those payments made before the redistribution.

(7) A State plan amendment submitted to CMS by September 30, 1992 that provides for a reduction in disproportionate share hospital payments.

§ 447.297 Limitations on aggregate payments for disproportionate share hospitals beginning October 1, 1992.

(a) *Applicability.* The provisions of this section apply to the 50 States and the District of Columbia, but not to any State whose entire Medicaid program is operated under a waiver granted under section 1115 of the Act.

(b) *National payment target.* The national payment target for disproportionate share hospital (DSH) payments for any Federal fiscal year is equal to 12 percent of the total medical assistance expenditures that will be made during the Federal fiscal year under State plans, excluding administrative costs. A preliminary national expenditure target will be published by CMS prior to October 1 of each year. This preliminary national expenditure target will be superseded by a final national expenditure target published by April 1 of each Federal fiscal year, as specified in paragraph (d) of this section.

(c) *State disproportionate share hospital allotments.* Prior to October 1 of each Federal fiscal year, CMS will publish in the FEDERAL REGISTER preliminary State DSH allotments for each State. These preliminary State DSH allotments will be determined using the most current applicable actual and estimated State expenditure information as reported to CMS and adjusted by CMS as may be necessary using the methodology described in § 447.298. CMS will publish final State DSH allotments by April 1 of each Federal fiscal year, as described in paragraph (d) of this section.

(d) *Final national disproportionate share hospitals expenditure target and State disproportionate share hospitals allotments.*

(1) CMS will revise the preliminary national expenditure target and the preliminary State DSH allotments by April 1 of each Federal fiscal year. The final national DSH expenditure target and State DSH allotments will be based on the most current applicable actual and estimated expenditure information reported to CMS and adjusted by CMS as may be necessary immediately prior to the April 1 publication date. The final national expenditure target and State DSH allotments will not be recalculated for that Federal fiscal year based upon any subsequent actual or estimated expenditure information reported to CMS.

(2) If CMS determines that at any time a State has exceeded its final DSH allotment for a Federal fiscal year, FFP attributable to the excess DSH expenditures will be disallowed.

(3) If a State's actual DSH expenditures applicable to a Federal fiscal year are less than its final State DSH allotment for that Federal fiscal year, the State is permitted, to the extent allowed by its approved State plan, to make additional DSH expenditures applicable to that Federal fiscal year up to the amount of its final DSH allotment for that Federal fiscal year.

(e) *Publication of limits.* (1) Before the beginning of each Federal fiscal year, CMS will publish in the FEDERAL REGISTER—

(i) A preliminary national DSH expenditure target for the Federal fiscal year; and

(ii) A preliminary DSH allotment for each State for the Federal fiscal year.

(2) The final national DSH expenditure target and State DSH allotments will be published in the FEDERAL REGISTER by April 1 of each Federal fiscal year.

[57 FR 55143, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

§ 447.298 State disproportionate share hospital allotments.

(a) *Calculation of State's base allotment for Federal fiscal year 1993.* (1) For Federal fiscal year 1993, CMS will calculate for each State a DSH allotment, using the State's ''base allotment.'' The State's base allotment is the greater of:

(i) The total amount of the State's projected DSH payments for Federal fiscal year 1992 under the State plan applicable to Federal fiscal year 1992, calculated in accordance with paragraph (a)(2) of this section; or

(ii) $1,000,000.

(2) In calculating the State's DSH payments applicable to Federal fiscal year 1992, CMS will derive amounts from payments applicable to the period of October 1, 1991, through September 30, 1992, under State plans or plan amendments that meet the requirements specified in § 447.296(b). The calculation will not include—

(i) DSH payment adjustments made by the State applicable to the period October 1, 1991 through December 31, 1991 under State plans or plan amendments that do not meet the criteria described in § 447.296; and

(ii) Retroactive DSH payments made in 1992 that are not applicable to Federal fiscal year 1992.

(3) CMS will calculate a percentage for each State by dividing the DSH base allotment by the total unadjusted medical assistance expenditures, excluding administrative costs, made during Federal fiscal year 1992. On the basis of this percentage, CMS will classify each State as a ''high-DSH'' or ''low-DSH'' State.

(i) If the State's base allotment exceeded 12 percent of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, CMS will classify the State as a ''high-DSH'' State.

(ii) If the State's base allotment was 12 percent or less of its total unadjusted medical assistance expenditures made under the State plan in Federal fiscal year 1992, CMS will classify the State as a ''low-DSH'' State.

(b) *State disproportionate share hospital allotments for Federal fiscal year 1993.* (1) For Federal fiscal year 1993, CMS will calculate a DSH allotment for each low-DSH State that equals the State's base allotment described under paragraph (a) of this section, increased by State growth, as specified in paragraph (d) of this section.

(2) For high-DSH States, the dollar amount of DSH payments in Federal fiscal year 1993 may not exceed the dollar amount of DSH payments applicable to Federal fiscal year 1992 (that is, the State base allotment).

(c) *State disproportionate share hospital allotment for Federal fiscal years 1994 and after.* For Federal fiscal years 1994 and after—

(1) For low-DSH States, CMS will calculate the DSH allotment for each Federal fiscal year by increasing the prior year's State DSHs allotment by—

(i) State growth, as specified in paragraph (d) of this section; and

(ii) A supplemental amount, if applicable, as described in paragraph (e) of this section.

(2) For high-DSH States, the dollar amount of DSH payments applicable to any Federal fiscal year may not exceed the dollar amount of payments applicable to Federal fiscal year 1992 (that is, the State base allotment). This payment limitation will apply until the Federal fiscal year in which the State's DSH payments applicable to that Federal fiscal year, expressed as a percentage of the State's total unadjusted medical assistance expenditures in that Federal fiscal year, equal 12 percent or less. When a high-DSH State's percentage equals 12 percent or less, the State will be reclassified as a low-DSH State.

(d) *State growth.* (1) The State growth for a State in a Federal fiscal year is equal to the product of—

(i) The growth factor that is CMS's projected percentage increase in the State's total unadjusted medical assistance expenditures (including administrative costs) relative to the corresponding amount in the previous year; and

(ii) The State's prior year DSH allotment.

(2) If the growth factor is zero or is negative, the State growth is zero.

(3) If a low-DSH State experiences a level of negative growth to the extent that its previous Federal fiscal year's DSH allotment would be more than 12 percent of its current Federal fiscal year's total unadjusted medical assistance expenditures (excluding administrative costs), the low-DSH State's previous year's DSH allotment will be reduced to the extent necessary to maintain the individual low-DSH State's 12-percent limit and that amount will become the low-DSH State's DSH allotment for the current Federal fiscal year. In no Federal fiscal year will a low-DSH State's DSH allotment be allowed to exceed its individual State 12-percent limit.

(e) *Supplemental amount available for low-DSH States.*

(1) A supplemental amount is the State's share of a pool of money (referred to as a redistribution pool).

(2) CMS will calculate the redistribution pool for the appropriate Federal fiscal year by subtracting from the projected national DSH expenditure target the following:

(i) The total of the State DSH base allotments for all high-DSH States;

(ii) The total of the previous year's State DSH allotments for all low-DSH States;

(iii) The State growth amount for all low-DSH States; and

(iv) The total amount of additional DSH payment adjustments made in order to meet the minimum payment adjustments required under section 1923(c)(l) of the Act, which are made in accordance with § 447.296(b)(5).

(3) CMS will determine the percent of the redistribution pool for each low-DSH State on the basis of each State's relative share of the total unadjusted medical assistance expenditures for the Federal fiscal year compared to the total unadjusted medical assistance expenditures for the Federal fiscal year projected to be made by all low-DSH States. The percent of the redistribution pool that each State will receive is equal to the State's total unadjusted medical assistance expenditures divided by the total unadjusted medical assistance expenditures for all low-DSH States.

(4) CMS will not provide any low-DSH State a supplemental amount that would result in the State's total DSH allotment exceeding 12 percent of its projected total unadjusted medical assistance expenditures. CMS will reallocate any supplemental amounts not allocated to States because of this 12-percent limitation to other low-DSH States in accordance with the percentage determined in paragraph (e)(3) of this section.

(5) CMS will not reallocate to low-DSH States the difference between any State's actual DSH expenditures applicable to a Federal fiscal year and its State DSH allotment applicable to that Federal fiscal year. Thus, any unspent DSH allotment may not be reallocated.

(f) *Special provision.* Any increases in a State's aggregate disproportionate payments, that are made to meet the minimum payment requirements specified in § 447.296(b)(5), may exceed the State base allotment to the extent such increases are made to satisfy the minimum payment requirement. In such cases, CMS will adjust the State's base allotment in the subsequent Federal fiscal year to include the increased minimum payments.

[57 FR 55143, Nov. 24, 1992, as amended at 58 FR 43182, Aug. 13, 1993]

§ 447.299 Reporting requirements.

(a) Beginning with the first quarter of Federal fiscal year 1993, each State must submit to CMS the quarterly aggregate amount of its disproportionate share hospital payments made to each individual public and private provider or facility. States' reports must present a complete, accurate, and full disclosure of all of their DSH programs and expenditures.

(b) Each State must report the aggregate information specified under paragraph (a) of this section on a quarterly basis in accordance with procedures established by CMS.

(c) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description of each DSH program, the legal basis of each DSH program, and the amount of DSH payments made to each individual public and private provider or facility each quarter. This information must be made available to Federal reviewers upon request.

(d) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP CMS estimates is attributable to the expenditures made to the disproportionate share hospitals as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited by law, FFP for those expenditures will be released when the State complies with all reporting requirements.

Subpart F—Payment Methods for Other Institutional and Non-institutional Services

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted. Redesignated at 46 FR 47973, Sept. 30, 1981, and further redesignated at 58 FR 6095, Jan. 26, 1993.

§ 447.300 Basis and purpose.

In this subpart, §§ 447.302 through 447.334 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

[46 FR 48560, Oct. 1, 1981, as amended at 61 FR 38398, July 24, 1996]

§ 447.301 Definitions.

For the purposes of this subpart—

Brand name means any registered trade name commonly used to identify a drug.

Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

Multiple source drug means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

[52 FR 28657, July 31, 1987]

§ 447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

[46 FR 48560, Oct. 1, 1981]

§ 447.304 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and coinsurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is not available for a State's expenditures for services that are in excess of the amounts allowable under this subpart.

NOTE: The Secretary may waive any limitation on reimbursement imposed by subpart F of this part for experiments conducted under section 402 of Pub. L. 90–428, Incentives for Economy Experimentation, as amended by section 222(b) of Pub. L. 92–603, and under section 222(a) of Pub. L. 92–603.

[46 FR 48560, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981, as amended at 66 FR 3176, Jan. 12, 2001]

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital and clinic services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for outpatient services furnished by hospitals and clinics within one of the following categories:

(1) State government-owned or operated facilities (that is, all facilities that are either owned or operated by the State).

(2) Non-State government-owned or operated facilities (that is, all government facilities that are neither owned nor operated by the State).

(3) Privately-owned and operated facilities.

(b) *General rules.* (1) Upper payment limit refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(2) Except as provided in paragraph (c) of this section, aggregate Medicaid payments to a group of facilities within one of the categories described in paragraph (a) of this section may not exceed the upper payment limit described in paragraph (b)(1) of this section.

(c) *Exception—Indian Health Services and tribal facilities.* The limitation in paragraph (b) of this section does not

apply to Indian Health Services facilities and tribal facilities that are funded through the Indian Self-Determination and Education Assistance Act (Public Law 93–638).

(d) *Compliance dates.* Except as permitted under paragraph (e) of this section, a State must comply with the upper payment limit described in paragraph (b)(1) of this section by one of the following dates:

(1) *For non-State government-owned or operated hospitals*—March 19, 2002.

(2) *For all other facilities*—March 13, 2001.

(e) *Transition periods*—(1) *Definitions.* For purposes of this paragraph, the following definitions apply:

(i) *Transition period* refers to the period of time beginning March 13, 2001 through the end of one of the schedules permitted under paragraph (e)(2)(ii) of this section.

(ii) *UPL* stands for the upper payment limit described in paragraph (b)(1) of this section for the referenced year.

(iii) *X* stands for the payments to a specific group of providers described in paragraph (a) of this section in State FY 2000 that exceeded the amount that would have been under the upper payment limit described in paragraph (b) of this section if that limit had been applied to that year.

(2) *General rules.* (i) The amount that a State's payment exceeded the upper payment limit described in paragraph (b) of this section must not increase.

(ii) A State with an approved State plan amendment payment provision effective on one of the following dates and that makes payments that exceed the upper payment limit described in paragraph (b) of this section to providers described in paragraph (a) of this section may follow the respective transition schedule:

(A) For State plan provisions that are effective after September 30, 1999 and were approved before January 22, 2001, payments may exceed the upper payment limit in paragraph (b) of this section until September 30, 2002.

(B) *For approved plan provisions that are effective after October 1, 1992 and before October 1, 1999, payments during the transition period may not exceed the following—*

(*1*) For State FY 2003: State FY 2003 UPL + .75X.

(*2*) For State FY 2004: State FY 2004 UPL + .50X.

(*3*) For State FY 2005: State FY 2005 UPL + .25X.

(*4*) For State FY 2006; State FY 2006 UPL.

(C) *For approved plan provisions that are effective on or before October 1, 1992, payments during the transition period may not exceed the following:*

(*1*) For State FY 2004: State FY 2004 UPL + .85X.

(*2*) For State FY 2005: State FY 2005 UPL + .70X.

(*3*) For State FY 2006: State FY 2006 UPL + .55X.

(*4*) For State FY 2007: State FY 2007 UPL + .40X.

(*5*) For State FY 2008: State FY 2008 UPL + .25X.

(*6*) For the portion of State FY 2009 before October 1, 2008: State FY 2009 UPL + .10X.

(*7*) Beginning October 1, 2008: UPL described in paragraph (b) of this section.

(D) For State plan provisions that were effective after September 30, 1999, submitted to CMS before March 13, 2001, and approved by CMS after January 21, 2001, payments may exceed the limit in paragraph (b) of this section until the later of November 5, 2001, or 1 year from the approved effective date of the State plan provision.

(iii) When State FY 2003 begins after September 30, 2002, the reduction schedule in paragraphs (e)(2)(ii)(C)(1) through (e)(2)(ii)(C)(7) will begin on State FY 2003.

(iv) If a State meets the criteria in paragraph (e)(2)(ii) of this section and its State plan amendment expires before the end of the applicable transition period, the State may continue making payments that exceed the UPL described in paragraph (b) of this section in accordance with the applicable transition schedule described in paragraph (e)(2)(ii) of this section.

(v) A State with an approved State plan amendment payment provision that makes payments up to 150 percent of the UPL described in paragraph (b)(1) of this section to providers described in paragraph (a)(2) of this section does not qualify for a transition period.

(f) *Reporting requirements for payments during the transition periods.* States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the limit under paragraph (b)(1) of this section, must report annually the following information to CMS:

(1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.

(2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

[66 FR 3176, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2611, Jan. 18, 2002]

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

DRUGS

§ 447.331 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, the amount that would result from the application of the specific limits established in accordance with § 447.332. If a specific limit has not been established under § 447.332, then the rule for ''other drugs'' set forth in paragraph (b) applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.332 must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.332 does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like ''brand necessary'' is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

[52 FR 28657, July 31, 1987]

§ 447.332 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) CMS will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category ''A'' in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) CMS publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) CMS will identify the sources used in compiling these lists.

(b) *Specific upper limits.* The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not

exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by CMS that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

[52 FR 28658, July 31, 1987]

§ 447.333 State plan requirements, findings and assurances.

(a) *State plan.* The State plan must describe comprehensively the agency's payment methodology for prescription drugs.

(b) *Findings and assurances.* Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:

(1) *Findings.* The agency must make the following separate and distinct findings:

(i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with § 447.332(a) of this subpart, are in accordance with the upper limits specified in § 447.332(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart.

(2) *Assurances.* The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.331 and 447.332 concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.

(c) *Recordkeeping.* The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

[52 FR 28658, July 31, 1987]

§ 447.334 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

§ 447.342 [Reserved]

PREPAID CAPITATION PLANS

§ 447.362 Upper limits of payment: Nonrisk contract.

Under a nonrisk contract, Medicaid payments to the contractor may not exceed—

(a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to recipients: plus

(b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

[48 FR 54025, Nov. 30, 1983]

RURAL HEALTH CLINIC SERVICES

§ 447.371 Services furnished by rural health clinics.

The agency must pay for rural health clinic services, as defined in § 440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in § 440.20(c) of this subchapter, as follows:

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in part 413 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.

(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined

by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:

(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the Medicare reimbursement rate per visit, as specified in § 405.2426 of this chapter.

(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a Medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.

(d) For purposes of paragraph (c) (1) and (3) of this section, ''visit'' means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

[43 FR 45253, Sept. 29, 1978, as amended at 51 FR 34833, Sept. 30, 1986]

Subparts G–H [Reserved]

Subpart I—Payment for Outpatient Prescription Drugs Under Drug Rebate Agreements

SOURCE: 68 FR 51917, Aug. 29, 2003, unless otherwise noted.

§§ 447.500–447.532 [Reserved]

§ 447.534 Manufacturer reporting requirements.

(a)–(g) [Reserved]

(h) *Recordkeeping requirements.* (1)(i) A manufacturer must retain records (written or electronic) for 10 years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the average manufacturer price and best price are derived, including a record of any assumptions made in the calculations. The 10-year timeframe applies to a manufacturer's quarterly submission of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(ii) A manufacturer must retain records beyond the 10-year period if both of the following circumstances exist:

(A) The records are the subject of an audit or of a government investigation related to pricing data that are used in average manufacturer price or best price of which the manufacturer is aware.

(B) The audit findings or investigation related to the average manufacturer price and best price have not been resolved.

(2) [Reserved]

(i) *Timeframe for reporting revised average manufacturer price or best price.* A manufacturer must report to CMS revisions to average manufacturer price or best price for a period not to exceed 12 quarters from the quarter in which the data were due.

[68 FR 51917, Aug. 29, 2003, as amended at 69 FR 513, Jan. 6, 2004; 69 FR 68818, Nov. 26, 2004]

§§ 447.536–447.550 [Reserved]

PART 455—PROGRAM INTEGRITY: MEDICAID

Sec.

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 43 FR 45262, Sept. 29, 1978, unless otherwise noted.

§ 455.1 Basis and scope.

This part sets forth requirements for a State fraud detection and investigation program, and for disclosure of information on ownership and control.

(a) Under the authority of sections 1902(a)(4), 1903(i)(2), and 1909 of the Social Security Act, Subpart A provides State plan requirements for the identification, investigation, and referral of suspected fraud and abuse cases. In addition, the subpart requires that the State—

(1) Report fraud and abuse information to the Department; and

(2) Have a method to verify whether services reimbursed by Medicaid were actually furnished to recipients.

(b) Subpart B implements sections 1124, 1126, 1902(a)(36), 1903(i)(2), and 1903(n) of the Act. It requires that providers and fiscal agents must agree to disclose ownership and control information to the Medicaid State agency.

[51 FR 34787, Sept. 30, 1986]

§ 455.2 Definitions.

As used in this part unless the context indicates otherwise—

Abuse means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

Conviction or *Convicted* means that a judgment of conviction has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending.

Exclusion means that items or services furnished by a specific provider who has defrauded or abused the Medicaid program will not be reimbursed under Medicaid.

Fraud means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.

Furnished refers to items and services provided directly by, or under the direct supervision of, or ordered by, a practitioner or other individual (either as an employee or in his or her own capacity), a provider, or other supplier of services. (For purposes of denial of reimbursement within this part, it does not refer to services ordered by one party but billed for and provided by or under the supervision of another.)

Practitioner means a physician or other individual licensed under State law to practice his or her profession.

Suspension means that items or services furnished by a specified provider who has been convicted of a program-related offense in a Federal, State, or local court will not be reimbursed under Medicaid.

[48 FR 3755, Jan. 27, 1983, as amended at 50 FR 37375, Sept. 13, 1985; 51 FR 34788, Sept. 30, 1986]

§ 455.3 Other applicable regulations.

Part 1002 of this title sets forth the following:

(a) State plan requirements for excluding providers for fraud and abuse, and suspending practitioners convicted of program-related crimes.

(b) The limitations on FFP for services furnished by excluded providers or suspended practitioners.

(c) The requirements and procedures for reinstatement after exclusion or suspension.

(d) Requirements for the establishment and operation of State Medicaid fraud control units and the rates of FFP for their fraud control activities.

[51 FR 34788, Sept. 30, 1986]

Subpart A—Medicaid Agency Fraud Detection and Investigation Program

§ 455.12 State plan requirement.

A State plan must meet the requirements of §§ 455.13 through 455.23.

[52 FR 48817, Dec. 28, 1987]

§ 455.13 Methods for identification, investigation, and referral.

The Medicaid agency must have—

(a) Methods and criteria for identifying suspected fraud cases;

(b) Methods for investigating these cases that—

(1) Do not infringe on the legal rights of persons involved; and

(2) Afford due process of law; and

(c) Procedures, developed in cooperation with State legal authorities, for referring suspected fraud cases to law enforcement officials.

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3755, Jan. 27, 1983]

§ 455.14 Preliminary investigation.

If the agency receives a complaint of Medicaid fraud or abuse from any source or identifies any questionable practices, it must conduct a preliminary investigation to determine whether there is sufficient basis to warrant a full investigation.

[48 FR 3756, Jan. 27, 1983]

§ 455.15 Full investigation.

If the findings of a preliminary investigation give the agency reason to believe that an incident of fraud or abuse has occurred in the Medicaid program, the agency must take the following action, as appropriate:

(a) If a provider is suspected of fraud or abuse, the agency must—

(1) In States with a State Medicaid fraud control unit certified under subpart C of part 1002 of this title, refer the case to the unit under the terms of its agreement with the unit entered into under § 1002.309 of this title; or

(2) In States with no certified Medicaid fraud control unit, or in cases where no referral to the State Medicaid fraud control unit is required under paragraph (a)(1) of this section, conduct a full investigation or refer the case to the appropriate law enforcement agency.

(b) If there is reason to believe that a recipient has defrauded the Medicaid program, the agency must refer the case to an appropriate law enforcement agency.

(c) If there is reason to believe that a recipient has abused the Medicaid program, the agency must conduct a full investigation of the abuse.

[48 FR 3756, Jan. 27, 1983, as amended at 51 FR 34788, Sept. 30, 1986]

§ 455.16 Resolution of full investigation.

A full investigation must continue until—

(a) Appropriate legal action is initiated;

(b) The case is closed or dropped because of insufficient evidence to support the allegations of fraud or abuse; or

(c) The matter is resolved between the agency and the provider or recipient. This resolution may include but is not limited to—

(1) Sending a warning letter to the provider or recipient, giving notice that continuation of the activity in question will result in further action;

(2) Suspending or terminating the provider from participation in the Medicaid program;

(3) Seeking recovery of payments made to the provider; or

(4) Imposing other sanctions provided under the State plan.

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3756, Jan. 27, 1983]

§ 455.17 Reporting requirements.

The agency must report the following fraud or abuse information to the appropriate Department officials at intervals prescribed in instructions.

(a) The number of complaints of fraud and abuse made to the agency that warrant preliminary investigation.

(b) For each case of suspected provider fraud and abuse that warrants a full investigation—

(1) The provider's name and number;

(2) The source of the complaint;

(3) The type of provider;

(4) The nature of the complaint;

(5) The approximate range of dollars involved; and

(6) The legal and administrative disposition of the case, including actions taken by law enforcement officials to whom the case has been referred.

(Approved by the Office of Management and Budget under control number 0938–0076)

[43 FR 45262, Sept. 29, 1978, as amended at 48 FR 3756, Jan. 27, 1983]

§ 455.18 Provider's statements on claims forms.

(a) Except as provided in § 455.19, the agency must provide that all provider claims forms be imprinted in boldface type with the following statements, or with alternate wording that is approved by the Regional CMS Administrator:

(1) ''This is to certify that the foregoing information is true, accurate, and complete.''

(2) ''I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws.''

(b) The statements may be printed above the claimant's signature or, if they are printed on the reverse of the form, a reference to the statements must appear immediately preceding the claimant's signature.

§ 455.19 Provider's statement on check.

As an alternative to the statements required in § 455.18, the agency may print the following wording above the claimant's endorsement on the reverse of checks or warrants payable to each provider: ''I understand in endorsing or depositing this check that payment will be from Federal and State funds and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws.''

§ 455.20 Recipient verification procedure.

(a) The agency must have a method for verifying with recipients whether services billed by providers were received.

(b) In States receiving Federal matching funds for a mechanized claims processing and information retrieval system under part 433, subpart C, of this subchapter, the agency must provide prompt written notice as required by § 433.116 (e) and (f).

[48 FR 3756, Jan. 27, 1983, as amended at 56 FR 8854, Mar. 1, 1991]

§ 455.21 Cooperation with State Medicaid fraud control units.

In a State with a Medicaid fraud control unit established and certified under subpart C of this part,

(a) The agency must—

(1) Refer all cases of suspected provider fraud to the unit;

(2) If the unit determines that it may be useful in carrying out the unit's responsibilities, promptly comply with a request from the unit for—

(i) Access to, and free copies of, any records or information kept by the agency or its contractors;

(ii) Computerized data stored by the agency or its contractors. These data

must be supplied without charge and in the form requested by the unit; and

(iii) Access to any information kept by providers to which the agency is authorized access by section 1902(a)(27) of the Act and § 431.107 of this subchapter. In using this information, the unit must protect the privacy rights of recipients; and

(3) On referral from the unit, initiate any available administrative or judicial action to recover improper payments to a provider.

(b) The agency need not comply with specific requirements under this subpart that are the same as the responsibilities placed on the unit under subpart D of this part.

§ 455.23 Withholding of payments in cases of fraud or willful misrepresentation.

(a) *Basis for withholding.* The State Medicaid agency may withhold Medicaid payments, in whole or in part, to a provider upon receipt of reliable evidence that the circumstances giving rise to the need for a withholding of payments involve fraud or willful misrepresentation under the Medicaid program. The State Medicaid agency may withhold payments without first notifying the provider of its intention to withhold such payments. A provider may request, and must be granted, administrative review where State law so requires.

(b) *Notice of withholding.* The State agency must send notice of its withholding of program payments within 5 days of taking such action. The notice must set forth the general allegations as to the nature of the withholding action, but need not disclose any specific information concerning its ongoing investigation. The notice must:

(1) State that payments are being withheld in accordance with this provision;

(2) State that the withholding is for a temporary period, as stated in paragraph (c) of this section, and cite the circumstances under which withholding will be terminated;

(3) Specify, when appropriate, to which type or types of Medicaid claims withholding is effective; and

(4) Inform the provider of the right to submit written evidence for consideration by the agency.

(c) *Duration of withholding.* All withholding of payment actions under this section will be temporary and will not continue after:

(1) The agency or the prosecuting authorities determine that there is insufficient evidence of fraud or willful misrepresentation by the provider; or

(2) Legal proceedings related to the provider's alleged fraud or willful misrepresentation are completed.

[52 FR 48817, Dec. 28, 1987]

Subpart B—Disclosure of Information by Providers and Fiscal Agents

SOURCE: 44 FR 41644, July 17, 1979, unless otherwise noted.

§ 455.100 Purpose.

This subpart implements sections 1124, 1126, 1902(a)(38), 1903(i)(2), and 1903(n) of the Social Security Act. It sets forth State plan requirements regarding—

(a) Disclosure by providers and fiscal agents of ownership and control information; and

(b) Disclosure of information on a provider's owners and other persons convicted of criminal offenses against Medicare, Medicaid, or the title XX services program.

The subpart also specifies conditions under which the Administrator will deny Federal financial participation for services furnished by providers or fiscal agents who fail to comply with the disclosure requirements.

§ 455.101 Definitions.

Agent means any person who has been delegated the authority to obligate or act on behalf of a provider.

Disclosing entity means a Medicaid provider (other than an individual practitioner or group of practitioners), or a fiscal agent.

Other disclosing entity means any other Medicaid disclosing entity and any entity that does not participate in Medicaid, but is required to disclose certain ownership and control information because of participation in any of

the programs established under title V, XVIII, or XX of the Act. This includes:

(a) Any hospital, skilled nursing facility, home health agency, independent clinical laboratory, renal disease facility, rural health clinic, or health maintenance organization that participates in Medicare (title XVIII);

(b) Any Medicare intermediary or carrier; and

(c) Any entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which it claims payment under any plan or program established under title V or title XX of the Act.

Fiscal agent means a contractor that processes or pays vendor claims on behalf of the Medicaid agency.

Group of practitioners means two or more health care practitioners who practice their profession at a common location (whether or not they share common facilities, common supporting staff, or common equipment).

Indirect ownership interest means an ownership interest in an entity that has an ownership interest in the disclosing entity. This term includes an ownership interest in any entity that has an indirect ownership interest in the disclosing entity.

Managing employee means a general manager, business manager, administrator, director, or other individual who exercises operational or managerial control over, or who directly or indirectly conducts the day-to-day operation of an institution, organization, or agency.

Ownership interest means the possession of equity in the capital, the stock, or the profits of the disclosing entity.

Person with an ownership or control interest means a person or corporation that—

(a) Has an ownership interest totaling 5 percent or more in a disclosing entity;

(b) Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

(c) Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

(d) Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

(e) Is an officer or director of a disclosing entity that is organized as a corporation; or

(f) Is a partner in a disclosing entity that is organized as a partnership.

Significant business transaction means any business transaction or series of transactions that, during any one fiscal year, exceed the lesser of $25,000 and 5 percent of a provider's total operating expenses.

Subcontractor means—

(a) An individual, agency, or organization to which a disclosing entity has contracted or delegated some of its management functions or responsibilities of providing medical care to its patients; or

(b) An individual, agency, or organization with which a fiscal agent has entered into a contract, agreement, purchase order, or lease (or leases of real property) to obtain space, supplies, equipment, or services provided under the Medicaid agreeement.

Supplier means an individual, agency, or organization from which a provider purchases goods and services used in carrying out its responsibilities under Medicaid (e.g., a commercial laundry, a manufacturer of hospital beds, or a pharmaceutical firm).

Wholly owned supplier means a supplier whose total ownership interest is held by a provider or by a person, persons, or other entity with an ownership or control interest in a provider.

[44 FR 41644, July 17, 1979, as amended at 51 FR 34788, Sept. 30, 1986]

§ 455.102 Determination of ownership or control percentages.

(a) *Indirect ownership interest.* The amount of indirect ownership interest is determined by multiplying the percentages of ownership in each entity. For example, if A owns 10 percent of the stock in a corporation which owns 80 percent of the stock of the disclosing entity, A's interest equates to an 8 percent indirect ownership interest in the disclosing entity and must be reported. Conversely, if B owns 80 percent of the stock of a corporation which owns 5 percent of the stock of the disclosing

entity, B's interest equates to a 4 percent indirect ownership interest in the disclosing entity and need not be reported.

(b) *Person with an ownership or control interest.* In order to determine percentage of ownership, mortgage, deed of trust, note, or other obligation, the percentage of interest owned in the obligation is multiplied by the percentage of the disclosing entity's assets used to secure the obligation. For example, if A owns 10 percent of a note secured by 60 percent of the provider's assets, A's interest in the provider's assets equates to 6 percent and must be reported. Conversely, if B owns 40 percent of a note secured by 10 percent of the provider's assets, B's interest in the provider's assets equates to 4 percent and need not be reported.

§ 455.103 State plan requirement.

A State plan must provide that the requirements of §§ 455.104 through 455.106 are met.

§ 455.104 Disclosure by providers and fiscal agents: Information on ownership and control.

(a) *Information that must be disclosed.* The Medicaid agency must require each disclosing entity to disclose the following information in accordance with paragraph (b) of this section:

(1) The name and address of each person with an ownership or control interest in the disclosing entity or in any subcontractor in which the disclosing entity has direct or indirect ownership of 5 percent or more;

(2) Whether any of the persons named, in compliance with paragraph (a)(1) of this section, is related to another as spouse, parent, child, or sibling.

(3) The name of any other disclosing entity in which a person with an ownership or control interest in the disclosing entity also has an ownership or control interest. This requirement applies to the extent that the disclosing entity can obtain this information by requesting it in writing from the person. The disclosing entity must—

(i) Keep copies of all these requests and the responses to them;

(ii) Make them available to the Secretary or the Medicaid agency upon request; and

(iii) Advise the Medicaid agency when there is no response to a request.

(b) *Time and manner of disclosure.* (1) Any disclosing entity that is subject to periodic survey and certification of its compliance with Medicaid standards must supply the information specified in paragraph (a) of this section to the State survey agency at the time it is surveyed. The survey agency must promptly furnish the information to the Secretary and the Medicaid agency.

(2) Any disclosing entity that is not subject to periodic survey and certification and has not supplied the information specified in paragraph (a) of this section to the Secretary within the prior 12-month period, must submit the information to the Medicaid agency before entering into a contract or agreement to participate in the program. The Medicaid agency must promptly furnish the information to the Secretary.

(3) Updated information must be furnished to the Secretary or the State survey or Medicaid agency at intervals between recertification or contract renewals, within 35 days of a written request.

(c) *Provider agreements and fiscal agent contracts.* A Medicaid agency shall not approve a provider agreement or a contract with a fiscal agent, and must terminate an existing agreement or contract, if the provider or fiscal agent fails to disclose ownership or control information as required by this section.

(d) *Denial of Federal financial participation (FFP).* FFP is not available in payments made to a provider or fiscal agent that fails to disclose ownership or control information as required by this section.

§ 455.105 Disclosure by providers: Information related to business transactions.

(a) *Provider agreements.* A Medicaid agency must enter into an agreement with each provider under which the provider agrees to furnish to it or to the Secretary on request, information

related to business transactions in accordance with paragraph (b) of this section.

(b) *Information that must be submitted.* A provider must submit, within 35 days of the date on a request by the Secretary or the Medicaid agency, full and complete information about—

(1) The ownership of any subcontractor with whom the provider has had business transactions totaling more than $25,000 during the 12-month period ending on the date of the request; and

(2) Any significant business transactions between the provider and any wholly owned supplier, or between the provider and any subcontractor, during the 5-year period ending on the date of the request.

(c) *Denial of Federal financial participation (FFP).* (1) FFP is not available in expenditures for services furnished by providers who fail to comply with a request made by the Secretary or the Medicaid agency under paragraph (b) of this section or under § 420.205 of this chapter (Medicare requirements for disclosure).

(2) FFP will be denied in expenditures for services furnished during the period beginning on the day following the date the information was due to the Secretary or the Medicaid agency and ending on the day before the date on which the information was supplied.

§ 455.106 Disclosure by providers: Information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person who:

(1) Has ownership or control interest in the provider, or is an agent or managing employee of the provider; and

(2) Has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, or the title XX services program since the inception of those programs.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of the Department of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must also promptly notify the Inspector General of the Department of any action it takes on the provider's application for participation in the program.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has an ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services Program.

(2) The Medicaid agency may refuse to enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

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AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302), unless otherwise noted.

SOURCE: 43 FR 45266, Sept. 29, 1978, unless otherwise noted.

Subpart A—General Provisions

§ 456.1 Basis and purpose of part.

(a) This part prescribes requirements concerning control of the utilization of Medicaid services including—

(1) A statewide program of control of the utilization of all Medicaid services; and

(2) Specific requirements for the control of the utilization of Medicaid services in institutions.

(3) Specific requirements for an outpatient drug use review program.

(b) The requirements in this part are based on the following sections of the Act. Table 1 shows the relationship between these sections of the Act and the requirements in this part.

(1) *Methods and procedures to safeguard against unnecessary utilization of care and services.* Section 1902(a)(30) requires that the State plan provide methods and procedures to safeguard against unnecessary utilization of care and services.

(2) *Penalty for failure to have an effective program to control utilization of institutional services.* Section 1903(g)(1) provides for a reduction in the amount of Federal Medicaid funds paid to a State for long-stay inpatient services if the State does not make a showing satisfactory to the Secretary that it has an effective program of control over utilization of those services. This penalty provision applies to inpatient services in hospitals, mental hospitals, and intermediate care facilities (ICF's). Specific requirements are:

(i) Under section 1903(g)(1)(A), a physician must certify at admission, and a physician (or physician assistant or nurse practitioner under the supervision of a physician) must periodically recertify, the individual's need for inpatient care.

(ii) Under section 1903(g)(1)(B), services must be furnished under a plan established and periodically evaluated by a physician.

(iii) Under section 1903(g)(1)(C), the State must have in effect a continuous program of review of utilization of care and services under section 1902(a)(30) whereby each admission is reviewed or screened in accordance with criteria established by medical and other professional personnel.

(iv) Under section 1903(g)(1)(D), the State must have an effective program under sections 1902(a) (26) and (31) of review of care in intermediate care facilities and mental hospitals. This must include evaluation at least annually of the professional management of each case.

(3) *Medical review in mental hospitals.* Section 1902(a)(26)(A) requires that the plan provide for a program of medical review that includes a medical evaluation of each individual's need for care in a mental hospital, a plan of care, and, where applicable, a plan of rehabilitation.

(4) *Independent professional review in intermediate care facilities.* Section 1902(a)(31)(A) requires that the plan provide for a program of independent professional review that includes a medical evaluation of each individual's need for intermediate care and a written plan of service.

(5) *Inspection of care and services in institutions.* Sections 1902(a)(26) (B) and (C) and 1902(a)(31) (B) and (C) require that the plan provide for periodic inspections and reports, by a team of professional persons, of the care being provided to each recipient in institutions for mental diseases (IMD's), and ICF's participating in Medicaid.

(6) *Denial of FFP for failure to have specified utilization review procedures.* Section 1903(i)(4) provides that FFP is not available in a State's expenditures for hospital or mental hospital services unless the institution has in effect a utilization review plan that meets Medicare requirements. However, the Secretary may waive this requirement if the Medicaid agency demonstrates to his satisfaction that it has utilization review procedures superior in effectiveness to the Medicare procedures.

(7) *State health agency guidance on quality and appropriateness of care and services.* Section 1902(a)(33)(A) requires that the plan provide that the State health or other appropriate medical agency establish a plan for review, by professional health personnel, of the appropriateness and quality of Medicaid services to provide guidance to the Medicaid agency and the State licensing agency in administering the Medicaid program.

(8) *Drug use review program.* Section 1927(g) of the Act provides that, for payment to be made under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a drug use review (DUR) program. It also requires that each State provide, either directly or through a contract with a private organization, for the establishment of a DUR Board.

TABLE 1

[This table relates the regulations in this part to the sections of the Act on which they are based.]

Subpart A—General	1902(a)(30) 1902(a)(33)(A)
Subpart B—Utilization Control: All Medicaid Services.	1902(a)(30)
Subpart C—Utilization Control: Hospitals	
Certification of need for care	1903(g)(1)(A)
Plan of care	1903(g)(1)(B)
Utilization review plan (including admission review).	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart D—Utilization Control: Mental Hospitals	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review.	1902(a)(26)(A) 1903(g)(1)(C)
Plan of care	1902(a)(26)(A) 1903(g)(1)(B)
Admission and plan of care requirements for individuals under 21.	1902(a)(26)(A) 1903(g)(1) (B), (C)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart F—Utilization Control: Intermediate Care Facilities	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review.	1902(a)(31)(A) 1903(g)(1)(C)
Plan of care	1902(a)(31)(A) 1903(g)(1)(B)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements.	1905 (a)(16) and (h)
Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals and Mental Hospitals.	
Subpart I—Inspections of Care in Intermediate Care Facilities and Institutions for Mental Diseases.	
Subpart J—Penalty for Failure To Make a Satisfactory Showing of An Effective Institutional Utilization Control Program.	1903(g)
Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims.	1927(g) and (h)

[43 FR 45266, Sept. 29, 1978, as amended at 46 FR 48561, Oct. 1, 1981; 57 FR 49408, Nov. 2, 1992; 61 FR 38398, July 24, 1996]

§ 456.2 State plan requirements.

(a) A State plan must provide that the requirements of this part are met.

(b) These requirements may be met by the agency by:

(1) Assuming direct responsibility for assuring that the requirements of this part are met; or

(2) Deeming of medical and utilization review requirements if the agency contracts with a QIO to perform that review, which in the case of inpatient acute care review will also serve as the initial determination for QIO medical necessity and appropriateness review for patients who are dually entitled to benefits under Medicare and Medicaid.

(c) In accordance with § 431.15 of this subchapter, FFP will be available for expenses incurred in meeting the requirements of this part.

[46 FR 48566, Oct. 1, 1981, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.3 Statewide surveillance and utilization control program.

The Medicaid agency must implement a statewide surveillance and utilization control program that—

(a) Safeguards against unnecessary or inappropriate use of Medicaid services and against excess payments;

(b) Assesses the quality of those services;

(c) Provides for the control of the utilization of all services provided under the plan in accordance with subpart B of this part; and

(d) Provides for the control of the utilization of inpatient services in accordance with subparts C through I of this part.

§ 456.4 Responsibility for monitoring the utilization control program.

(a) The agency must—

(1) Monitor the statewide utilization control program;

(2) Take all necessary corrective action to ensure the effectiveness of the program;

(3) Establish methods and procedures to implement this section;

(4) Keep copies of these methods and procedures on file; and

(5) Give copies of these methods and procedures to all staff involved in carrying out the utilization control program.

§ 456.5 Evaluation criteria.

The agency must establish and use written criteria for evaluating the appropriateness and quality of Medicaid services. This section does not apply to services in hospitals and mental hospitals. For these facilities, see the following sections: §§ 456.122 and 456.132 of subpart C; and § 456.232 of subpart D.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.6 Review by State medical agency of appropriateness and quality of services.

(a) The Medicaid agency must have an agreement with the State health agency or other appropriate State medical agency, under which the health or medical agency is responsible for establishing a plan for the review by professional health personnel of the appropriateness and quality of Medicaid services.

(b) The purpose of this review plan is to provide guidance to the Medicaid agency in the administration of the State plan and, where applicable, to the State licensing agency described in § 431.610.

Subpart B—Utilization Control: All Medicaid Services

§ 456.21 Scope.

This subpart prescribes utilization control requirements applicable to all services provided under a State plan.

§ 456.22 Sample basis evaluation of services.

To promote the most effective and appropriate use of available services and facilities the Medicaid agency must have procedures for the on-going evaluation, on a sample basis, of the need for and the quality and timeliness of Medicaid services.

§ 456.23 Post-payment review process.

The agency must have a post-payment review process that—

(a) Allows State personnel to develop and review—

(1) Recipient utilization profiles;

(2) Provider service profiles; and

(3) Exceptions criteria; and

(b) Identifies exceptions so that the agency can correct misutilization practices of recipients and providers.

Subpart C—Utilization Control: Hospitals

§ 456.50 Scope.

This subpart prescribes requirements for control of utilization of inpatient hospital services, including requirements concerning—

(a) Certification of need for care;

(b) Plan of care; and

(c) Utilization review plans.

§ 456.51 Definitions.

As used in this subpart:

Inpatient hospital services—

(a) Include—

(1) Services provided in an institution other than an institution for mental disease, as defined in § 440.10;

(2) [Reserved]

(3) Services provided in specialty hospitals and

(b) Exclude services provided in mental hospitals. Utilization control requirements for mental hospitals appear in subpart D.

Medical care appraisal norms or *norms* means numerical or statistical measures of usually observed performance.

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 22041, June 17, 1986]

CERTIFICATION OF NEED FOR CARE

§ 456.60 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that inpatient services in a hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a hospital, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a hospital are needed.

(2) Recertifications must be made at least every 60 days after certification.

[46 FR 48561, Oct. 1, 1981]

PLAN OF CARE

§ 456.80 Individual written plan of care.

(a) Before admission to a hospital or before authorization for payment, a physician and other personnel involved in the care of the individual must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Social services;

(vi) Diet;

(4) Plans for continuing care, as appropriate; and

(5) Plans for discharge, as appropriate.

(c) Orders and activities must be developed in accordance with physician's instructions.

(d) Orders and activities must be reviewed and revised as appropriate by all personnel involved in the care of an individual.

(e) A physician and other personnel involved in the recipient's case must review each plan of care at least every 60 days.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.100 Scope.

Sections 456.101 through 456.145 of this subpart prescribe requirements for a written utilization review (UR) plan for each hospital providing Medicaid services. Sections 456.105 and 456.106 prescribe administrative requirements: §§ 456.111 through 456.113 prescribe informational requirements; §§ 456.121 through 456.129 prescribe requirements for admission review; §§ 456.131 through 456.137 prescribe requirements for continued stay review; and §§ 456.141 through 456.145 prescribe requirements for medical care evaluation studies.

§ 456.101 UR plan required for inpatient hospital services.

(a) A State plan must provide that each hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the hospital furnishes him.

(b) Each written hospital UR plan must meet the requirements under §§ 456.101 through 456.145.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.105 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.106 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, ''UR committee'' includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the hospital staff;

(2) A group outside the hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality;

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of the patient whose care is being reviewed; or

(2) Has a financial interest in any hospital.

UR Plan: Informational Requirements

§ 456.111 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed for the UR committee to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.70.

(e) Initial and subsequent continued stay review dates described under §§ 456.128 and 456.133.

(f) Date of operating room reservation, if applicable.

(g) Justification of emergency admission, if applicable.

(h) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(i) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.112 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.113 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR Plan: Review of Need for Admission[1]

§ 456.121 Admission review required.

The UR plan must provide for a review of each recipient's admission to the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.122 through 456.129.

§ 456.122 Evaluation criteria for admission review.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for admission; and

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

[1] The Department was enjoined in 1975 in the case of American Medical Assn. et al. v. Weinberger, 395 F. Supp. 515 (N.D. Ill., 1975), aff'd., 522 F2d 921 (7th cir., 1975) from implementing the admission review requirements contained in §§ 456.121–456.127. This case was dismissed on the condition that these requirements be revised. They are presently being revised, and will not be in force until that revision is completed.

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.123 Admission review process.

The UR plan must provide that—

(a) Admission review is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup, or designee evaluates the admission against the criteria developed under § 456.122 and applies close professional scrutiny to cases selected under § 456.129(b);

(c) If the committee, subgroup, or designee finds that the admission is needed, the committee assigns an initial continued stay review date in accordance with § 456.128;

(d) If the committee, subgroup, or designee finds that the admission does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for admission;

(e) If the committee or subgroup making the review under paragraph (d) of this section finds that the admission is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(f) If the attending physician does not present additional information or clarification of the need for the admission, the decision of the committee or subgroup is final; and

(g) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the admission. If they find that the admission is not needed, their decision if final.

§ 456.124 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for admission under § 456.123 (e) through (g) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.125 Time limits for admission review.

Except as required under § 456.127, the UR plan must provide that review of each recipient's admission to the hospital is conducted—

(a) Within one working day after admission, for an individual who is receiving Medicaid at that time; or

(b) Within one working day after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.126 Time limits for final decision and notification of adverse decision.

Except as required under § 456.127, the UR plan must provide that the committee makes a final decision on a recipient's need for admission and gives notice of an adverse final decision—

(a) Within two working days after admission, for an individual who is receiving Medicaid at that time; or

(b) Within two working days after the hospital is notified of the application for Medicaid, for an individual who applies while in the hospital.

§ 456.127 Pre-admission review.

The UR plan must provide for review and final decision prior to admission for certain providers or categories of admissions that the UR committee designates under § 456.142(b) (4)(iii) to receive pre-admission review.

§ 456.128 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the hospital under the admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under § 456.129;

(2) The individual's condition; and

(3) The individual's projected discharge date;

(c)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These regional norms are based on current and statistically valid data on duration of stay in hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose case is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate; and

(d) The committee ensures that the initial continued stay review date is recorded in the individual's record.

§ 456.129 Description of methods and criteria: Initial continued stay review date; close professional scrutiny; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign the initial continued stay review date under § 456.128.

(b) The methods that the committee uses to select categories of admission to receive close professional scrutiny under § 456.123(b); and

(c) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

UR Plan: Review of Need for Continued Stay

§ 456.131 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.132 through 456.137.

§ 456.132 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.133 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.128 and 456.134(a);

(b) The committee assigns a subsequent review date each time it decides under § 456.135 that the continued stay is needed; and

(c) The committee ensures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.134 Description of methods and criteria: Subsequent continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign subsequent continued stay review dates under § 456.133; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.135 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the hospital, the committee,

subgroup or designee reviews and evaluates the documentation described under § 456.111 against the criteria developed under § 456.132 and applies close professional scrutiny to cases selected under § 456.129(b);

(d) If the committee, subgroup, or designee finds that a recipient's continued stay in the hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.133;

(e) If the committee, subgroup, or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his reviews before it makes a final decision on the need for the continued stay;

(g) If the attending physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and

(h) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. If they find that the recipient no longer needs inpatient hospital services, their decision is final.

§ 456.136 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.135 (f) through (h) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.137 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.136 of an adverse final decision within 2 working days after the assigned continued stay review dates, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.136 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.141 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.142 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review

process for admissions or continued stay cases;

(ii) Recommend more effective and efficient hospital care procedures; or

(iii) Designate certain providers or categories of admissions for review prior to admission.

§ 456.143 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions;

(2) Durations of stay;

(3) Ancillary services furnished, including drugs and biologicals;

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for changes beneficial to patients, staff, the hospital, and the community.

§ 456.144 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data;

(b) External organizations that compile statistics, design profiles, and produce other comparative data;

(c) Cooperative endeavors with—

(1) QIOs;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.145 Number of studies required to be performed.

The hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart D—Utilization Control: Mental Hospitals

§ 456.150 Scope.

This subpart prescribes requirements for control of utilization of inpatient services in mental hospitals, including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.151 Definitions.

As used in this subpart:

Medical care appraisal norms or *norms* means numerical or statistical measures of usually observed performance.

Medical care criteria or *criteria* means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

Certification of Need for Care

§ 456.160 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that inpatient services in a mental hospital are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in a mental hospital, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that inpatient services in a mental hospital are needed.

(2) Recertification must be made at least every 60 days after certification.

[46 FR 48561, Oct. 1, 1981]

Medical, Psychiatric, and Social Evaluations and Admission Review

§ 456.170 Medical, psychiatric, and social evaluations.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must make a medical evaluation of each applicant's or recipient's need for care in the hospital; and appropriate professional personnel must make a psychiatric and social evaluation.

(b) Each medical evaluation must include—

(1) Diagnoses;

(2) Summary of present medical findings;

(3) Medical history;

(4) Mental and physical functional capacity;

(5) Prognoses; and

(6) A recommendation by a physician concerning—

(i) Admission to the mental hospital; or

(ii) Continued care in the mental hospital for individuals who apply for Medicaid while in the mental hospital.

§ 456.171 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.170.

PLAN OF CARE

§ 456.180 Individual written plan of care.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures recommended for the health and safety of the patient;

(5) Plans for continuing care, including review and modification to the plan of care; and

(6) Plans for discharge.

(c) The attending or staff physician and other personnel involved in the recipient's care must review each plan of care at least every 90 days.

§ 456.181 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the facility, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENTS

§ 456.200 Scope.

Sections 456.201 through 456.245 of this subpart prescribe requirements for a written utilization review (UR) plan for each mental hospital providing Medicaid services. Sections 456.205 and 456.206 prescribe administrative requirements; §§ 456.211 through 456.213 prescribe informational requirements; §§ 456.231 through 456.238 prescribe requirements for continued stay review; and §§ 456.241 through 456.245 prescribe requirements for medical care evaluation studies.

§ 456.201 UR plan required for inpatient mental hospital services.

(a) The State plan must provide that each mental hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the mental hospital furnishes him.

(b) Each written mental hospital UR plan must meet the requirements under §§ 456.201 through 456.245.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.205 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.206 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, ''UR committee'' includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, one of whom is knowledgeable in the diagnosis and treatment of mental diseases, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the mental hospital staff;

(2) A group outside the mental hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality; or

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of patients whose care is being reviewed; or

(2) Has a financial interest in any mental hospital.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.211 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.172.

(e) Initial and subsequent continued stay review dates described under §§ 456.233 and 456.234.

(f) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(g) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.212 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.213 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.231 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the mental hospital to decide whether it is needed, in accordance with the requirements of §§ 456.232 through 456.238.

§ 456.232 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.233 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the mental hospital under admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) If an individual applies for Medicaid while in the mental hospital, the committee assigns the initial continued stay review date within 1 working day after the mental hospital is notified of the application for Medicaid;

(c) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under § 456.235(a);

(2) The individual's condition; and

(3) The individual's projected discharge date;

(d)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These norms are based on current and statistically valid data on duration of stay in mental hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose need for continued stay is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate;

(e) The initial continued stay review date is not in any case later than 30 days after admission of the individual or notice to the mental hospital of his application for Medicaid; and

(f) The committee insures that the initial continued stay review date is recorded in the individual's record.

§ 456.234 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.235(a) and 456.233;

(b) The committee assigns a subsequent continued stay review date at least every 90 days each time it decides under § 456.236 that the continued stay is needed; and

(c) The committee insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.235 Description of methods and criteria: Continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign initial and subsequent continued stay review dates under §§ 456.233 and 456.234 of this subpart; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.236 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the mental hospital, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.211 against the criteria developed under § 456.232 and applies close professional scrutiny to cases described under § 456.232(b).

(d) If the committee, subgroup or designee finds that a recipient's continued stay in the mental hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.234;

(e) If the committee, subgroup or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending or staff physician and gives him an opportunity to present his views before it makes a

final decision on the need for the continued stay;

(g) If the attending or staff physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and

(h) If the attending or staff physician presents additional information or clarification, at least two physician members of the committee, one of whom is knowledgeable in the treatment of mental diseases, review the need for the continued stay. If they find that the recipient no longer needs inpatient mental hospital services, their decision is final.

§ 456.237 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.236 (f) through (h) is sent to—

(a) The hospital administrator;

(b) The attending or staff physician;

(c) The Medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.238 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.237 of an adverse decision within 2 working days after the assigned continued stay review date, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.237 within 2 working days after the date of the final decision.

UR Plan: Medical Care Evaluation Studies

§ 456.241 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.242 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the mental hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process; or

(ii) Recommend more effective and efficient hospital care procedures.

§ 456.243 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the mental hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions.

(2) Durations of stay.

(3) Ancillary services furnished, including drugs and biologicals.

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for change beneficial to patients, staff, the hospital, and the community.

§ 456.244 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data.

(b) External organizations that compile statistics, design profiles, and produce other comparative data.

(c) Cooperative endeavors with—

(1) QIOs;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 43198, Dec. 1, 1986]

§ 456.245 Number of studies required to be performed.

The mental hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart E [Reserved]

Subpart F—Utilization Control: Intermediate Care Facilities

§ 456.350 Scope.

This subpart prescribes requirements for control of utilization of intermediate care facility (ICF) services including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.351 Definition.

As used in this subpart:

Intermediate care facility services means those items and services furnished in an intermediate care facility as defined in §§ 440.140 and 440.150 of this subchapter, but excludes those services if they are provided in religious nonmedical institutions as defined in § 440.170(b) of this chapter.

[43 FR 45266, Sept. 29, 1978, as amended at 64 FR 67052, Nov. 30, 1999]

CERTIFICATION OF NEED FOR CARE

§ 456.360 Certification and recertification of need for inpatient care.

(a) *Certification.* (1) A physician must certify for each applicant or recipient that ICF services are or were needed.

(2) The certification must be made at the time of admission or, if an individual applies for assistance while in an ICF, before the Medicaid agency authorizes payment.

(b) *Recertification.* (1) A physician, or physician assistant or nurse practitioner (as defined in § 491.2 of this chapter) acting within the scope of practice as defined by State law and under the supervision of a physician, must recertify for each applicant or recipient that ICF services are needed.

(2) Recertification must be made at least—

(i) Every 12 months after certification in an institution for the mentally retarded or persons with related conditions; and

(ii) Every 60 days after certification in an ICF other than an institution for the mentally retarded or persons with related conditions.

[46 FR 48561, Oct. 1, 1981, as amended at 50 FR 33034, Aug. 16, 1985]

MEDICAL, PSYCHOLOGICAL, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.370 Medical, psychological, and social evaluations.

(a) Before admission to an ICF or before authorization for payment, an interdisciplinary team of health professionals must make a comprehensive medical and social evaluation and, where appropriate, a psychological evaluation of each applicant's or recipient's need for care in the ICF.

(b) In an institution for the mentally retarded or persons with related conditions, the team must also make a psychological evaluation of need for care. The psychological evaluation must be made before admission or authorization of payment, but not more than three months before admission.

(c) Each evaluation must include—

(1) Diagnoses;

(2) Summary of present medical, social, and where appropriate, developmental findings;

(3) Medical and social family history;
(4) Mental and physical functional capacity;
(5) Prognoses;
(6) Kinds of services needed;
(7) Evaluation by an agency worker of the resources available in the home, family and community; and
(8) A recommendation concerning—
(i) Admission to the ICF; or
(ii) Continued care in the ICF for individuals who apply for Medicaid while in the ICF.

§ 456.371 Exploration of alternative services.

If the comprehensive evaluation recommends ICF services for an applicant or recipient whose needs could be met by alternative services that are currently unavailable, the facility must enter this fact in the recipient's record and begin to look for alternative services.

§ 456.372 Medicaid agency review of need for admission.

Medical and other professional personnel of the Medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.370.

PLAN OF CARE

§ 456.380 Individual written plan of care.

(a) Before admission to an ICF or before authorization for payment, a physician must establish a written plan of care for each applicant or recipient.
(b) The plan of care must include—
(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;
(2) A description of the functional level of the individual;
(3) Objectives;
(4) Any orders for—
(i) Medications;
(ii) Treatments;
(iii) Restorative and rehabilitative services;
(iv) Activities;
(v) Therapies;
(vi) Social services;
(vii) Diet; and
(viii) Special procedures designed to meet the objectives of the plan of care;
(5) Plans for continuing care, including review and modification of the plan of care; and
(6) Plans for discharge.
(c) The team must review each plan of care at least every 90 days.

§ 456.381 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—
(a) At the time of admission; or
(b) If the individual is already in the ICF, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.400 Scope.

Sections 456.401 through 456.438 of this subpart prescribe requirements for a written utilization review (UR) plan for each ICF providing Medicaid services. Sections 456.405 through 456.407 prescribe administrative requirements; §§ 456.411 through 456.413 prescribe informational requirements; and §§ 456.431 through 456.438 prescribe requirements for continued stay review.

§ 456.401 State plan UR requirements and options; UR plan required for intermediate care facility services.

(a) The State plan must provide that—
(1) UR is performed for each ICF that furnishes inpatient services under the plan;
(2) Each ICF has on file a written UR plan that provides for review of each recipient's need for the services that the ICF furnishes him; and
(3) Each written ICF UR plan meets requirements under §§ 456.401 through 456.438.
(b) The State plan must specify the method used to perform UR, which may be—
(1) Review conducted by the facility;
(2) Direct review in the facility by individuals—
(i) Employed by the medical assistance unit of the Medicaid agency; or
(ii) Under contract to the Medicaid agency; or
(3) Any other method.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.405 Description of UR review function: How and when.

The UR plan must include a written description of—

(a) How UR is performed in the ICF; and

(b) When UR is performed.

§ 456.406 Description of UR review function: Who performs UR; disqualification from performing UR.

(a) The UR plan must include a written description of who performs UR in the ICF.

(b) UR must be performed using a method specified under § 456.401(b) by a group of professional personnel that includes—

(1) At least one physician;

(2) In an ICF that cares primarily for mental patients, at least one individual knowledgeable in the treatment of mental diseases; and

(3) In an institution for the mentally retarded, a least one individual knowledgeable in the treatment of mental retardation.

(c) The group performing UR may not include any individual who—

(1) Is directly responsible for the care of the recipient whose care is being reviewed;

(2) Is employed by the ICF; or

(3) Has a financial interest in any ICF.

§ 456.407 UR responsibilities of administrative staff.

The UR plan must describe—

(a) The UR support responsibilities of the ICF's administrative staff; and

(b) Procedures used by the staff for taking needed corrective action.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.411 Recipient information required for UR.

The UR plan must provide that each recipient's record include information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) The name of the qualified mental retardation professional (as defined under § 442.401 of this subchapter), if applicable.

(d) Date of admission, and dates of application for and authorization of Medicaid benefits if application is made after admission.

(e) The plan of care required under § 456.372;

(f) Initial and subsequent continued stay review dates described under §§ 456.433 and 456.434.

(g) Reasons and plan for continued stay, if the attending physician or qualified mental retardation professional believes continued stay is necessary.

(h) Other supporting material that the UR group believes appropriate to be included in the record.

§ 456.412 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the group performing UR; and

(b) The type and frequency of reports made by the UR group, and arrangements for distribution of the reports to appropriate individuals.

§ 456.413 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.431 Continued stay review required.

(a) The UR plan must provide for a review of each recipients continued stay in the ICF at least every 6 months to decide whether it is needed.

(b) The UR plan requirement for continued stay review may be met by—

(1) Reviews that are performed in accordance with the requirements of §§ 456.432 through 456.437; or

(2) Reviews that meet on-site inspection requirements under subpart I if—

(i) The composition of the independent professional review team under subpart I meets the requirements of § 456.406; and

(ii) Reviews are conducted as frequently as required under §§ 456.433 and 456.434.

§ 456.432 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The group performing UR develops written criteria to assess the need for continued stay.

(b) The group develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.433 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the ICF under admission review requirements of this subpart, the group performing UR assigns a specified date by which the need for his continued stay will be reviewed;

(b) The group performing UR bases its assignment of the initial continued stay review date on the methods and criteria required to be described under § 456.435(a);

(c) The initial continued stay review date is—

(1) Not later than 6 months after admission; or

(2) Earlier than 6 months after admission, if indicated at the time of admission; and

(d) The group performing UR insures that the initial continued stay review date is recorded in the recipient's record.

§ 456.434 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The group performing UR assigns subsequent continued stay review dates in accordance with § 456.435.

(b) The group assigns a subsequent continued stay review date each time it decides under § 456.436 that the continued stay is needed—

(1) At least every 6 months; or

(2) More frequently than every six months if indicated at the time of continued stay review; and

(c) The group insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.435 Description of methods and criteria: Continued stay review dates.

The UR plan must describe the methods and criteria that the group performing UR uses to assign initial and subsequent continued stay review dates under §§ 456.433 and 456.434.

§ 456.436 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The group performing UR; or

(2) A designee of the UR group;

(b) The group or its designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date.

(c) For each continued stay of a recipient in the ICF, the group or its designee reviews and evaluates the documentation described under § 456.411 against the criteria developed under § 456.432 and applies close professional scrutiny to cases described under § 456.432(b);

(d) If the group or its designee finds that a recipient's continued stay in the ICF is needed, the group assigns a new continued stay review date in accordance with § 456.434;

(e) If the group or its designee finds that a continued stay case does not meet the criteria, the group or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the group or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician or, in institutions for the mentally retarded, the recipient's qualified mental retardation professional, within 1 working day of its decision, and gives him 2 working days from the notification date to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending physician or qualified mental retardation professional does not present additional information or clarification of the need for the continued stay, the decision of the UR group is final;

(h) If the attending physician or qualified mental retardation professional presents additional information or clarification, the need for continued stay is reviewed by—

(1) The physician member(s) of the UR group, in cases involving a medical determination; or

(2) The UR group, in cases not involving a medical determination; and

(i) If the individuals performing the review under paragraph (h) of this section find that the recipient no longer needs ICF services, their decision is final.

§ 456.437 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.436 (g) through (i) is sent to—

(a) The ICF administrator;

(b) The attending physician;

(c) The qualified mental retardation professional, if applicable;

(d) The Medicaid agency;

(e) The recipient; and

(f) If possible, the next of kin or sponsor.

§ 456.438 Time limits for notification of adverse decision.

The UR plan must provide that the group gives notice under § 456.437 of an adverse decision not later than 2 days after the date of the final decision.

Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements

§ 456.480 Scope.

This subpart concerns admission and plan of care requirements that apply to inpatient psychiatric services for individuals under age 21 in hospitals, mental hospitals, and intermediate care facilities.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.481 Admission certification and plan of care.

If a facility provides inpatient psychiatric services to a recipient under age 21—

(a) The admission certification by the review team required in § 441.152 satisfies the requirement for physician certification of need for care in §§ 456.60, 456.160, and 456.360; and

(b) The development and review of the plan of care required in § 441.154 satisfies the requirement for physician recertification of need for care in the sections cited in paragraph (a) and the requirement for establishment and periodic review of the plan of care in §§ 456.80, 456.180, and 456.380.

(c) The plan of care must be established by the team described in § 441.156.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.482 Medical, psychiatric, and social evaluations.

If a facility provides inpatient psychiatric services to a recipient under age 21, the medical, psychiatric, and social evaluations required by §§ 456.170, and 456.370 must be made by the team described in § 441.153.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals and Mental Hospitals

§ 456.500 Purpose.

For hospitals and mental hospitals, this subpart—

(a) Prescribes conditions for the availability of FFP relating to UR plans;

(b) Prescribes conditions for granting a waiver of UR plan requirements; and

(c) Prescribes conditions for granting a variance in UR plan requirements for remote facilities.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.501 UR plans as a condition for FFP.

(a) Except when waived under §§ 456.505 through 456.508, FFP is not available in expenditures for Medicaid services furnished by a hospital or mental hospital unless the facility has in effect a UR plan that meets the utilization review requirements for Medicare under section 1861(k) of the Act.

(b) A facility that participates in Medicare and Medicaid must use the same UR standards and procedures and review committee for Medicaid as it uses for Medicare.

(c) A facility that does not participate in Medicare must meet the UR plan requirements in subpart C or D of this part, which are equivalent to the Medicare UR plan requirements in §§ 405.1137, 482.30, and 482.60 of this chapter.

[43 FR 45266, Sept. 29, 1978, as amended at 51 FR 22042, June 17, 1986; 61 FR 38399, July 24, 1996]

UR PLAN: WAIVER OF REQUIREMENTS

§ 456.505 Applicability of waiver.

The Administrator may waive the UR plan requirements of subparts C or D of this part, except for provisions relating to disqualification of UR committee members under § 456.106 of subpart C, and § 456.206 of subpart D, if the Medicaid agency—

(a) Applies for a waiver; and

(b) Demonstrates to the Administrator's satisfaction that it has in operation specific UR procedures that are superior in their effectiveness to the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.506 Waiver options for Medicaid agency.

(a) The agency may apply for a waiver at any time it has the procedures referred to under § 456.505(b) in operation at least—

(1) On a demonstration basis; or

(2) In any part of the State.

(b) Any hospital or mental hospital participating under the plan that is not covered by a waiver must continue to meet all the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.507 Review and granting of waiver requests.

(a) When the agency applies for a waiver, the Administrator will assess the agency's UR procedures and grant the waiver if he determines that the procedures meet criteria he establishes.

(b) The Administrator will review and evaluate each waiver between 1 and 2 years after he has granted it and between 1 and 2 years periodically thereafter.

§ 456.508 Withdrawal of waiver.

(a) The Administrator will withdraw a waiver if he determines that State procedures are no longer superior in their effectiveness to the procedures required for UR plans under subpart C or D of this part.

(b) If a waiver is withdrawn by the Administrator, each hospital or mental hospital covered by the waiver must meet all the UR plan requirements under subpart C or D of this part.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

UR PLAN: REMOTE FACILITY VARIANCES FROM TIME REQUIREMENTS

§ 456.520 Definitions.

As used in §§ 456.521 through 456.525 of this subpart:

Available physician or other professional personnel means an individual who—

(a) Is professionally qualified;

(b) Is not precluded from participating in UR under § 456.107 of subpart C; or § 456.207 of subpart D; and

(c) Is not precluded from effective participation in UR because he requires more than approximately 1 hour to travel between the remote facility and his place of work.

Remote facility means a facility located in an area that does not have enough available physicians or other professional personnel to perform UR as required under subparts C or D of this part, and for which the State requests a variance.

Variance means permission granted by the Administrator to the Medicaid agency for a specific remote facility to use time periods different from those specified for the start and completion of reviews of all cases under the following sections: §§ 456.125, 456.126, 456.136, and 456.137 of subpart C; and § 456.238 of subpart D.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.521 Conditions for granting variance requests.

(a) Except as described under paragraph (b) of this section, the administrator may grant a variance for a specific remote facility if the agency submits concurrently—

(1) A request for the variance that documents to his satisfaction that the facility is unable to meet the time requirements for which the variance is requested; and

(2) A revised UR plan for the facility.

(b) The Administrator will not grant a variance if the remote facility is operating under a UR plan waiver that the Secretary has granted or is considering under §§ 456.505 through 456.508.

§ 456.522 Content of request for variance.

The agency's request for a variance must include—

(a) The name, location, and type of the remote facility;

(b) The number of total patient admissions and the average daily patient census at the facility in the 6 months preceding the request;

(c) The number of Medicare and Medicaid patient admissions and the average daily Medicare and Medicaid patient census at the facility in the 6 months preceding the request;

(d) The name and location of each hospital, mental hospital, and ICF located within a 50-mile radius of the facility;

(e) The distance and average travel time between the remote facility and each facility listed in paragraph (e) of this section;

(f) Documentation by the facility of its attempts to obtain the services of available physicians or other professional personnel, or both;

(g) The names of all physicians on the active staff, and the names of all other professional personnel on the staff whose availability is relevant to the request;

(h) The practice locations of available physicians and the estimated number of available professional personnel whose availability is relevant to the request;

(i) Documentation by the facility of its inability to perform UR within the time requirements for which the variance is requested and its good faith efforts to comply with the UR plan requirements of subpart C or D of this part;

(j) An assurance by the facility that it will continue its good faith efforts to meet the UR plan requirements of subpart C or D of this part; and

(k) A statement of whether a planning or conditional PSRO exists in the area where the facility is located.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.523 Revised UR plan.

(a) The revised UR plan for the remote facility must specify the methods and procedures that the facility will use if a variance is granted to insure that it—

(1) Maintains effective and timely control over the utilization of services; and

(2) Conducts reviews in a way that improves the quality of care provided to patients.

(b) The revised UR plan for the remote facility is the basis for validation of UR under sec. 1903(g)(2) of the Act for the period when a variance is in effect.

§ 456.524 Notification of Administrator's action and duration of variance.

(a) The Administrator—

(1) Will notify the agency of the action he takes on its request for a variance; and

(2) Will specify the period of time, not to exceed 1 year, for which the variance may be granted.

(b) When it receives the Administrator's notification, the agency must promptly notify the remote facility of his action.

§ 456.525 Request for renewal of variance.

(a) The agency must submit a request for renewal of a variance to the Administrator at least 30 days before the variance expires.

(b) The renewal request must contain the information required under § 456.522.

(c) The renewal request must show, to the Administrator's satisfaction, that the remote facility continues to meet the requirements of §§ 456.521 through 456.523.

Subpart I—Inspections of Care in Intermediate Care Facilities and Institutions for Mental Diseases

§ 456.600 Purpose.

This subpart prescribes requirements for periodic inspections of care and services intermediate care facilities (ICF's), and institutions for mental diseases (IMD's).

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.601 Definitions.

For purposes of this subpart—

Facility means an institution for mental diseases, or an intermediate care facility.

Intermediate care facility includes institutions for the mentally retarded or persons with related conditions but excludes religious nonmedical institutions as defined in § 440.170(b) of this chapter.

Institution for mental diseases includes a mental hospital, a psychiatric facility, and an intermediate care facility that primarily cares for mental patients.

Psychiatric facility includes a facility or program that provides inpatient psychiatric services for individuals under 21, as specified in § 441.151 of this chapter, but does not include psychiatric wards in acute care hospitals.

[44 FR 56337, Oct. 1, 1979, as amended at 61 FR 38399, July 24, 1996; 64 FR 67052, Nov. 30, 1999]

§ 456.602 Inspection team.

(a) A team, as described in this section and § 456.603 must periodically inspect the care and services provided to recipients in each facility.

(b) Each team conducting periodic inspections must have a least one member who is at physician or registered nurse and other appropriate health and social service personnel.

(c) For an IMD other than an ICF, each team must have a psychiatrist or physician knowledgeable about mental institutions and other appropriate mental health and social service personnel.

(d) For an ICF that primarily cares for mental patients, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(e) For an institution for the mentally retarded or persons with related conditions, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(f) For ICFs primarily serving individuals 65 years of age or older, each team must have at least one member who knows the problems and needs of those individuals.

(g) If there is no physician on the team, the Medicaid agency must insure that a physician is available to provide consultation to the team.

(h) If a team has one or more physicians, it must be supervised by a physician.

§ 456.603 Financial interests and employment of team members.

(a) Except as provided in paragraph (b) of this section—

(1) [Reserved]

(2) No member of a team that reviews care in an ICF may have a financial interest in or be employed by any ICF.

(b) A member of a team that reviews care in an IMD or an institution for the mentally retarded or persons with related conditions—

(1) May not have a financial interest in any institution of that same type but may have a financial interest in other facilities or institutions; and

(2) May not review care in an institution where he is employed but may review care in any other facility or institution.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.604 Physician team member inspecting care of recipients.

No physician member of a team may inspect the care of a recipient for whom he is the attending physician.

§ 456.605 Number and location of teams.

There must be a sufficient number of teams so located within the State that onsite inspections can be made at appropriate intervals in each facility caring for recipients.

§ 456.606 Frequency of inspections.

The team and the agency must determine, based on the quality of care and services being provided in a facility and the condition of recipients in the facility, at what intervals inspections will be made. However, the team must inspect the care and services provided to each recipient in the facility at least annually.

§ 456.607 Notification before inspection.

No facility may be notified of the time of inspection more than 48 hours before the scheduled arrival of the team.

§ 456.608 Personal contact with and observation of recipients and review of records.

(a) For recipients under age 21 in psychiatric facilities and recipients in ICFs, other than those described in paragraph (b) of this section, the team's inspection must include—

(1) Personal contact with and observation of each recipient; and

(2) Review of each recipient's medical record.

(b) For recipients age 65 or older in IMDs, the team's inspection must include—

(1) Review of each recipient's medical record; and

(2) If the record does not contain complete reports of periodic assessments required by § 441.102 of this subchapter or, if such reports are inadequate, personal contact with and observation of each recipient

[43 FR 45266, Sept. 29, 1978, as amended at 44 FR 17940, Mar. 23, 1979; 61 FR 38399, July 24, 1996]

§ 456.609 Determinations by team.

The team must determine in its inspection whether—

(a) The services available in the facility are adequate to—

(1) Meet the health needs of each recipient, and the rehabilitative and social needs of each recipient in an ICF; and

(2) Promote his maximum physical, mental, and psychosocial functioning.

(b) It is necessary and desirable for the recipient to remain in the facility;

(c) It is feasible to meet the recipient's health needs and, in an ICF, the recipient's rehabilitative needs, through alternative institutional or noninstitutional services; and

(d) Each recipient under age 21 in a psychiatric facility and each recipient in an institution for the mentally retarded or persons with related conditions is receiving active treatment as defined in § 441.154 of this subchapter.

§ 456.610 Basis for determinations.

In making the determinations on adequacy of services and related matters under § 456.609 for each recipient, the team may consider such items as whether—

(a) The medical evaluation, any required social and psychological evaluations, and the plan of care are complete and current; the plan of care and, where required, the plan of rehabilitation are followed; and all ordered services, including dietary orders, are provided and properly recorded;

(b) The attending physician reviews prescribed medications—

(1) At least every 30 days in psychiatric facilities, and mental hospitals; and

(2) At least quarterly in ICFs;

(c) Tests or observations of each recipient indicated by his medication regimen are made at appropriate times and properly recorded;

(d) Physician, nurse, and other professional progress notes are made as required and appear to be consistent with the observed condition of the recipient;

(e) The recipient receives adequate services, based on such observations as—

(1) Cleanliness;

(2) Absence of bedsores;

(3) Absence of signs of malnutrition or dehydration; and

(4) Apparent maintenance of maximum physical, mental, and psychosocial funtion;

(f) In an ICF, the recipient receives adequate rehabilitative services, as evidenced by—

(1) A planned program of activities to prevent regression; and

(2) Progress toward meeting objectives of the plan of care;

(g) The recipient needs any service that is not furnished by the facility or through arrangements with others; and

(h) The recipient needs continued placement in the facility or there is an appropriate plan to transfer the recipient to an alternate method of care.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.611 Reports on inspections.

(a) The team must submit a report promptly to the agency on each inspection.

(b) The report must contain the observations, conclusions, and recommendations of the team concerning—

(1) The adequacy, appropriateness, and quality of all services provided in the facility or through other arrangements, including physician services to recipients; and

(2) Specific findings about individual recipients in the facility.

(c) The report must include the dates of the inspection and the names and qualifications of the members of the team.

[43 FR 45266, Sept. 29, 1978, as amended at 44 FR 56337, Oct. 1, 1979]

§ 456.612 Copies of reports.

The agency must send a copy of each inspection report to—

(a) The facility inspected;

(b) The facility's utilization review committee;

(c) The agency responsible for licensing, certification, or approval of the facility for purposes of Medicare and Medicaid; and

(d) Other State agencies that use the information in the reports to perform their official function, including, if inspection reports concern IMD's, the appropriate State mental health authorities.

§ 456.613 Action on reports.

The agency must take corrective action as needed based on the report and recommendations of the team submitted under this subpart.

§ 456.614 Inspections by utilization review committee.

A utilization review committee under subparts C through F of this part may conduct the periodic inspections required by this subpart if—

(a) The committee is not based in the facility being reviewed; and

(b) The composition of the committee meets the requirements of this subpart.

Subpart J—Penalty for Failure To Make a Satisfactory Showing of an Effective Institutional Utilization Control Program

AUTHORITY: Secs. 1102 and 1903(g) of the Social Security Act (42 U.S.C. 1302 and 1396 b(g)).

SOURCE: 44 FR 56338, Oct. 1, 1979, unless otherwise noted.

§ 456.650 Basis, purpose and scope.

(a) *Basis.* Section 1903(g) of the Act requires that FFP for long-stay inpatient services at a level of care be reduced, by a specified formula, for any quarter in which a State fails to make a satisfactory showing that it has an effective program of utilization control for that level of care.

(b) *Purpose.* This subpart specifies—

(1) What States must do to make a satisfactory showing;

(2) How the Administrator will determine whether reductions will be imposed; and

(3) How the required reductions will be implemented.

(c) *Scope.* The reductions required by this subpart do not apply to—

(1) Services provided under a contract with a health maintenance organization; or

(2) Facilities in which a QIO is performing medical and utilization reviews under contract with the Medicaid

agency in accordance with § 431.630 of this chapter.

[44 FR 56338, Oct. 1, 1979, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986]

§ 456.651 Definitions.

For purposes of this subpart—

Facility, with respect to inpatient psychiatric services for individuals under 21, includes a psychiatric program as specified in § 441.151 of this chapter.

Level of care means one of the following types of inpatient services: hospital, mental hospital, intermediate care facility, or psychiatric services for individuals under 21.

Long-stay services means services provided to a recipient after a total of 60 days of inpatient stay (90 in the case of mental hospital services) during a 12-month period beginning July 1, not counting days of stay paid for wholly or in part by Medicare.

[43 FR 45266, Sept. 29, 1978, as amended at 61 FR 38399, July 24, 1996]

§ 456.652 Requirements for an effective utilization control program.

(a) *General requirements.* In order to avoid a reduction in FFP, the Medicaid agency must make a satisfactory showing to the Administrator, in each quarter, that it has met the following requirements for each recipient:

(1) Certification and recertification of the need for inpatient care, as specified in §§ 456.60, 456.160, 456.360 and 456.481.

(2) A plan of care established and periodically reviewed and evaluated by a physician, as specified in §§ 456.80, 456.180, and 456.481.

(3) A continuous program of utilization review under which the admission of each recipient is reviewed or screened in accordance with section 1903(g)(1)(C) of the Act; and

(4) A regular program of reviews, including medical evaluations, and annual on-site reviews of the care of each recipient, as specified in §§ 456.170, and 456.482 and subpart I of this part.

(b) *Annual on-site review requirements.* (1) An agency meets the quarterly on-site review requirements of paragraph (a)(4) of this section for a quarter if it completes on-site reviews of each recipient in every facility in the State, and in every State-owned facility regardless of location, by the end of the quarter in which a review is required under paragraph (b)(2) of this section.

(2) An on-site review is required in a facility by the end of a quarter if the facility entered the Medicaid program during the same calendar quarter 1 year earlier or has not been reviewed since the same calendar quarter 1 year earlier. If there is no Medicaid recipient in the facility on the day a review is scheduled, the review is not required until the next quarter in which there is a Medicaid recipient in the facility.

(3) If a facility is not reviewed in the quarter in which it is required to be reviewed under paragraph (b)(2) of this section, it will continue to require a review in each subsequent quarter until the review is performed.

(4) The requirement for an on-site review in a given quarter is not affected by the addition or deletion of a level of care in a facility's provider agreement.

(c) *Facilities without valid provider agreements.* The requirements of paragraphs (a) and (b) of this section apply with respect to recipients for whose care the agency intends to claim FFP even if the recipients receive care in a facility whose provider agreement has expired or been terminated.

[44 FR 56338, Oct. 1, 1979, as amended at 46 FR 48561, Oct. 1, 1981; 61 FR 38399, July 24, 1996]

§ 456.653 Acceptable reasons for not meeting requirements for annual on-site review.

The Administrator will find an agency's showing satisfactory, even if it failed to meet the annual review requirements of § 456.652(a)(4), if—

(a) The agency demonstrates that—

(1) It completed reviews by the end of the quarter in at least 98 percent of all facilities requiring review by the end of the quarter;

(2) It completed reviews by the end of the quarter in all facilities with 200 or more certified Medicaid beds requiring review by the end of the quarter; and

(3) With respect to all unreviewed facilities, the agency exercised good faith and due diligence by attempting to review those facilities and would have succeeded but for events beyond its control which it could not have reasonably anticipated; or

(b) The agency demonstrates that it failed to meet the standard in paragraph (a) (1) and (2) of this section by the close of the quarter for technical reasons, but met the standard within 30 days after the close of the quarter. Technical reasons are circumstances within the agency's control.

(c) Facilities that are reviewed under paragraph (b) of this section, after the quarter in which they were due for review, retain their original anniversary quarter due date for purposes of subsequent reviews.

§ 456.654 Requirements for content of showings and procedures for submittal.

(a) An agency's showing for a quarter must—

(1) Include a certification by the agency that the requirements of § 456.652(a) (1) through (4) were met during the quarter for each level of care or, if applicable, a certification of the reasons the annual on-site review requirements of § 456.652(a)(4) were not met in any facilities;

(2) For all mental hospitals, intermediate care facilities, and facilities providing inpatient psychiatric services for individuals under 21, participating in Medicaid any time during the 12–month period ending on the last day of the quarter, list each facility by level of care, name, address and provider number;

(3) For each facility entering or leaving the program during the 12–month period ending on the last day of the quarter, list the beginning or ending dates of the provider agreement and supply a copy of the provider agreement;

(4) If review has been contracted to a QIO under § 431.630 of this chapter, list the date the QIO contracted for review.

(5) List all dates of on-site reviews completed by review teams anytime during the 12–month period ending on the last day of the quarter;

(6) For all facilities in which an on-site review was required but not conducted, list the facility by name, address and provider number;

(7) For each on-site review in a mental hospital, intermediate care facility that primarily cares for mental patients, or inpatient psychiatric facility, list the name and qualifications of one team member who is a physician; and

(8) For each on-site review in an intermediate care facility that does not primarily care for mental patients, list the name and qualifications of one team member who is either a physician or registered nurse.

(b) The quarterly showing must be in the form prescribed by the Administrator.

(c) The quarterly showing must be postmarked or received within 30 days after the close of the quarter for which it is made, unless the agency demonstrates good cause for later submittal and the showing is postmarked or received within 45 days after the close of the quarter. Good cause means unanticipated circumstances beyond the agency's control.

[44 FR 56338, Oct. 1, 1979, as amended at 50 FR 15327, Apr. 17, 1985; 51 FR 43198, Dec. 1, 1986; 61 FR 38399, July 24, 1996]

§ 456.655 Validation of showings.

(a) The Administrator will periodically validate showings submitted under § 456.654. Validation procedures will include on-site sample surveys of institutions and surveys at the Medicaid agencies.

(b) The Administrator will not find an agency's showing satisfactory if the information obtained through his validation procedures demonstrates, that any of the requirements of § 456.652(a) (1) through (4) were not met during the quarter for which the showing was made.

§ 456.656 Reductions in FFP.

(a) If the Administrator determines an agency's showing does not meet each of the requirements of this subpart, he will give the agency 30 days notice before making the required reduction.

(b) If the Administrator determines that a showing for any quarter is unsatisfactory on its face, he will make the required reduction in the grant award based on the Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program for that quarter. (This form CMS–64 is described in § 430.30(c) of this chapter.)

(c) If the Administrator finds a showing satisfactory on its face, but after validation determines the showing to be unsatisfactory, he will notify the agency of any required reduction in FFP no later than the first day of the fourth calendar quarter following the calendar quarter for which the showing was made. Any required reduction will be made by amending or adjusting the agency's grant award.

(d) The agency may request reconsideration of a reduction in accordance with the procedures specified in 45 CFR part 16.

§ 456.657 Computation of reductions in FFP.

(a) For each level of care specified in a provider agreement, and for each quarter for which a satisfactory showing is not made, the amount of the reduction in FFP is computed as follows:

(1) For each level of care, the number of recipients who received services in facilities that did not meet the requirements of this subpart is divided by the total number of recipients who received services in facilities for which a showing was required under this subpart. If any of the requirements specified in § 456.652(a)(1) through (4) were not met for any recipient in a facility, the reduction will be computed on the total number of recipients in that facility at the level of care in question.

(2) The fraction obtained in paragraph (a)(1) of this section is multiplied by one-third.

(3) The product obtained in paragraph (a)(2) of this section is multiplied by the Federal Medical Assistance Percentage (FMAP).

(4) The product obtained in paragraph (a)(3) of this section is multiplied by the agency payments for longstay services furnished during the quarter at that level of care.

(b) If any of the data required to compute the amount of the reduction in FFP are unavailable, the Administrator will substitute an estimate. If the agency determines the exact data to the satisfaction of the Administrator, the estimate may later be adjusted. If the number of recipients in individual facilities is not available, the fraction specified in paragraph (a)(1) of this section will be estimated, for each level of care, by dividing the number of facilities in which the requirements were not met by the total number of facilities for which a showing is required under this subpart.

Subpart K—Drug Use Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims

SOURCE: 57 FR 49408, Nov. 2, 1992, unless otherwise noted.

§ 456.700 Scope.

This subpart prescribes requirements for—

(a) An outpatient DUR program that includes prospective drug review, retrospective drug use review, and an educational program;

(b) The establishment, composition, and functions of a State DUR Board; and

(c) An optional point-of-sale electronic claims management system for processing claims for covered outpatient drugs.

§ 456.702 Definitions.

For purposes of this subpart—

Abuse is defined as in § 455.2 of this chapter.

Adverse medical result means a clinically significant undesirable effect, experienced by a patient, due to a course of drug therapy.

Appropriate and medically necessary means drug prescribing and dispensing that is in conformity with the predetermined standards established in accordance with § 456.703.

Criteria is defined as in § 466.1 of this chapter.

Fraud is defined as in § 455.2 of this chapter.

Gross overuse means repetitive overutilization without therapeutic benefit.

Inappropriate and medically unnecessary means drug prescribing and dispensing not in conformity with the definition of *appropriate and medically necessary*.

Overutilization means use of a drug in a quantity, strength, or duration that is greater than necessary to achieve a desired therapeutic goal or that puts

the recipient at risk of a clinically significant undesirable effect, or both.

Predetermined standards means criteria and standards that have been established in accordance with the requirements of § 456.703.

Standards is defined as in § 466.1 of this chapter.

Underutilization means use of a drug by a recipient in insufficient quantity, strength, or duration to achieve a desired therapeutic goal or that puts the recipient at risk of a clinically significant undesired effect, or both.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§ 456.703 Drug use review program.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in order for FFP to be paid or made available under section 1903 of the Act for covered outpatient drugs, the State must have in operation, by not later than January 1, 1993, a DUR program consisting of prospective drug review, retrospective drug use review, and an educational program that meets the requirements of this subpart. The goal of the State's DUR program must be to ensure appropriate drug therapy, while permitting sufficient professional prerogatives to allow for individualized drug therapy.

(b) *Exception for drugs dispensed to certain nursing facility residents.* Prospective drug review and retrospective drug use review (including interventions and education) under the DUR program are not required for drugs dispensed to residents of nursing facilities that are in compliance with the drug regimen review procedures set forth in part 483 of this chapter. This does not preclude the State agency from making such drugs subject to prospective DUR or retrospective DUR or both, provided the State agency makes the drugs subject to all the requirements of this subpart applicable to the respective review.

(c) *Exemption for certain covered outpatient drugs dispensed by hospitals and health maintenance organizations.* (1) The State plan must provide that covered outpatient drugs dispensed by a hospital using drug formulary systems and billed to the plan at no more than the hospital's purchasing costs are not subject to the requirements of this subpart. Individual hospitals requesting this exemption must provide assurances to the State agency that they meet the requirements specified in section 1927(j)(2) of the Act.

(2) The State plan must provide that covered outpatient drugs dispensed by health maintenance organizations are not subject to the requirements of this subpart.

(d) *Use of predetermined standards.* A DUR program must assess drug use information against predetermined standards.

(e) *Source of predetermined standards.* The predetermined standards must be—

(1) Developed directly by the State or its contractor;

(2) Obtained by the State through contracts with commercial vendors of DUR services;

(3) Obtained by the State from independent organizations, such as the United States Pharmacopeial Convention, or entities receiving funding from the Public Health Service, CMS, or State agencies; or

(4) Any combination of paragraphs (e)(1) through (e)(3) of this section.

(f) *Requirements for predetermined standards.* The predetermined standards used in the DUR program must meet the following requirements:

(1) The source materials for their development are consistent with peer-reviewed medical literature (that is, scientific, medical, and pharmaceutical publications in which original manuscripts are published only after having been critically reviewed by unbiased independent experts) and the following compendia:

(i) American Hospital Formulary Service Drug Information;

(ii) United States Pharmacopeia-Drug Information;

(iii) American Medical Association Drug Evaluations.

(2) Differences between source materials were resolved by physicians and pharmacists developing consensus solutions. The consensus process means the reliance, by the criteria developers, on the expertise of physicians and pharmacists to evaluate differences in criteria source materials and to come to agreement on how differences should be resolved.

(3) They are non-proprietary and readily available to providers of services. Systems and algorithms using the predetermined standards may remain proprietary.

(4) They are clinically-based and scientifically valid.

(5) The review based on clinical criteria uses predetermined standards to determine the population at risk of a clinically significant adverse medical result and applies standards, appropriate to this population, across providers and patients to determine the provider outliers whose prescribing, dispensing, or consumption practices may not conform to accepted standards of care. Various statistical measures (including mean, range, or other measures at the discretion of the State) may be applied to these data. Standards may be considered in deciding if an in-depth review is needed to determine whether to intervene once the potential therapeutic problems have been identified through the use of clinical criteria.

(6) They have been tested against claims data prior to adoption in order to validate the level of possibly significant therapeutic problems without undue levels of false positives.

(7) The predetermined standards for prospective and retrospective DUR are compatible.

(8) They are subjected to ongoing evaluation and modification either as a result of actions by their developer or as a result of recommendations by the DUR Board.

(g) *Access to predetermined standards.* Upon their adoption, predetermined standards must be available to the public. Pharmacists and physicians must be informed of the existence of predetermined standards and of how they can obtain copies of them.

(h) *Confidentiality of patient related data.* In implementing the DUR program, the agency must establish, in regulations or through other means, policies concerning confidentiality of patient related data that are consistent with applicable Federal confidentiality requirements at part 431, subpart F of this chapter; the State Pharmacy Practice Act; and the guidelines adopted by the State Board of Pharmacy or other relevant licensing bodies.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§ 456.705 Prospective drug review.

(a) *General.* Except as provided in §§ 456.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient, and applicable State law (including State Board policy incorporated in the State law by reference) must establish standards for counseling of the recipient or the recipient's caregiver. The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements, including guidelines on counseling, profiling, and documentation of prospective DUR activities by the pharmacists. The pharmacies, in turn, must provide this information to their pharmacists. This information is to be based on guidelines provided by this subpart and by other sources that the State may specify.

(b) *Point-of-sale or point-of-distribution review.* Except as provided in §§ 456.703 (b) and (c), the State plan must provide for point-of-sale or point-of-distribution review of drug therapy using predetermined standards before each prescription is filled or delivered to the recipient or the recipient's caregiver. The review must include screening to identify potential drug therapy problems of the following types:

(1) Therapeutic duplication, that is, the prescribing and dispensing of two or more drugs from the same therapeutic class such that the combined daily dose puts the recipient at risk of an adverse medical result or incurs additional program costs without additional therapeutic benefit.

(2) Drug-disease contraindication, that is, the potential for, or the occurrence of—

(i) An undesirable alteration of the therapeutic effect of a given drug because of the presence, in the patient for whom it is prescribed, of a disease condition; or

(ii) An adverse effect of the drug on the patient's disease condition.

(3) Adverse drug-drug interaction, that is, the potential for, or occurrence

of, a clinically significant adverse medical effect as a result of the recipient using two or more drugs together.

(4) Incorrect drug dosage, that is, the dosage lies outside the daily dosage specified in predetermined standards as necessary to achieve therapeutic benefit. Dosage is the strength multiplied by the quantity dispensed divided by day's supply.

(5) Incorrect duration of drug treatment, that is, the number of days of prescribed therapy exceeds or falls short of the recommendations contained in the predetermined standards.

(6) Drug-allergy interactions, that is, the significant potential for, or the occurrence of, an allergic reaction as a result of drug therapy.

(7) Clinical abuse/misuse, that is, the occurrence of situations referred to in the definitions of abuse, gross overuse, overutilization, and underutilization, as defined in § 456.702, and incorrect dosage and incorrect duration, as defined in paragraphs (b)(4) and (b)(5) of this section, respectively.

(c) *Drug counseling.* (1) As part of the prospective drug review program, standards for counseling by pharmacists of recipients or the recipients' caregivers must be established by State law or other method that is satisfactory to the State agency. A State agency's counseling standards must address special situations where the patient or the patient's representative, is not readily available to receive the offer to counsel or the actual counseling, for example, prescriptions delivered offsite or through the mail. The State agency, at a minimum, must also address the following issues in their counseling standards:

(i) Whether the offer to counsel is required for new prescriptions only, or for both new and refill prescriptions;

(ii) Whether pharmacists must make the offer to counsel or auxiliary personnel are authorized to make the offer;

(iii) Whether only a patient's refusal of the offer to counsel must be documented, or whether documentation of all offers is required;

(iv) Whether documentation of counseling is required; and

(v) Whether counseling is required in situations where the patient's representative is not readily available to receive a counseling offer or the counseling itself.

(2) The standards must meet the following requirements:

(i) They must require pharmacists to offer to counsel (in person, whenever practicable, or through access to a telephone service that is toll-free for long-distance calls) each recipient or recipient's caregiver who presents a prescription. A pharmacist whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Mail order pharmacies are required to provide toll-free telephone service for long distance calls.

(ii) They need not require a pharmacist to provide consultation when a Medicaid recipient or the recipient's caregiver refuses that consultation.

(iii) They must specify what documentation by the pharmacy of refusal of the offer of counseling is required.

(3) The standards must specify that the counseling include those matters listed in paragraphs (c)(3)(i) through (c)(3)(viii) of this section that, in the exercise of his or her professional judgement (consistent with State law regarding the provision of such information), the pharmacist considers significant as well as other matters the pharmacist considers significant.

(i) The name and description of the medication;

(ii) The dosage form, dosage, route of administration, and duration of drug therapy;

(iii) Special directions and precautions for preparation, administration, and use by the patient;

(iv) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) Techniques for self-monitoring drug therapy;

(vi) Proper storage;

(vii) Prescription refill information; and

(viii) Action to be taken in the event of a missed dose.

(d) *Profiling.* The State agency must require that, in the case of Medicaid recipients, the pharmacist make a reasonable effort to obtain, record, and

maintain patient profiles containing, at a minimum, the information listed in paragraphs (d)(1) through (d)(3) of this section.

(1) Name, address, telephone number, date of birth (or age), and gender of the patient;

(2) Individual history, if significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

(3) Pharmacist's comments relevant to the individual's drug therapy.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48824, Sept. 23, 1994]

§ 456.709 Retrospective drug use review.

(a) *General.* The State plan must provide for a retrospective DUR program for ongoing periodic examination (no less frequently than quarterly) of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and Medicaid recipients, or associated with specific drugs or groups of drugs. This examination must involve pattern analysis, using predetermined standards, of physician prescribing practices, drug use by individual patients and, where appropriate, dispensing practices of pharmacies. This program must be provided through the State's mechanized drug claims processing and information retrieval systems approved by CMS (that is, the Medicaid Management Information System (MMIS)) or an electronic drug claims processing system that is integrated with MMIS. States that do not have MMIS systems may use existing systems provided that the results of the examination of drug claims as described in this section are integrated within their existing system.

(b) *Use of predetermined standards.* Retrospective DUR includes, but is not limited to, using predetermined standards to monitor for the following:

(1) Therapeutic appropriateness, that is, drug prescribing and dispensing that is in conformity with the predetermined standards.

(2) Overutilization and underutilization, as defined in § 456.702.

(3) Appropriate use of generic products, that is, use of such products in conformity with State product selection laws.

(4) Therapeutic duplication as described in § 456.705(b)(1).

(5) Drug-disease contraindication as described in § 456.705(b)(2).

(6) Drug-drug interaction as described in § 456.705(b)(3).

(7) Incorrect drug dosage as described in § 456.705(b)(4).

(8) Incorrect duration of drug treatment as described in § 456.705(b)(5).

(9) Clinical abuse or misuse as described in § 456.705(b)(7).

§ 456.711 Educational program.

The State plan must provide for ongoing educational outreach programs that, using DUR Board data on common drug therapy problems, educate practitioners on common drug therapy problems with the aim of improving prescribing and dispensing practices. The program may be established directly by the DUR Board or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies, or other organizations. The program must include the interventions listed in paragraphs (a) through (d) of this section. The DUR Board determines the content of education regarding common therapy problems and the circumstances in which each of the interventions is to be used.

(a) Dissemination of information to physicians and pharmacists in the State concerning the duties and powers of the DUR Board and the basis for the standards required by § 456.705(c) for use in assessing drug use.

(b) Written, oral, or electronic reminders containing patient-specific or drug-specific information (or both) and suggested changes in prescribing or dispensing practices. These reminders must be conveyed in a manner designed to ensure the privacy of patient-related information.

(c) Face-to-face discussions, with follow up discussions when necessary, between health care professionals expert in appropriate drug therapy and selected prescribers and pharmacists who have been targeted for educational

intervention on optimal prescribing, dispensing, or pharmacy care practices.

(d) Intensified review or monitoring of selected prescribers or dispensers.

§ 456.712 Annual report.

(a) *DUR Board report.* The State must require the DUR Board to prepare and submit an annual DUR report to the Medicaid agency that contains information specified by the State.

(b) *Medicaid agency report.* The Medicaid agency must prepare and submit, on an annual basis, a report to the Secretary that incorporates the DUR Board's report and includes the following information:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use. After the first annual report, information regarding only new or changed criteria must be provided and deleted criteria must be identified.

(4) A description of the steps taken by the State to include in the prospective and retrospective DUR program drugs dispensed to residents of a nursing facility that is not in compliance with the drug regimen review procedures set forth in part 483 of this chapter. After the first annual report, only changes must be reported.

(5) A description of the actions taken by the State Medicaid agency and the DUR Board to ensure compliance with the requirements for predetermined standards at § 456.703(f) and with the access to the predetermined standards requirement at § 456.703(g). After the first annual report, only changes must be reported.

(6) A description of the nature and scope of the retrospective DUR program.

(7) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(8) A description of the steps taken by the State Agency to monitor compliance by pharmacies with the prospective DUR counseling requirements contained in Federal and State laws and regulations. After the first annual report, only changes must be reported.

(9) Clear statements of purpose that delineate the respective goals, objectives, and scopes of responsibility of the DUR and surveillance and utilization (SUR) functions. These statements must clarify the working relationships between DUR and SUR functions and other entities such as the Medicaid Fraud Control Unit and State Board of Pharmacy. The annual report also must include a statement delineating how functional separation will be maintained between the fraud and abuse activities and the educational activities. After the first annual report, only changes must be reported.

(10) An estimate of the cost savings generated as a result of the DUR program. This report must identify costs of DUR and savings to the Medicaid drug program attributable to prospective and retrospective DUR.

§ 456.714 DUR/surveillance and utilization review relationship.

(a) The retrospective DUR requirements in this subpart parallel a portion of the surveillance and utilization review (SUR) requirements in subpart A of this part and in part 455 of this chapter.

(b) A State agency may direct DUR staffs to limit review activities to those that focus on what constitutes appropriate and medically necessary care to avoid duplication of activities relating to fraud and abuse under the SUR program.

[59 FR 48825, Sept. 23, 1994]

§ 456.716 DUR Board.

(a) *State DUR Board requirement and member qualifications.* Each State must establish, either directly or through a contract with a private organization, a DUR Board. The DUR Board must include health care professionals who have recognized knowledge and expertise in at least one of the following:

(1) Clinically appropriate prescribing of covered outpatient drugs.

(2) Clinically appropriate dispensing and monitoring of covered outpatient drugs.

(3) Drug use review, evaluation, and intervention.

(4) Medical quality assurance.

(b) *Board composition.* At least one-third but not more than 51 percent of the DUR Board members must be physicians, and at least one-third of the Board members must be pharmacists. These physicians and pharmacists must be actively practicing and licensed.

(c) *Medicaid agency/DUR Board relationship.* The Medicaid agency is ultimately responsible for ensuring that the DUR program is operational and conforms with the requirements of this subpart. The agency has the authority to accept or reject the recommendations or decisions of the DUR Board.

(d) *DUR Board activities.* The State agency must ensure that the operational tasks involved in carrying out the DUR Board activities set forth at section 1927(g)(3)(C) of the Act are assigned, limited only by the requirements of section 1927(g)(3)(C) of the Act, based on consideration of operational requirements and on where the necessary expertise resides. Except as limited by the requirements of section 1927(g)(3)(C) of the Act, the State agency may alter the suggested working relationships set forth in this paragraph.

(1) *Application of predetermined standards: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Evaluate the use of the predetermined standards, including assessing the operational effect of the predetermined standards in use, and make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(iii) Recommend guidelines governing written predetermined standards that pharmacies not using approved software must use in conducting prospective DUR.

(2) *Application of predetermined standards: Medicaid agency role.* The Medicaid agency or its contractor should perform the following activities:

(i) Submit predetermined standards to the DUR Board for its review and recommendations before the Medicaid agency applies them to drug claims data.

(ii) If prospective DUR is conducted using an electronic claims management (ECM) system, apply software approved by the Board.

(iii) If prospective DUR is not conducted through an ECM system, as part of general compliance monitoring, ensure that Medicaid participating pharmacies conduct prospective drug review that screens for the potential drug therapy problems listed in section 1927(g)(2)(A) of the Act.

(3) *Retrospective DUR: Board's activities.* The DUR Board should perform the following activities:

(i) Review and make recommendations on predetermined standards submitted to it by the Medicaid agency or the agency's contractor.

(ii) Make recommendations to the Medicaid agency or the agency's contractor concerning modification or elimination of existing predetermined standards or the addition of new ones.

(4) *Retrospective DUR: Medicaid agency role.* The Medicaid agency or its contractor should apply the predetermined standards to drug claims data in order to generate reports that identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

(5) *Education program (including interventions): Board's activities.* The DUR Board must perform the following activities:

(i) Identify and develop educational topics if education of practitioners on common drug therapy problems is needed to improve prescribing or dispensing practices.

(ii) Make recommendations as to which mix of the interventions set forth in §§ 456.711 (a) through (d) would most effectively lead to improvement in the quality of drug therapy. The DUR board recommendations must be based upon an in-depth review of the results of the application of predetermined standards against claims data reports, must be appropriate based upon program experience, and must match the educational program with the drug therapy problems identified.

(iii) Periodically re-evaluate and, if necessary, modify the interventions.

(6) *Education program (including interventions): Medicaid agency's role.* The Medicaid agency or its contractor should perform the following activities.

(i) Apply predetermined standards to drug claims data to generate reports that provide the basis for retrospective education and interventions and furnish those reports to the Board.

(ii) Carry out the educational programs and interventions specified by the Board.

(e) *Funding for the Board.* FFP is available for expenses associated with the operation of the DUR Board in carrying out its responsibilities, and payment is made under procedures established in part 433 of this chapter as follows:

(1) If the requirements for skilled professional medical personnel at § 432.50 of this chapter are met, at the rate of 75 percent.

(2) If the requirements for skilled professional medical personnel at § 432.50 of this chapter are not met, at the rate specified in § 456.719.

[57 FR 49408, Nov. 2, 1992, as amended at 59 FR 48825, Sept. 23, 1994]

§ 456.719 Funding for DUR program.

FFP is available for sums that the Secretary determines are attributable to the Statewide adoption of a DUR program as described in this subpart, and payment is made under procedures established in part 433 of this chapter as follows:

(a) For funds expended by the State during calendar years 1991 through 1993, at the rate of 75 percent.

(b) For funds expended by the State after December 31, 1993, at the rate of 50 percent.

§ 456.722 Electronic claims management system.

(a) *Point-of-sale system.* Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is, immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. The State determines who must participate in an ECM system and who may decline to do so. If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) *Functional requirements.* The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. The real-time requirement for prescriptions filled for nursing facilities and prescriptions filled by mail order dispensers may be waived by the State to permit claims to be processed in the batch mode at the end of the day or other time mutually agreed to by the nursing facility or mail order dispenser and Medicaid agency.

(1) Eligibility verification, including identification of the following:

(i) Third-party payers.

(ii) Recipients in managed care programs.

(iii) Recipients and providers in restricted service programs (for example, lock-in and lock-out).

(iv) Properly enrolled providers.

(2) Claims data capture, including the following:

(i) Transfer of claims information from the pharmacy to the Medicaid agency or the Medicaid agency's contractor.

(ii) Identification of prescriber.

(iii) Minimum data set (as defined in Part 11 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

(c) *Additional requirements.* In order to receive FFP for its ECM system, the

State must meet the following requirements:

(1) The ECM system must be acquired through applicable competitive procurement process in the State and must be the most cost-effective telecommunications network and automatic data processing services and equipment. The procurement must meet the procurement requirements set forth in 45 CFR part 74, subpart P, and appendix G-O of OMB circular A–102. The request for proposal (RFP) may be substituted for the advance planning and implementation documents otherwise required by part 433 of this chapter, 45 CFR 95.205, and 45 CFR part 307. A cost-benefit analysis must accompany the RFP. If in its advance planning document, a State establishes that a separate procurement is not cost-effective, modification of an existing fiscal agent contract will be acceptable. In this case, procurement of network services and equipment (but not software modifications) must be competitively procured.

(2) States wishing to do prospective DUR as part of their ECM must do the following:

(i) Submit a cost benefit analysis showing the cost-effectiveness of such a system. A State's decisions as to who must participate in the ECM system and who may decline to do so must be included in the cost-benefit analysis.

(ii) Establish a central State-wide electronic repository for capturing, storing, and updating data for all prescriptions dispensed and for providing access to such data by all authorized participants.

(iii) Design the system to assess data for a review of drug therapy before each prescription is filled or delivered to a Medicaid recipient. The type of review conducted must meet the requirements for prospective drug review set forth in § 456.705.

(3) ECM is considered a subsystem and must be fully integrated with the remainder of the State's MMIS. In addition, information about ECM claims must be part of the single comprehensive utilization and management reporting system used by the DUR program.

§ 456.725 Funding of ECM system.

(a) For funds expended during calendar quarters in fiscal years 1991 and 1992 and attributable to the design, development, and implementation of an on-line, real-time claims management system (that is, the most cost-effective telecommunications network and automatic data processing services and equipment) that meets the requirements of § 456.722, FFP is available at a matching rate of 90 percent. After fiscal year 1992, ECM subsystems are funded at the standard applicable MMIS enhanced rates, subject to the requirements of part 433, subpart A of this chapter.

(b) FFP is available at a matching rate of 75 percent for funds expended for the following:

(1) Telecommunications equipment and other equipment to directly access MMIS files.

(2) Telecommunications equipment (such as modems and point of sale terminals) furnished to providers.

(3) Operational costs including telecommunications network costs, provided that the ECM system includes eligibility verification systems, electronic claims capture, claims adjudication (except for payment), and a claims data process that is integrated into a single comprehensive utilization and information reporting system.

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457.1190 Application of review procedures when States offer premium assistance for group health plans.

AUTHORITY: Section 1102 of the Social Security Act (42 U.S.C. 1302).

SOURCE: 65 FR 33622, May 24, 2000, unless otherwise noted.

Subpart A—Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

SOURCE: 66 FR 2670, Jan. 11, 2001, unless otherwise noted.

§ 457.1 Program description.

Title XXI of the Social Security Act, enacted in 1997 by the Balanced Budget Act, authorizes Federal grants to States for provision of child health assistance to uninsured, low-income children. The program is jointly financed by the Federal and State governments and administered by the States. Within broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures.

§ 457.2 Basis and scope of subchapter D.

(a) *Basis.* This subchapter implements title XXI of the Act, which authorizes Federal grants to States for the provision of child health assistance to uninsured, low-income children.

(b) *Scope.* The regulations in subchapter D set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP) to enable States to provide health benefits coverage to targeted low-income children, as defined at § 457.310.

§ 457.10 Definitions and use of terms.

For purposes of this part the following definitions apply:

American Indian/Alaska Native (AI/AN) means—

(1) A member of a Federally recognized Indian tribe, band, or group;

(2) An Eskimo or Aleut or other Alaska Native enrolled by the Secretary of the Interior pursuant to the Alaska Native Claims Settlement Act, 43 U.S.C. 1601 et. seq.; or

(3) A person who is considered by the Secretary of the Interior to be an Indian for any purpose.

Applicant means a child who has filed an application (or who has an application filed on their behalf) for health benefits coverage through the State Children's Health Insurance Program. A child is an applicant until the child receives coverage through SCHIP.

Child means an individual under the age of 19 including the period from conception to birth.

Child health assistance means payment for part or all of the cost of health benefits coverage provided to targeted low-income children for the services listed at § 457.402.

Combination program means a program under which a State implements both a Medicaid expansion program and a separate child health program.

Cost sharing means premium charges, enrollment fees, deductibles, coinsurance, copayments, or other similar fees that the enrollee has responsibility for paying.

Creditable health coverage has the meaning given the term ''creditable coverage'' at 45 CFR 146.113 and includes coverage that meets the requirements of § 457.410 and is provided to a targeted low-income child.

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

(1) Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of a woman or her unborn child;

(2) Serious impairment of bodily function; or

(3) Serious dysfunction of any bodily organ or part.

Emergency services means health care services that are—

(1) Furnished by any provider qualified to furnish such services; and (2) Needed to evaluate, treat, or stabilize an emergency medical condition.

Enrollee means a child who receives health benefits coverage through SCHIP.

Enrollment cap means a limit, established by the State in its State plan, on the total number of children permitted to enroll in a State's separate child health program.

Family income means income as determined by the State for a family as defined by the State.

Federal fiscal year starts on the first day of October each year and ends on the last day of the following September.

Fee-for-service entity has the meaning assigned in § 457.902.

Group health insurance coverage has the meaning assigned at 45 CFR 144.103.

Group health plan has the meaning assigned at 45 CFR 144.103.

Health benefits coverage means an arrangement under which enrolled individuals are protected from some or all liability for the cost of specified health care services.

Health care services means any of the services, devices, supplies, therapies, or other items listed in § 457.402.

Health insurance coverage has the meaning assigned at 45 CFR 144.103.

Health insurance issuer has the meaning assigned at 45 CFR 144.103.

Health maintenance organization (HMO) plan has the meaning assigned at § 457.420.

Health services initiatives means activities that protect the public health, protect the health of individuals, improve or promote a State's capacity to deliver public health services, or strengthen the human and material resources necessary to accomplish public health goals relating to improving the health of children (including targeted low-income children and other low-income children).

Joint application has the meaning assigned at § 457.301.

Low-income child means a child whose family income is at or below 200 percent of the poverty line for the size of the family involved.

Managed care entity (MCE) means an entity that enters into a contract to provide services in a managed care delivery system, including but not limited to managed care organizations, prepaid health plans, and primary care case managers.

Medicaid applicable income level means, with respect to a child, the effective income level (expressed as a percentage of the poverty line) specified under the policies of the State plan under title XIX of the Act (including for these purposes, a section 1115 waiver authorized by the Secretary or under the authority of section 1902(r)(2) of the Act) as of March 31, 1997 for the child to be eligible for medical assistance under either section 1902(l)(2) or 1905(n)(2) of the Act.

Medicaid expansion program means a program under which a State receives Federal funding to expand Medicaid eligibility to optional targeted low-income children.

Optional targeted low-income child has the meaning assigned at § 435.4 (for States) and § 436.3 (for Territories) of this chapter.

Period of presumptive eligibility has the meaning assigned at § 457.301.

Poverty line/Federal poverty level means the poverty guidelines updated annually in the FEDERAL REGISTER by the U.S. Department of Health and Human Services under authority of 42 U.S.C. 9902(2).

Preexisting condition exclusion has the meaning assigned at 45 CFR 144.103.

Premium assistance program means a component of a separate child health program, approved under the State plan, under which a State pays part or all of the premiums for a SCHIP enrollee or enrollees' group health insurance coverage or coverage under a group health plan.

Presumptive income standard has the meaning assigned at § 457.301.

Public agency has the meaning assigned in § 457.301.

Qualified entity has the meaning assigned at § 457.301.

Separate child health program means a program under which a State receives Federal funding from its title XXI allotment to provide child health assistance through obtaining coverage that meets the requirements of section 2103 of the Act and § 457.402.

State means all States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa and the Northern Mariana Islands. The Territories are excluded from this definition for purposes of § 457.740.

State Children's Health Insurance Program (SCHIP) means a program established and administered by a State, jointly funded with the Federal government, to provide child health assistance to uninsured, low-income children through a separate child health program, a Medicaid expansion program, or a combination program.

State health benefits plan has the meaning assigned in § 457.301.

State plan means the title XXI State child health plan.

Targeted low-income child has the meaning assigned in § 457.310.

Uncovered or uninsured child means a child who does not have creditable health coverage.

Well-baby and well-child care services means regular or preventive diagnostic and treatment services necessary to ensure the health of babies, children and adolescents as defined by the State. For purposes of cost sharing, the term has the meaning assigned at § 457.520.

[66 FR 2670, Jan. 11, 2001, as amended at 67 FR 61974, Oct. 2, 2002]

§ 457.30 Basis, scope, and applicability of subpart A.

(a) *Statutory basis.* This subpart implements the following sections of the Act:

(1) Section 2101(b), which requires that the State submit a State plan.

(2) Section 2102(a), which sets forth requirements regarding the contents of the State plan.

(3) Section 2102(b), which relates to eligibility standards and methodologies.

(4) Section 2102(c), which requires that the State plan include a description of the procedures to be used by the State to accomplish outreach and coordination with other health insurance programs.

(5) Section 2106, which specifies the process for submission, approval, and amendment of State plans.

(6) Section 2107(c), which requires that the State plan include a description of the process used to involve the public in the design and implementation of the plan.

(7) Section 2107(d), which requires that the State plan include a description of the budget for the plan.

(8) Section 2107(e), which provides that certain provisions of title XIX and title XI of the Act apply under title XXI in the same manner that they apply under title XIX.

(b) *Scope.* This subpart sets forth provisions governing the administration of SCHIP, the general requirements for a State plan, and a description of the process for review of a State plan or plan amendment.

(c) *Applicability.* This subpart applies to all States that request Federal financial participation to provide child health assistance under title XXI.

§ 457.40 State program administration.

(a) *Program operation.* The State must implement its program in accordance with the approved State plan, any approved State plan amendments, the requirements of title XXI and title XIX (as appropriate), and the requirements in this chapter. CMS monitors the operation of the approved State plan and plan amendments to ensure compliance with the requirements of title XXI, title XIX (as appropriate) and this chapter.

(b) *State authority to submit State plan.* A State plan or plan amendment must be signed by the State Governor, or signed by an individual who has been delegated authority by the Governor to submit it.

(c) *State program officials.* The State must identify in the State plan or State plan amendment, by position or title, the State officials who are responsible for program administration and financial oversight.

(d) *State legislative authority.* The State plan must include an assurance that the State will not claim expenditures for child health assistance prior to the time that the State has legislative authority to operate the State plan or plan amendment as approved by CMS.

§ 457.50 State plan.

The State plan is a comprehensive written statement, submitted by the State to CMS for approval, that describes the purpose, nature, and scope of the State's SCHIP and gives an assurance that the program is administered in conformity with the specific requirements of title XXI, title XIX (as appropriate), and the regulations in this chapter. The State plan contains all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program.

§ 457.60 Amendments.

A State may seek to amend its approved State plan in whole or in part at any time through the submission of an amendment to CMS. When the State plan amendment has a significant impact on the approved budget, the amendment must include an amended budget that describes the State's planned expenditures for a 1-year period. A State must amend its State plan whenever necessary to reflect—

(a) Changes in Federal law, regulations, policy interpretations, or court decisions that affect provisions in the approved State plan;

(b) Changes in State law, organization, policy, or operation of the program that affect the following program elements described in the State plan:

(1) Eligibility standards, enrollment caps, and disenrollment policies as described in § 457.305.

(2) Procedures to prevent substitution of private coverage as described in § 457.805, and in § 457.810 for premium assistance programs.

(3) The type of health benefits coverage offered, consistent with the options described in § 457.410.

(4) Addition or deletion of specific categories of benefits covered under the State plan.

(5) Basic delivery system approach as described in § 457.490.

(6) Cost-sharing as described in § 457.505.

(7) Screen and enroll procedures, and other Medicaid coordination procedures as described in § 457.350.

(8) Review procedures as described in § 457.1120.

(9) Other comparable required program elements.

(c) Changes in the source of the State share of funding, except for changes in the type of non-health care related revenues used to generate general revenue.

[66 FR 2670, Jan. 11, 2001, as amended at 66 FR 33822, June 25, 2001]

§ 457.65 Effective date and duration of State plans and plan amendments.

(a) *Effective date in general.* Except as otherwise limited by this section—

(1) A State plan or plan amendment takes effect on the day specified in the plan or plan amendment, but no earlier than October 1, 1997.

(2) The effective date may be no earlier than the date on which the State begins to incur costs to implement its State plan or plan amendment.

(3) A State plan amendment that takes effect prior to submission of the amendment to CMS may remain in effect only until the end of the State fiscal year in which the State makes it effective, or, if later, the end of the 90-day period following the date on which the State makes it effective, unless the State submits the amendment to CMS for approval before the end of that State fiscal year or that 90-day period.

(b) *Amendments relating to eligibility or benefits.* A State plan amendment that eliminates or restricts eligibility or benefits may not be in effect for longer than a 60-day period, unless the amendment is submitted to CMS before the end of that 60-day period. The amendment may not take effect unless—

(1) The State certifies that it has provided prior public notice of the proposed change in a form and manner provided under applicable State law; and

(2) The public notice was published before the requested effective date of the change.

(c) *Amendments relating to cost sharing.* A State plan amendment that implements cost-sharing charges, increases existing cost-sharing charges, or increases the cumulative cost-sharing maximum as set forth at § 457.560 is considered an amendment that restricts benefits and must meet the requirements in paragraph (b) of this section.

(d) *Amendments relating to enrollment procedures.* A State plan amendment that implements a required period of uninsurance, increases the length of existing required periods of uninsurance, or institutes or extends the use of waiting lists, enrollments caps or closed enrollment periods is considered an amendment that restricts eligibility and must meet the requirements in paragraph (b) of this section.

(e) *Amendments relating to the source of State funding.* A State plan amendment that changes the source of the State share of funding can take effect

no earlier than the date of submission of the amendment.

(f) *Continued approval.* An approved State plan continues in effect unless—

(1) The State adopts a new plan by obtaining approval under § 457.60 of an amendment to the State plan;

(2) Withdraws its plan in accordance with § 457.170(b); or

(3) The Secretary finds substantial noncompliance of the plan with the requirements of the statute or regulations.

§ 457.70 Program options.

(a) *Health benefits coverage options.* A State may elect to obtain health benefits coverage under its plan through—

(1) A separate child health program;

(2) A Medicaid expansion program; or

(3) A combination program.

(b) *State plan requirement.* A State must include in the State plan or plan amendment a description of the State's chosen program option.

(c) *Medicaid expansion program requirements.* A State plan under title XXI for a State that elects to obtain health benefits coverage through its Medicaid plan must—

(1) Meet the requirements of—

(i) Subpart A;

(ii) Subpart B (to the extent that the State claims administrative costs under title XXI);

(iii) Subpart F (with respect to determination of the allotment for purposes of the enhanced matching rate, determination of the enhanced matching rate, and payment of any claims for administrative costs under title XXI only);

(iv) Subpart G; and

(v) Subpart J (if the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims based on a community based health delivery system).

(2) Be consistent with the State's Medicaid State plan, or an approvable amendment to that plan, as required under title XIX.

(d) *Separate child health program requirements.* A State that elects to obtain health benefits coverage under its plan through a separate child health program must meet all the requirements of part 457.

(e) *Combination program requirements.* A State that elects to obtain health benefits coverage through both a separate child health program and a Medicaid expansion program must meet the requirements of paragraphs (c) and (d) of this section.

§ 457.80 Current State child health insurance coverage and coordination.

A State plan must include a description of—

(a) The extent to which, and manner in which, children in the State, including targeted low-income children and other classes of children, by income level and other relevant factors, currently have creditable health coverage (as defined in § 457.10) and, if sufficient information is available, whether the creditable health coverage they have is under public health insurance programs or health insurance programs that involve public-private partnerships;

(b) Current State efforts to provide or obtain creditable health coverage for uncovered children, including the steps the State is taking to identify and enroll all uncovered children who are eligible to participate in public health insurance programs and health insurance programs that involve public-private partnerships; and

(c) Procedures the State uses to accomplish coordination of SCHIP with other public and private health insurance programs, sources of health benefits coverage for children, and relevant child health programs, such as title V, that provide health care services for low-income children. Such procedures include those designed to—

(1) Increase the number of children with creditable health coverage;

(2) Assist in the enrollment in SCHIP of children determined ineligible for Medicaid; and

(3) Ensure that only eligible targeted low-income children are covered under SCHIP, such as those procedures required under §§ 457.350 and 457.353, as applicable.

§ 457.90 Outreach.

(a) *Procedures required.* A State plan must include a description of procedures used to inform families of children likely to be eligible for child

health assistance under the plan or under other public or private health coverage programs of the availability of the programs, and to assist them in enrolling their children in one of the programs.

(b) *Examples.* Outreach strategies may include but are not limited to the following:

(1) Education and awareness campaigns, including targeted mailings and information distribution through various organizations.

(2) Enrollment simplification, such as simplified or joint application forms.

(3) Application assistance, including opportunities to apply for child health assistance under the plan through community-based organizations and in combination with other benefits and services available to children.

§ 457.110 Enrollment assistance and information requirements.

(a) *Information disclosure.* The State must make accurate, easily understood, linguistically appropriate information available to families of potential applicants, applicants and enrollees, and provide assistance to these families in making informed decisions about their health plans, professionals, and facilities.

(b) *Required information.* The State must make available to potential applicants and provide applicants and enrollees the following information in a timely manner:

(1) Types of benefits, and amount, duration and scope of benefits available under the program.

(2) Cost-sharing requirements as described in § 457.525.

(3) Names and locations of current participating providers.

(4) If an enrollment cap is in effect or the State is using a waiting list, a description of the procedures relating to the cap or waiting list, including the process for deciding which children will be given priority for enrollment, how children will be informed of their status on a waiting list and the circumstances under which enrollment will reopen.

(5) Information on physician incentive plans as required by § 457.985.

(6) Review processes available to applicants and enrollees as described in the State plan pursuant to § 457.1120.

§ 457.120 Public involvement in program development.

A State plan must include a description of the method the State uses to—

(a) Involve the public in both the design and initial implementation of the program;

(b) Ensure ongoing public involvement once the State plan has been implemented; and

(c) Ensure interaction with Indian Tribes and organizations in the State on the development and implementation of the procedures required at § 457.125.

§ 457.125 Provision of child health assistance to American Indian and Alaska Native children.

(a) *Enrollment.* A State must include in its State plan a description of procedures used to ensure the provision of child health assistance to American Indian and Alaska Native children.

(b) *Exemption from cost sharing.* The procedures required by paragraph (a) of this section must include an exemption from cost sharing for American Indian and Alaska Native children in accordance with § 457.535.

§ 457.130 Civil rights assurance.

The State plan must include an assurance that the State will comply with all applicable civil rights requirements, including title VI of the Civil Rights Act of 1964, title II of the Americans with Disabilities Act of 1990, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, 45 CFR part 80, part 84, and part 91, and 28 CFR part 35.

§ 457.135 Assurance of compliance with other provisions.

The State plan must include an assurance that the State will comply, under title XXI, with the following provisions of titles XIX and XI of the Social Security Act:

(a) Section 1902(a)(4)(C) (relating to conflict of interest standards).

(b) Paragraphs (2), (16) and (17) of section 1903(i) (relating to limitations on payment).

(c) Section 1903(w) (relating to limitations on provider donations and taxes).

(d) Section 1132 (relating to periods within which claims must be filed).

§ 457.140 Budget.

The State plan, or plan amendment that has a significant impact on the approved budget, must include a budget that describes the State's planned expenditures for a 1-year period. The budget must describe—

(a) Planned use of funds, including—

(1) Projected amount to be spent on health services;

(2) Projected amount to be spent on administrative costs, such as outreach, child health initiatives, and evaluation; and

(3) Assumptions on which the budget is based, including cost per child and expected enrollment; and

(b) Projected sources of non-Federal plan expenditures, including any requirements for cost sharing by enrollees.

§ 457.150 CMS review of State plan material.

(a) *Basis for action.* CMS reviews each State plan and plan amendment to determine whether it meets or continues to meet the requirements for approval under relevant Federal statutes, regulations, and guidelines furnished by CMS to assist in the interpretation of these regulations.

(b) *Action on complete plan.* CMS approves or disapproves the State plan or plan amendment only in its entirety.

(c) *Authority.* The CMS Administrator exercises delegated authority to review and then to approve or disapprove the State plan or plan amendment, or to determine that previously approved material no longer meets the requirements for approval. The Administrator does not make a final determination of disapproval without first consulting the Secretary.

(d) *Initial submission.* The Administrator designates an official to receive the initial submission of State plans.

(e) *Review process.* (1) The Administrator designates an individual to coordinate CMS's review for each State that submits a State plan.

(2) CMS notifies the State of the identity of the designated individual in the first correspondence relating to that plan, and at any time there is a change in the designated individual.

(3) In the temporary absence of the designated individual during regular business hours, an alternate individual will act in place of the designated individual.

§ 457.160 Notice and timing of CMS action on State plan material.

(a) *Notice of final determination.* The Administrator provides written notification to the State of the approval or disapproval of a State plan or plan amendment.

(b) *Timing.* (1) A State plan or plan amendment will be considered approved unless CMS, within 90 calendar days after receipt of the State plan or plan amendment in the CMS central office, sends the State—

(i) Written notice of disapproval; or

(ii) Written notice of additional information it needs in order to make a final determination.

(2) A State plan or plan amendment is considered received when the designated official or individual, as determined in § 457.150(d) and (e), receives an electronic, fax or paper copy of the complete material.

(3) If CMS requests additional information, the 90-day review period for CMS action on the State plan or plan amendment—

(i) Stops on the day CMS sends a written request for additional information or the next business day if the request is sent on a Federal holiday or weekend; and

(ii) Resumes on the next calendar day after the CMS designated individual receives an electronic, fax, or hard copy from the State of all the requested additional information, unless the information is received after 5 p.m. eastern standard time on a day prior to a non-business day or any time on a non-business day, in which case the review period resumes on the following business day.

(4) The 90-day review period cannot stop or end on a non-business day. If the 90th calendar day falls on a non-business day, CMS will consider the 90th day to be the next business day.

(5) CMS may send written notice of its need for additional information as many times as necessary to obtain the complete information necessary to review the State plan or plan amendment.

§ 457.170 Withdrawal process.

(a) *Withdrawal of proposed State plans or plan amendments.* A State may withdraw a proposed State plan or plan amendment, or any portion of a proposed State plan or plan amendment, at any time during the review process by providing written notice to CMS of the withdrawal.

(b) *Withdrawal of approved State plans.* A State may request withdrawal of an approved State plan by submitting a State plan amendment to CMS in accordance with § 457.60.

Subpart B—General Administration—Reviews and Audits; Withholding for Failure to Comply; Deferral and Disallowance of Claims; Reduction of Federal Medical Payments

§ 457.200 Program reviews.

(a) *Review of State and local administration of the SCHIP plan.* In order to determine whether the State is complying with the Federal requirements and the provisions of its plan, CMS reviews State and local administration of the SCHIP plan through analysis of the State's policies and procedures, on-site reviews of selected aspects of agency operation, and examination of samples of individual case records.

(b) *Action on review findings.* If Federal or State reviews reveal serious problems with respect to compliance with any Federal or State plan requirement, the State must correct its practice accordingly.

§ 457.202 Audits.

(a) *Purpose.* The Department's Office of Inspector General (OIG) periodically audits State operations in order to determine whether—

(1) The program is being operated in a cost-efficient manner; and

(2) Funds are being properly expended for the purposes for which they were appropriated under Federal and State law and regulations.

(b) *Reports.* (1) The OIG releases audit reports simultaneously to State officials and the Department's program officials.

(2) The reports set forth OIG opinion and recommendations regarding the practices it reviewed, and the allowability of the costs it audited.

(3) Cognizant officials of the Department make final determinations on all audit findings.

(c) *Action on audit exceptions*—(1) *Concurrence or clearance.* The State agency has the opportunity of concurring in the exceptions or submitting additional facts that support clearance of the exceptions.

(2) *Appeal.* Any exceptions that are not disposed of under paragraph (c)(1) of this section are included in a disallowance letter that constitutes the Department's final decision unless the State requests reconsideration by the Appeals Board. (Specific rules are set forth in § 457.212.)

(3) *Adjustment.* If the decision by the Board requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

§ 457.203 Administrative and judicial review of action on State plan material.

(a) *Request for reconsideration.* Any State dissatisfied with the Administrator's action on State plan material under § 457.150 may, within 60 days after receipt of the notice of final determination provided under § 457.160(a), request that the Administrator reconsider whether the State plan or plan amendment conforms with the requirements for approval.

(b) *Notice of hearing.* Within 30 days after receipt of the request, the Administrator notifies the State of the time and place of a hearing to be held for the purpose of reconsideration.

(c) *Hearing procedures.* The hearing procedures set forth in part 430, subpart D of this chapter govern a hearing requested under this section.

(d) *Effect of hearing decision.* CMS does not delay the denial of Federal funds, if required by the Administrator's original determination, pending a

hearing decision. If the Administrator determines that his or her original decision was incorrect, CMS will pay the State a lump sum equal to any funds incorrectly denied.

[66 FR 2674, Jan. 11, 2001]

§ 457.204 Withholding of payment for failure to comply with Federal requirements.

(a) *Basis for withholding.* CMS withholds payments to the State, in whole or in part, only if, after giving the State notice, a reasonable opportunity for correction, and an opportunity for a hearing, the Administrator finds—

(1) That the plan is in substantial noncompliance with the requirements of title XXI of the Act; or

(2) That the State is conducting its program in substantial noncompliance with either the State plan or the requirements of title XXI of the Act. (Hearings are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions. These efforts may be continued even if a date and place have been set for the hearing.)

(b) *Noncompliance of the plan.* A question of noncompliance of a State plan may arise from an unapprovable change in the approved State plan or the failure of the State to change its approved plan to conform to a new Federal requirement for approval of State plans.

(c) *Noncompliance in practice.* A question of noncompliance in practice may arise from the State's failure to actually comply with a Federal requirement, regardless of whether the plan itself complies with that requirement.

(d) *Notice, reasonable opportunity for correction, and implementation of withholding.* If the Administrator makes a finding of noncompliance under paragraph (a) of this section, the following steps apply:

(1) *Preliminary notice.* The Administrator provides a preliminary notice to the State—

(i) Of the findings of noncompliance;

(ii) The proposed enforcement actions to withhold payments; and

(iii) If enforcement action is proposed, that the State has a reasonable opportunity for correction, described in paragraph (d)(2) of this section, before the Administrator takes final action.

(2) *Opportunity for corrective action.* If enforcement actions are proposed, the State must submit evidence of corrective action related to the findings of noncompliance to the Administrator within 30 days from the date of the preliminary notification. Corrective action is action to ensure that the plan is, and will be, administered consistent with applicable law and regulations, to ameliorate past deficiencies in plan administration, or to ensure that enrollees will be treated equitably.

(3) *Final notice.* Taking into account any evidence submitted by the State under paragraph (d)(2) of this section, the Administrator makes a final determination related to the findings of noncompliance, and provides a final notice to the State—

(i) Of the final determination on the findings of noncompliance;

(ii) If enforcement action is appropriate—

(A) No further payments will be made to the State (or that payments will be made only for those portions or aspects of the programs that are not affected by the noncompliance); and

(B) The total or partial withholding will continue until the Administrator is satisfied that the State's plan and practice are, and will continue to be, in compliance with Federal requirements.

(4) *Hearing.* An opportunity for a hearing will be provided to the State prior to withholding under paragraph (d)(5) of this section.

(5) Withholding. CMS withholds payments, in whole or in part, until the Administrator is satisfied regarding the State's compliance.

[65 FR 33622, May 24, 2000, as amended at 66 FR 2674, Jan. 11, 2001]

§ 457.206 Administrative appeals under SCHIP.

Three distinct types of determinations are subject to Departmental reconsideration upon request by a State.

(a) *Compliance with Federal requirements.* A determination that a State's plan or proposed plan amendments, or its practice under the plan do not meet

(or continue to meet) Federal requirements are subject to the hearing provisions of 42 CFR part 430, subpart D of this chapter.

(b) *FFP in State SCHIP expenditures.* Disallowances of FFP in State SCHIP expenditures (mandatory grants) are subject to Departmental reconsideration by the Departmental Appeals Board (the Board) in accordance with procedures set forth in 45 CFR part 16.

(c) *Discretionary grants disputes.* Determinations listed in 45 CFR part 16, appendix A, pertaining to discretionary grants, such as grants for special demonstration projects under Section 1115 of the Act, that may be awarded to an SCHIP agency, are subject to reconsideration by the Departmental Grant Appeals Board.

§ 457.208 Judicial review.

(a) *Right to judicial review.* Any State dissatisfied with the Administrator's final determination on approvability of plan material (§ 457.203) or compliance with Federal requirements (§ 457.204) has a right to judicial review.

(b) *Petition for review.* (1) The State must file a petition for review with the U.S. Court of Appeals for the circuit in which the State is located, within 60 days after it is notified of the determination.

(2) After the clerk of the court files a copy of the petition with the Administrator, the Administrator files in the court the record of the proceedings on which the determination was based.

(c) *Court action.* (1) The court is bound by the Administrator's findings of fact, if they are supported by substantial evidence.

(2) The court has jurisdiction to affirm the Administrator's decision, to set it aside in whole or in part, or, for good cause, to remand the case for additional evidence.

(d) *Response to remand.* (1) If the court remands the case, the Administrator may make new or modified findings of fact and may modify his or her previous determination.

(2) The Administrator certifies to the court the transcript and record of the further proceedings.

(e) *Review by the Supreme Court.* The judgment of the appeals court is subject to review by the U.S. Supreme Court upon certiorari or certification, as provided in 28 U.S.C. 1254.

[65 FR 33622, May 24, 2000, as amended at 66 FR 2674, Jan. 11, 2001]

§ 457.210 Deferral of claims for FFP.

(a) *Requirements for deferral.* Payment of a claim or any portion of a claim for FFP is deferred only if—

(1) The Regional Administrator or the Administrator questions its allowability and needs additional information in order to resolve the question; and

(2) CMS takes action to defer the claim (by excluding the claimed amount from the grant award) within 60 days after the receipt of a Quarterly Statement of Expenditures (prepared in accordance with CMS instructions) that includes that claim.

(b) *Notice of deferral and State's responsibility.* (1) Within 15 days of the action described in paragraph (a)(2) of this section, the Regional Administrator sends the State a written notice of deferral that—

(i) Identifies the type and amount of the deferred claim and specifies the reason for deferral; and

(ii) Requests the State to make available all the documents and materials the CMS regional office believes are necessary to determine the allowability of the claim.

(2) It is the responsibility of the State to establish the allowability of a deferred claim.

(c) *Handling of documents and materials.* (1) Within 60 days (or within 120 days if the State requests an extension) after receipt of the notice of deferral, the State must make available to the CMS regional office, in readily reviewable form, all requested documents and materials except any that it identifies as not being available.

(2) CMS regional office staff initiates review within 30 days after receipt of the documents and materials.

(3) If the Regional Administrator finds that the materials are not in readily reviewable form or that additional information is needed, he or she promptly notifies the State that it has 15 days to submit the readily reviewable or additional materials.

(4) If the State does not provide the necessary materials within 15 days, the

Regional Administrator disallows the claim.

(5) The Regional Administrator has 90 days, after all documentation is available in readily reviewable form, to determine the allowability of the claim.

(6) If the Regional Administrator cannot complete review of the material within 90 days, CMS pays the claim, subject to a later determination of allowability.

(d) *Effect of decision to pay a deferred claim.* Payment of a deferred claim under paragraph (c)(6) of this section does not preclude a subsequent disallowance based on the results of an audit or financial review. (If there is a subsequent disallowance, the State may request reconsideration as provided in paragraph (e)(2) of this section.)

(e) *Notice and effect of decision on allowability.* (1) The Regional Administrator or the Administrator gives the State written notice of his or her decision to pay or disallow a deferred claim.

(2) If the decision is to disallow, the notice informs the State of its right to reconsideration in accordance with 45 CFR part 16.

§ 457.212 Disallowance of claims for FFP.

(a) *Notice of disallowance and of right to reconsideration.* When the Regional Administrator or the Administrator determines that a claim or portion of claim is not allowable, he or she promptly sends the State a disallowance letter that includes the following, as appropriate:

(1) The date or dates on which the State's claim for FFP was made.

(2) The time period during which the expenditures in question were made or claimed to have been made.

(3) The date and amount of any payment or notice of deferral.

(4) A statement of the amount of FFP claimed, allowed, and disallowed and the manner in which these amounts were computed.

(5) Findings of fact on which the disallowance determination is based or a reference to other documents previously furnished to the State or included with the notice (such as a report of a financial review or audit) that contain the findings of fact on which the disallowance determination is based.

(6) Pertinent citations to the law, regulations, guides and instructions supporting the action taken.

(7) A request that the State make appropriate adjustment in a subsequent expenditure report.

(8) Notice of the State's right to request reconsideration of the disallowance and the time allowed to make the request.

(9) A statement indicating that the disallowance letter is the Department's final decision unless the State requests reconsideration under paragraph (b)(2) of this section.

(b) *Reconsideration of FFP disallowance.* (1) The Departmental Appeals Board reviews disallowances of FFP under title XXI.

(2) A State may request reconsideration with a request to the Chair, Departmental Appeals Board, within 30 days after receipt of the disallowance letter, which must include—

(i) A copy of the disallowance letter;

(ii) A statement of the amount in dispute; and

(iii) A brief statement of why the disallowance is wrong.

(c) *Reconsideration procedures.* The reconsideration procedures are those set forth in 45 CFR part 16.

(d) *Implementation of decisions.* If the reconsideration decision requires an adjustment of FFP, either upward or downward, a subsequent grant award promptly reflects the amount of increase or decrease.

§ 457.216 Treatment of uncashed or canceled (voided) SCHIP checks.

(a) *Purpose.* This section provides rules to ensure that States refund the Federal portion of uncashed or canceled (voided) checks under title XXI.

(b) *Definitions.* As used in this section—

Canceled (voided) check means an SCHIP check issued by a State or fiscal agent that prior to its being cashed is canceled (voided) by the State or fiscal agent, thus preventing disbursement of funds.

Fiscal agent means an entity that processes or pays vendor claims for the SCHIP agency.

Uncashed check means an SCHIP check issued by a State or fiscal agent that has not been cashed by the payee.

Warrant means an order by which the SCHIP agency or local agency without the authority to issue checks recognizes a claim. Presentation of a warrant by the payee to a State officer with authority to issue checks will result in release of funds due.

(c) *Refund of Federal financial participation (FFP) for uncashed checks*—(1) *General provisions.* If a check remains uncashed beyond a period of 180 days from the date it was issued; that is, the date of the check, it is no longer regarded as an allowable program expenditure. If the State has claimed and received FFP for the amount of the uncashed check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the State agency must identify those checks that remain uncashed beyond a period of 180 days after issuance. The SCHIP agency must refund all FFP that it received for uncashed checks by adjusting the Quarterly Statement of Expenditures for that quarter. If an uncashed check is cashed after the refund is made, the State may file a claim. The claim will be considered to be an adjustment to the costs for the quarter in which the check was originally claimed. This claim will be paid if otherwise allowed by the Act and the regulations issued in accordance with the Act.

(3) If the State does not refund the appropriate amount as specified in paragraph (c)(2) of this section, the amount will be disallowed.

(d) *Refund of FFP for canceled (voided) checks*—(1) *General provisions.* If the State has claimed and received FFP for the amount of a canceled (voided) check, it must refund the amount of FFP received.

(2) *Report of refund.* At the end of each calendar quarter, the SCHIP agency must identify those checks that were canceled (voided). The State must refund all FFP that it received for canceled (voided) checks by adjusting the Quarterly Statement of Expenditures for that quarter.

(3) If the State does not refund the appropriate amount as specified in paragraph (d)(2) of this section, the amount will be disallowed.

§ 457.218 Repayment of Federal funds by installments.

(a) *Basic conditions.* When Federal payments have been made for claims that are later found to be unallowable, the State may repay the Federal Funds by installments if the following conditions are met:

(1) The amount to be repaid exceeds 2½ percent of the estimated or actual annual State share for the State SCHIP program; and

(2) The State has given the Regional Administrator written notice, before total repayment was due, of its intent to repay by installments.

(b) *Annual State share determination.* CMS determines whether the amount to be repaid exceeds 2½ percent of the annual State share as follows:

(1) If the State SCHIP program is ongoing, CMS uses the annual estimated State share of State SCHIP expenditures. This is the sum of the estimated State shares for four consecutive quarters, beginning with the quarter in which the first installment is to be paid, as shown on the State's latest CMS–21B form.

(2) If the State SCHIP program has been terminated by Federal law or by the State, CMS uses the actual State share. The actual State share is that shown on the State's Quarterly Statement of Expenditures reports for the last four quarters before the program was terminated.

(c) *Repayment amounts, schedules, and procedures*—(1) *Repayment amount.* The repayment amount may not include any amount previously approved for installment repayment.

(2) *Repayment schedule.* The number of quarters allowed for repayment is determined on the basis of the ratio of the repayment amount to the annual State share of State SCHIP expenditures. The higher the ratio of the total repayment amount is to the annual State share, the greater the number of quarters allowed, as follows:

Total repayment amount as percentage of State share of annual expenditures for State SCHIP	Number of quarters to make repayment
2.5 pct. or less	1

Total repayment amount as percentage of State share of annual expenditures for State SCHIP	Number of quarters to make repayment
Greater than 2.5, but not greater than 5	2
Greater than 5, but not greater than 7.5	3
Greater than 7.5, but not greater than 10	4
Greater than 10, but not greater than 15	5
Greater than 15, but not greater than 20	6
Greater than 20, but not greater than 25	7
Greater than 25, but not greater than 30	8
Greater than 30, but not greater than 47.5 ...	9
Greater than 47.5, but not greater than 65 ...	10
Greater than 65, but not greater than 82.5 ...	11
Greater than 82.5, but not greater than 100	12

(3) *Quarterly repayment amounts.* The quarterly repayment amounts for each of the quarters in the repayment schedule may not be less than the following percentages of the estimated State share of the annual expenditures for SCHIP:

For each of the following quarters	Repayment installment may not be less than these percentages
1 to 4	2.5
5 to 8	5.0
9 to 12	17.5

(4) *Extended schedule.* The repayment schedule may be extended beyond 12 quarterly installments if the total repayment amount exceeds 100 percent of the estimated State share of annual expenditures. In these circumstances, the repayment schedule in paragraph (c)(2) of this section is followed for repayment of the amount equal to 100 percent of the annual State share. The remaining amount of the repayment is in quarterly amounts equal to not less than 17.5 percent of the estimated State share of annual expenditures.

(5) *Repayment process.* Repayment is accomplished through adjustment in the quarterly grants over the period covered by the repayment schedule. If the State chooses to repay amounts representing higher percentages during the early quarters, any corresponding reduction in required minimum percentages is applied first to the last scheduled payment, then to the next to the last payment, and so forth as necessary.

(6) *Offsetting of retroactive claims.* (i) The amount of a retroactive claim to be paid a State is offset against any amounts to be, or already being, repaid by the State in installments. Under this provision, the State may choose to:

(A) Suspend payments until the retroactive claim due the State has, in fact, been offset; or

(B) Continue payments until the reduced amount of its debt (remaining after the offset), has been paid in full. This second option would result in a shorter payment period.

(ii) A retroactive claim for the purpose of this regulation is a claim applicable to any period ending 12 months or more before the beginning of the quarter in which CMS would pay that claim.

[65 FR 33622, May 24, 2000; 65 FR 38027, June 19, 2000; 65 FR 52042, Aug. 28, 2000]

§ 457.220 Public funds as the State share of financial participation.

(a) Public funds may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraphs (b) and (c) of this section.

(b) The public funds are appropriated directly to the State or local SCHIP agency, or transferred from other public agencies (including Indian tribes) to the State or local agency and under its administrative control, or certified by the contributing public agency as representing expenditures eligible for FFP under this section.

(c) The public funds are not Federal funds, or are Federal funds authorized by the Federal law to be used to match other Federal funds.

§ 457.222 FFP for equipment.

Claims for Federal financial participation in the cost of equipment under SCHIP are determined in accordance with subpart G of 45 CFR part 95. Requirements concerning the management and disposition of equipment under SCHIP are also prescribed in subpart G of 45 CFR part 95.

§ 457.224 FFP: Conditions relating to cost sharing.

(a) No FFP is available for the following amounts, even when related to services or benefit coverage which is or could be provided under a State SCHIP program—

(1) Any cost sharing amounts that beneficiaries should have paid as enrollment fees, premiums, deductibles,

coinsurance, copayments, or similar charges.

(2) Any amounts paid by the agency for health benefits coverage or services furnished to individuals who would not be eligible for that coverage or those services under the approved State child health plan, whether or not the individual paid any required premium or enrollment fee.

(b) The amount of expenditures under the State child health plan must be reduced by the amount of any premiums and other cost-sharing received by the State.

§ 457.226 Fiscal policies and accountability.

A State plan must provide that the SCHIP agency and, where applicable, local agencies administering the plan will—

(a) Maintain an accounting system and supporting fiscal records to assure that claims for Federal funds are in accord with applicable Federal requirements;

(b) Retain records for 3 years from date of submission of a final expenditure report;

(c) Retain records beyond the 3-year period if audit findings have not been resolved; and

(d) Retain records for nonexpendable property acquired under a Federal grant for 3 years from the date of final disposition of that property.

§ 457.228 Cost allocation.

A State plan must provide that the single or appropriate SCHIP Agency will have an approved cost allocation plan on file with the Department in accordance with the requirements contained in subpart E of 45 CFR part 95. Subpart E also sets forth the effect on FFP if the requirements contained in that subpart are not met.

§ 457.230 FFP for State ADP expenditures.

FFP is available for State ADP expenditures for the design, development, or installation of mechanized claims processing and information retrieval systems and for the operation of certain systems. Additional HHS regulations and CMS procedures regarding the availability of FFP for ADP expenditures are in 45 CFR part 74, 45 CFR part 95, subpart F, and part 11, State Medicaid Manual.

§ 457.232 Refunding of Federal Share of SCHIP overpayments to providers and referral of allegations of waste, fraud or abuse to the Office of Inspector General.

(a) Quarterly Federal payments to the States under title XXI (SCHIP) of the Act are to be reduced or increased to make adjustment for prior overpayments or underpayments that the Secretary determines have been made.

(b) The Secretary will consider the pro rata Federal share of the net amount recovered by a State during any quarter to be an overpayment.

(c) Allegations or indications of waste fraud and abuse with respect to the SCHIP program shall be referred promptly to the Office of Inspector General.

§ 457.236 Audits.

The SCHIP agency must assure appropriate audit of records on costs of provider services.

§ 457.238 Documentation of payment rates.

The SCHIP agency must maintain documentation of payment rates and make it available to HHS upon request.

Subpart C—State Plan Requirements: Eligibility, Screening, Applications, and Enrollment

SOURCE: 66 FR 2675, Jan. 11, 2001, unless otherwise noted.

§ 457.300 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2102 of the Act, which relates to eligibility standards and methodologies, coordination with other health insurance programs, and outreach and enrollment efforts to identify and enroll children who are eligible to participate in other public health insurance programs;

(2) Section 2105(c)(6)(B) of the Act, which relates to the prohibition against expenditures for child health assistance provided to children eligible

for coverage under other Federal health care programs other than programs operated or financed by the Indian Health Service; and

(3) Section 2110(b) of the Act, which provides a definition of targeted low-income child.

(b) *Scope.* This subpart sets forth the requirements relating to eligibility standards and to screening, application and enrollment procedures.

(c) *Applicability.* The requirements of this subpart apply to child health assistance provided under a separate child health program. Regulations relating to eligibility, screening, applications and enrollment that are applicable to a Medicaid expansion program are found at §431.636, §435.4, §435.229, §435.1102, §436.3, §436.229, and §436.1102 of this chapter.

§457.301 Definitions and use of terms.

As used in this subpart—

Joint application means a form used to apply for the separate child health program that, when transmitted to the Medicaid agency following a screening that shows the child is potentially eligible for Medicaid, may also be used to apply for Medicaid.

Period of presumptive eligibility means a period that begins on the date on which a qualified entity determines that a child is presumptively eligible and ends with the earlier of—

(1) In the case of a child on whose behalf a separate child health program application has been filed, the day on which a decision is made on that application; or

(2) In the case of a child on whose behalf an application for the separate child health program has not been filed, the last day of the month following the month in which the determination of presumptive eligibility was made.

Presumptive income standard means the highest income eligibility standard established under the plan that is most likely to be used to establish eligibility of a child of the age involved.

Public agency means a State, county, city or other type of municipal agency, including a public school district, transportation district, irrigation district, or any other type of public entity.

Qualified entity means an entity that is determined by the State to be capable of making determinations of presumptive eligibility for children, and that—

(1) Furnishes health care items and services covered under the approved plan and is eligible to receive payments under the approved plan;

(2) Is authorized to determine eligibility of a child to participate in a Head Start program under the Head Start Act;

(3) Is authorized to determine eligibility of a child to receive child care services for which financial assistance is provided under the Child Care and Development Block Grant Act of 1990;

(4) Is authorized to determine eligibility of an infant or child to receive assistance under the special nutrition program for women, infants, and children (WIC) under section 17 of the Child Nutrition Act of 1966;

(5) Is authorized to determine eligibility of a child for medical assistance under the Medicaid State plan, or eligibility of a child for child health assistance under the State Children's Health Insurance Program;

(6) Is an elementary or secondary school, as defined in section 14101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 8801);

(7) Is an elementary or secondary school operated or supported by the Bureau of Indian Affairs;

(8) Is a State or Tribal child support enforcement agency;

(9) Is an organization that—

(i) Provides emergency food and shelter under a grant under the Stewart B. McKinney Homeless Assistance Act;

(ii) Is a State or Tribal office or entity involved in enrollment in the program under this title, Part A of title IV, or title XXI; or

(iii) Determines eligibility for any assistance or benefits provided under any program of public or assisted housing that receives Federal funds, including the program under section 8 or any other section of the United States Housing Act of 1937 (42 U.S.C. 1437) or under the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 et seq.); and

(10) Any other entity the State so deems, as approved by the Secretary.

State health benefits plan means a health insurance coverage plan that is offered or organized by the State government on behalf of State employees or other public agency employees within the State. The term does not include a plan in which the State provides no contribution toward the cost of coverage and in which no State employees participate, or a plan that provides coverage only for a specific type of care, such as dental or vision care.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001]

§ 457.305 State plan provisions.

The State plan must include a description of—

(a) The standards, consistent with §§ 457.310 and 457.320, used to determine the eligibility of children for coverage under the State plan.

(b) The State's policies governing enrollment and disenrollment; processes for screening applicant children for and, if eligible, facilitating their enrollment in Medicaid; and processes for implementing waiting lists and enrollment caps (if any).

§ 457.310 Targeted low-income child.

(a) *Definition.* A targeted low-income child is a child who meets the standards set forth below and the eligibility standards established by the State under § 457.320.

(b) *Standards.* A targeted low-income child must meet the following standards:

(1) *Financial need standard.* A targeted low-income child:

(i) Has a family income at or below 200 percent of the Federal poverty line for a family of the size involved;

(ii) Resides in a State with no Medicaid applicable income level or;

(iii) Resides in a State that has a Medicaid applicable income level and has family income that either—

(A) Exceeds the Medicaid applicable income level for the age of such child, but not by more than 50 percentage points; or

(B) Does not exceed the income level specified for such child to be eligible for medical assistance under policies of the State plan under title XIX on June 1, 1997.

(2) *No other coverage standard.* A targeted low-income child must not be—

(i) Found eligible or potentially eligible for Medicaid under policies of the State plan (determined through either the Medicaid application process or the screening process described at § 457.350); or

(ii) Covered under a group health plan or under health insurance coverage, as defined in section 2791 of the Public Health Service Act, unless the plan or health insurance coverage program has been in operation since before July 1, 1997 and is administered by a State that receives no Federal funds for the program's operation. A child is not considered covered under a group health plan or health insurance coverage if the child does not have reasonable geographic access to care under that plan.

(3) For purposes of this section, policies of the State plan under title XIX plan include policies under a Statewide demonstration project under section 1115(a) of the Act other than a demonstration project that covered an expanded group of eligible children but that either—

(i) Did not provide inpatient hospital coverage; or

(ii) Limited eligibility to children previously enrolled in Medicaid, imposed premiums as a condition of initial or continued enrollment, and did not impose a general time limit on eligibility.

(c) *Exclusions.* Notwithstanding paragraph (a) of this section, the following groups are excluded from the definition of targeted low-income children:

(1) *Children eligible for certain State health benefits coverage.* (i) A targeted low-income child may not be eligible for health benefits coverage under a State health benefits plan in the State on the basis of a family member's employment with a public agency, even if the family declines to accept the coverage.

(ii) A child is considered eligible for health benefits coverage under a State health benefits plan if a more than nominal contribution to the cost of health benefits coverage under a State health benefits plan is available from the State or public agency with respect

to the child or would have been available from those sources on November 8, 1999. A contribution is considered more than nominal if the State or public agency makes a contribution toward the cost of an employee's dependent(s) that is $10 per family, per month, more than the State or public agency's contribution toward the cost of covering the employee only.

(2) *Residents of an institution.* A child must not be—

(i) An inmate of a public institution as defined at § 435.1010 of this chapter; or

(ii) A patient in an institution for mental diseases, as defined at § 435.1010 of this chapter, at the time of initial application or any redetermination of eligibility.

[66 FR 2675, Jan. 11, 2001, as amended at 71 FR 39229, July 12, 2006]

§ 457.320 Other eligibility standards.

(a) *Eligibility standards.* To the extent consistent with title XXI of the Act and except as provided in paragraph (b) of this section, the State plan may adopt eligibility standards for one or more groups of children related to—

(1) Geographic area(s) served by the plan;

(2) Age (up to, but not including, age 19);

(3) Income;

(4) Resources;

(5) Spenddowns;

(6) Disposition of resources;

(7) Residency, in accordance with paragraph (d) of this section;

(8) Disability status, provided that such standards do not restrict eligibility;

(9) Access to, or coverage under, other health coverage; and

(10) Duration of eligibility, in accordance with paragraph (e) of this section.

(b) *Prohibited eligibility standards.* In establishing eligibility standards and methodologies, a State may *not*—

(1) Cover children with a higher family income without covering children with a lower family income within any defined group of covered targeted low-income children;

(2) Deny eligibility based on a pre-existing medical condition;

(3) Discriminate on the basis of diagnosis;

(4) Require any family member who is not requesting services to provide a social security number (including those family members whose income or resources might be used in making the child's eligibility determination);

(5) Exclude American Indian or Alaska Native children based on eligibility for, or access to, medical care funded by the Indian Health Service;

(6) Exclude individuals based on citizenship or nationality, to the extent that the children are U.S. citizens, U.S. nationals or qualified aliens, (as defined at section 431 of the Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996, as amended by the BBA of 1997, except to the extent that section 403 of PRWORA precludes them from receiving Federal means-tested public benefits); or

(7) Violate any other Federal laws or regulations pertaining to eligibility for a separate child health program under title XXI.

(c) *Self-declaration of citizenship.* In establishing eligibility for coverage under a separate child health plan, a State may accept self-declaration of citizenship (including nationals of the U.S.), provided that the State has implemented effective, fair, and non-discriminatory procedures for ensuring the integrity of its application process.

(d) *Residency.* The State may establish residency requirements, except that a State may not—

(1) Impose a durational residency requirement;

(2) Preclude the following individuals from declaring residence in a State—

(i) A non-institutionalized child who is not a ward of the State, if the child is physically located in that State, including as a result of the parent's or caretaker's employment in that State;

(ii) An institutionalized child who is not a ward of a State, if the State is the State of residence of the child's custodial parent's or caretaker at the time of placement;

(iii) A child who is a ward of a State, regardless of the child's physical location; or

(iv) A child whose custodial parent or caretaker is involved in work of a transient nature, if the State is the parent's or caretaker's home State.

(e) *Duration of eligibility.* (1) The State may not impose a lifetime cap or other time limit on the eligibility of an individual applicant or enrollee, based on the length of time such applicant or enrollee has received benefits under the State's separate child health program.

(2) Eligibility must be redetermined at least every 12 months.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001]

§ 457.340 Application for and enrollment in a separate child health program.

(a) *Application assistance.* A State must afford families an opportunity to apply for child health assistance without delay, provided that the State has not reached an approved enrollment cap, and offer assistance to families in understanding and completing applications and in obtaining any required documentation.

(b) *Use of social security number.* A State may require a social security number for each individual requesting services consistent with the requirements at § 435.910(b), (e), (f), and (g) of this chapter.

(c) *Notice of rights and responsibilities.* A State must inform applicants at the time of application, in writing and orally if appropriate, about the application and eligibility requirements, the time frame for determining eligibility, and the right to review of eligibility determinations as described in § 457.1130.

(d) *Timely determinations of eligibility.* (1) The agency must promptly determine eligibility and issue a notice of decision within the time standards established, except in circumstances that are beyond the agency's control.

(2) A State must establish time standards for determining eligibility. These standards may not exceed forty-five calendar days (excluding days during which the application has been suspended, pursuant to § 457.350(f)(1)).

(3) In applying the time standards, the State must define ''date of application'' and must count each calendar day from the date of application to the day the agency mails or otherwise provides notice of its eligibility decision.

(e) *Notice of decision concerning eligibility.* A State must provide each applicant or enrollee a written notice of any decision on the application or other determination concerning eligibility.

(1) If eligibility is approved, the notice must include information on the enrollee's rights and responsibilities under the program, including the opportunity for review of matters described in § 457.1130.

(2) If eligibility is denied, suspended or terminated, the State must provide notice in accordance with § 457.1180. In the case of a suspension or termination of eligibility, the State must provide sufficient notice to enable the child's parent or caretaker to take any appropriate actions that may be required to allow coverage to continue without interruption.

(f) *Effective date of eligibility.* A State must specify a method for determining the effective date of eligibility for its separate child health program, which can be determined based on the date of application or through any other reasonable method.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001]

§ 457.350 Eligibility screening and facilitation of Medicaid enrollment.

(a) *State plan requirement.* The State plan must include a description of—

(1) The screening procedures that the State will use, at intake and any follow-up eligibility determination, including any periodic redetermination, to ensure that only targeted low-income children are furnished child health assistance under the plan; and

(2) The procedures that the State will use to ensure that the Medicaid application and enrollment process is initiated and that Medicaid enrollment is facilitated for children found, through the screening process, to be potentially eligible for Medicaid.

(b) *Screening objectives.* (1) A State must use screening procedures to identify, at a minimum, any applicant or enrollee who is potentially eligible for Medicaid under one of the poverty-level-related groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act, applying whichever standard

and corresponding methodology generally results in a higher income eligibility level for the age group of the child being screened.

(2) Screening procedures must also identify any applicant or enrollee who would be potentially eligible for Medicaid services based on the eligibility of his or her mother under one of the poverty level groups described in section 1902(l) of the Act, section 1931 of the Act, or a Medicaid demonstration project approved under section 1115 of the Act.

(c) *Income eligibility test.* To identify the children described in paragraph (b) of this section, a State must either initially apply the gross income test described in paragraph (c)(1) of this section and then use an adjusted income test described in paragraph (c)(2) of this section for applicants whose gross income is above the appropriate Medicaid income standard, or use only the adjusted income test.

(1) *Initial gross income test.* Under this test, a State initially screens for Medicaid eligibility by comparing gross family income to the appropriate Medicaid income standard.

(2) *Adjusted income test.* Under this test, a State screens for Medicaid eligibility by comparing adjusted family income to the appropriate Medicaid income standard. The State must apply Medicaid standards and methodologies relating to income for the particular Medicaid eligibility group, including all income exclusions and disregards, except those that apply only in very limited circumstances.

(d) *Resource eligibility test.* (1) If a State applies a resource test for children under the Medicaid eligibility group used for screening purposes as described in paragraph (b) of this section and a child has been determined potentially income eligible for Medicaid, the State must also screen for Medicaid eligibility by comparing family resources to the appropriate Medicaid resource standard.

(2) In conducting the screening, the State must apply Medicaid standards and methodologies related to resources for the particular Medicaid eligibility group, including all resource exclusions and disregards, except those that apply only in very limited circumstances.

(e) *Children found potentially ineligible for Medicaid.* If a State uses a screening procedure other than a full determination of Medicaid eligibility under all possible eligibility groups, and the screening process reveals that the child does not appear to be eligible for Medicaid, the State must provide the child's family with the following in writing:

(1) A statement that based on a limited review, the child does not appear eligible for Medicaid, but Medicaid eligibility can only be determined based on a full review of a Medicaid application under all Medicaid eligibility groups;

(2) Information about Medicaid eligibility and benefits; and

(3) Information about how and where to apply for Medicaid under all eligibility groups.

(4) The State will determine the written format and timing of the information regarding Medicaid eligibility, benefits, and the application process required under this paragraph (e).

(f) *Children found potentially eligible for Medicaid.* If the screening process reveals that the child is potentially eligible for Medicaid, the State must establish procedures in coordination with the Medicaid agency that facilitate enrollment in Medicaid and avoid duplicative requests for information and documentation and must—

(1) Except as provided in § 457.355, find the child ineligible, provisionally ineligible, or suspend the child's application for the separate child health program unless and until a completed Medicaid application for that child is denied, or the child's circumstances change, and promptly transmit the separate child health application to the Medicaid agency as provided in paragraph (f)(3)(ii) of this section; and

(2) If a State uses a joint application for its Medicaid and separate child health programs, promptly transmit the application, or the information obtained through the application, and all relevant documentation to the Medicaid agency; or

(3) If a State does not use a joint application for its Medicaid and separate child health programs:

(i) Promptly inform the child's parent or caretaker in writing and, if appropriate, orally that the child has been found likely to be eligible for Medicaid; provide the family with a Medicaid application and offer information about what, if any, further information, documentation, or other steps are needed to complete the Medicaid application process; and offer assistance in completing the application process;

(ii) Promptly transmit the separate child health program application; or the information obtained through the application, and all other relevant information and documentation, including the results of the screening process, to the Medicaid agency for a final determination of Medicaid eligibility in accordance with the requirements of §§ 431.636 and 457.1110 of this chapter; or

(4) Establish other effective and efficient procedures, in coordination with the Medicaid agency, as described and approved in the State plan that ensure that children who are screened as potentially eligible for Medicaid are able to apply for Medicaid without delay and, if eligible, are enrolled in Medicaid in a timely manner; and

(5) Determine or redetermine eligibility for the separate child health program, if—

(i) The State is notified pursuant to § 431.636 of this chapter that the child has been found ineligible for Medicaid, consistent with the time standards established pursuant to § 457.340(c); or

(ii) The State is notified prior to the final Medicaid eligibility determination that the child's circumstances have changed and another screening shows that the child is not likely to be eligible for Medicaid.

(g) *Informed application decisions.* To enable a family to make an informed decision about applying for Medicaid or completing the Medicaid application process, a State must provide the child's family with information, in writing, about—

(1) The State's Medicaid program, including the benefits covered, and restrictions on cost sharing; and

(2) Eligibility rules that prohibit children who have been screened eligible for Medicaid from being enrolled in a separate child health program, other than provisional temporary enrollment while a final Medicaid eligibility determination is being made.

(3) The State will determine the written format and timing of the information regarding Medicaid eligibility, benefits, and the application process required under this paragraph (g).

(h) *Waiting lists, enrollment caps and closed enrollment.* The State must establish procedures to ensure that—

(1) The procedures developed in accordance with this section have been followed for each child applying for a separate child health program before placing the child on a waiting list or otherwise deferring action on the child's application for the separate child health program; and

(2) Families are informed that a child may be eligible for Medicaid if circumstances change while the child is on a waiting list for separate child health program.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001; 67 FR 61974, Oct. 2, 2002]

§ 457.353 Monitoring and evaluation of screening process.

States must monitor and establish a mechanism to evaluate the screen and enroll process described at § 457.350 to ensure that children who are screened potentially eligible for Medicaid are enrolled in Medicaid, if eligible, and that children who are found ineligible for Medicaid are enrolled in the separate child health program, if eligible.

§ 457.355 Presumptive eligibility.

(a) *General rule.* Consistent with subpart D of this part, the State may pay costs of coverage under a separate child health program, during a period of presumptive eligibility for children applying for coverage under the separate child health program, pending the screening process and a final determination of eligibility (including applicants found through screening to be potentially eligible for Medicaid)

(b) *Expenditures for coverage during a period of presumptive eligibility.* Expenditures for coverage during a period of presumptive eligibility implemented in accordance with § 435.1102 of this chapter may be considered as expenditures

for child health assistance under the plan.

[66 FR 2675, Jan. 11, 2001, as amended at 66 FR 33823, June 25, 2001]

§ 457.380 Eligibility verification.

(a) The State must establish procedures to ensure the integrity of the eligibility determination process.

(b) A State may establish reasonable eligibility verification mechanisms to promote enrollment of eligible children and may permit applicants and enrollees to demonstrate that they meet eligibility requirements through self-declaration or affirmation except that a State may permit self-declaration of citizenship only if the State has effective, fair and non-discriminatory procedures to ensure the integrity of the application process in accordance with § 457.320(c).

Subpart D—State Plan Requirements: Coverage and Benefits

SOURCE: 66 FR 2678, Jan. 11, 2001, unless otherwise noted.

§ 457.401 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2102(a)(7) of the Act, which requires that States make assurances relating to, the quality and appropriateness of care, and access to covered services;

(2) Section 2103 of the Act, which outlines coverage requirements for children's health insurance;

(3) Section 2109 of the Act, which describes the relation of the SCHIP program to other laws;

(4) Section 2110(a) of the Act, which describes child health assistance; and

(5) Section 2110(c) of the Act, which contains definitions applicable to this subpart.

(b) *Scope.* This subpart sets forth requirements for health benefits coverage and child health assistance under a separate child health plan.

(c) *Applicability.* The requirements of this subpart apply to child health assistance provided under a separate child health program and do not apply to a Medicaid expansion program.

§ 457.402 Definition of child health assistance.

For the purpose of this subpart, the term ''child health assistance'' means payment for part or all of the cost of health benefits coverage provided to targeted low-income children for the following services:

(a) Inpatient hospital services.

(b) Outpatient hospital services.

(c) Physician services.

(d) Surgical services.

(e) Clinic services (including health center services) and other ambulatory health care services.

(f) Prescription drugs and biologicals and the administration of these drugs and biologicals, only if these drugs and biologicals are not furnished for the purpose of causing, or assisting in causing, the death, suicide, euthanasia, or mercy killing of a person.

(g) Over-the-counter medications.

(h) Laboratory and radiological services.

(i) Prenatal care and pre-pregnancy family planning services and supplies.

(j) Inpatient mental health services, other than services described in paragraph (r) of this section but including services furnished in a State-operated mental hospital and including residential or other 24-hour therapeutically planned structured services.

(k) Outpatient mental health services, other than services described in paragraph (s) of this section but including services furnished in a State-operated mental hospital and including community-based services.

(l) Durable medical equipment and other medically-related or remedial devices (such as prosthetic devices, implants, eyeglasses, hearing aids, dental devices and adaptive devices).

(m) Disposable medical supplies.

(n) Home and community-based health care services and related supportive services (such as home health nursing services, personal care, assistance with activities of daily living, chore services, day care services, respite care services, training for family members and minor modification to the home.)

(o) Nursing care services (such as nurse practitioner services, nurse midwife services, advanced practice nurse services, private duty nursing, pediatric nurse services and respiratory care services) in a home, school, or other setting.

(p) Abortion only if necessary to save the life of the mother or if the pregnancy is the result of rape or incest.

(q) Dental services.

(r) Inpatient substance abuse treatment services and residential substance abuse treatment services.

(s) Outpatient substance abuse treatment services.

(t) Case management services.

(u) Care coordination services.

(v) Physical therapy, occupational therapy, and services for individuals with speech, hearing and language disorders.

(w) Hospice care.

(x) Any other medical, diagnostic, screening, preventive, restorative, remedial, therapeutic, or rehabilitative services (whether in a facility, home, school, or other setting) if recognized by State law and only if the service is—

(1) Prescribed by or furnished by a physician or other licensed or registered practitioner within the scope of practice as defined by State law;

(2) Performed under the general supervision or at the direction of a physician; or

(3) Furnished by a health care facility that is operated by a State or local government or is licensed under State law and operating within the scope of the license.

(y) Premiums for private health care insurance coverage.

(z) Medical transportation.

(aa) Enabling services (such as transportation, translation, and outreach services) only if designed to increase the accessibility of primary and preventive health care services for eligible low-income individuals.

(bb) Any other health care services or items specified by the Secretary and not excluded under this subchapter.

§ 457.410 Health benefits coverage options.

(a) *Types of health benefits coverage.* States may choose to obtain any of the following four types of health benefits coverage:

(1) Benchmark coverage in accordance with § 457.420.

(2) Benchmark-equivalent coverage in accordance with § 457.430.

(3) Existing comprehensive State-based coverage in accordance with § 457.440.

(4) Secretary-approved coverage in accordance with § 457.450.

(b) *Required coverage.* Regardless of the type of health benefits coverage, described at paragraph (a) of this section, that the State chooses to obtain, the State must obtain coverage for—

(1) Well-baby and well-child care services as defined by the State;

(2) Age-appropriate immunizations in accordance with the recommendations of the Advisory Committee on Immunization Practices (ACIP); and

(3) Emergency services as defined in § 457.10.

§ 457.420 Benchmark health benefits coverage.

Benchmark coverage is health benefits coverage that is substantially equal to the health benefits coverage in one of the following benefit plans:

(a) *Federal Employees Health Benefit Plan (FEHBP).* The standard Blue Cross/Blue Shield preferred provider option service benefit plan that is described in, and offered to Federal employees under, 5 U.S.C. 8903(1).

(b) *State employee plan.* A health benefits plan that is offered and generally available to State employees in the State.

(c) *Health maintenance organization (HMO) plan.* A health insurance coverage plan that is offered through an HMO (as defined in section 2791(b)(3) of the Public Health Service Act) and has the largest insured commercial, non-Medicaid enrollment in the State.

§ 457.430 Benchmark-equivalent health benefits coverage.

(a) *Aggregate actuarial value.* Benchmark-equivalent coverage is health benefits coverage that has an aggregate actuarial value determined in accordance with § 457.431 that is at least actuarially equivalent to the coverage under one of the benchmark packages specified in § 457.420.

(b) *Required coverage.* In addition to the coverage required under § 457.410(b), benchmark-equivalent health benefits coverage must include coverage for the following categories of services:

(1) Inpatient and outpatient hospital services.

(2) Physicians' surgical and medical services.

(3) Laboratory and x-ray services.

(c) *Additional coverage.* (1) In addition to the categories of services in paragraph (b) of this section, benchmark-equivalent coverage may include coverage for any additional services specified in § 457.402.

(2) If the benchmark coverage package used by the State for purposes of comparison in establishing the aggregate actuarial value of the benchmark-equivalent coverage package includes coverage for prescription drugs, mental health services, vision services or hearing services, then the actuarial value of the coverage for each of these categories of service in the benchmark-equivalent coverage package must be at least 75 percent of the value of the coverage for such a category or service in the benchmark plan used for comparison by the State.

(3) If the benchmark coverage package does not cover one of the categories of services in paragraph (c)(2) of this section, then the benchmark-equivalent coverage package may, but is not required to, include coverage for that category of service.

§ 457.431 Actuarial report for benchmark-equivalent coverage.

(a) To obtain approval for benchmark-equivalent health benefits coverage described under § 457.430, the State must submit to CMS an actuarial report that contains an actuarial opinion that the health benefits coverage meets the actuarial requirements under § 457.430. The report must also specify the benchmark coverage used for comparison.

(b) The actuarial report must state that it was prepared—

(1) By an individual who is a member of the American Academy of Actuaries;

(2) Using generally accepted actuarial principles and methodologies of the American Academy of Actuaries;

(3) Using a standardized set of utilization and price factors;

(4) Using a standardized population that is representative of privately insured children of the age of those expected to be covered under the State plan;

(5) Applying the same principles and factors in comparing the value of different coverage (or categories of services);

(6) Without taking into account any differences in coverage based on the method of delivery or means of cost control or utilization used; and

(7) Taking into account the ability of a State to reduce benefits by considering the increase in actuarial value of health benefits coverage offered under the State plan that results from the limitations on cost sharing (with the exception of premiums) under that coverage.

(c) The actuary who prepares the opinion must select and specify the standardized set and population to be used under paragraphs (b)(3) and (b)(4) of this section.

(d) The State must provide sufficient detail to explain the basis of the methodologies used to estimate the actuarial value or, if requested by CMS, to replicate the State's result.

§ 457.440 Existing comprehensive State-based coverage.

(a) *General requirements.* Existing comprehensive State-based health benefits is coverage that—

(1) Includes coverage of a range of benefits;

(2) Is administered or overseen by the State and receives funds from the State;

(3) Is offered in the State of New York, Florida or Pennsylvania; and

(4) Was offered as of August 5, 1997.

(b) *Modifications.* A State may modify an existing comprehensive State-based coverage program described in paragraph (a) of this section if—

(1) The program continues to include a range of benefits;

(2) The State submits an actuarial report demonstrating that the modification does not reduce the actuarial value of the coverage under the program below the lower of either—

(i) The actuarial value of the coverage under the program as of August 5, 1997; or

(ii) The actuarial value of a benchmark benefit package as described in § 457.430 evaluated at the time the modification is requested.

§ 457.450 Secretary-approved coverage.

Secretary-approved coverage is health benefits coverage that, in the determination of the Secretary, provides appropriate coverage for the population of targeted low-income children covered under the program. Secretary-approved coverage, for which no actuarial analysis is required, may include, but is not limited to the following:

(a) Coverage that is the same as the coverage provided to children under the Medicaid State plan.

(b) Comprehensive coverage for children offered by the State under a Medicaid demonstration project approved by the Secretary under section 1115 of the Act.

(c) Coverage that either includes the full Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) benefit or that the State has extended to the entire Medicaid population in the State.

(d) Coverage that includes benchmark health benefits coverage, as specified in § 457.420, plus any additional coverage.

(e) Coverage that is the same as the coverage provided under § 457.440.

(f) Coverage, including coverage under a group health plan purchased by the State, that the State demonstrates to be substantially equivalent to or greater than coverage under a benchmark health benefits plan, as specified in § 457.420, through use of a benefit-by-benefit comparison which demonstrates that coverage for each benefit meets or exceeds the corresponding coverage under the benchmark health benefits plan.

[66 FR 33823, June 25, 2001]

§ 457.470 Prohibited coverage.

A State is not required to provide health benefits coverage under the plan for an item or service for which payment is prohibited under title XXI even if any benchmark health benefits plan includes coverage for that item or service.

§ 457.475 Limitations on coverage: Abortions.

(a) *General rule.* FFP under title XXI is not available in expenditures for an abortion, or in expenditures for the purchase of health benefits coverage that includes coverage of abortion services unless the abortion services meet the conditions specified in paragraph (b) of this section.

(b) *Exceptions*—(1) *Life of mother.* FFP is available in expenditures for abortion services when a physician has found that the abortion is necessary to save the life of the mother.

(2) *Rape or incest.* FFP is available in expenditures for abortion services performed to terminate a pregnancy resulting from an act of rape or incest.

(c) *Partial Federal funding prohibited.* (1) FFP is not available to a State for any amount expended under the title XXI plan to assist in the purchase, in whole or in part, of health benefits coverage that includes coverage of abortions other than those specified in paragraph (b) of this section.

(2) If a State wishes to have managed care entities provide abortions in addition to those specified in paragraph (b) of this section, those abortions must be provided under a separate contract using non-Federal funds. A State may not set aside a portion of the capitated rate paid to a managed care entity to be paid with State-only funds, or append riders, attachments or addenda to existing contracts with managed care entities to separate the additional abortion services from the other services covered by the contract.

(3) Nothing in this section affects the expenditure by a State, locality, or private person or entity of State, local, or private funds (other than those expended under the State plan) for any abortion services or for health benefits coverage that includes coverage of abortion services.

§ 457.480 Preexisting condition exclusions and relation to other laws.

(a) *Preexisting condition exclusions.* (1) Except as permitted under paragraph (a)(2) of this section, the State may not

permit the imposition of any pre-existing condition exclusion for covered services under the State plan.

(2) If the State obtains health benefits coverage through payment or a contract for health benefits coverage under a group health plan or group health insurance coverage, the State may permit the imposition of a pre-existing condition exclusion but only to the extent that the exclusion is permitted under the applicable provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (ERISA) and title XXVII of the Public Health Service Act.

(b) *Relation of title XXI to other laws.* (1) ERISA. Nothing in this title affects or modifies section 514 of ERISA with respect to a group health plan as defined by section 2791(a)(1) of the Public Health Service Act.

(2) *Health Insurance Portability and Accountability Act (HIPAA).* Health benefits coverage provided under a State plan and coverage provided as a cost-effective alternative, as described in subpart J of this part, is creditable coverage for purposes of part 7 of subtitle B of title II of ERISA, title XXVII of the Public Health Service Act, and subtitle K of the Internal Revenue Code of 1986.

(3) *Mental Health Parity Act (MHPA).* Health benefits coverage under a group health plan provided under a State plan must comply with the requirements of the MHPA of 1996 regarding parity in the application of annual and lifetime dollar limits to mental health benefits in accordance with 45 CFR 146.136.

(4) *Newborns and Mothers Health Protection Act (NMHPA).* Health benefits coverage under a group health plan provided under a State plan must comply with the requirements of the NMHPA of 1996 regarding requirements for minimum hospital stays for mothers and newborns in accordance with 45 CFR 146.130 and 148.170.

§ 457.490 Delivery and utilization control systems.

A State that elects to obtain health benefits coverage through a separate child health program must include in its State plan a description of the child health assistance provided under the plan for targeted low-income children, including a description of the proposed methods of delivery and utilization control systems. A State must—

(a) Describe the methods of delivery of child health assistance including the choice of financing and the methods for assuring delivery of the insurance products and delivery of health care services covered by such products to the enrollees, including any variations; and

(b) Describe utilization control systems designed to ensure that enrollees receiving health care services under the State plan receive only appropriate and medically necessary health care consistent with the benefit package described in the approved State plan.

§ 457.495 State assurance of access to care and procedures to assure quality and appropriateness of care.

A State plan must include a description of the methods that a State uses for assuring the quality and appropriateness of care provided under the plan, including how the State will assure:

(a) Access to well-baby care, well-child care, well-adolescent care and childhood and adolescent immunizations.

(b) Access to covered services, including emergency services as defined at § 457.10.

(c) Appropriate and timely procedures to monitor and treat enrollees with chronic, complex, or serious medical conditions, including access to an adequate number of visits to specialists experienced in treating the specific medical condition and access to out-of-network providers when the network is not adequate for the enrollee's medical condition.

(d) That decisions related to the prior authorization of health services are completed as follows:

(1) In accordance with the medical needs of the patient, within 14 days after receipt of a request for services. A possible extension of up to 14 days may be permitted if the enrollee requests the extension or if the physician or health plan determines that additional information is needed; or

(2) In accordance with existing State law regarding prior authorization of health services.

[66 FR 2678, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

Subpart E—State Plan Requirements: Enrollee Financial Responsibilities

SOURCE: 66 FR 2681, Jan. 11, 2001, unless otherwise noted.

§ 457.500 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Section 2101(a) of the Act, which provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; and

(2) Section 2103(e) of the Act, which sets forth provisions regarding State plan requirements and options for cost sharing.

(b) *Scope.* This subpart consists of provisions relating to the imposition under a separate child health program of cost-sharing charges including enrollment fees, premiums, deductibles, coinsurance, copayments, and similar cost-sharing charges.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs.

§ 457.505 General State plan requirements.

The State plan must include a description of—

(a) The amount of premiums, deductibles, coinsurance, copayments, and other cost sharing imposed;

(b) The methods, including the public schedule, the State uses to inform enrollees, applicants, providers and the general public of the cost-sharing charges, the cumulative cost-sharing maximum, and any changes to these amounts;

(c) The disenrollment protections as required under § 457.570;

(d) In the case of coverage obtained through premium assistance for group health plans—

(1) The procedures the State uses to ensure that eligible children are not charged copayments, coinsurance, deductibles or similar fees on well-baby and well-child care services described at § 457.520, and that any cost sharing complies with the requirements of this subpart;

(2) The procedures to ensure that American Indian and Alaska Native children are not charged premiums, copayments, coinsurance, deductibles, or similar fees in accordance with § 457.535;

(3) The procedures to ensure that eligible children are not charged cost sharing in excess of the cumulative cost-sharing maximum specified in § 457.560.

(e) Procedures that do not primarily rely on a refund given by the State for overpayment on behalf of an eligible child to ensure compliance with this subpart.

[66 FR 2681, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§ 457.510 Premiums, enrollment fees, or similar fees: State plan requirements.

When a State imposes premiums, enrollment fees, or similar fees on enrollees, the State plan must describe—

(a) The amount of the premium, enrollment fee or similar fee imposed on enrollees;

(b) The time period for which the charge is imposed;

(c) The group or groups that are subject to the premiums, enrollment fees, or similar charges;

(d) The consequences for an enrollee or applicant who does not pay a charge, and the disenrollment protections adopted by the State in accordance with § 457.570; and

(e) The methodology used to ensure that total cost-sharing liability for a family does not exceed the cumulative cost-sharing maximum specified in § 457.560.

§ 457.515 Co-payments, coinsurance, deductibles, or similar cost-sharing charges: State plan requirements.

To impose copayments, coinsurance, deductibles or similar charges on enrollees, the State plan must describe—

(a) The service for which the charge is imposed;

(b) The amount of the charge;

(c) The group or groups of enrollees that may be subject to the cost-sharing charge;

(d) The consequences for an enrollee who does not pay a charge, and the disenrollment protections adopted by the State in accordance with § 457.570;

(e) The methodology used to ensure that total cost-sharing liability for a family does not exceed the cumulative cost-sharing maximum specified in § 457.560; and

(f) An assurance that enrollees will not be held liable for cost-sharing amounts for emergency services that are provided at a facility that does not participate in the enrollee's managed care network beyond the copayment amounts specified in the State plan for emergency services as defined in § 457.10.

§ 457.520 Cost sharing for well-baby and well-child care services.

(a) A State may not impose copayments, deductibles, coinsurance or other cost sharing with respect to the well-baby and well-child care services covered under the State plan in either the managed care delivery setting or the fee-for-service delivery setting.

(b) For the purposes of this subpart, at a minimum, any of the following services covered under the State plan will be considered well-baby and well-child care services:

(1) All healthy newborn physician visits, including routine screening, whether provided on an inpatient or outpatient basis.

(2) Routine physical examinations as recommended and updated by the American Academy of Pediatrics (AAP) ''Guidelines for Health Supervision III'' and described in ''Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents.''

(3) Laboratory tests associated with the well-baby and well-child routine physical examinations as described in paragraph (b)(2) of this section.

(4) Immunizations and related office visits as recommended and updated by the Advisory Committee on Immunization Practices (ACIP).

(5) Routine preventive and diagnostic dental services (such as oral examinations, prophylaxis and topical fluoride applications, sealants, and x-rays) as described in the most recent guidelines issued by the American Academy of Pediatric Dentistry (AAPD).

§ 457.525 Public schedule.

(a) The State must make available to the groups in paragraph (b) of this section a public schedule that contains the following information:

(1) Current cost-sharing charges.

(2) Enrollee groups subject to the charges.

(3) Cumulative cost-sharing maximums.

(4) Mechanisms for making payments for required charges.

(5) The consequences for an applicant or an enrollee who does not pay a charge, including the disenrollment protections required by § 457.570.

(b) The State must make the public schedule available to the following groups:

(1) Enrollees, at the time of enrollment and reenrollment after a redetermination of eligibility, and when cost-sharing charges and cumulative cost-sharing maximums are revised.

(2) Applicants, at the time of application.

(3) All participating providers.

(4) The general public.

§ 457.530 General cost-sharing protection for lower income children.

The State may vary premiums, deductibles, coinsurance, copayments or any other cost sharing based on family income only in a manner that does not favor children from families with higher income over children from families with lower income.

§ 457.535 Cost-sharing protection to ensure enrollment of American Indians and Alaska Natives.

States may not impose premiums, deductibles, coinsurance, copayments or any other cost-sharing charges on children who are American Indians or Alaska Natives, as defined in § 457.10.

§ 457.540 Cost-sharing charges for children in families with incomes at or below 150 percent of the FPL.

The State may impose premiums, enrollment fees, deductibles, copayments, coinsurance, cost sharing and other similar charges for children whose family income is at or below 150 percent of the FPL as long as—

(a) Aggregate monthly enrollment fees, premiums, or similar charges imposed on a family are less than or equal to the maximum amounts permitted under § 447.52 of this chapter for a Medicaid eligible family of the same size and income;

(b) Any copayments, coinsurance, deductibles or similar charges for children whose family income is at or below 100 percent of the FPL are equal to or less than the amounts permitted under § 447.54 of this chapter;

(c) For children whose family income is from 101 percent to 150 percent of the FPL, any copayments, coinsurance, deductibles or similar charges are equal to or less than the maximum amounts permitted under § 457.555;

(d) The State does not impose more than one type of cost-sharing charge (deductible, copayment, or coinsurance) on a service;

(e) The State only imposes one copayment based on the total cost of services furnished during one office visit; and

(f) Aggregate annual cost sharing of all types, with respect to all targeted low-income children in a family, does not exceed the maximum permitted under § 457.560(a).

[66 FR 2681, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§ 457.555 Maximum allowable cost-sharing charges on targeted low-income children in families with income from 101 to 150 percent of the FPL.

(a) *Non-institutional services.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State plan must provide that for non-institutional services, including emergency services—

(1) Any copayment or similar charge the State imposes under a fee-for-service delivery system does not exceed the following amounts:

Total cost of services provided during a visit	Maximum amount chargeable to enrollee
$15.00 or less	$1.00
$15.01 to $40	2.00
$40.01 to $80	3.00
$80.01 or more	5.00

(2) Any copayment that the State imposes for services provided by a managed care organization may not exceed $5.00 per visit;

(3) Any coinsurance rate the State imposes may not exceed 5 percent of the payment the State directly or through contract makes for the service; and

(4) Any deductible the State imposes may not exceed $3.00 per month, per family for each period of eligibility.

(b) *Institutional services.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the maximum deductible, coinsurance or copayment charge for each institutional admission may not exceed 50 percent of the payment the State would make under the Medicaid fee-for-service system for the first day of care in the institution.

(c) *Institutional emergency services.* Any copayment that the State imposes on emergency services provided by an institution may not exceed $5.00.

(d) *Nonemergency use of the emergency room.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, the State may charge up to twice the charge for non-institutional services, up to a maximum amount of $10.00, for services furnished in a hospital emergency room if those services are not emergency services as defined in § 457.10.

(e) *Standard copayment amount.* For targeted low-income children whose family income is from 101 to 150 percent of the FPL, a standard copayment amount for any service may be determined by applying the maximum copayment amounts specified in paragraphs (a), (b), and (c) of this section to the State's average or typical payment for that service.

§ 457.560 Cumulative cost-sharing maximum.

(a) A State may not impose premiums, enrollment fees, copayments,

coinsurance, deductibles, or similar cost-sharing charges that, in the aggregate, exceed 5 percent of a family's total income for the length of a child's eligibility period in the State.

(b) The State must inform the enrollee's family in writing and orally if appropriate of their individual cumulative cost-sharing maximum amount at the time of enrollment and reenrollment.

[66 FR 2681, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§ 457.570 Disenrollment protections.

(a) The State must give enrollees reasonable notice of and an opportunity to pay past due premiums, copayments, coinsurance, deductibles or similar fees prior to disenrollment.

(b) The disenrollment process must afford the enrollee an opportunity to show that the enrollee's family income has declined prior to disenrollment for non payment of cost-sharing charges, and in the event that such a showing indicates that the enrollee may have become eligible for Medicaid or for a lower level of cost sharing, the State must facilitate enrolling the child in Medicaid or adjust the child's cost-sharing category as appropriate.

(c) The State must provide the enrollee with an opportunity for an impartial review to address disenrollment from the program in accordance with § 457.1130(a)(3).

Subpart F—Payments to States

§ 457.600 Purpose and basis of this subpart.

This subpart interprets and implements—

(a) Section 2104 of the Act which specifies the total allotment amount available for allotment to each State for child health assistance for fiscal years 1998 through 2007, the formula for determining each State allotment for a fiscal year, including the Commonwealth and Territories, and the amounts of payments for expenditures that are applied to reduce the State allotments.

(b) Section 2105 of the Act which specifies the provisions for making payment to States, the limitations and conditions on such payments, and the calculation of the enhanced Federal medical assistance percentage.

§ 457.602 Applicability.

The provisions of this subpart apply to the 50 States and the District of Columbia, and the Commonwealths and Territories.

§ 457.606 Conditions for State allotments and Federal payments for a fiscal year.

(a) *Basic conditions.* In order to receive a State allotment for a fiscal year, a State must have a State child health plan submitted in accordance with section 2106 of the Act, and

(1) For fiscal years 1998 and 1999, the State child health plan must be approved before October 1, 1999;

(2) For fiscal years after 1999, the State child health plan must be approved by the end of the fiscal year;

(3) An allotment for a fiscal year is not available to a State prior to the beginning of the fiscal year; and

(4) Federal payments out of an allotment are based on State expenditures which are allowable under the approved State child health plan.

(b) Federal payments for States' Children's Health Insurance Program (SCHIP) expenditures under an approved State child health plan are—

(1) Limited to the amount of available funds remaining in State allotments calculated in accordance with the allotment process and formula specified in §§ 457.608 and 457.610, and payment process in §§ 457.614 and 457.616.

(2) Available based on a percentage of State SCHIP expenditures, at a rate equal to the enhanced Federal medical assistance percentage (FMAP) for each fiscal year, calculated in accordance with § 457.622.

(3) Available through the grants process specified in § 457.630.

§ 457.608 Process and calculation of State allotments for a fiscal year.

(a) *General*—(1) State allotments for a fiscal year are determined by CMS for each State and the District of Columbia with an approved State child health plan, as described in paragraph (e) of

this section, and for each Commonwealth and Territory, as described in paragraph (f) of this section.

(2) In order to determine each State allotment, CMS determines the national total allotment amount for each fiscal year available to the 50 States and the District of Columbia, as described in paragraph (c) of this section, and the total allotment amount available for each fiscal year for allotment to the Commonwealths and Territories, as described in paragraph (d) of this section.

(3) The amount of allotments redistributed under section 2104(f) of the Act will not be applied or taken into account in determining the amounts of a fiscal year allotment for a State and the District of Columbia under this section.

(b) *Definition of Proportion.* As used in this section, *proportion* means the amount of the allotment for a State or the District of Columbia for a fiscal year, divided by the national total allotment amount available for allotment to all States and the District of Columbia, as specified in paragraph (c) of this section, for that fiscal year.

(c) *National total allotment amount for the 50 States and the District of Columbia.* (1) The national total allotment amount available for allotment to the 50 States and the District of Columbia is determined by subtracting the following amounts in the following order from the total appropriation specified in section 2104(a) of the Act for the fiscal year—

(i) The total allotment amount available for allotment for each fiscal year to the Commonwealths and Territories, as determined in paragraph (d)(1) of this section;

(ii) The total amount of the grant for the fiscal year for children with Type I Diabetes under Section 4921 of Public Law 105–33. This is $30,000,000 for each of the fiscal years 1998 through 2002; and

(iii) The total amount of the grant for the fiscal year for diabetes programs for Indians under Section 4922 of Public Law 105–33. This is $30,000,000 for each of the fiscal years 1998 through 2002.

(2) The following formula illustrates the calculation of the national total allotment amount available for allotment to the 50 States and the District of Columbia for a fiscal year:

$$A_{TA} = S_{2104(a)} - T_{2104(c)} - D_{4921} - D_{4922}$$

A_{TA} = National total allotment amount available for allotment to the 50 States and the District of Columbia for the fiscal year.

$S_{2104(a)}$ = Total appropriation for the fiscal year indicated in Section 2104(a) of the Act.

$T_{2104(c)}$ = Total allotment amount for a fiscal year available for allotment to the Commonwealths and Territories; as determined under paragraph (d)(1) of this section.

D_{4921} = Amount of total grant for children with Type I Diabetes under Section 4921 of Public Law 105–33. This is $30,000,000 for each of the fiscal years 1998 through 2002.

(d) *Total allotment amount available to the Commonwealths and Territories*—(1) *General.* The total allotment amount available to all the Commonwealths and Territories for a fiscal year is equal to .25 percent of the total appropriation for the fiscal year indicated in section 2104(a) of the Act, plus the additional amount for the fiscal year specified in paragraph (d)(2) of this section.

(2) *Additional amounts for allotment to the Commonwealths and Territories.* The following amounts are available for allotment to the Commonwealths and Territories for the indicated fiscal years in addition to the amount specified in paragraph (d)(1) of this section: For FY 1999, $32 million; for each of FY 2000 and FY 2001, $34.2 million; for each fiscal year FY 2002 through 2004, $25.2 million; for each fiscal year FY 2005 and FY 2006, $32.4 million; and for FY 2007, $40 million. The additional amount for allotment for FY 1999 for the Commonwealths and Territories was provided under Public Law 105–277. The additional amounts for allotment for FY 2000 through FY 2007 were provided for the Commonwealths and Territories under section 702 of Public Law 106–113.

(e) *Determination of State allotments for a fiscal year*—(1) *General.* The allotment for a State and the District of Columbia for a fiscal year is the product of:

(i) The proportion for the State or the District of Columbia for the fiscal year, as defined in paragraph (b) of this

section, and determined after application of the provisions of paragraphs (e)(2) and (3), related to the preadjusted proportion, and the floors, ceilings, and reconciliation process, respectively; and

(ii)(A) The national total allotment amount available for allotment for the fiscal year, as specified in paragraph (c) of this section. The State and the District of Columbia's allotment for a fiscal year is determined in accordance with the following general formula:

$SA_i = P_i \times A_{TA}$

SA_i = Allotment for a State or District of Columbia for a fiscal year.

P_i = Proportion for a State or District of Columbia for a fiscal year.

A_{TA} = Total amount available for allotment to the 50 States and the District of Columbia for the fiscal year.

(B) There are two steps for determining the proportion for a State and the District of Columbia. The first step determines the preadjusted proportions, and is described under paragraph (e)(2) of this section. The first step applies in determining the proportion for all fiscal years. The second step applies floors and ceilings and, if necessary, applies a reconciliation to the preadjusted proportion. The second step is described in paragraph (e)(3) of this section. The second step applies in determining the proportion only for FY 2000 and subsequent fiscal years. For FY 1998 and FY 1999, the preadjusted proportion is the State or District of Columbia's proportion for the fiscal year.

(2) *Determination of the Preadjusted Proportions for a Fiscal Year.* (i)The methodology for determining the State preadjusted proportion, referring to the determination of the proportion before the application of floors and ceilings and reconciliation for a fiscal year is in accordance with the following formula:

$PP_i = (C_i \times SCF_i)/ \Sigma(C_i \times x\ SCF_i)$

PP_i = Preadjusted proportion for a State or District of Columbia for a fiscal year.

C_i = *Number of children* in a State (section 2104(b)(1)(A)(I) of the Act) for a fiscal year. This number is based on the number of low-income children for a State for a fiscal year and the number of low-income children for a State for a fiscal year with no health insurance coverage for the fiscal year determined on the basis of the arithmetic average of the number of such children as reported and defined in the 3 most recent March supplements to the Current Population Survey (CPS) of the Bureau of the Census, and for FY 2000 and subsequent fiscal years, officially available before the beginning of the calendar year in which the fiscal year begins. For FY 1998 and FY 1999, the availability of the CPS data obtained from the Bureau of the Census is as specified in paragraphs (e)(4) and (5) of this section, respectively. (section 2104(b)(2)(B) of the Act).

(ii) For each of the fiscal years 1998 and 1999, the number of children is equal to the number of low-income children in the State for the fiscal year with no health insurance coverage. For fiscal year 2000, the number of children is equal to the sum of 75 percent of the number of low-income children in the State for the fiscal year with no health insurance coverage and 25 percent of the number of low-income children in the State for the fiscal year. For fiscal years 2001 and thereafter, the number of children is equal to the sum of 50 percent of the number of low-income children in the State for the fiscal year with no health insurance coverage and 50 percent of the number of low-income children in the State for the fiscal year. (section 2104(b)(2)(A) of the Act).

SCF_i = *State cost factor for a State* (section 2104(b)(1)(A)(ii) of the Act). For a fiscal year, this is equal to: .15 + .85 $\times (W_i/W_N)$ (section 2104(b)(3)(A) of the Act).

W_i = The annual average wages per employee for a State for such year (section 2104(b)(3)(A)(ii)(I) of the Act).

W_N = The annual average wages per employee for the 50 States and the District of Columbia (section 2104(b)(3)(A)(ii)(II) of the Act). The annual average wages per employee for a State or for all States and the District of Columbia for a fiscal year is equal to the average of such wages for employees in the health services industry (SIC 80), as reported by the Bureau of Labor Statistics of the Department of Labor for each of the most recent 3 years, and for FY 2000 and subsequent fiscal years, finally available before the beginning of the calendar year in which the fiscal year begins. For FY 1998 and FY 1999, the availability of the wage data obtained from the Bureau of Labor Statistics is as specified in paragraphs (e)(4) and (5), respectively. (section 2104(b)(3)(B) of the Act).

$\Sigma(C_i \times SCF_i)$ = The sum of the products of ($C_i \times SCF_i$) for each State (section 2104(b)(1)(B) of the Act).

A_{TA} = Total amount available for allotment to the 50 States and the District of Columbia for the fiscal year as determined under paragraph (c) of this section.

(3) *Application of floors and ceilings and reconciliation in determining proportion.* (i) *Floors and ceilings in proportions.* The preadjusted State proportions for a fiscal year are subject to the application of floors and ceilings in paragraphs (e)(3)(i)(A) and (B) of this section.

(A) The proportion floors, or minimum proportions, that apply in determining a State's proportion for the fiscal year are:

(*1*) $2,000,000 divided by the total of the amount available nationally;

(*2*) 90 percent of the State's proportion for the previous fiscal year; and

(*3*) 70 percent of the State's proportion for FY 1999.

(B) The proportion ceiling, or maximum proportion, for a fiscal year that applies in determining the State's fiscal year proportion is 145 percent of the State's proportion for FY 1999.

(ii) *Reconciliation of State proportions.* If, after the application of the floors and ceilings in paragraph (e)(3)(i), the sum of the States' proportions is not equal to one, the Secretary will reconcile the States' proportions by applying either paragraph (e)(3)(i)(A) or (B) of this paragraph, as appropriate, such that the sum of the proportions after reconciliation equals one. If, after the application of the floors and ceilings in paragraph (e)(3)(i), the sum of the States' proportions is equal to one, no reconciliation is necessary, and the States' proportions will be the same as the preadjusted proportions determined under paragraph (e)(2) of this section.

(A) If, after the application of the floors and ceilings under paragraphs (e)(3)(i)(A) and (B) of this section, the sum of the States' proportions is greater than one, the Secretary will establish a maximum percentage increase in States' proportions, such that when applied to the States' proportions, the sum of the proportions is exactly equal to one.

(B) If, after the application of the floors and ceilings under paragraphs (e)(3)(i)(A) and (B), the sum of the proportions is less than one, the Secretary will increase States' proportions (as computed before the application of the floors under paragraph (e)(3)(i)(A)) in a pro rata manner (but not to exceed the 145 percent ceiling computed under paragraph (e)(3)(i)(B)), such that when applied to the States' proportions, the sum of the proportions is exactly equal to one.

(4) *Data used for calculating the FY 1998 SCHIP allotments.* The FY 1998 SCHIP allotments were calculated in accordance with the methodology described in paragraphs (e)(1) and (2) of this section, using the most recent official and final data that were available from the Bureau of the Census and the Bureau of Labor Statistics, respectively, prior to the September 1 before the beginning of FY 1998 (that is, through August 31, 1997). In particular, through August 31, 1997, the only official data available on the numbers of children were data from the 3 March CPSs conducted in March 1994, 1995, and 1996 that reflected data for the 3 calendar years 1993, 1994, and 1995.

(5) *Data used for calculating the FY 1999 SCHIP allotments.* In accordance with section 101(f) of Public Law 105–277, the FY 1999 allotments were calculated in accordance with the methodology described in paragraph (e)(2) of this section, using the same data as were used in calculating the FY 1998 SCHIP allotments.

(f) *Methodology for determining the Commonwealth and Territory allotments for a fiscal year.* The total amount available for the Commonwealths and Territories for each fiscal year, as determined under paragraph (d) of this section, is allotted to each Territory and Commonwealth below which has an approved State child health plan. These allotments are in the proportion that the following percentages for each Commonwealth Territory bear to the sum of such percentages, as specified in section 2104(c)(2) of the Act:

Puerto Rico—91.6%
Guam—3.5%
Virgin Islands—2.6%
American Samoa—1.2%
Northern Mariana Islands—1.1%

(g) *Reserved State allotments for a fiscal year.* (1) For FY 2000 and subsequent

fiscal years, CMS determines and publishes the State reserved allotments for a fiscal year for each State, the District of Columbia, and Commonwealths and Territories in the FEDERAL REGISTER based on the most recent official and final data available before the beginning of the calendar year in which the fiscal year begins for the number of children and the State cost factor.

(2) For FY 1998 and FY 1999, CMS determined and published the State reserved allotments using the available data described in paragraphs (e)(4) and (e)(5) of this section, respectively, on the basis of the statutory allotment formula as it existed prior to the enactment of Public Law 106–113.

(3) If all States, the District of Columbia, and the Commonwealths and Territories have approved State child health plans in place prior to the beginning of the fiscal year, as appropriate, CMS may publish the allotments as final in the FEDERAL REGISTER, without the need for publication as reserved allotments.

(h) *Final allotments.* (1) Final State allotments for FY 1998 and FY 1999 for each State, the District of Columbia, and the Commonwealths and Territories are determined by CMS based only on those States, the District of Columbia, and the Commonwealths and Territories that have approved State child health plans by the end of fiscal year 1999, in accordance with the formula and methodology specified in paragraphs (a) through (g) of this section.

(2) Final State allotments for a fiscal year after FY 1999 for each State, the District of Columbia, and the Commonwealths and Territories are determined by CMS based only on those States, the District of Columbia, and the Commonwealths and Territories that have approved State child health plans by the end of the fiscal year, in accordance with the formula and methodology specified in paragraphs (a) through (g) of this section.

(3) CMS determines and publishes the States' final fiscal year allotments in the FEDERAL REGISTER based on the same data, with respect to the number of children and State cost factor, as were used in determining the reserved allotments for the fiscal year.

§ 457.610 Period of availability for State allotments for a fiscal year.

The amount of a final allotment for a fiscal year, as determined under § 457.608(h) and reduced to reflect certain Medicaid expenditures in accordance with § 457.616, remains available until expended for Federal payments based on expenditures claimed during a 3-year period of availability, beginning with the fiscal year of the final allotment and ending with the end of the second fiscal year following the fiscal year.

§ 457.614 General payment process.

(a) A State may make claims for Federal payment based on expenditures incurred by the State prior to or during the period of availability related to that fiscal year.

(b) In order to receive Federal financial participation (FFP) for a State's claims for payment for the State's expenditures, a State must—

(1) Submit budget estimates of quarterly funding requirements for Medicaid and the State Children's Health Insurance Programs; and

(2) Submit an expenditure report.

(c) Based on the State's quarterly budget estimates, CMS—

(1) Issues an advance grant to a State as described in § 457.630;

(2) Tracks and applies Federal payments claimed quarterly by each State, the District of Columbia, and each Commonwealth and Territory to ensure that payments do not exceed the applicable allotments for the fiscal year; and

(3) Track and apply relevant State, District of Columbia, Commonwealth and Territory expenditures reported each quarter against the 10 percent limit on expenditures other than child health assistance for standard benefit package, on a fiscal year basis as specified in § 457.618.

§ 457.616 Application and tracking of payments against the fiscal year allotments.

(a) *Categories of payments applied to reduce the State allotments.* In accordance with the principles described in

paragraph (c) of this section, the following categories of payments are applied to reduce the State allotments for a fiscal year:

(1) Payments made to the State for expenditures claimed during the fiscal year under its title XIX Medicaid program, to the extent the payments were made on the basis of the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act for expenditures attributable to children described in section 1905(u)(2) of the Act.

(2) Payments made to the State for expenditures claimed during the fiscal year under its title XIX Medicaid program, to the extent the payments were made on the basis of the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act for expenditures attributable to children described in section 1905(u)(3) of the Act.

(3) Payments made to a State under section 1903(a) of the Act for expenditures claimed by the State during a fiscal year that are attributable to the provision of medical assistance to a child during a presumptive eligibility period under section 1920A of the Act.

(4) Payments made to a State under its title XXI State Children's Health Insurance Program with respect to section 2105(a) of the Act for expenditures claimed by the State during a fiscal year.

(b) *Application of principles.* CMS applies the principles in paragraph (c) of this section to—

(1) Coordinate the application of the payments made to a State for the State's expenditures claimed under the Medicaid and State Children's Health Insurance programs against the State allotment for a fiscal year;

(2) Determine the order of these payments in that application; and

(3) Determine the application of payments against multiple State Child Health Insurance Program fiscal year allotments.

(c) *Principles for applying Federal payments against the allotment.* CMS—

(1) Applies the payments attributable to Medicaid expenditures specified in paragraphs (a)(1) through (a)(3) of this section, against the State child health plan allotment for a fiscal year before State child health plan expenditures specified in paragraph (a)(4) of this section are applied.

(2) Applies the payments attributable to Medicaid and State child health plan expenditures specified in paragraph (a) of this section against the applicable allotments for a fiscal year based on the quarter in which the expenditures are claimed by the State.

(3) Applies payments against the State allotments for a fiscal year in a manner that is consistent for all States.

(4) Applies payments attributable to Medicaid expenditures specified in paragraphs (a)(1) through (a)(3) of this section, in an order that maximizes Federal reimbursement for States. Expenditures for which the enhanced FMAP is available are applied before expenditures for which the regular FMAP is available.

(5) Applies payments for expenditures against State Child Health Insurance Program fiscal year allotments in the least administratively burdensome, and most effective and efficient manner; payments are applied on a quarterly basis as they are claimed by the State, and are applied to reduce the earliest fiscal year State allotments before the payments are applied to reduce later fiscal year allotments.

(6) Subject to paragraphs (c)(6)(i) and (ii) of this section, applies payments for expenditures for a fiscal year's allotment against a subsequent fiscal year's allotment; however, the subsequent fiscal year's allotment must be available at the time of application. For example, if the allotment for fiscal year 1998 has been fully expended, payments for expenditures claimed in fiscal year 1998 are carried over for application against the fiscal year 1999 allotment when it becomes available.

(i) In accordance with § 457.618, the amount of non-primary expenditures that are within the 10 percent limit for the fiscal year for which they are claimed may be applied against a fiscal year allotment or allotments available in a subsequent fiscal year.

(ii) In accordance with § 457.618, the amounts of non-primary expenditures that exceed the 10 percent limit for the fiscal year for which they are claimed may not be applied against a fiscal

year allotment or allotments available in a subsequent fiscal year.

(7) Carries over unexpended amounts of a State's allotment for a fiscal year for use in subsequent fiscal years through the end of the 3-year period of availability. For example, if the amounts of the fiscal year 1998 allotment are not fully expended by the end of fiscal year 1998, these amounts are carried over to fiscal year 1999 and are available to provide FFP for expenditures claimed by the State for that fiscal year.

(d) *Amount of Federal payment for expenditures claimed.* The amount of the Federal payment for expenditures claimed by a State, District of Columbia, or the Commonwealths and Territories is determined by the enhanced FMAP applicable to the fiscal year in which the State paid the expenditure. For example, Federal payment for an expenditure paid by a State in fiscal year 1998 that was carried over to fiscal year 1999 (in accordance with paragraph(c)(6) of this section), because the State exceeded its fiscal year 1998 allotment, is available at the fiscal year 1998 enhanced FMAP rate.

§457.618 Ten percent limit on certain State Children's Health Insurance Program expenditures.

(a) *Expenditures.* (1) *Primary expenditures* are expenditures under a State plan for child health assistance to targeted low-income children in the form of a standard benefit package, and Medicaid expenditures claimed during the fiscal year to the extent Federal payments made for these expenditures on the basis of the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act that are used to calculate the 10 percent limit.

(2) *Non-primary expenditures* are other expenditures under a State plan. Subject to the 10 percent limit described in paragraph (c) of this section, a State may receive Federal funds at the enhanced FMAP for 4 categories of non-primary expenditures:

(i) Administrative expenditures;

(ii) Outreach;

(iii) Health initiatives; and

(iv) Certain other child health assistance.

(b) *Federal payment.* Federal payment will not be available based on a State's non-primary expenditures for a fiscal year which exceed the 10 percent limit of the total of expenditures under the plan, as specified in paragraph (c) of this section.

(c) *10 Percent Limit.* The 10 percent limit is—

(1) Applied on an annual fiscal year basis;

(2) Calculated based on the total computable expenditures claimed by the State on quarterly expenditure reports submitted for a fiscal year. Expenditures claimed on a quarterly report for a different fiscal year may not be used in the calculation; and

(3) Calculated using the following formula:

$$L10\% = (A1 + U2 + U3)/9;$$

L10% = 10 Percent Limit for a fiscal year

A1 = Total computable amount of expenditures for the fiscal year under section 2105(a)(1) of the Act for which Federal payments are available at the enhanced FMAP described in Section 2105(b) of the Act;

U2 = Total computable expenditures for medical assistance for which Federal payments are made during the fiscal year based on the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act for individuals described in section 1905(u)(2) of the Act; and

U3 = Total computable expenditures for medical assistance for which Federal payments are made during the fiscal year based on the enhanced FMAP described in sections 1905(b) and 2105(b) of the Act for individuals described in section 1905(u)(3) of the Act.

(d) The expenditures under section 2105(a)(2) of the Act that are subject to the 10 percent limit are applied—

(1) On an annual fiscal year basis; and

(2) Against the 10 percent limit in the fiscal year for which the State submitted a quarterly expenditure report including the expenditures. Expenditures claimed on a quarterly report for one fiscal year may not be applied against the 10 percent limit for any other fiscal year.

(e)(1) The 10 percent limit for a fiscal year, as calculated under paragraph (c)(3) of this section, may be no greater than 10 percent of the total computable amount (determined under paragraph

(e)(2) of this section) of the State allotment or allotments available in that fiscal year. Therefore, the 10 percent limit is the lower of the amount calculated under paragraph (c)(3) of this section, and 10 percent of the total computable amount of the State allotment available in that fiscal year.

(2) As used in paragraph (e)(1) of this section, the total computable amount of a State's allotment for a fiscal year is determined by dividing the State's allotment for the fiscal year by the State's enhanced FMAP for the year. For example, if a State allotment for a fiscal year is $65 million and the enhanced FMAP rate for the fiscal year is 65 percent, the total computable amount of the allotment for the fiscal year is $100 million ($65 million/.65). In this example, the 10 percent limit may be no greater than a total computable amount of $10 million (10 percent of $100 million).

§ 457.622 Rate of FFP for State expenditures.

(a) *Basis.* Sections 1905(b), 2105(a) and 2105(b) of the Act provides for payments to States from the States' allotments for a fiscal year, as determined under § 457.608, for part of the cost of expenditures for services and administration made under an approved State child health assistance plan. The rate of payment is generally the enhanced Federal medical assistance percentage described below.

(b) *Enhanced Federal medical assistance percentage (Enhanced FMAP)—Computations.* The enhanced FMAP is the lower of the following:

(1) 70 percent of the regular FMAP determined under section 1905(b) of the Act, plus 30 percentage points; or

(2) 85 percent.

(c) *Conditions for availability of enhanced FMAP based on a State's expenditures*—The enhanced FMAP is available for payments based on a State's expenditures claimed under the State's title XXI program from the State's fiscal year allotment only under the following conditions:

(1) The State has an approved title XXI State child health plan;

(2) The expenditures are allowable under the State's approved title XXI State child health plan;

(3) State allotment amounts are available in the fiscal year, that is, the State's allotment or allotments (as reduced in accordance with § 457.616) remain available for a fiscal year and have not been fully expended.

(4) Expenditures claimed against the 10 percent limit are within the State's 10 percent limit for the fiscal year.

(5) For States that elect to extend eligibility to unborn children under the approved Child Health Plan, the State does not adopt eligibility standards and methodologies for purposes of determining a child's eligibility under the Medicaid State plan that were more restrictive than those applied under policies of the State plan in effect on June 1, 1997. This limitation applies also to more restrictive standards and methodologies for determining eligibility for services for a child based on the eligibility of a pregnant woman.

(d) *Categories of expenditures for which enhanced FMAP are available.* Except as otherwise provided below, the enhanced FMAP is available with respect to the following States' expenditures:

(1) Child health assistance under the plan for targeted low-income children in the form of providing health benefits coverage that meets the requirements of section 2103 of the Act; and

(2) Subject to the 10 percent limit provisions under § 457.618(a)(2), the following expenditures:

(i) Payment for other child health assistance for targeted low-income children;

(ii) Expenditures for health services initiatives under the State child health assistance plan for improving the health of children (including targeted low-income children);

(iii) Expenditures for outreach activities; and

(iv) Other reasonable costs incurred by the State to administer the State child health assistance plan.

(e) *SCHIP administrative expenditures and SCHIP related title XIX administrative expenditures*—(1) *General rule.* Allowable title XXI administrative expenditures should support the operation of the State child health assistance plan. In general, FFP for administration under title XXI is not available for costs of activities related to the operation of other programs.

(2) *Exception.* FFP is available under title XXI, at the enhanced FFP rate, for Medicaid administrative expenditures attributable to the provision of medical assistance to children described in sections 1905(u)(2) and 1905(u)(3), and during the presumptive eligibility period described in section 1920A of the Act, to the extent that the State does not claim those costs under the Medicaid program.

(3) FFP is not available in expenditures for administrative activities for items or services included within the scope of another claimed expenditure.

(4) FFP is available in expenditures for activities defined in sections 2102(c)(1) and 2105(a)(2)(C) of the Act as outreach to families of children likely to be eligible for child health assistance under the plan or under other public or private health coverage programs to inform these families of the availability of, and to assist them in enrolling their children in such a program.

(5) FFP is available in administrative expenditures for activities specified in sections 2102(c)(2) of the Act as coordination of the administration of the State Children's Health Insurance Program with other public and private health insurance programs. FFP would not be available for the costs of administering the other public and private health insurance programs. Coordination activities must be distinguished from other administrative activities common among different programs.

[65 FR 33622, May 24, 2000, as amended at 67 FR 61974, Oct. 2, 2002]

§ 457.626 Prevention of duplicate payments.

(a) *General rule.* No payment shall be made to a State for expenditures for child health assistance under its State child health plan to the extent that:

(1) A non-governmental health insurer would have been obligated to pay for those services but for a provision of its insurance contract that has the effect of limiting or excluding those obligations based on the actual or potential eligibility of the individual for child health assistance under the State child health insurance plan.

(2) Payment has been made or can reasonably be expected to be made promptly under any other Federally operated or financed health insurance or benefits program, other than a program operated or financed by the Indian Health Service.

(3) Services are for an unborn child and are payable under Medicaid as a service to an eligible pregnant woman under that program.

(b) *Definitions.* As used in paragraph (a) of this section—

Non-governmental health insurer includes any health insurance issuer, group health plan, or health maintenance organization, as those terms are defined in 45 CFR 144.103, which is not part of, or wholly owned by, a governmental entity.

Prompt payment can reasonably be expected when payment is required by applicable statute, or under an approved State plan.

Programs operated or financed by the Indian Health Service means health programs operated by the Indian Health Service, or Indian tribe or tribal organization pursuant to a contract, grant, cooperative agreement or compact with the Indian Health Service under the authority of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450, *et seq.*), or by an urban Indian organization in accordance with a grant or contract with the Indian Health Service under the authority of title V of the Indian Health Care Improvement Act (25 U.S.C. 1601, *et seq.*).

[65 FR 33622, May 24, 2000, as amended at 67 FR 61974, Oct. 2, 2002]

§ 457.628 Other applicable Federal regulations.

Other regulations applicable to SCHIP programs include the following:

(a) HHS regulations in 42 CFR Subpart B—433.51–433.74 sources of non-Federal share and Health Care-Related Taxes and Provider-Related Donations; these regulations apply to States' SCHIPs in the same manner as they apply to States' Medicaid programs.

(b) HHS Regulations in 45 CFR subtitle A:

Part 16—Procedures of the Departmental Appeals Board.

Part 74—Administration of Grants (except as specifically excepted).

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services: Effectuation of title VI of the Civil Rights Act of 1964.

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80.

Part 84—Nondiscrimination on the Basis of Handicap in Programs and activities Receiving or Benefiting From Federal Financial Assistance.

Part 95—General Administration—grant programs (public assistance and medical assistance).

§ 457.630 Grants procedures.

(a) *General provisions.* Once CMS has approved a State child health plan, CMS makes quarterly grant awards to the State to cover the Federal share of expenditures for child health assistance, other child health assistance, special health initiatives, outreach and administration.

(1) For fiscal year 1998, a State must submit a budget request in an appropriate format for the 4 quarters of the fiscal year. CMS bases the grant awards for the 4 quarters of fiscal year 1998 based on the State's budget requests for those quarters.

(2) For fiscal years after 1998, a State must submit a budget request in an appropriate format for the first 3 quarters of the fiscal year. CMS bases the grant awards for the first 3 quarters of the fiscal year on the State's budget requests for those quarters.

(3) For fiscal years after 1998, a State must also submit a budget request for the fourth quarter of the fiscal year. The amount of this quarter's grant award is based on the difference between a State's final allotment for the fiscal year, and the total of the grants for the first 3 quarters that were already issued in order to ensure that the total of all grant awards for the fiscal year are equal to the State's final allotment for that fiscal year.

(4) The amount of the quarterly grant is determined on the basis of information submitted by the State (in quarterly estimate and quarterly expenditure reports) and other pertinent information. This information must be submitted by the State through the Medicaid Budget and Expenditure System (MBES) for the Medicaid program, and through the Child Health Budget and Expenditure System (CBES) for the title XXI program.

(b) *Quarterly estimates.* The State Children's Health Insurance Program agency must submit Form CMS–21B (State Children's Health Insurance Program Budget Report for State Children's Health Insurance Program State expenditures) to the CMS central office (with a copy to the CMS regional office) 45 days before the beginning of each quarter.

(c) *Expenditure reports.* (1) The State must submit Form CMS–64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) and Form CMS–21 (Quarterly State Children's Health Insurance Program Statement of Expenditures for title XXI), to central office (with a copy to the regional office) not later than 30 days after the end of the quarter.

(2) This report is the State's accounting of actual recorded expenditures. This disposition of Federal funds may not be reported on the basis of estimates.

(d) *Additional required information.* A State must provide CMS with the following information regarding the administration of the title XXI program:

(1) Name and address of the State Agency/organization administering the program;

(2) The employer identification number (EIN); and

(3) A State official contact name and telephone number.

(e) *Grant award*—(1) *Computation by CMS.* Regional office staff analyzes the State's estimates and sends a recommendation to the central office. Central office staff considers the State's estimates, the regional office recommendations and any other relevant information, including any adjustments to be made under paragraph (e)(2) of this section, and computes the grant.

(2) *Content of award.* The grant award computation form shows the estimate of expenditures for the ensuing quarter, and the amounts by which that estimate is increased or decreased because of an increase or overestimate for prior quarters, or for any of the following reasons:

(i) Penalty reductions imposed by law.

(ii) Deferrals or disallowances.

(iii) Interest assessments.

(iv) Mandated adjustments such as those required by Section 1914 of the Act.

(3) *Effect of award.* The grant award authorizes the State to draw Federal funds as needed to pay the Federal share of disbursements.

(4) *Draw procedure.* The draw is through a commercial bank and the Federal Reserve system against a continuing letter of credit certified to the Secretary of the Treasury in favor of the State payee. (The letter of credit payment system was established in accordance with Treasury Department regulations—Circular No.1075.)

(f) *General administrative requirements.* With the following exceptions, the provisions of 45 CFR part 74, that establish uniform administrative requirements and cost principles, apply to all grants made to States under this subpart:

(1) Subpart G—Matching and Cost Sharing; and

(2) Subpart I—Financial Report Requirement.

Subpart G—Strategic Planning, Reporting, and Evaluation

SOURCE: 66 FR 2683, Jan. 11, 2001, unless otherwise noted.

§ 457.700 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Sections 2107(a), (b) and (d) of the Act, which set forth requirements for strategic planning, reports, and program budgets; and

(2) Section 2108 of the Act, which sets forth provisions regarding annual reports and evaluation.

(b) *Scope.* This subpart sets forth requirements for strategic planning, monitoring, reporting and evaluation under title XXI.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs and Medicaid expansion programs.

§ 457.710 State plan requirements: Strategic objectives and performance goals.

(a) *Plan description.* A State plan must include a description of—

(1) The strategic objectives as described in paragraph (b) of this section;

(2) The performance goals as described in paragraph (c) of this section; and

(3) The performance measurements, as described in paragraph (d) of this section, that the State has established for providing child health assistance to targeted low-income children under the plan and otherwise for maximizing health benefits coverage for other low-income children and children generally in the State.

(b) *Strategic objectives.* The State plan must identify specific strategic objectives relating to increasing the extent of creditable health coverage among targeted low-income children and other low-income children.

(c) *Performance goals.* The State plan must specify one or more performance goals for each strategic objective identified.

(d) *Performance measurements.* The State plan must describe how performance under the plan is—

(1) Measured through objective, independently verifiable means; and

(2) Compared against performance goals.

(e) *Core elements.* The State's strategic objectives, performance goals and performance measures must include a common core of national performance goals and measures consistent with the data collection, standard methodology, and verification requirements, as developed by the Secretary.

§ 457.720 State plan requirement: State assurance regarding data collection, records, and reports.

A State plan must include an assurance that the State collects data, maintains records, and furnishes reports to the Secretary, at the times and in the standardized format the Secretary may require to enable the Secretary to monitor State program administration and compliance and to evaluate and compare the effectiveness of State plans under Title XXI of the Act. This includes collection of data

and reporting as required under § 431.970 of this chapter.

[71 FR 51084, Aug. 28, 2006]

§ 457.740 State expenditures and statistical reports.

(a) *Required quarterly reports.* A State must submit reports to CMS that contain quarterly program expenditures and statistical data no later than 30 days after the end of each quarter of the Federal fiscal year. A State must collect required data beginning on the date of implementation of the approved State plan. Territories are exempt from the definition of ''State'' for purposes of the required quarterly reporting under this section. The quarterly reports must include data on—

(1) Program expenditures;

(2) The number of children enrolled in the title XIX Medicaid program, the separate child health program, and the Medicaid expansion program, as applicable, as of the last day of each quarter of the Federal fiscal year; and

(3) The number of children under 19 years of age who are enrolled in the title XIX Medicaid program, the separate child health program, and in the Medicaid expansion program, as appropriate, by the following categories:

(i) Age (under 1 year of age, 1 through 5 years of age, 6 through 12 years of age, and 13 through 18 years of age).

(ii) Gender, race, and ethnicity.

(iii) Service delivery system (managed care, fee-for-service, and primary care case management).

(iv) Family income as a percentage of the Federal poverty level as described in paragraph (b) of this section.

(b) *Reportable family income categories.* (1) A State that does not impose cost sharing or a State that imposes cost sharing based on a fixed percentage of income must report by two family income categories:

(i) At or below 150 percent of FPL.

(ii) Over 150 percent of FPL.

(2) A State that imposes a different level or percentage of cost sharing at different poverty levels must report by poverty level categories that match the poverty level categories used for purposes of cost sharing.

(c) *Required unduplicated counts.* Thirty days after the end of the Federal fiscal year, the State must submit an unduplicated count for the Federal fiscal year of children who were enrolled in the Medicaid program, the separate child health program, and the Medicaid expansion program, as appropriate, by age, gender, race, ethnicity, service delivery system, and poverty level categories described in paragraphs (a) and (b) of this section.

§ 457.750 Annual report.

(a) *Report required for each Federal fiscal year.* A State must report to CMS by January 1 following the end of each Federal fiscal year, on the results of the State's assessment of the operation of the State plan.

(b) *Contents of annual report.* In the annual report required under paragraph (a) of this section, a State must—

(1) Describe the State's progress in reducing the number of uncovered, low-income children and; in meeting other strategic objectives and performance goals identified in the State plan; and provide information related to a core set of national performance goals and measures as developed by the Secretary;

(2) Report on the effectiveness of the State's policies for discouraging the substitution of public coverage for private coverage;

(3) Identify successes and barriers in State plan design and implementation, and the approaches the State is considering to overcome these barriers;

(4) Describe the State's progress in addressing any specific issues (such as outreach) that the State plan proposed to periodically monitor and assess;

(5) Provide an updated budget for a 3-year period that describes those elements required in § 457.140, including any changes in the sources of the non-Federal share of State plan expenditures;

(6) Identify the total State expenditures for family coverage and total number of children and adults, respectively, covered by family coverage during the preceding Federal fiscal year;

(7) Describe the State's current income standards and methodologies for its Medicaid expansion program, separate child health program, and title XIX Medicaid program, as appropriate.

(c) *Methodology for estimate of number of uninsured, low-income children.* (1) To report on the progress made in reducing the number of uninsured, low-income children as required in paragraph (b) of this section, a State must choose a methodology to establish an initial baseline estimate of the number of low-income children who are uninsured in the State.

(i) A State may base the estimate on data from—

(A) The March supplement to the Current Population Survey (CPS);

(B) A State-specific survey;

(C) A statistically adjusted CPS; or

(D) Another appropriate source.

(ii) If the State does not base the estimate on data from the March supplement to the CPS, the State must submit a description of the methodology used to develop the initial baseline estimate and the rationale for its use.

(2) The State must provide an annual estimate of changes in the number of uninsured in the State using—

(i) The same methodology used in establishing the initial baseline; or

(ii) Another methodology based on new information that enables the State to establish a new baseline.

(3) If a new methodology is used, the State must also provide annual estimates based on either the March supplement to the CPS or the methodology used to develop the initial baseline.

[66 FR 2683, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

Subpart H—Substitution of Coverage

SOURCE: 66 FR 2684, Jan. 11, 2001, unless otherwise noted.

§ 457.800 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements section 2102(b)(3)(C) of the Act, which provides that the State plan must include a description of procedures the State uses to ensure that health benefits coverage provided under the State plan does not substitute for coverage under group health plans.

(b) *Scope.* This subpart sets forth State plan requirements relating to substitution of coverage in general and specific requirements relating to substitution of coverage under premium assistance programs.

(c) *Applicability.* The requirements of this subpart apply to separate child health programs.

§ 457.805 State plan requirement: Procedures to address substitution under group health plans.

The State plan must include a description of reasonable procedures to ensure that health benefits coverage provided under the State plan does not substitute for coverage provided under group health plans as defined at § 457.10.

§ 457.810 Premium assistance programs: Required protections against substitution.

A State that operates a premium assistance program, as defined at § 457.10, must provide the protections against substitution of SCHIP coverage for coverage under group health plans specified in this section. The State must describe these protections in the State plan; and report on results of monitoring of substitution in its annual reports.

(a) *Minimum period without coverage under a group health plan.* For health benefits coverage provided through premium assistance for group health plans, the following rules apply:

(1) An enrollee must not have had coverage under a group health plan for a period of at least 6 months prior to enrollment in a premium assistance program. A State may not require a minimum period without coverage under a group health plan that exceeds 12 months.

(2) States may permit reasonable exceptions to the requirement for a minimum period without coverage under a group health plan for—

(i) Involuntary loss of coverage under a group health plan, due to employer termination of coverage for all employees and dependents;

(ii) Economic hardship;

(iii) Change to employment that does not offer dependent coverage; or

(iv) Other reasons proposed by the State and approved as part of the State plan.

(3) The requirement for a minimum period without coverage under a group health plan does not apply to a child who, within the previous 6 months, has received coverage under a group health plan through Medicaid under section 1906 of the Act.

(4) The Secretary may waive the 6-month waiting period requirement described in this section at her discretion.

(b) *Employer contribution.* For health benefits coverage obtained through premium assistance for group health plans, the employee who is eligible for the coverage must apply for the full premium contribution available from the employer.

(c) *Cost effectiveness.* In establishing cost effectiveness—

(1) The State's cost for coverage for children under premium assistance programs must not be greater than the cost of other SCHIP coverage for these children; and

(2) The State may base its demonstration of cost effectiveness on an assessment of the cost of coverage for children under premium assistance programs to the cost of other SCHIP coverage for these children, done on a case-by-case basis, or on the cost of premium assisted coverage in the aggregate.

(d) *State evaluation.* The State must evaluate and report in the annual report (in accordance with § 457.750(b)(2)) the amount of substitution that occurs as a result of premium assistance programs and the effect of those programs on access to coverage.

Subpart I—Program Integrity

SOURCE: 66 FR 2685, Jan. 11, 2001, unless otherwise noted.

§ 457.900 Basis, scope and applicability.

(a) *Statutory basis.* This subpart implements—

(1) Section 2101(a) of the Act, which provides that the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner; and

(2) Section 2107(e) of the Act, which provides that certain title XIX and title XI provisions, including the following, apply to States under title XXI in the same manner as they apply to a State under title XIX:

(i) Section 1902(a)(4)(C) of the Act, relating to conflict of interest standards.

(ii) Paragraphs (2), (16), and (17), of section 1903(i) of the Act, relating to limitations on payment.

(iii) Section 1903(w) of the Act, relating to limitations on provider taxes and donations.

(iv) Section 1124 of the Act, relating to disclosure of ownership and related information.

(v) Section 1126 of the Act, relating to disclosure of information about certain convicted individuals.

(vi) Section 1128 of the Act, relating to exclusions.

(vii) Section 1128A of the Act, relating to civil monetary penalties.

(viii) Section 1128B(d) of the Act, relating to criminal penalties for certain additional charges.

(ix) Section 1132 of the Act, relating to periods within which claims must be filed.

(b) *Scope.* This subpart sets forth requirements, options, and standards for program integrity assurances that must be included in the approved State plan.

(c) *Applicability.* This subpart applies to separate child health programs. Medicaid expansion programs are subject to the program integrity rules and requirements specified under title XIX.

§ 457.902 Definitions

As used in this subpart—

Actuarially sound principles means generally accepted actuarial principles and practices that are applied to determine aggregate utilization patterns, are appropriate for the population and services to be covered, and have been certified by actuaries who meet the qualification standards established by the Actuarial Standards Board.

Fee-for-service entity means any individual or entity that furnishes services under the program on a fee-for-service basis, including health insurance services.

§ 457.910 State program administration.

The State's child health program must include—

(a) Methods of administration that the Secretary finds necessary for the proper and efficient operation of the separate child health program; and

(b) Safeguards necessary to ensure that—

(1) Eligibility will be determined appropriately in accordance with subpart C of this part; and

(2) Services will be provided in a manner consistent with administrative simplification and with the provisions of subpart D of this part.

§ 457.915 Fraud detection and investigation.

(a) *State program requirements.* The State must establish procedures for ensuring program integrity and detecting fraudulent or abusive activity. These procedures must include the following:

(1) Methods and criteria for identifying suspected fraud and abuse cases.

(2) Methods for investigating fraud and abuse cases that—

(i) Do not infringe on legal rights of persons involved; and

(ii) Afford due process of law.

(b) *State program integrity unit.* The State may establish an administrative agency responsible for monitoring and maintaining the integrity of the separate child health program.

(c) *Program coordination.* The State must develop and implement procedures for referring suspected fraud and abuse cases to the State program integrity unit (if such a unit is established) and to appropriate law enforcement officials. Law enforcement officials include the—

(1) U.S. Department of Health and Human Services Office of Inspector General (OIG);

(2) U.S. Attorney's Office, Department of Justice (DOJ);

(3) Federal Bureau of Investigation (FBI); and

(4) State Attorney General's office.

§ 457.925 Preliminary investigation.

If the State agency receives a complaint of fraud or abuse from any source or identifies questionable practices, the State agency must conduct a preliminary investigation or take otherwise appropriate action within a reasonable period of time to determine whether there is sufficient basis to warrant a full investigation.

§ 457.930 Full investigation, resolution, and reporting requirements.

The State must establish and implement effective procedures for investigating and resolving suspected and apparent instances of fraud and abuse. Once the State determines that a full investigation is warranted, the State must implement procedures including, but not limited to the following:

(a) Cooperate with and refer potential fraud and abuse cases to the State program integrity unit, if such a unit exists.

(b) Conduct a full investigation.

(c) Refer the fraud and abuse case to appropriate law enforcement officials.

§ 457.935 Sanctions and related penalties.

(a) A State may not make payments for any item or service furnished, ordered, or prescribed under a separate child health program to any provider who has been excluded from participating in the Medicare and Medicaid programs.

(b) The following provisions and their corresponding regulations apply to a State under title XXI, in the same manner as these provisions and regulations apply to a State under title XIX:

(1) Part 455, subpart B of this chapter.

(2) Section 1124 of the Act pertaining to disclosure of ownership and related information.

(3) Section 1126 of the Act pertaining to disclosure by institutions, organizations, and agencies of owners and certain other individuals who have been convicted of certain offenses.

(4) Section 1128 of the Act pertaining to exclusions.

(5) Section 1128A of the Act pertaining to civil monetary penalties.

(6) Section 1128B of the Act pertaining to criminal penalties for acts involving Federal health care programs.

(7) Section 1128E of the Act pertaining to the reporting of final adverse actions on liability findings made

against health care providers, suppliers, and practitioners under the health care fraud and abuse data collection program.

§ 457.940 Procurement standards.

(a) A State must submit to CMS a written assurance that title XXI services will be provided in an effective and efficient manner. The State must submit the assurance—

(1) With the initial State plan; or

(2) For States with approved plans, with the first request to amend the approved plan.

(b) A State must—

(1) Provide for free and open competition, to the maximum extent practical, in the bidding of all procurement contracts for coverage or other services in accordance with the procurement requirements of 45 CFR 74.43 or 45 CFR 92.36, as applicable; or

(2) Use payment rates based on public or private payment rates for comparable services for comparable populations, consistent with principles of actuarial soundness as defined at § 457.902.

(c) A State may establish higher rates than permitted under paragraph (b) of this section if such rates are necessary to ensure sufficient provider participation, provider access, or to enroll providers who demonstrate exceptional efficiency or quality in the provision of services.

(d) All contracts under this part must include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74 or 45 CFR part 92, as applicable.

(e) The State must provide to CMS, if requested, a description of the manner in which rates were developed in accordance with the requirements of paragraphs (b) or (c) of this section.

[66 FR 2685, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§ 457.945 Certification for contracts and proposals.

Entities that contract with the State under a separate child health program must certify the accuracy, completeness, and truthfulness of information in contracts and proposals, including information on subcontractors, and other related documents, as specified by the State.

§ 457.950 Contract and payment requirements including certification of payment-related information.

(a) *Managed care entity (MCE).* A State that makes payments to an MCE under a separate child health program, based on data submitted by the MCE, must ensure that its contract requires the MCE to provide—

(1) Enrollment information and other information required by the State;

(2) An attestation to the accuracy, completeness, and truthfulness of claims and payment data, under penalty of perjury;

(3) Access for the State, CMS, and the HHS Office of the Inspector General to enrollee health claims data and payment data, in conformance with the appropriate privacy protections in the State; and

(4) A guarantee that the MCE will not avoid costs for services covered in its contract by referring enrollees to publicly supported health care resources.

(b) *Fee-for-service entities.* A State that makes payments to fee-for-service entities under a separate child health program must—

(1) Establish procedures to ensure that the entity certifies and attests that information on claim forms is truthful, accurate, and complete;

(2) Ensure that fee-for-service entities understand that payment and satisfaction of the claims will be from Federal and State funds, and that any false claims may be prosecuted under applicable Federal or State laws; and

(3) Require, as a condition of participation, that fee-for-service entities provide the State, CMS and/or the HHS Office of the Inspector General with access to enrollee health claims data, claims payment data and related records.

§ 457.955 Conditions necessary to contract as a managed care entity (MCE).

(a) The State must assure that any entity seeking to contract as an MCE under a separate child health program has administrative and management

arrangements or procedures designed to safeguard against fraud and abuse.

(b) The State must ensure that the arrangements or procedures required in paragraph (a) of this section—

(1) Enforce MCE compliance with all applicable Federal and State standards;

(2) Prohibit MCEs from conducting any unsolicited personal contact with a potential enrollee by an employee or agent of a managed care entity for the purpose of influencing the individual to enroll with the entity; and

(3) Include a mechanism for the MCE to report to the State, to CMS, or to the Office of Inspector General (OIG) as appropriate, information on violations of law by subcontractors or enrollees of an MCE and other individuals.

(c) With respect to enrollees, the reporting requirement in paragraph (b)(3) of this section applies only to information on violations of law that pertain to enrollment in the plan, or the provision of, or payment for, health services.

(d) The State may inspect, evaluate, and audit MCEs at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent and abusive activity.

§457.960 Reporting changes in eligibility and redetermining eligibility.

If the State requires reporting of changes in circumstances that may affect the enrollee's eligibility for child health assistance, the State must:

(a) Establish procedures to ensure that enrollees make timely and accurate reports of any such change; and

(b) Promptly redetermine eligibility when the State has information about these changes.

§457.965 Documentation.

The State must include in each applicant's record facts to support the State's determination of the applicant's eligibility for SCHIP.

§457.980 Verification of enrollment and provider services received.

The State must establish and maintain systems to identify, report, and verify the accuracy of claims for those enrolled children who meet requirements of section 2105(a) of the Act, where enhanced Federal medical assistance percentage computations apply.

[66 FR 2685, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§457.985 Integrity of professional advice to enrollees.

The State must ensure through its contracts for coverage and services that its contractors comply with—

(a) Section 422.206(a) of this chapter, which prohibits interference with health care professionals' advice to enrollees and requires that professionals provide information about treatment in an appropriate manner; and

(b) Sections 422.208 and 422.210 of this chapter, which place limitations on physician incentive plans, and information disclosure requirements related to those physician incentive plans, respectively.

Subpart J—Allowable Waivers: General Provisions

SOURCE: 66 FR 2686, Jan. 11, 2001, unless otherwise noted.

§457.1000 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2105(c)(2)(B) of the Act, which sets forth the requirements to permit a State to exceed the 10 percent cost limit on expenditures other than benefit expenditures; and

(2) Section 2105(c)(3) of the Act, which permits the purchase of family coverage.

(b) *Scope.* This subpart sets forth requirements for obtaining a waiver under title XXI.

(c) *Applicability.* This subpart applies to separate child health programs; and applies to Medicaid expansion programs when the State claims administrative costs under title XXI and seeks a waiver of limitations on such claims for use of a community-based health delivery system. This subpart does not apply to demonstrations requested under section 1115 of the Act.

[66 FR 2686, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

§ 457.1003 CMS review of waiver requests.

CMS will review the waiver requests under this subpart using the same time frames used for State plan amendments, as specified in § 457.160.

§ 457.1005 Cost-effective coverage through a community-based health delivery system.

(a) *Availability of waiver.* The Secretary may waive the requirements of § 457.618 (the 10 percent limit on expenditures not used for health benefits coverage for targeted low-income children, that meets the requirements of § 457.410) in order to provide child health assistance to targeted low-income children under the State plan through a cost-effective, community-based health care delivery system, such as through contracts with health centers receiving funds under section 330 of the Public Health Service Act or with hospitals such as those that receive disproportionate share payment adjustments under section 1886(c)(5)(F) or section 1923 of the Act.

(b) *Requirements for obtaining a waiver.* To obtain a waiver for cost-effective coverage through a community-based health delivery system, a State must demonstrate that—

(1) The coverage meets all of the requirements of this part, including subpart D and subpart E.

(2) The cost of such coverage, on an average per child basis, does not exceed the cost of coverage under the State plan.

(c) *Three-year approval period.* An approved waiver remains in effect for no more than 3 years.

(d) *Application of cost savings.* If the cost of coverage of a child under a community-based health delivery system is equal to or less than the cost of coverage of a child under the State plan, the State may use the difference in the cost of coverage for each child enrolled in a community-based health delivery system for—

(1) Other child health assistance, health services initiatives, or outreach; or

(2) Any reasonable costs necessary to administer the State's program.

§ 457.1010 Purchase of family coverage.

A State may purchase family coverage that includes coverage for targeted low-income children if the State establishes that—

(a) Purchase of family coverage is cost-effective under the standards described in § 457.1015;

(b) The State does not purchase the coverage if it would otherwise substitute for health insurance coverage that would be provided to targeted, low-income children but for the purchase of family coverage; and

(c) The coverage for the family otherwise meets the requirements of this part.

§ 457.1015 Cost-effectiveness.

(a) *Definition.* For purposes of this subpart, ''cost-effective'' means that the State's cost of purchasing family coverage that includes coverage for targeted low-income children is equal to or less than the State's cost of obtaining coverage under the State plan only for the eligible targeted low-income children involved.

(b) *Cost comparisons.* A State may demonstrate cost-effectiveness by comparing the cost of coverage for the family to the cost of coverage only for the targeted low-income children under the health benefits package offered by the State under the State plan for which the child is eligible.

(c) *Individual or aggregate basis.* (1) The State may base its demonstration of the cost-effectiveness of family coverage on an assessment of the cost of family coverage for individual families, done on a case-by-case basis, or on the cost of family coverage in the aggregate.

(2) The State must assess cost-effectiveness in its initial request for a waiver and then annually.

(3) For any State that chooses the aggregate cost method, if an annual assessment of the cost-effectiveness of family coverage in the aggregate reveals that it is not cost-effective, the State must assess cost-effectiveness on a case-by-case basis.

(d) *Reports on family coverage.* A State with a waiver under this section must include in its annual report pursuant to § 457.750, the cost of family coverage

purchased under the waiver, and the number of children and adults, respectively, covered under family coverage pursuant to the waiver.

Subpart K—State Plan Requirements: Applicant and Enrollee Protections

SOURCE: 66 FR 2687, Jan. 11, 2001, unless otherwise noted.

§ 457.1100 Basis, scope and applicability.

(a) *Statutory basis.* This subpart interprets and implements—

(1) Section 2101(a) of the Act, which states that the purpose of title XXI of the Act is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner;

(2) Section 2102(a)(7)(B) of the Act, which requires that the State plan include a description of the methods used to assure access to covered services, including emergency services;

(3) Section 2102(b)(2) of the Act, which requires that the State plan include a description of methods of establishing and continuing eligibility and enrollment; and

(4) Section 2103 of the Act, which outlines coverage requirements for a State that provides child health assistance through a separate child health program.

(b) *Scope.* This subpart sets forth minimum standards for privacy protection and for procedures for review of matters relating to eligibility, enrollment, and health services.

(c) *Applicability.* This subpart only applies to a separate child health program.

§ 457.1110 Privacy protections.

The State must ensure that, for individual medical records and any other health and enrollment information maintained with respect to enrollees, that identifies particular enrollees (in any form), the State establishes and implements procedures to—

(a) Abide by all applicable Federal and State laws regarding confidentiality and disclosure, including those laws addressing the confidentiality of information about minors and the privacy of minors, and privacy of individually identifiable health information;

(b) Comply with subpart F of part 431 of this chapter;

(c) Maintain the records and information in a timely and accurate manner;

(d) Specify and make available to any enrollee requesting it—

(1) The purposes for which information is maintained or used; and

(2) To whom and for what purposes the information will be disclosed outside the State;

(e) Except as provided by Federal and State law, ensure that each enrollee may request and receive a copy of records and information pertaining to the enrollee in a timely manner and that an enrollee may request that such records or information be supplemented or corrected.

§ 457.1120 State plan requirement: Description of review process.

(a) The State must have one of the following review processes:

(1) *Program specific review.* A process that meets the requirements of §§ 457.1130, 457.1140, 457.1150, 457.1160, 457.1170, and 457.1180; or

(2) *Statewide Standard Review.* A process that complies with State review requirements currently in effect for all health insurance issuers (as defined in section 2791 of the Public Health Service Act) in the State.

(b) The State plan must include a description of the State's review process.

[66 FR 33824, June 25, 2001]

§ 457.1130 Program specific review process: Matters subject to review.

(a) *Eligibility or enrollment matter.* A State must ensure that an applicant or enrollee has an opportunity for review, consistent with §§ 457.1140 and 457.1150, of a—

(1) Denial of eligibility;

(2) Failure to make a timely determination of eligibility; and

(3) Suspension or termination of enrollment, including disenrollment for failure to pay cost sharing.

(b) *Health services matter.* A State must ensure that an enrollee has an opportunity for external review of a—

(1) Delay, denial, reduction, suspension, or termination of health services,

in whole or in part, including a determination about the type or level of services; and

(2) Failure to approve, furnish, or provide payment for health services in a timely manner.

(c) *Exception.* A State is not required to provide an opportunity for review of a matter described in paragraph (a) or (b) of this section if the sole basis for the decision is a provision in the State plan or in Federal or State law requiring an automatic change in eligibility, enrollment, or a change in coverage under the health benefits package that affects all applicants or enrollees or a group of applicants or enrollees without regard to their individual circumstances.

§ 457.1140 Program specific review process: Core elements of review.

In adopting the procedures for review of matters described in § 457.1130, a State must ensure that—

(a) Reviews are conducted by an impartial person or entity in accordance with § 457.1150;

(b) Review decisions are timely in accordance with § 457.1160;

(c) Review decisions are written; and

(d) Applicants and enrollees have an opportunity to—

(1) Represent themselves or have representatives of their choosing in the review process;

(2) Timely review their files and other applicable information relevant to the review of the decision;

(3) Fully participate in the review process, whether the review is conducted in person or in writing, including by presenting supplemental information during the review process; and

(4) Receive continued enrollment in accordance with § 457.1170.

§ 457.1150 Program specific review process: Impartial review.

(a) *Eligibility or enrollment matter.* The review of a matter described in § 457.1130(a) must be conducted by a person or entity who has not been directly involved in the matter under review.

(b) *Health services matter.* The State must ensure that an enrollee has an opportunity for an independent external review of a matter described in § 457.1130(b). External review must be conducted by the State or a contractor other than the contractor responsible for the matter subject to external review.

§ 457.1160 Program specific review process: Time frames.

(a) *Eligibility or enrollment matter.* A State must complete the review of a matter described in § 457.1130(a) within a reasonable amount of time. In setting time frames, the State must consider the need for expedited review when there is an immediate need for health services.

(b) *Health services matter.* The State must ensure that reviews are completed in accordance with the medical needs of the patient. If the medical needs of the patient do not dictate a shorter time frame, the review must be completed within the following time frames:

(1) *Standard timeframe.* A State must ensure that external review, as described in § 457.1150(b), is completed within 90 calendar days of the date an enrollee requests internal (if available) or external review. If both internal and external review are available to the enrollee, both types of review must be completed within the 90 calendar day period.

(2) *Expedited timeframe.* A State must ensure that external review, as described in § 457.1150(b), is completed within 72 hours of the time an enrollee requests external review, if the enrollee's physician or health plan determines that operating under the standard time frame could seriously jeopardize the enrollee's life or health or ability to attain, maintain or regain maximum function. If the enrollee has access to internal and external review, then each level of review may take no more than 72 hours. The State may extend the 72-hour time frame by up to 14 calendar days, if the enrollee requests an extension.

§ 457.1170 Program specific review process: Continuation of enrollment.

A State must ensure the opportunity for continuation of enrollment pending

the completion of review of a suspension or termination of enrollment, including a decision to disenroll for failure to pay cost sharing.

§ 457.1180 Program specific review process: Notice.

A State must provide enrollees and applicants timely written notice of any determinations required to be subject to review under § 457.1130 that includes the reasons for the determination, an explanation of applicable rights to review of that determination, the standard and expedited time frames for review, the manner in which a review can be requested, and the circumstances under which enrollment may continue pending review.

§ 457.1190 Application of review procedures when States offer premium assistance for group health plans.

A State that has a premium assistance program through which it provides coverage under a group health plan that does not meet the requirements of a program specific review or a Statewide standard review, as described in § 457.1120, must give applicants and enrollees the option to obtain health benefits coverage other than through that group health plan. The State must provide this option at initial enrollment and at each redetermination of eligibility.

[66 FR 2686, Jan. 11, 2001, as amended at 66 FR 33824, June 25, 2001]

SUBCHAPTER E—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395).

SOURCE: 64 FR 66279, Nov. 24, 1999, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 460 appear at 67 FR 61504, Oct. 1, 2002.

Subpart A—Basis, Scope, and Definitions

§ 460.2 Basis.

This part implements sections 1894, 1905(a), and 1934 of the Act, which authorize the following:

(a) Medicare payments to, and coverage of benefits under, PACE.

(b) The establishment of PACE as a State option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE.

§ 460.4 Scope and purpose.

(a) *General.* This part sets forth the following:

(1) The requirements that an entity must meet to be approved as a PACE organization that operates a PACE program under Medicare and Medicaid.

(2) How individuals may qualify to enroll in a PACE program.

(3) How Medicare and Medicaid payments will be made for PACE services.

(4) Provisions for Federal and State monitoring of PACE programs.

(5) Procedures for sanctions and terminations.

(b) *Program purpose.* PACE provides pre-paid, capitated, comprehensive health care services designed to meet the following objectives:

(1) Enhance the quality of life and autonomy for frail, older adults.

(2) Maximize dignity of, and respect for, older adults.

(3) Enable frail, older adults to live in the community as long as medically and socially feasible.

(4) Preserve and support the older adult's family unit.

§ 460.6 Definitions.

As used in this part, unless the context indicates otherwise, the following definitions apply:

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, as determined by CMS.

Medicare beneficiary means an individual who is entitled to Medicare Part A benefits or enrolled under Medicare Part B, or both.

Medicaid participant means an individual determined eligible for Medicaid who is enrolled in a PACE program.

Medicare participant means a Medicare beneficiary who is enrolled in a PACE program.

PACE stands for programs of all-inclusive care for the elderly.

PACE center means a facility operated by a PACE organization where primary care is furnished to participants.

PACE organization means an entity that has in effect a PACE program agreement to operate a PACE program under this part.

PACE program agreement means an agreement between a PACE organization, CMS, and the State administering agency for the operation of a PACE program.

Participant means an individual who is enrolled in a PACE program.

Services includes both items and services.

State administering agency means the State agency responsible for administering the PACE program agreement.

Trial period means the first 3 contract years in which a PACE organization operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration waiver program.

Subpart B—PACE Organization Application and Waiver Process

§ 460.10 Purpose.

This subpart sets forth the application requirements for an entity that seeks approval from CMS as a PACE organization and the process by which a PACE organization may request waiver of certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).

[67 FR 61504, Oct. 1, 2002]

§ 460.12 Application requirements.

(a) *General.* (1) An individual authorized to act for the entity must submit to CMS a complete application that describes how the entity meets all requirements in this part.

(2) [Reserved]

(3) CMS accepts applications from entities that seek approval as PACE organizations beginning on February 22, 2000 except for the following:

(i) Beginning on November 24, 1999, CMS accepts applications from entities that meet the requirements for priority consideration in processing of applications, as provided in § 460.14.

(ii) Beginning on January 10, 2000, CMS accepts applications from entities that meet the requirements for special consideration in processing applications, as provided in § 460.16.

(b) *State assurance.* An entity's application must be accompanied by an assurance from the State administering agency of the State in which the program is located indicating that the State—

(1) Considers the entity to be qualified to be a PACE organization; and

(2) Is willing to enter into a PACE program agreement with the entity.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002]

§ 460.14 Priority consideration.

Until August 5, 2000, CMS gives priority consideration in processing applications for PACE organization status to an entity that meets either of the following criteria:

(a) Is operating under PACE demonstration waivers under one of the following authorities:

(1) Section 603(c) of the Social Security Amendments of 1983, as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985.

(2) Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986.

(b) Has applied to operate under a PACE demonstration under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 as of May 1, 1997.

§ 460.16 Special consideration.

Until August 5, 2000, CMS gives special consideration in processing applications to an entity that meets the following conditions:

(a) Indicated, by May 1, 1997, a specific intent to become a PACE organization through formal activities.

(b) Includes documentation of its formal activities.

§ 460.18 CMS evaluation of applications.

CMS evaluates an application for approval as a PACE organization on the basis of the following information:

(a) Information contained in the application.

(b) Information obtained through onsite visits conducted by CMS or the State administering agency.

(c) Information obtained by the State administering agency.

§ 460.20 Notice of CMS determination.

(a) *Time limit for notification of determination.* Within 90 days after an entity submits a complete application to CMS, CMS takes one of the following actions:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis

for the denial and the process for requesting reconsideration of the denial.

(3) Requests additional information needed to make a final determination.

(b) *Additional information requested.* If CMS requests from an entity additional information needed to make a final determination, within 90 days after CMS receives all requested information from the entity, CMS takes one of the following actions:

(1) Approves the application.

(2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

(c) *Deemed approval.* An application is deemed approved if CMS fails to act on the application within 90 days after one of the following dates:

(1) The date the application is submitted by the organization.

(2) The date CMS receives all requested additional information.

(d) *Date of submission.* For purposes of the 90-day time limit described in this section, the date that an application is submitted to CMS is the date on which the application is delivered to the address designated by CMS.

§ 460.22 Service area designation.

(a) An entity must state in its application the service area it proposes for its program.

(b) CMS, in consultation with the State administering agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

§ 460.24 Limit on number of PACE program agreements.

(a) *Numerical limit.* Except as specified in paragraph (b) of this section, CMS does not permit the number of PACE organizations with which agreements are in effect under this part or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, to exceed the following:

(1) As of August 5, 1997—40.

(2) As of each succeeding August 5, the numerical limit for the preceding year plus 20, without regard to the actual number of agreements in effect on a previous anniversary date. (For example, the limit is 60 on August 5, 1998 and 80 on August 5, 1999.)

(b) *Exception.* The numerical limit does not apply to a private, for-profit PACE organization that meets the following conditions:

(1) Is operating under a demonstration project waiver under section 1894(h) and 1934(h) of the Act.

(2) Was operating under a waiver and subsequently qualifies for PACE organization status in accordance with sections 1894(a)(3)(B)(ii) and 1934(a)(3)(B)(ii) of the Act.

§ 460.26 Submission and evaluation of waiver requests.

(a) A PACE organization must submit its waiver request through the State administering agency for initial review. The State administering agency forwards waiver requests to CMS along with any concerns or conditions regarding the waiver.

(b) CMS evaluates a waiver request from a PACE organization on the basis of the following information:

(1) The adequacy of the description and rationale for the waiver provided by the PACE organization, including any additional information requested by CMS.

(2) Information obtained by CMS and the State administering agency in onsite reviews and monitoring of the PACE organization.

(c) Requirements related to the following principles may not be waived:

(1) A focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

(2) The delivery of comprehensive, integrated acute and long-term care services.

(3) An interdisciplinary team approach to care management and service delivery.

(4) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.

(5) The assumption by the provider of full financial risk.

[67 FR 61505, Oct. 1, 2002; 67 FR 63966, Oct. 16, 2002]

§ 460.28 Notice of CMS determination on waiver requests.

(a) *Time limit for notification of determination.* Within 90 days after receipt of a waiver request, CMS takes one of the following actions:

(1) Approves the request.

(2) Denies the request and notifies the PACE organization in writing of the basis for the denial.

(b) *Date of receipt.* For purposes of the 90-day time limit described in this section, the date that a waiver request is received by CMS from the State administering agency is the date on which the request is delivered to the address designated by CMS.

(c) *Waiver approval.* (1) A waiver request is deemed approved if CMS fails to act on the request within 90 days after the date the waiver request is received by CMS.

(2) CMS may withdraw approval of a waiver for good cause.

[67 FR 61505, Oct. 1, 2002]

Subpart C—PACE Program Agreement

§ 460.30 Program agreement requirement.

(a) A PACE organization must have an agreement with CMS and the State administering agency for the operation of a PACE program by the PACE organization under Medicare and Medicaid.

(b) The agreement must be signed by an authorized official of CMS, the PACE organization and the State administering agency.

(c) CMS may only sign program agreements with PACE organizations that are located in States with approved State plan amendments electing PACE as an optional benefit under their Medicaid State plan.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002]

§ 460.32 Content and terms of PACE program agreement.

(a) *Required content.* A PACE program agreement must include the following information:

(1) A designation of the service area of the organization's program. The area may be identified by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, as applicable. CMS and the State administering agency must approve any change in the designated service area.

(2) The organization's commitment to meet all applicable requirements under Federal, State, and local laws and regulations, including provisions of the Civil Rights Act, the Age Discrimination Act, and the Americans With Disabilities Act.

(3) The effective date and term of the agreement.

(4) A description of the organizational structure of the PACE organization and information on administrative contacts, including the following:

(i) Name and phone number of the program director.

(ii) Name of all governing body members.

(iii) Name and phone number of a contact person for the governing body.

(5) A participant bill of rights approved by CMS and an assurance that the rights and protections will be provided.

(6) A description of the process for handling participant grievances and appeals.

(7) A statement of the organization's policies on eligibility, enrollment, voluntary disenrollment, and involuntary disenrollment.

(8) A description of services available to participants.

(9) A description of the organization's quality assessment and performance improvement program.

(10) A statement of the levels of performance required by CMS on standard quality measures.

(11) A statement of the data and information required by CMS and the State administering agency to be collected on participant care.

(12) The capitation rates for Medicare and Medicaid.

(13) A description of procedures that the organization will follow if the PACE program agreement is terminated.

(b) *Optional content.* (1) An agreement may provide additional requirements for individuals to qualify as PACE program eligible individuals, in accordance with § 460.150(b)(4).

(2) An agreement may contain any additional terms and conditions agreed

to by the parties if the terms and conditions are consistent with sections 1894 and 1934 of the Act and regulations in this part.

§ 460.34 Duration of PACE program agreement.

An agreement is effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate.

Subpart D—Sanctions, Enforcement Actions, and Termination

§ 460.40 Violations for which CMS may impose sanctions.

In addition to other remedies authorized by law, CMS may impose any of the sanctions specified in §§ 460.42 and 460.46 if CMS determines that a PACE organization commits any of the following violations:

(a) Fails substantially to provide to a participant medically necessary items and services that are covered PACE services, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the participant.

(b) Involuntarily disenrolls a participant in violation of § 460.164.

(c) Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid recipients, or both, who are eligible to enroll in a PACE program, on the basis of an individual's health status or need for health care services.

(d) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by § 460.150, by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicates a need for substantial future medical services.

(e) Imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted.

(f) Misrepresents or falsifies information that is furnished—

(1) To CMS or the State under this part; or

(2) To an individual or any other entity under this part.

(g) Prohibits or otherwise restricts a covered health care professional from advising a participant who is a patient of the professional about the participant's health status, medical care, or treatment for the participant's condition or disease, regardless of whether the PACE program provides benefits for that care or treatment, if the professional is acting within his or her lawful scope of practice.

(h) Operates a physician incentive plan that does not meet the requirements of section 1876(i)(8) of the Act.

(i) Employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under section 1128 or section 1128A of the Act (or with any entity that employs or contracts with that individual) for the provision of health care, utilization review, medical social work, or administrative services.

§ 460.42 Suspension of enrollment or payment by CMS.

(a) *Enrollment.* If a PACE organization commits one or more violations specified in § 460.40, CMS may suspend enrollment of Medicare beneficiaries after the date CMS notifies the organization of the violation.

(b) *Payment.* If a PACE organization commits one or more violations specified in § 460.40, for individuals enrolled after the date CMS notifies the PACE organization of the violation, CMS may take the following actions:

(1) Suspend Medicare payment to the PACE organization.

(2) Deny payment to the State for medical assistance for services furnished under the PACE program agreement.

(c) *Term of suspension.* A suspension or denial of payment remains in effect until CMS is satisfied that the following conditions are met:

(1) The PACE organization has corrected the cause of the violation.

(2) The violation is not likely to recur.

§ 460.46 Civil money penalties.

(a) CMS may impose civil money penalties up to the following maximum amounts:

(1) For each violation regarding enrollment or disenrollment specified in § 460.40 (c) or (d), $100,000 plus $15,000 for each individual not enrolled as a result

of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment.

(2) For each violation regarding excessive premiums specified in § 460.40(e), $25,000 plus double the excess amount above the permitted premium charged a participant by the PACE organization. (The excess amount charged is deducted from the penalty and returned to the participant).

(3) For each misrepresentation or falsification of information, specified in § 460.40(f)(1), $100,000.

(4) For any other violation specified in § 460.40, $25,000.

(b) The provisions of section 1128A of the Act (other than subsections (a) and (b)) apply to a civil money penalty under this section in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

§ 460.48 Additional actions by CMS or the State.

After consultation with the State administering agency, if CMS determines that the PACE organization is not in substantial compliance with requirements in this part, CMS or the State administering agency may take one or more of the following actions:

(a) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.

(b) Withhold some or all payments under the PACE program agreement until the organization corrects the deficiency.

(c) Terminate the PACE program agreement.

§ 460.50 Termination of PACE program agreement.

(a) *Termination of agreement by CMS or State.* CMS or a State administering agency may terminate at any time a PACE program agreement for cause, including, but not limited to the circumstances in paragraphs (b) or (c) of this section.

(b) *Termination due to uncorrected deficiencies.* CMS or the State administering agency may terminate a PACE program agreement if CMS or the State administering agency determines that both of the following circumstances exist:

(1) Either—

(i) There are significant deficiencies in the quality of care furnished to participants; or

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement.

(2) Within 30 days of the date of the receipt of written notice of a determination made under paragraph (b)(1) of this section, the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies, or failed to continue implementation of the plan of correction.

(c) *Termination due to health and safety risk.* CMS or a State administering agency may terminate a PACE program agreement if CMS or the State administering agency determines that the PACE organization cannot ensure the health and safety of its participants. This determination may result from the identification of deficiencies that CMS or the State administering agency determines cannot be corrected.

(d) *Termination of agreement by PACE organization.* A PACE organization may terminate an agreement after timely notice to CMS, the State administering agency, and participants, as follows:

(1) To CMS and the State administering agency, 90 days before termination.

(2) To participants, 60 days before termination.

§ 460.52 Transitional care during termination.

(a) The PACE organization must develop a detailed written plan for phase-down in the event of termination, which describes how the organization plans to take the following actions:

(1) Inform participants, the community, CMS and the State administering agency in writing about termination and transition procedures.

(2) Assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits.

(3) Transition participants' care to other providers.

(4) Terminate marketing and enrollment activities.

(b) An entity whose PACE program agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers.

§ 460.54 Termination procedures.

(a) Except as provided in paragraph (b) of this section, if CMS terminates an agreement with a PACE organization, it furnishes the PACE organization with the following:

(1) A reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of CMS's determination that cause exists for termination.

(2) Reasonable notice and opportunity for hearing (including the right to appeal an initial determination) before terminating the agreement.

(b) CMS may terminate an agreement without invoking the procedures described in paragraph (a) of this section if CMS determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

Subpart E—PACE Administrative Requirements

§ 460.60 PACE organizational structure.

(a) A PACE organization must be, or be a distinct part of, one of the following:

(1) An entity of city, county, State, or Tribal government.

(2) A private not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger corporation, or a department of a corporation.

(b) *Program director*. The organization must employ, or contract with in accordance with § 460.70, a program director who is responsible for oversight and administration of the entity.

(c) *Medical director*. The organization must employ, or contract with in accordance with § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality assessment and performance improvement program.

(d) *Organizational chart*. (1) The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities.

(2) The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities.

(3) A PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 60 days before the change takes effect.

(4) Changes in organizational structure must be approved in advance by CMS and the State administering agency.

(5) Changes in organizational structure approved by CMS and the State administering agency must be forwarded to the consumer advisory committee described in § 460.62(c) of this part for dissemination to participants as appropriate.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002]

§ 460.62 Governing body.

(a) *Governing body*. A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and responsibility for the following:

(1) Governance and operation of the organization.

(2) Development of policies consistent with the mission.

(3) Management and provision of all services, including the management of contractors.

(4) Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities.

(5) Fiscal operations.

(6) Development of policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of participants.

(7) Quality assessment and performance improvement program.

(b) *Community representation.* A PACE organization must ensure community representation on issues related to participant care. This may be achieved by having a community representative on the governing body.

(c) *Consumer advisory committee.* A PACE organization must establish a consumer advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee.

§ 460.64 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, each member of the staff (employee or contractor) of the PACE organization must meet the following conditions:

(1) Be legally authorized (currently licensed or, if applicable, certified or registered) to practice in the State in which he or she performs the function or actions.

(2) Only act within the scope of his or her authority to practice.

(b) *Federally-defined qualifications for physician.* (1) A physician must meet the qualifications and conditions in § 410.20 of this chapter.

(2) A primary care physician must have a minimum of 1 year's experience working with a frail or elderly population.

(c) *Qualifications when no State licensing laws, State certification, or registration requirements exist.* If there are no State licensing laws, State certification, or registration applicable to the profession, the following requirements must be met:

(1) *Registered nurse.* A registered nurse must meet the following requirements:

(i) Be a graduate of a school of professional nursing.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(2) *Social worker.* A social worker must meet the following requirements:

(i) Have a master's degree in social work from an accredited school of social work.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(3) *Physical therapist.* A physical therapist must meet the following requirements:

(i) Be a graduate of a physical therapy curriculum approved by one of the following:

(A) The American Physical Therapy Association.

(B) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(C) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(D) Other equivalent organizations approved by the Secretary.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(4) *Occupational therapist.* An occupational therapist must meet the following requirements:

(i) Be a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association or other equivalent organizations approved by the Secretary.

(ii) Be eligible for the National Registration Examination of the American Occupational Therapy Association.

(iii) Have 2 years of appropriate experience as an occupational therapist and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determination of proficiency does not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

(iv) Have a minimum of 1 year's experience working with a frail or elderly population.

(5) *Recreation therapist or activities coordinator.* A recreation therapist or activities coordinator must have 2 years experience in a social or recreational program providing and coordinating services for a frail or elderly population within the last 5 years, one of which was full-time in a patient activities program in a health care setting.

(6) *Dietitian.* A dietitian must meet the following requirements:

(i) Have a baccalaureate or advanced degree from an accredited college with major studies in food and nutrition or dietetics.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(7) *Drivers.* A PACE center driver must meet the following requirements:

(i) Have a valid driver's license to operate a van or bus in the State of operation.

(ii) Be capable of, and experienced in, transporting individuals with special mobility needs.

§ 460.66 Training.

(a) The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.

(b) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.

§ 460.68 Program integrity.

(a) *Persons with criminal convictions.* A PACE organization must not employ individuals or contract with organizations or individuals—

(1) Who have been excluded from participation in the Medicare or Medicaid programs;

(2) Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act; or

(3) In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

(b) *Direct or indirect interest in contracts.* No member of the PACE organization's governing body or any immediate family member may have a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE organization.

(c) [Reserved]

(d) *Disclosure requirements.* A PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002]

§ 460.70 Contracted services.

(a) *General rule.* The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services as described in § 460.100.

(b) *Contract requirements.* A contract between a PACE organization and a contractor must meet the following requirements:

(1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following:

(i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.

(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.

(iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities.

(2) A contractor must be accessible to participants, located either within or

near the PACE organization's service area.

(3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.

(c) *List of contractors.* A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

(d) *Copies of signed contracts.* The PACE organization must furnish a copy of each signed contract for inpatient care to CMS and the State administering agency.

(e) *Content of contract.* Each contract must be in writing and include the following information:

(1) Name of contractor.

(2) Services furnished (including work schedule if appropriate).

(3) Payment rate and method.

(4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.

(5) Contractor agreement to do the following:

(i) Furnish only those services authorized by the PACE interdisciplinary team.

(ii) Accept payment from the PACE organization as payment in full, and not bill participants, CMS, the State administering agency, or private insurers.

(iii) Hold harmless CMS, the State, and PACE participants if the PACE organization does not pay for services performed by the contractor in accordance with the contract.

(iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.

(v) Submit reports required by the PACE organization.

(vi) Agree to perform all the duties related to its position as specified in this part.

(vii) Participate in interdisciplinary team meeting as required.

(viii) Agree to be accountable to the PACE organization.

(ix) Cooperate with the competency evaluation program and direct participant care requirements specified in § 460.71.

(f) *Contracting with another entity to furnish PACE Center services.* (1) A PACE organization may only contract for PACE Center services if it is fiscally sound as defined in § 460.80(a) of this part and has demonstrated competence with the PACE model as evidenced by successful monitoring by CMS and the State administering agency.

(2) The PACE organization retains responsibility for all participants and may only contract for the PACE Center services identified in § 460.98(d).

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002]

§ 460.71 Oversight of direct participant care.

(a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position.

(1) The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.

(2) The PACE organization must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors).

(3) The competency program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals.

(4) The PACE organization must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.

(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

(1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.

(2) Comply with the requirements of § 460.68(a) regarding persons with criminal convictions.

(3) Have verified current certifications or licenses for their respective positions.

(4) Are free of communicable diseases.

(5) Have been oriented to the PACE program.

(6) Agree to abide by the philosophy, practices, and protocols of the PACE organiztion.

[67 FR 61505, Oct. 1, 2002]

§ 460.72 Physical environment.

(a) *Space and equipment*—(1) *Safe design.* A PACE center must meet the following requirements:

(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.

(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.

(2) *Primary care clinic.* The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining.

(3) *Equipment maintenance.* A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

(b) *Fire safety*—(1) *General rule.* Except as otherwise provided in this section—

(i) A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association that apply to the type of setting in which the center is located. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to PACE centers.

(2) *Exceptions.* (i) The Life Safety Code provisions do not apply in a State in which CMS determines that a fire and safety code imposed by State law adequately protects participants and staff.

(ii) CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the center, but only if the waiver does not adversely affect the health and safety of the participants and staff.

(3) Beginning March 13, 2006, a PACE center must be in compliance with Chapter 9.2.9, Emergency Lighting.

(4) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to PACE centers.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment

00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(c) *Emergency and disaster preparedness*—(1) *Procedures.* The PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public.

(2) *Emergencies defined.* Emergencies include, but are not limited, to the following:

(i) Fire.

(ii) Equipment, water, or power failure.

(iii) Care-related emergencies.

(iv) Natural disasters likely to occur in the organization's geographic area. (An organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location.)

(3) *Emergency training.* A PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and participants to ensure that staff demonstrate a knowledge of emergency procedures, including informing participants what to do, where to go, and whom to contact in case of an emergency.

(4) *Availability of emergency equipment.* Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs, along with staff who know how to use the equipment, must be on the premises of every center at all times and be immediately available. The organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

(5) *Annual test of emergency and disaster plan.* At least annually, a PACE organization must actually test, evaluate, and document the effectiveness of its emergency and disaster plans.

[64 FR 66279, Nov. 24, 1999, as amended at 68 FR 1386, Jan. 10, 2003; 69 FR 49266, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55340, Sept. 22, 2006, § 460.72 was amended by revising paragraph (b)(5)(iii), by removing the last sentence of paragraph (b)(5)(iv), by removing the period at the end of paragraph (b)(5)(iv) and adding in its place ''; and'', and adding paragraph (b)(5)(v), effective Oct. 23, 2006. For the convenience of the user, the added and revised text is set forth as follows:

§ 460.72 Physical environment.

* * * * *

(b) * * *

(5) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

§ 460.74 Infection control.

(a) *Standard procedures.* The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

(b) *Infection control plan.* The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:

(1) Ensures a safe and sanitary environment.

(2) Prevents and controls the transmission of disease and infection.

(c) *Contents of infection control plan.* The infection control plan must include, but is not limited to, the following:

(1) Procedures to identify, investigate, control, and prevent infections in every center and in each participant's place of residence.

(2) Procedures to record any incidents of infection.

(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.

§ 460.76 Transportation services.

(a) *Safety, accessibility, and equipment.* A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

(b) *Maintenance of vehicles.* (1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.

(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.

(c) *Communication with PACE center.* The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.

(d) *Training.* The PACE organization must train all transportation personnel (employees and contractors) in the following:

(1) Managing the special needs of participants.

(2) Handling emergency situations.

(e) *Changes in care plan.* As part of the interdisciplinary team process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant's care plan to transportation personnel.

§ 460.78 Dietary services.

(a) *Meal requirements.* (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must provide each participant with a nourishing, palatable, well-balanced meal that meets the daily nutritional and special dietary needs of each participant. Each meal must meet the following requirements:

(i) Be prepared by methods that conserve nutritive value, flavor, and appearance.

(ii) Be prepared in a form designed to meet individual needs.

(iii) Be prepared and served at the proper temperature.

(2) The PACE organization must provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:

(i) Refuses the food served.

(ii) Cannot tolerate the food served.

(iii) Does not eat adequately.

(3) The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.

(b) *Sanitary conditions.* The PACE organization must do the following:

(1) Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization.

(2) Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions.

(3) Dispose of garbage and refuse properly.

§ 460.80 Fiscal soundness.

(a) *Fiscally sound operation.* A PACE organization must have a fiscally sound operation, as demonstrated by the following:

(1) Total assets greater than total unsubordinated liabilities.

(2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency.

(b) *Insolvency plan.* The organization must have a documented plan in the event of insolvency, approved by CMS and the State administering agency, which provides for the following:

(1) Continuation of benefits for the duration of the period for which capitation payment has been made.

(2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.

(3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

(c) *Arrangements to cover expenses.* (1) A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:

(i) One month's total capitation revenue to cover expenses the month before insolvency.

(ii) One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operations.

(2) Arrangements to cover expenses may include, but are not limited to, the following:

(i) Insolvency insurance or reinsurance.

(ii) Hold harmless arrangement.

(iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

§ 460.82 Marketing.

(a) *Information that a PACE organization must include in its marketing materials.* (1) A PACE organization must inform the public about its program and give prospective participants the following written information:

(i) An adequate description of the PACE organization's enrollment and disenrollment policies and requirements.

(ii) PACE enrollment procedures.

(iii) Description of benefits and services.

(iv) Premiums.

(v) Other information necessary for prospective participants to make an informed decision about enrollment.

(2) Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.

(b) *Approval of marketing information.* (1) CMS must approve all marketing information before distribution by the PACE organization, including any revised or updated material.

(2) CMS reviews initial marketing information as part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.

(3) Once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following:

(i) *Time period for approval.* CMS approves or disapproves marketing information within 45 days after CMS receives the information from the organization.

(ii) *Deemed approval.* Marketing information is deemed approved, and the organization can distribute it, if CMS and the State administering agency do not disapprove the marketing material within the 45-day review period.

(c) *Special language requirements.* A PACE organization must furnish printed marketing materials to prospective and current participants as specified below:

(1) In English and in any other principal languages of the community.

(2) In Braille, if necessary.

(d) *Information on restriction of services.* (1) Marketing materials must inform a potential participant that he or she must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PACE organization or from an entity authorized by the PACE organization.

(2) All marketing materials must state clearly that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

(e) *Prohibited marketing practices.* A PACE organization must ensure that its employees or its agents do not use prohibited marketing practices which includes the following:

(1) Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age.

(2) Activities that could mislead or confuse potential participants, or misrepresent the PACE organization, CMS, or the State administering agency.

(3) Gifts or payments to induce enrollment.

(4) Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment.

(5) Unsolicited door-to-door marketing.

(f) *Marketing Plan.* A PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

Subpart F—PACE Services

§ 460.90 PACE benefits under Medicare and Medicaid.

If a Medicare beneficiary or Medicaid recipient chooses to enroll in a PACE program, the following conditions apply:

(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.

(b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.

§ 460.92 Required services.

The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(a) All Medicaid-covered services, as specified in the State's approved Medicaid plan.

(b) Interdisciplinary assessment and treatment planning.

(c) Primary care, including physician and nursing services.

(d) Social work services.

(e) Restorative therapies, including physical therapy, occupational therapy, and speech-language pathology services.

(f) Personal care and supportive services.

(g) Nutritional counseling.

(h) Recreational therapy.

(i) Transportation.

(j) Meals.

(k) Medical specialty services including, but not limited to the following:

(1) Anesthesiology.
(2) Audiology.
(3) Cardiology.
(4) Dentistry.
(5) Dermatology.
(6) Gastroenterology.
(7) Gynecology.
(8) Internal medicine.
(9) Nephrology.
(10) Neurosurgery.
(11) Oncology.
(12) Ophthalmology.
(13) Oral surgery.
(14) Orthopedic surgery.
(15) Otorhinolaryngology.
(16) Plastic surgery.
(17) Pharmacy consulting services.
(18) Podiatry.
(19) Psychiatry.
(20) Pulmonary disease.
(21) Radiology.
(22) Rheumatology.
(23) General surgery.
(24) Thoracic and vascular surgery.
(25) Urology.

(l) Laboratory tests, x-rays and other diagnostic procedures.

(m) Drugs and biologicals.

(n) Prosthetics, orthotics, durable medical equipment, corrective vision devices, such as eyeglasses and lenses, hearing aids, dentures, and repair and maintenance of these items.

(o) Acute inpatient care, including the following:

(1) Ambulance.
(2) Emergency room care and treatment room services.
(3) Semi-private room and board.
(4) General medical and nursing services.
(5) Medical surgical/intensive care/coronary care unit.
(6) Laboratory tests, x-rays and other diagnostic procedures.
(7) Drugs and biologicals.
(8) Blood and blood derivatives.
(9) Surgical care, including the use of anesthesia.
(10) Use of oxygen.
(11) Physical, occupational, respiratory therapies, and speech-language pathology services.
(12) Social services.

(p) Nursing facility care.

(1) Semi-private room and board.
(2) Physician and skilled nursing services.

(3) Custodial care.

(4) Personal care and assistance.

(5) Drugs and biologicals.

(6) Physical, occupational, recreational therapies, and speech-language pathology, if necessary.

(7) Social services.

(8) Medical supplies and appliances.

(q) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

§ 460.94 Required services for Medicare participants.

(a) Except for Medicare requirements that are waived for the PACE program, as specified in paragraph (b) of this section, the PACE benefit package for Medicare participants must include the following services:

(1) The scope of hospital insurance benefits described in part 409 of this chapter.

(2) The scope of supplemental medical insurance benefits described in part 410 of this chapter.

(b) *Waivers of Medicare coverage requirements.* The following Medicare requirements are waived for purposes of the PACE program and do not apply:

(1) The provisions of subpart F of part 409 of this chapter that limit coverage of institutional services.

(2) The provisions of subparts G and H of part 409 of this chapter, and parts 412 through 414 of this chapter that relate to payment for benefits.

(3) The provisions of subparts D and E of part 409 of this chapter that limit coverage of extended care services or home health services.

(4) The provisions of subpart D of part 409 of this chapter that impose a 3-day prior hospitalization requirement for coverage of extended care services.

(5) Sections 411.15(g) and (k) of this chapter that may prevent payment for PACE program services to PACE participants.

§ 460.96 Excluded services.

The following services are excluded from coverage under PACE:

(a) Any service that is not authorized by the interdisciplinary team, even if it is a required service, unless it is an emergency service.

(b) In an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the interdisciplinary team as part of the participant's plan of care).

(c) Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy.

(d) Experimental medical, surgical, or other health procedures.

(e) Services furnished outside of the United States, except as follows:

(1) In accordance with §§ 424.122 through 424.124 of this chapter.

(2) As permitted under the State's approved Medicaid plan.

§ 460.98 Service delivery.

(a) *Plan.* A PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.

(b) *Provision of services.* (1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care.

(2) These services must be furnished in at least the PACE center, the home, and inpatient facilities.

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

(c) *Minimum services furnished at each PACE center.* At a minimum, the following services must be furnished at each PACE center:

(1) Primary care, including physician and nursing services.

(2) Social services.

(3) Restorative therapies, including physical therapy and occupational therapy.

(4) Personal care and supportive services.

(5) Nutritional counseling.

(6) Recreational therapy.

(7) Meals.

(d) *Center operation.* (1) A PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.

(2) A PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, a PACE organization must increase the number of PACE centers, staff, or other PACE services.

(3) If a PACE organization operates more than one center, each center must offer the full range of services and have sufficient staff to meet the needs of participants.

(e) *Center attendance.* The frequency of a participant's attendance at a center is determined by the interdisciplinary team, based on the needs and preferences of each participant.

§ 460.100 Emergency care.

(a) *Written plan.* A PACE organization must establish and maintain a written plan to handle emergency care. The plan must ensure that CMS, the State, and PACE participants are held harmless if the PACE organization does not pay for emergency services.

(b) *Emergency care.* Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers, would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that meet the following requirements:

(1) Are furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization's service area.

(2) Are needed to evaluate or stabilize an emergency medical condition.

(c) An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(1) Serious jeopardy to the health of the participant.

(2) Serious impairment to bodily functions.

(3) Serious dysfunction of any bodily organ or part.

(d) *Explanation to participant.* The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services.

(e) *On-call providers.* The plan must provide for the following:

(1) An on-call provider, available 24-hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services.

(2) Coverage of urgently needed out-of-network and post-stabilization care services when either of the following conditions are met:

(i) The services are preapproved by the PACE organization.

(ii) The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval.

§ 460.102 Interdisciplinary team.

(a) *Basic requirement.* A PACE organization must meet the following requirements:

(1) Establish an interdisciplinary team at each center to comprehensively assess and meet the individual needs of each participant.

(2) Assign each participant to an interdisciplinary team functioning at the PACE center that the participant attends.

(b) *Composition of interdisciplinary team.* The interdisciplinary team must be composed of at least the following members:

(1) Primary care physician.

(2) Registered nurse.

(3) Social worker.

(4) Physical therapist.

(5) Occupational therapist.

(6) Recreational therapist or activity coordinator.

(7) Dietitian.

(8) PACE center manager.

(9) Home care coordinator.

(10) Personal care attendant or his or her representative.

(11) Driver or his or her representative.

(c) *Primary care physician.* (1) Primary medical care must be furnished to a participant by a PACE primary care physician.

(2) Each primary care physician is responsible for the following:

(i) Managing a participant's medical situations.

(ii) Overseeing a participant's use of medical specialists and inpatient care.

(d) *Responsibilities of interdisciplinary team.* (1) The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery.

(2) Each team member is responsible for the following:

(i) Regularly informing the interdisciplinary team of the medical, functional, and psychosocial condition of each participant.

(ii) Remaining alert to pertinent input from other team members, participants, and caregivers.

(iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation polices established by the medical director.

(3) The members of the interdisciplinary team must serve primarily PACE participants.

(e) *Exchange of information between team members.* The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers consistent with the requirements for confidentiality in § 460.200(e).

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61506, Oct. 1, 2002]

§ 460.104 Participant assessment.

(a) *Initial comprehensive assessment*—(1) *Basic requirement.* The interdisciplinary team must conduct an initial comprehensive assessment on each participant. The assessment must be completed promptly following enrollment.

(2) As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person, at appropriate intervals, and develop a discipline-specific assessment of the participant's health and social status:

(i) Primary care physician.

(ii) Registered nurse.

(iii) Social worker.

(iv) Physical therapist or occupational therapist, or both.

(v) Recreational therapist or activity coordinator.

(vi) Dietitian.

(vii) Home care coordinator.

(3) At the recommendation of individual team members, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the comprehensive assessment process.

(4) *Comprehensive assessment criteria.* The comprehensive assessment must include, but is not limited to, the following:

(i) Physical and cognitive function and ability.

(ii) Medication use.

(iii) Participant and caregiver preferences for care.

(iv) Socialization and availability of family support.

(v) Current health status and treatment needs.

(vi) Nutritional status.

(vii) Home environment, including home access and egress.

(viii) Participant behavior.

(ix) Psychosocial status.

(x) Medical and dental status.

(xi) Participant language.

(b) *Development of plan of care.* The interdisciplinary team must promptly consolidate discipline-specific assessments into a single plan of care for each participant through discussion in team meetings and consensus of the entire interdisciplinary team. In developing the plan of care, female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.

(c) *Periodic reassessment*—(1) *Semiannual reassessment.* On at least a semiannual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

(i) Primary care physician.

(ii) Registered nurse.

(iii) Social worker.

(iv) Recreational therapist or activity coordinator.

(v) Other team members actively involved in the development or implementation of the participant's plan of care, for example, home care coordinator, physical therapist, occupational therapist, or dietitian.

(2) *Annual reassessment.* On at least an annual basis, the following members of the interdisciplinary team must conduct an in-person reassessment:

(i) Physical therapist or occupational therapist, or both.

(ii) Dietitian.

(iii) Home care coordinator.

(3) *Reassessment based on change in participant status or at the request of the participant or designated representative.* If the health or psychosocial status of a participant changes or if a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the members of the interdisciplinary team, listed in paragraph (a)(2) of this section, must conduct an in-person reassessment.

(i) The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.

(ii) Except as provided in paragraph (c)(3)(iii) of this section, the interdisciplinary team must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the interdisciplinary team receives the request for reassessment.

(iii) The interdisciplinary team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:

(A) The participant or designated representative requests the extension.

(B) The team documents its need for additional information and how the delay is in the interest of the participant.

(iv) The PACE organization must explain any denial of a request to the participant or the participant's designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language.

(v) If the participant or designated representative is dissatisfied with the decision on the request, the PACE organization is responsible for the following:

(A) Informing the participant or designated representative of his or her right to appeal the decision as specified in § 460.122.

(B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.

(C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in § 460.122(e).

(D) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.

(d) *Changes to plan of care.* Team members who conduct a reassessment must meet the following requirements:

(1) Reevaluate the participant's plan of care.

(2) Discuss any changes in the plan with the interdisciplinary team.

(3) Obtain approval of the revised plan from the interdisciplinary team and the participant (or designated representative).

(4) Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires.

(e) *Documentation.* Interdisciplinary team members must document all assessment and reassessment information in the participant's medical record.

§ 460.106 Plan of care.

(a) *Basic requirement.* The interdisciplinary team must promptly develop a comprehensive plan of care for each participant.

(b) *Content of plan of care.* The plan of care must meet the following requirements:

(1) Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.

(2) Identify measurable outcomes to be achieved.

(c) *Implementation of the plan of care.* (1) The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.

(2) The team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other providers.

(d) *Evaluation of plan of care.* On at least a semi-annual basis, the interdisciplinary team must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

(e) *Participant and caregiver involvement in plan of care.* The team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The team must document the plan of care, and any changes made to it, in the participant's medical record.

Subpart G—Participant Rights

§ 460.110 Bill of rights.

(a) *Written bill of rights.* A PACE organization must have a written participant bill of rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, the ones specified in § 460.112.

(b) *Explanation of rights.* The organization must inform a participant upon enrollment, in writing, of his or her rights and responsibilities, and all rules and regulations governing participation.

(c) *Protection of rights.* The organization must protect and provide for the exercise of the participant's rights.

§ 460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

(b) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information

and to receive assistance in making informed health care decisions. Specifically, each participant has the following rights:

(1) To be fully informed in writing of the services available from the PACE organization, including identification of all services that are delivered through contracts, rather than furnished directly by the PACE organization at the following times:

(i) Before enrollment.

(ii) At enrollment.

(iii) When there is a change in services.

(2) To have the enrollment agreement, described in §460.154, fully explained in a manner understood by the participant.

(3) To examine, or upon reasonable request, to be assisted to examine the results of the most recent review of the PACE organization conducted by CMS or the State administering agency and any plan of correction in effect.

(c) *Choice of providers.* Each participant has the right to a choice of health care providers, within the PACE organization's network, that is sufficient to ensure access to appropriate high-quality health care. Specifically, each participant has the right to the following:

(1) To choose his or her primary care physician and specialists from within the PACE network.

(2) To request that a qualified specialist for women's health services furnish routine or preventive women's health services.

(3) To disenroll from the program at any time.

(d) *Access to emergency services.* Each participant has the right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

(e) *Participation in treatment decisions.* Each participant has the right to participate fully in all decisions related to his or her treatment. A participant who is unable to participate fully in treatment decisions has the right to designate a representative. Specifically, each participant has the following rights:

(1) To have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.

(2) To have the PACE organization explain advance directives and to establish them, if the participant so desires, in accordance with §§489.100 and 489.102 of this chapter.

(3) To be fully informed of his or her health and functional status by the interdisciplinary team.

(4) To participate in the development and implementation of the plan of care.

(5) To request a reassessment by the interdisciplinary team.

(6) To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (that is, due to medical reasons or for the participant's welfare, or that of other participants). The PACE organization must document the justification in the participant's medical record.

(f) *Confidentiality of health information.* Each participant has the right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care information protected. Each participant also has the right to review and copy his or her own medical records and request amendments to those records. Specifically, each participant has the following rights:

(1) To be assured of confidential treatment of all information contained in the health record, including information contained in an automated data bank.

(2) To be assured that his or her written consent will be obtained for the release of information to persons not otherwise authorized under law to receive it.

(3) To provide written consent that limits the degree of information and the persons to whom information may be given.

(g) *Complaints and appeals.* Each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review. Specifically,

each participant has the following rights:

(1) To be encouraged and assisted to voice complaints to PACE staff and outside representatives of his or her choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.

(2) To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in § 460.122.

§ 460.114 Restraints.

(a) The PACE organization must limit use of restraints to the least restrictive and most effective method available. The term restraint includes either a physical restraint or a chemical restraint.

(1) A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

(2) A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.

(b) If the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the use must meet the following conditions:

(1) Be imposed for a defined, limited period of time, based upon the assessed needs of the participant.

(2) Be imposed in accordance with safe and appropriate restraining techniques.

(3) Be imposed only when other less restrictive measures have been found to be ineffective to protect the participant or others from harm.

(4) Be removed or ended at the earliest possible time.

(c) The condition of the restrained participant must be continually assessed, monitored, and reevaluated.

§ 460.116 Explanation of rights.

(a) *Written policies.* A PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, if any, and staff understand these rights.

(b) *Explanation of rights.* The PACE organization must fully explain the rights to the participant and his or her representative, if any, at the time of enrollment in a manner understood by the participant.

(c) *Display.* The PACE organization must meet the following requirements:

(1) Write the participant rights in English and in any other principal languages of the community.

(2) Display the participant rights in a prominent place in the PACE center.

§ 460.118 Violation of rights.

The PACE organization must have established documented procedures to respond to and rectify a violation of a participant's rights.

§ 460.120 Grievance process.

For purposes of this part, a grievance is a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished.

(a) *Process to resolve grievances.* A PACE organization must have a formal written process to evaluate and resolve medical and nonmedical grievances by participants, their family members, or representatives.

(b) *Notification to participants.* Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process.

(c) *Minimum requirements.* At a minimum, the PACE organization's grievance process must include written procedures for the following:

(1) How a participant files a grievance.

(2) Documentation of a participant's grievance.

(3) Response to, and resolution of, grievances in a timely manner.

(4) Maintenance of confidentiality of a participant's grievance.

(d) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(e) *Explaining the grievance process.* The PACE organization must discuss with and provide to the participant in

writing the specific steps, including timeframes for response, that will be taken to resolve the participant's grievance.

(f) *Analyzing grievance information.* The PACE organization must maintain, aggregate, and analyze information on grievance proceedings. This information must be used in the PACE organization's internal quality assessment and performance improvement program.

§ 460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service.

(a) *PACE organization's written appeals process.* The PACE organization must have a formal written appeals process, with specified timeframes for response, to address noncoverage or nonpayment of a service.

(b) *Notification of participants.* Upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a request for services or payment, the PACE organization must give a participant written information on the appeals process.

(c) *Minimum requirements.* At a minimum, the PACE organization's appeals process must include written procedures for the following:

(1) Timely preparation and processing of a written denial of coverage or payment as provided in § 460.104(c)(3).

(2) How a participant files an appeal.

(3) Documentation of a participant's appeal.

(4) Appointment of an appropriately credentialed and impartial third party who was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal.

(5) Responses to, and resolution of, appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the organization receives an appeal.

(6) Maintenance of confidentiality of appeals.

(d) *Notification.* A PACE organization must give all parties involved in the appeal the following:

(1) Appropriate written notification.

(2) A reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

(e) *Services furnished during appeals process.* During the appeals process, the PACE organization must meet the following requirements:

(1) For a Medicaid participant, continue to furnish the disputed services until issuance of the final determination if the following conditions are met:

(i) The PACE organization is proposing to terminate or reduce services currently being furnished to the participant.

(ii) The participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.

(2) Continue to furnish to the participant all other required services, as specified in subpart F of this part.

(f) *Expedited appeals process.* (1) A PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain maximum function would be seriously jeopardized, absent provision of the service in dispute.

(2) Except as provided in paragraph (f)(3) of this section, the PACE organization must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal.

(3) The PACE organization may extend the 72-hour timeframe by up to 14 calendar days for either of the following reasons:

(i) The participant requests the extension.

(ii) The organization justifies to the State administering agency the need for additional information and how the delay is in the interest of the participant.

(g) Determination in favor of participant. A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is

made in favor of the participant on appeal.

(h) Determination adverse to participant. For a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify the following:

(1) CMS.

(2) The State administering agency.

(3) The participant.

(i) *Analyzing appeals information.* A PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality assessment and performance improvement program.

§ 460.124 Additional appeal rights under Medicare or Medicaid.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

Subpart H—Quality Assessment and Performance Improvement

§ 460.130 General rule.

(a) A PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program.

(b) The program must reflect the full range of services furnished by the PACE organization.

(c) A PACE organization must take actions that result in improvements in its performance in all types of care.

§ 460.132 Quality assessment and performance improvement plan.

(a) *Basic rule.* A PACE organization must have a written quality assessment and performance improvement plan.

(b) *Annual review.* The PACE governing body must review the plan annually and revise it, if necessary.

(c) *Minimum plan requirements.* At a minimum, the plan must specify how the PACE organization proposes to meet the following requirements:

(1) Identify areas to improve or maintain the delivery of services and patient care.

(2) Develop and implement plans of action to improve or maintain quality of care.

(3) Document and disseminate to PACE staff and contractors the results from the quality assessment and performance improvement activities.

§ 460.134 Minimum requirements for quality assessment and performance improvement program.

(a) *Minimum program requirements.* A PACE organization's quality assessment and performance improvement program must include, but is not limited to, the use of objective measures to demonstrate improved performance with regard to the following:

(1) Utilization of PACE services, such as decreased inpatient hospitalizations and emergency room visits.

(2) Caregiver and participant satisfaction.

(3) Outcome measures that are derived from data collected during assessments, including data on the following:

(i) Physiological well being.

(ii) Functional status.

(iii) Cognitive ability.

(iv) Social/behavioral functioning.

(v) Quality of life of participants.

(4) Effectiveness and safety of staff-provided and contracted services, including the following:

(i) Competency of clinical staff.

(ii) Promptness of service delivery.

(iii) Achievement of treatment goals and measurable outcomes.

(5) Nonclinical areas, such as grievances and appeals, transportation services, meals, life safety, and environmental issues.

(b) *Basis for outcome measures.* Outcome measures must be based on current clinical practice guidelines and professional practice standards applicable to the care of PACE participants.

(c) *Minimum levels of performance.* The PACE organization must meet or exceed minimum levels of performance, established by CMS and the State administering agency, on standardized quality measures, such as influenza immunization rates, which are specified in the PACE program agreement.

(d) *Accuracy of data.* The PACE organization must ensure that all data used for outcome monitoring are accurate and complete.

§ 460.136 Internal quality assessment and performance improvement activities.

(a) *Quality assessment and performance improvement requirements.* A PACE organization must do the following:

(1) Use a set of outcome measures to identify areas of good or problematic performance.

(2) Take actions targeted at maintaining or improving care based on outcome measures.

(3) Incorporate actions resulting in performance improvement into standards of practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time.

(4) Set priorities for performance improvement, considering prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes.

(5) Immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant.

(b) *Quality assessment and performance improvement coordinator.* A PACE organization must designate an individual to coordinate and oversee implementation of quality assessment and performance improvement activities.

(c) *Involvement in quality assessment and performance improvement activities.* (1) A PACE organization must ensure that all interdisciplinary team members, PACE staff, and contract providers are involved in the development and implementation of quality assessment and performance improvement activities and are aware of the results of these activities.

(2) The quality improvement coordinator must encourage a PACE participant and his or her caregivers to be involved in quality assessment and performance improvement activities, including providing information about their satisfaction with services.

§ 460.138 Committees with community input.

A PACE organization must establish one or more committees, with community input, to do the following:

(a) Evaluate data collected pertaining to quality outcome measures.

(b) Address the implementation of, and results from, the quality assessment and performance improvement plan.

(c) Provide input related to ethical decisionmaking, including end-of-life issues and implementation of the Patient Self-Determination Act.

§ 460.140 Additional quality assessment activities.

A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with § 460.202.

Subpart I—Participant Enrollment and Disenrollment

§ 460.150 Eligibility to enroll in a PACE program.

(a) *General rule.* To enroll in a PACE program, an individual must meet eligibility requirements specified in this section. To continue to be eligible for PACE, an individual must meet the annual recertification requirements specified in § 460.160.

(b) *Basic eligibility requirements.* To be eligible to enroll in PACE, an individual must meet the following requirements:

(1) Be 55 years of age or older.

(2) Be determined by the State administering agency to need the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(3) Reside in the service area of the PACE organization.

(4) Meet any additional program specific eligibility conditions imposed under the PACE program agreement. These additional conditions may not modify the requirements of paragraph (b)(1) through (b)(3) of this section.

(c) *Other eligibility requirements.* (1) At the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety.

(2) The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement.

(d) *Eligibility under Medicare and Medicaid.* Eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid recipient. A potential PACE enrollee may be, but is not required to be, any or all of the following:

(1) Entitled to Medicare Part A.

(2) Enrolled under Medicare Part B.

(3) Eligible for Medicaid.

§ 460.152 Enrollment process.

(a) *Intake process.* Intake is an intensive process during which PACE staff members make one or more visits to a potential participant's place of residence and the potential participant makes one or more visits to the PACE center. At a minimum, the intake process must include the following activities:

(1) The PACE staff must explain to the potential participant and his or her representative or caregiver the following information:

(i) The PACE program, using a copy of the enrollment agreement described in § 460.154, specifically references the elements of the agreement including but not limited to § 460.154(e), (i) through (m), and (r).

(ii) The requirement that the PACE organization would be the participant's sole service provider and clarification that the PACE organization guarantees access to services, but not to a specific provider.

(iii) A list of the employees of the PACE organization who furnish care and the most current list of contracted health care providers under § 460.70(c).

(iv) Monthly premiums, if any.

(v) Any Medicaid spenddown obligations.

(2) The potential participant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid.

(3) The State administering agency must assess the potential participant, including any individual who is not eligible for Medicaid, to ensure that he or she needs the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(4) PACE staff must assess the potential participant to ensure that he or she can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligibility specified in this part.

(b) *Denial of Enrollment.* If a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must meet the following requirements:

(1) Notify the individual in writing of the reason for the denial.

(2) Refer the individual to alternative services, as appropriate.

(3) Maintain supporting documentation of the reason for the denial.

(4) Notify CMS and the State administering agency and make the documentation available for review.

§ 460.154 Enrollment agreement.

If the potential participant meets the eligibility requirements and wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the following information:

(a) Applicant's name, sex, and date of birth.

(b) Medicare beneficiary status (Part A, Part B, or both) and number, if applicable.

(c) Medicaid recipient status and number, if applicable.

(d) Other health insurance information, if applicable.

(e) Conditions for enrollment and disenrollment in PACE.

(f) Description of participant premiums, if any, and procedures for payment of premiums.

(g) Notification that a Medicaid participant and a participant who is eligible for both Medicare and Medicaid are not liable for any premiums, but may be liable for any applicable spenddown liability under §§ 435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under § 460.184.

(h) Notification that a Medicare participant may not disenroll from PACE at a social security office.

(i) Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit, after enrolling as a PACE participant is considered a voluntary disenrollment from PACE.

(j) Information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE.

(k) Description of PACE services available, including all Medicare and Medicaid covered services, and how services are obtained from the PACE organization.

(l) Description of the procedures for obtaining emergency and urgently needed out-of-network services.

(m) The participant bill of rights.

(n) Information on the process for grievances and appeals and Medicare/Medicaid phone numbers for use in appeals.

(o) Notification of a participant's obligation to inform the PACE organization of a move or lengthy absence from the organization's service area.

(p) An acknowledgment by the applicant or representative that he or she understands the requirement that the PACE organization must be the applicant's sole service provider.

(q) A statement that the PACE organization has an agreement with CMS and the State administering agency that is subject to renewal on a periodic basis and, if the agreement is not renewed, the program will be terminated.

(r) The applicant's authorization for disclosure and exchange of personal information between CMS, its agents, the State administering agency, and the PACE organization.

(s) The effective date of enrollment.

(t) The applicant's signature and the date.

§ 460.156 Other enrollment procedures.

(a) *Items a PACE organization must give a participant upon enrollment.* After the participant signs the enrollment agreement, the PACE organization must give the participant the following:

(1) A copy of the enrollment agreement.

(2) A PACE membership card.

(3) Emergency information to be posted in his or her home identifying the individual as a PACE participant and explaining how to access emergency services.

(4) Stickers for the participant's Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and include the phone number of the PACE organization.

(b) *Submittal of participant information to CMS and the State.* The PACE organization must submit participant information to CMS and the State administering agency, in accordance with established procedures.

(c) *Changes in enrollment agreement information.* If there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE organization must meet the following requirements:

(1) Give an updated copy of the information to the participant.

(2) Explain the changes to the participant and his or her representative or caregiver in a manner they understand.

§ 460.158 Effective date of enrollment.

A participant's enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

§ 460.160 Continuation of enrollment.

(a) *Duration of enrollment.* Enrollment continues until the participant's death, regardless of changes in health status, unless either of the following actions occur:

(1) The participant voluntarily disenrolls.

(2) The participant is involuntarily disenrolled, as described in § 460.164.

(b) *Annual recertification requirement.* At least annually, the State administering agency must reevaluate whether a participant needs the level of care required under the State Medicaid plan for coverage of nursing facility services.

(1) *Waiver of annual requirement.* (i) The State administering agency may permanently waive the annual recertification requirement for a participant if it determines that there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity.

(ii) The PACE organization must retain in the participant's medical record the documentation of the reason for waiving the annual recertification requirement.

(2) *Deemed continued eligibility.* If the State administering agency determines that a PACE participant no longer meets the State Medicaid nursing facility level of care requirements, the participant may be deemed to continue to be eligible for the PACE program until the next annual reevaluation, if, in the absence of continued coverage under this program, the participant reasonably would be expected to meet the nursing facility level of care requirement within the next 6 months.

(3) *Continued eligibility criteria.* (i) The State administering agency, in consultation with the PACE organization, makes a determination of continued eligibility based on a review of the participant's medical record and plan of care.

(ii) The criteria used to make the determination of continued eligibility must be specified in the program agreement.

§ 460.162 Voluntary disenrollment.

A PACE participant may voluntarily disenroll from the program without cause at any time.

§ 460.164 Involuntary disenrollment.

(a) *Reasons for involuntary disenrollment.* A participant may be involuntarily disenrolled for any of the following reasons:

(1) The participant fails to pay, or to make satisfactory arrangements to pay, any premium due the PACE organization after a 30-day grace period.

(2) The participant engages in disruptive or threatening behavior, as described in paragraph (b) of this section.

(3) The participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days, unless the PACE organization agrees to a longer absence due to extenuating circumstances.

(4) The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.

(5) The PACE program agreement with CMS and the State administering agency is not renewed or is terminated.

(6) The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers.

(b) *Disruptive or threatening behavior.* For purposes of this section, a participant who engages in disruptive or threatening behavior refers to a participant who exhibits either of the following:

(1) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or

(2) A participant with decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement.

(c) *Documentation of disruptive or threatening behavior.* If a PACE organization proposes to disenroll a participant who is disruptive or threatening, the organization must document the following information in the participant's medical record:

(1) The reasons for proposing to disenroll the participant.

(2) All efforts to remedy the situation.

(d) *Noncompliant behavior.* (1) A PACE organization may not disenroll a PACE participant on the grounds that the participant has engaged in noncompliant behavior if the behavior is related to a mental or physical condition of the participant, unless the participant's behavior jeopardizes his or her health or safety, or the safety of others.

(2) For purposes of this section, noncompliant behavior includes repeated noncompliance with medical advice and repeated failure to keep appointments.

(e) *State administering agency review and final determination.* Before an involuntary disenrollment is effective, the State administering agency must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment.

§ 460.166 Effective date of disenrollment.

(a) In disenrolling a participant, the PACE organization must take the following actions:

(1) Use the most expedient process allowed under Medicare and Medicaid procedures, as set forth in the PACE program agreement.

(2) Coordinate the disenrollment date between Medicare and Medicaid (for a participant who is eligible for both Medicare and Medicaid).

(3) Give reasonable advance notice to the participant.

(b) Until the date enrollment is terminated, the following requirements must be met:

(1) PACE participants must continue to use PACE organization services and remain liable for any premiums.

(2) The PACE organization must continue to furnish all needed services.

§ 460.168 Reinstatement in other Medicare and Medicaid programs.

To facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must do the following:

(a) Make appropriate referrals and ensure medical records are made available to new providers in a timely manner.

(b) Work with CMS and the State administering agency to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible.

§ 460.170 Reinstatement in PACE.

(a) A previously disenrolled participant may be reinstated in a PACE program.

(b) If the reason for disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant is reinstated in the PACE program with no break in coverage.

§ 460.172 Documentation of disenrollment.

A PACE organization must meet the following requirements:

(a) Have a procedure in place to document the reasons for all voluntary and involuntary disenrollments.

(b) Make documentation available for review by CMS and the State administering agency.

(c) Use the information on voluntary disenrollments in the PACE organization's internal quality assessment and performance improvement program.

Subpart J—Payment

§ 460.180 Medicare payment to PACE organizations.

(a) *Principle of payment.* Under a PACE program agreement, CMS makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicare participant in a payment area based on the rate it pays to a Medicare+Choice organization.

(b) *Determination of rate.* (1) The PACE program agreement specifies the monthly capitation amount for each year applicable to a PACE organization.

(2) Except as specified in paragraph (b)(4) of this section, the monthly capitation amount is based on the aged Part A and Part B payment rates established for purposes of payment to Medicare+Choice organizations. As used in this section, ''Medicare+Choice rates'' means the Part A and Part B rates calculated by CMS for making payment to Medicare+Choice organizations under section 1853 of the Act.

(3) The rates specified in paragraph (b)(2) of this section are adjusted by a frailty factor necessary to ensure comparability between PACE participants and the reference population in the Medicare system. The factor is specified in the PACE program agreement.

(4) For Medicare participants who require ESRD services, the monthly capitation amount is based on the Medicare+Choice State ESRD rate. The monthly rate is adjusted by a factor to recognize the frailer and older ESRD population being served by the PACE organization. The PACE program agreement specifies this factor.

(5) CMS may adjust the monthly capitation amount to take into account other factors CMS determines to be appropriate.

(6) The monthly capitation payment is a fixed amount, regardless of changes in the participant's health status.

(7) The monthly capitation payment amount is an all-inclusive payment for Medicare benefits provided to participants. A PACE organization must not seek any additional payment from Medicare. The only additional payment that a PACE organization may collect from, or on behalf of, a Medicare participant for PACE services is the following:

(i) Any applicable premium amount specified in § 460.186.

(ii) Any charge permitted under paragraph (d) of this section when Medicare is not the primary payer.

(iii) Any payment from the State, as specified in § 460.182, for a participant who is eligible for both Medicare and Medicaid.

(iv) Payment with respect to any applicable spenddown liability under §§ 435.121 and 435.831 of this chapter and any amount due under the post-eligibility treatment of income process under § 460.184 for a participant who is eligible for both Medicare and Medicaid.

(8) CMS computes the Medicare monthly capitation payment amount under a PACE program agreement so that the total payment level for all participants is less than the projected payment under Medicare for a comparable population not enrolled under a PACE program.

(c) *Adjustments to payments.* If the actual number of Medicare participants differs from the estimated number of participants on which the amount of the prospective monthly payment was based, CMS adjusts subsequent monthly payments to account for the difference.

(d) *Application of Medicare secondary payer provisions*—(1) *Basic rule.* CMS does not pay for services to the extent that Medicare is not the primary payer under part 411 of this chapter.

(2) *Responsibilities of the PACE organization.* The PACE organization must do the following:

(i) Identify payers that are primary to Medicare under part 411 of this chapter.

(ii) Determine the amounts payable by those payers.

(iii) Coordinate benefits to Medicare participants with the benefits of the primary payers.

(3) *Charges to other entities.* The PACE organization may charge other individuals or entities for PACE services covered under Medicare for which Medicare is not the primary payer, as specified in paragraphs (d)(4) and (5) of this section.

(4) *Charge to other insurers or the participant.* If a Medicare participant receives from a PACE organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PACE organization may charge any of the following:

(i) The insurance carrier, the employer, or any other entity that is liable for payment for the services under part 411 of this chapter.

(ii) The Medicare participant, to the extent that he or she has been paid by the carrier, employer, or other entity.

(5) *Charge to group health plan (GHP) or large group health plan (LGHP).* If Medicare is not the primary payer for services that a PACE organization furnished to a Medicare participant who is covered under a GHP or LGHP, the organization may charge the following:

(i) GHP or LGHP for those services.

(ii) Medicare participant to the extent that he or she has been paid by the GHP or LGHP for those services.

§ 460.182 Medicaid payment.

(a) Under a PACE program agreement, the State administering agency makes a prospective monthly payment

to the PACE organization of a capitation amount for each Medicaid participant.

(b) The monthly capitation payment amount is negotiated between the PACE organization and the State administering agency, and specified in the PACE program agreement. The amount represents the following:

(1) Is less than the amount that would otherwise have been paid under the State plan if the participants were not enrolled under the PACE program.

(2) Takes into account the comparative frailty of PACE participants.

(3) Is a fixed amount regardless of changes in the participant's health status.

(4) Can be renegotiated on an annual basis.

(c) The PACE organization must accept the capitation payment amount as payment in full for Medicaid participants and may not bill, charge, collect, or receive any other form of payment from the State administering agency or from, or on behalf of, the participant, except as follows:

(1) Payment with respect to any applicable spenddown liability under §§ 435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under § 460.184.

(2) Medicare payment received from CMS or from other payers, in accordance with § 460.180(d).

(d) State procedures for the enrollment and disenrollment of participants in the State's system, including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in that month, are included in the PACE program agreement.

§ 460.184 Post-eligibility treatment of income.

(a) A State may provide for post-eligibility treatment of income for Medicaid participants in the same manner as a State treats post-eligibility income for individuals receiving services under a waiver under section 1915(c) of the Act.

(b) Post-eligibility treatment of income is applied as it is under a waiver of section 1915(c) of the Act, as specified in §§ 435.726 and 435.735 of this chapter, and section 1924 of the Act.

§ 460.186 PACE premiums.

The amount that a PACE organization can charge a participant as a monthly premium depends on the participant's eligibility under Medicare and Medicaid, as follows:

(a) *Medicare Parts A and B.* For a participant who is entitled to Medicare Part A, enrolled under Medicare Part B, but not eligible for Medicaid, the premium equals the Medicaid capitation amount.

(b) *Medicare Part A only.* For a participant who is entitled to Medicare Part A, not enrolled under Medicare Part B, and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part B capitation rate.

(c) *Medicare Part B only.* For a participant who is enrolled only under Medicare Part B and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.

(d) *Medicaid, with or without Medicare.* A PACE organization may not charge a premium to a participant who is eligible for both Medicare and Medicaid, or who is only eligible for Medicaid.

Subpart K—Federal/State Monitoring

§ 460.190 Monitoring during trial period.

(a) *Trial period review.* During the trial period, CMS, in cooperation with the State administering agency, conducts comprehensive annual reviews of the operations of a PACE organization to ensure compliance with the requirements of this part.

(b) *Scope of review.* The review includes the following:

(1) An onsite visit to the PACE organization, which may include, but is not limited to, the following:

(i) Review of participants' charts.

(ii) Interviews with staff.

(iii) Interviews with participants and caregivers.

(iv) Interviews with contractors.

(v) Observation of program operations, including marketing, participant services, enrollment and disenrollment procedures, grievances, and appeals.

(2) A comprehensive assessment of an organization's fiscal soundness.

(3) A comprehensive assessment of the organization's capacity to furnish all PACE services to all participants.

(4) Any other elements that CMS or the State administering agency find necessary.

§ 460.192 Ongoing monitoring after trial period.

(a) At the conclusion of the trial period, CMS, in cooperation with the State administering agency, continues to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with all of the requirements of this part.

(b) Reviews include an on-site visit at least every 2 years.

§ 460.194 Corrective action.

(a) A PACE organization must take action to correct deficiencies identified during reviews.

(b) CMS or the State administering agency monitors the effectiveness of corrective actions.

(c) Failure to correct deficiencies may result in sanctions or termination, as specified in subpart D of this part.

§ 460.196 Disclosure of review results.

(a) CMS and the State administering agency promptly report the results of reviews under §§ 460.190 and 460.192 to the PACE organization, along with any recommendations for changes to the organization's program.

(b) CMS and the State administering agency make the results of reviews available to the public upon request.

(c) The PACE organization must post a notice of the availability of the results of the most recent review and any plans of correction or responses related to the most recent review.

(d) The PACE organization must make the review results available for examination in a place readily accessible to participants.

Subpart L—Data Collection, Record Maintenance, and Reporting

§ 460.200 Maintenance of records and reporting of data.

(a) *General rule.* A PACE organization must collect data, maintain records, and submit reports as required by CMS and the State administering agency.

(b) *Access to data and records.* A PACE organization must allow CMS and the State administering agency access to data and records including, but not limited to, the following:

(1) Participant health outcomes data.

(2) Financial books and records.

(3) Medical records.

(4) Personnel records.

(c) *Reporting.* A PACE organization must submit to CMS and the State administering agency all reports that CMS and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

(d) *Safeguarding data and records.* A PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(e) *Confidentiality of health information.* A PACE organization must establish written policies and implement procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain complete records and relevant information in an accurate and timely manner.

(3) Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, and other participant health information.

(f) *Retention of records.* (1) A PACE organization must retain records for the longest of the following periods:

(i) The period of time specified in State law.

(ii) Six years from the last entry date.

(iii) For medical records of disenrolled participants, 6 years after the date of disenrollment.

(2) If litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, specified in paragraph (f)(1) of this section, the PACE organization must retain the records until the completion of the litigation, or resolution of the claims or audit findings.

§ 460.202 Participant health outcomes data.

(a) A PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants.

(b) A PACE organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by CMS and the State administering agency. The items collected are specified in the PACE program agreement.

§ 460.204 Financial recordkeeping and reporting requirements.

(a) *Accurate reports.* A PACE organization must provide CMS and the State administering agency with accurate financial reports that are—

(1) Prepared using an accrual basis of accounting; and

(2) Verifiable by qualified auditors.

(b) *Accrual accounting.* A PACE organization must maintain an accrual accounting recordkeeping system that does the following:

(1) Accurately documents all financial transactions.

(2) Provides an audit trail to source documents.

(3) Generates financial statements.

(c) *Accepted reporting practices.* Except as specified under Medicare principles of reimbursement, as defined in part 413 of this chapter, a PACE organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry.

(d) *Audit or inspection.* A PACE organization must permit CMS and the State administering agency to audit or inspect any books and records of original entry that pertain to the following:

(1) Any aspect of services furnished.

(2) Reconciliation of participants' benefit liabilities.

(3) Determination of Medicare and Medicaid amounts payable.

§ 460.208 Financial statements.

(a) *General rule.* (1) Not later than 180 days after the organization's fiscal year ends, a PACE organization must submit a certified financial statement that includes appropriate footnotes.

(2) The financial statement must be certified by an independent certified public accountant.

(b) *Contents.* At a minimum, the certified financial statement must consist of the following:

(1) A certification statement.

(2) A balance sheet.

(3) A statement of revenues and expenses.

(4) A source and use of funds statement.

(c) *Quarterly financial statement*—(1) *During trial period.* A PACE organization must submit a quarterly financial statement throughout the trial period within 45 days after the last day of each quarter of the PACE organization's fiscal year.

(2) *After trial period.* If CMS or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, CMS or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

§ 460.210 Medical records.

(a) *Maintenance of medical records.* (1) A PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.

(2) The medical record for each participant must meet the following requirements:

(i) Be complete.

(ii) Accurately documented.

(iii) Readily accessible.

(iv) Systematically organized.

(v) Available to all staff.

(vi) Maintained and housed at the PACE center where the participant receives services.

(b) *Content of medical records.* At a minimum, the medical record must contain the following:

(1) Appropriate identifying information.

(2) Documentation of all services furnished, including the following:

(i) A summary of emergency care and other inpatient or long-term care services.

(ii) Services furnished by employees of the PACE center.

(iii) Services furnished by contractors and their reports.

(3) Interdisciplinary assessments, reassessments, plans of care, treatment, and progress notes that include the participant's response to treatment.

(4) Laboratory, radiological and other test reports.

(5) Medication records.

(6) Hospital discharge summaries, if applicable.

(7) Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin).

(8) Enrollment Agreement.

(9) Physician orders.

(10) Discharge summary and disenrollment justification, if applicable.

(11) Advance directives, if applicable.

(12) A signed release permitting disclosure of personal information.

(13) Accident and incident reports.

(c) *Transfer of medical records.* The organization must promptly transfer copies of medical record information between treatment facilities.

(d) *Authentication of medical records.* (1) All entries must be legible, clear, complete, and appropriately authenticated and dated.

(2) Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

SUBCHAPTER F—QUALITY IMPROVEMENT ORGANIZATIONS

PART 475—QUALITY IMPROVEMENT ORGANIZATIONS

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Subpart B [Reserved]

Subpart C—Utilization and Quality Control Quality Improvement Organizations

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475.106 Prohibition against contracting with payor organizations.
475.107 QIO contract award.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 475.1 Definitions.

For purposes of this part:

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;

(b) Has an indirect ownership interest equal to 5 percent or more;

(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to 5 percent or more; or

(d) Is the owner of an interest of 5 percent or more in any obligation secured by an entity, if the interest equals at least 5 percent of the value of the property or assets of the entity.

Health care facility means an institution that directly provides or supplies health care services for which payment may be made in whole or in part under Title XVIII of the Act. A health care facility may be a hospital, skilled nursing facility, home health agency, free-standing ambulatory surgical center, or outpatient facility or any other entity which provides or supplies direct care to Medicare beneficiaries.

Managing employee means a general manager, business manager, administrator, director or other individual who exercises operational or managerial control over the entity or organization, or who, directly or indirectly, conducts the day-to-day operations of the entity or organization.

Payor organization means any organization, other than a self-insured employer, which makes payments directly or indirectly to health care practitioners or providers whose health care services are reviewed by the organization or would be reviewed by the organization if it entered into a QIO contract. ''Payor organization'' also means any organization which is affiliated with any entity which makes payments as described above, by virtue of the organization having two or more governing body members who are also either governing body members, officers, partners, 5 percent or more owners or managing employees in a health maintenance organization or competitive medical plan.

Physician means:

(1) A doctor of medicine or osteopathy licensed under State law to practice medicine, surgery, or osteopathy in the State in which the QIO is located;

(2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice medicine, surgery, or osteopathy in the QIO area; and

(3) An individual licensed to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

[43 FR 32085, July 24, 1978, as amended at 49 FR 7206, Feb. 27, 1984. Redesignated at 50 FR 15327, Apr. 17, 1985, and amended at 50 FR 15328, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986. Redesignated at 64 FR 66279, Nov. 24, 1999]

Subpart B [Reserved]

Subpart C—Utilization and Quality Control Quality Improvement Organizations

SOURCE: 49 FR 7207, Feb. 27, 1984, unless otherwise noted. Redesignated at 50 FR 15327, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999.

§ 475.100 Scope and applicability.

This subpart implements sections 1152 and 1153(b) of the Social Security Act as amended by the Peer Review Improvement Act of 1982 (Pub. L. 97–248). It defines the types of organizations eligible to become QIOs and establishes certain limitations and priorities regarding QIO contracting.

§ 475.101 Eligibility requirements for QIO contracts.

In order to be eligible for a QIO contract an organization must—

(a) Be either a physician-sponsored organization as described in § 462.102; or a physician-access organization as described in § 462.103; and

(b) Demonstrate its ability to perform review as set forth in § 462.104.

§ 475.102 Eligibility of physician-sponsored organizations.

(a) In order to be eligible for designation as a physician-sponsored QIO, an organization must meet the following conditions:

(1) Be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area and who are representative of the physicians practicing in the area.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

(b) In order to meet the requirements of paragraph (a)(1) of this section, an organization must state and have documentation in its files showing that it is composed of at least 10 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area.

(c) In order to meet the requirements or paragraph (a)(2) of this section, an organization must—

(1) State and have documentation in its files demonstrating that it is composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area; or

(2) If the organization is not composed of at least 20 percent of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area, then the organization must demonstrate in its contract proposal, through letters of support from physicians or physician organizations, or through other means, that it is representative of the area physicians.

(d) Organizations that meet the requirements in paragraph (a) of this section will receive, during the contract evaluation process, a set number of bonus points.

[49 FR 7207, Feb. 27, 1984. Redesignated and amended at 50 FR 15327, 15328, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999]

§ 475.103 Eligibility of physician-access organizations.

(a) In order to be eligible for designation as a physician-access QIO, an organization must meet the following conditions:

(1) Have available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

(b) An organization meets the requirements of paragraph (a)(1) of this section if it demonstrates—

(1) That it has available to it at least one physician in every generally recognized specialty; and

(2) The existence of an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

[50 FR 15328, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 475.104 Requirements for demonstrating ability to perform review.

(a) A physician-sponsored or physician-access organization will be found capable of conducting review if CMS determines that the organization is able to set quantifiable performance objectives and perform the utilization and quality review functions established under section 1154 of the Social Security Act in an efficient and effective manner.

(b) CMS will determine that the organization is capable of conducting utilization and quality review if—

(1) The organization's proposed review system is adequate; and

(2) The organization has available sufficient resources (including access to medical review skills) to implement that system; and

(3) The organization's quantifiable objectives are acceptable.

(c) CMS may consider prior similar review experience in making determinations under paragraph (b) of this section.

(d) A State government that operates a Medicaid program will be considered incapable of performing utilization and quality review functions in an effective manner, unless the State demonstrates to the satisfaction of CMS that it will act with complete independence and objectivity.

§ 475.105 Prohibition against contracting with health care facilities.

(a) *Basic rule.* Except as permitted under paragraph (b) of this section, the following are not eligible for QIO contracts:

(1) A health care facility in the QIO area.

(2) An association of health care facilities in the QIO area.

(3) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility or association of health care facilities in the QIO area.

(b) *Exceptions.* Effective November 15, 1984, the prohibition stated in paragraph (a) of this section will not apply to a payor organization if CMS determines under § 462.106 that there is no other eligible organization available.

(c) *Subcontracting.* A QIO must not subcontract with a facility to conduct any review activities except for the review of the quality of care.

[50 FR 15328, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 475.106 Prohibition against contracting with payor organizations.

Payor organizations are not eligible to become QIOs for the area in which they make payments until November 15, 1984. If no QIO contract for an area is awarded before November 15, 1984, a payor organization will be determined eligible by CMS, if an eligible organization that is not a payor organization is unavailable at that time. CMS may determine the unavailability of nonpayor organizations based on the lack of response to an appropriate Request for Proposal.

[50 FR 15328, Apr. 17, 1985]

§ 475.107 QIO contract award.

CMS, in awarding QIO contracts, will take the following actions—

(a) Identify from among all proposals submitted in response to an RFP for a given QIO area all proposals submitted by organizations that meet the requirements of § 462.102 or § 462.103;

(b) Identify from among all proposals identified in paragraph (a) of this section all proposals that set forth minimally acceptable plans in accordance with the requirements of § 462.104 and the RFPs;

(c) Assign bonus points not to exceed 10% of the total points available to all physician-sponsored organizations identified in paragraph (b) of this section, consistent with statute; and

(d) Subject to the limitations established by §§ 462.105 and 462.106, award the contract for the given QIO area to the selected organization for a period of two years.

[49 FR 7207, Feb. 27, 1984. Redesignated and amended at 50 FR 15327, 15328, Apr. 17, 1985, and further redesignated at 64 FR 66279, Nov. 24, 1999]

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

Subpart A—General Provisions

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476.1 Definitions.

Subpart B [Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

GENERAL PROVISIONS

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476.104 Coordination of activities.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 44 FR 32081, June 4, 1979, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

Subpart A—General Provisions

§ 476.1 Definitions.

As used in this part, unless the context indicates otherwise:

Active staff privileges means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) to order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

Admission review means a review and determination by a QIO of the medical necessity and appropriateness of a patient's admission to a specific facility.

Continued stay review means QIO review that is performed after admission review and during a patient's hospitalization to determine the medical necessity and appropriateness of continuing the patient's stay at a hospital level of care.

Criteria means predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared.

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

DRG validation means a part of the prospective payment system in which a QIO validates that DRG assignments are based on the correct diagnostic and procedural information.

Elective, when applied to admission or to a health care service, means an admission or a service that can be delayed without substantial risk to the health of the individual.

Five percent or more owner means a person (including, where appropriate, a corporation) who:

(a) Has an ownership interest of 5 percent or more;

(b) Has an indirect ownership interest equal to 5 percent or more;

(c) Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to five percent or more; or

(d) Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

Health care facility or *facility* means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Health care practitioners other than physicians means those health professionals who do not hold a doctor of medicine or doctor of osteopathy degree, who meet all applicable State or Federal requirements for practice of their professions, and who are in active practice.

Hospital means a health care institution or distinct part of a health care institution, as defined in Section 1861(e)–(g) of the Act, other than a religious nonmedical institution as defined in §440.170(b) of this chapter.

Initial denial determination means an initial negative decision by a QIO, regarding the medical necessity, quality, or appropriateness of health care services furnished, or proposed to be furnished, to a patient.

Major clinical area means medicine, surgery, pediatrics, obstetrics and gynecology, or psychiatry.

Major procedure means a diagnostic or therapeutic procedure which involves a surgical or anesthetic risk or requires highly trained personnel or special facilities or equipment.

Non-facility organization means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the QIO area.

Norm means a pattern of performance in the delivery of health care services that is typical for a specified group.

Norms means numerical or statistical measures of average observed performance in the delivery of health care services.

Outliers means those cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Peer review means review by health care practitioners of services ordered or furnished by other practitioners in the same professional field.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient's admission for payment purposes.

Preadmission review means review prior to a patient's admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

Preprocedure review means review of a surgical or other invasive procedure prior to the conduct of the procedure.

QIO review means review performed in fulfillment of a contract with CMS, either by the QIO or its subcontractors.

Profile means aggregated data in formats that display patterns of health care services over a defined period of time.

Profile analysis means review and analysis of profiles to identify and consider patterns of health care services.

Quality review study means an assessment conducted by or for a QIO of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Regional norms, criteria, and standards means norms, criteria, and standards that apply to a geographic division which is larger than a QIO area.

Retrospective review means review that is conducted after services are provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.

Review responsibility means (1) the responsibility of the QIO to perform review functions prescribed under Part B of Title XI of the Act and the Social Security Amendments of 1983 (Pub. L. No. 98–21) and the regulations of this part; (2) the responsibility to fulfill the terms and meet the objectives set forth in the negotiated contract between CMS and the QIO; and (3) the authority of a QIO to make conclusive initial denial determinations regarding the medical necessity and appropriateness of health care and changes as a result of DRG validations.

Skilled nursing facility (SNF) means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a religious nonmedical institution as defined in §440.170(b) of this chapter

Standards means professionally developed expressions of the range of acceptable variation from a norm or criterion.

Subcontractor means a facility or a non-facility organization under contract with a QIO to perform QIO review functions.

Working day means any one of at least five days of each week (excluding, at the option of each QIO, legal holidays) on which the necessary personnel are available to perform review.

[44 FR 32081, June 4, 1979, as amended at 45 FR 67545, Oct. 10, 1980; 46 FR 48569, Oct. 1, 1981. Redesignated and amended at 50 FR 15328, 15329, Apr. 17, 1985; 51 FR 43197, Dec. 1, 1986. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 64 FR 67052, Nov. 30, 1999]

Subpart B [Reserved]

Subpart C—Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations (QIOs)

SOURCE: 50 FR 15330, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

GENERAL PROVISIONS

§ 476.70 Statutory bases and applicability.

(a) *Statutory basis.* Sections 1154, 1866(a)(1)(F) and 1886(f)(2) of the Act require that a QIO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary. Section 1154(a)(4) of the Act requires QIOs, or, in certain circumstances, non-QIO entities, to perform quality of care reviews of services furnished under risk-basis contracts by health maintenance organizations (HMOs) and competitive medical plans (CMPs) that are covered under subpart C of part 417 of this chapter.

(b) *Applicability.* The regulations in this subpart apply to review conducted by a QIO and its subcontractors. Section 466.72 of this part also applies, for purposes of quality of care reviews under section 1154(a)(4) of the Act, to non-QIO entities that enter into contracts to perform reviews of services furnished under risk-basis contracts by HMOs and CMPs under subpart C of part 417 of this chapter.

[52 FR 37457, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.71 QIO review requirements.

(a) *Scope of QIO review.* In its review, the QIO must determine (in accordance with the terms of its contract)—

(1) Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of illness or injury or to improve functioning of a malformed body member, or (with respect to pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness;

(2) Whether the quality of the services meets professionally recognized standards of health care;

(3) Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health care facility of a different type;

(4) Through DRG validation, the validity of diagnostic and procedural information supplied by the hospital;

(5) The completeness, adequacy and quality of hospital care provided;

(6) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges;

(7) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter; and

(8) Whether a hospital has misrepresented admission or discharge information or has taken an action that results in—

(i) The unnecessary admission of an individual entitled to benefits under part A;

(ii) Unnecessary multiple admissions of an individual; or

(iii) Other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(b) *Payment determinations.* On the basis of the review specified under paragraphs (a) (1), (3), (6), (7), and (8) of this section, the QIO must determine whether payment may be made for these services. A QIO may grant a period of not more than two days (grace days) for the purpose of arranging post discharge care when the provider did not know or could not reasonably be expected to have known that payment for the service(s) would not be made under the Medicare program as specified in § 405.330(b).

(c) *Other duties and functions.* (1) The QIO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) As directed by CMS, the QIO must review changes in DRG and LTC-DRG assignments made by the intermediary under the provisions of §§ 412.60(d) and 412.513(c) of this chapter that result in the assignment of a higher-weighted DRG or a different LTC-DRG. The QIO's review must verify that the diagnostic and procedural information supplied by the hospital is substantiated by the information in the medical record.

(d) *Coordination of sanction activities.* The QIO must carry out the responsibilities specified in subpart C of part 1004 of this title regarding imposition of sanctions on providers and practitioners who violate their statutory obligations under section 1156 of the Act.

[52 FR 37457, Oct. 7, 1987; 52 FR 47003, Dec. 11, 1987, as amended at 59 FR 45402, Sept. 1, 1994. Redesignated at 64 FR 66279, Nov. 24, 1999; 67 FR 56056, Aug. 30, 2002]

§ 476.72 Review of the quality of care of risk-basis health maintenance organizations and competitive medical plans.

(a) (1) For purposes of a review under section 1154(a)(4) of the Act, a QIO must determine whether the quality of services (including both inpatient and outpatient services) provided by an HMO or CMP meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

(2) Paragraph (a)(1) of this section will not apply with respect to a contract year if another entity has been awarded a contract to perform those reviews under section 1154(a)(4)(C) of the Act.

(b) For purposes of reviews under this section, non-QIO entities selected to perform these reviews under section 1154(a)(4)(C) of the Act are subject to the requirements of paragraph (a)(1) of this section and—

(1) Part 476 of this chapter regarding acquisition, protection, and disclosure of peer review information; and

(2) Part 1004 of Chapter V regarding a QIO's responsibilities, and sanctions on health care practitioners and providers.

[52 FR 37457, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.73 Notification of QIO designation and implementation of review.

(a) *Notice of CMS's decision.* CMS sends written notification of a QIO contract award to the State survey agency and Medicare fiscal intermediaries and carriers. The notification includes the effective dates of the QIO contract and specifies the area and types of health care facilities to be reviewed by the QIO. The QIO must make a similar notification when review responsibilities are subcontracted.

(b) *Notification to health care facilities and the public.* As specified in its contract with CMS, the QIO must—

(1) Provide, to each health care facility scheduled to come under review, a timely written notice that specifies the date and manner in which the QIO proposes to implement review, and the information to be furnished by the facility to each Medicare beneficiary upon admission as specified in § 466.78(b)(3) of this part.

(2) Publish, in at least one local newspaper of general circulation in the QIO area, a notice that states the date the QIO will assume review responsibilities and lists each area health care facility to be under review. The QIO must indicate that its plan for the review of health care services as approved in its contract with CMS is available for public inspection in the QIO's business office and give the address, telephone number and usual hours of business.

[50 FR 15330, Apr. 17, 1985. Redesignated at 52 FR 37457, Oct. 7, 1987, and further redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.74 General requirements for the assumption of review.

(a) A QIO must assume review responsibility in accordance with the schedule, functions and negotiated objectives specified in its contract with CMS.

(b) A QIO must notify the appropriate Medicare fiscal intermediary or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility.

(c) A QIO must maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with Medicare fiscal intermediaries and carriers;

(2) A copy of its currently approved review plan that includes the QIO's method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) A QIO must not subcontract with a facility to conduct any review activities except for the review of the quality of care. The QIO may subcontract with a non-facility organization to conduct review in a facility.

(e) If required by CMS, a QIO is responsible for compiling statistics based on the criteria contained in § 405.332 of this chapter and making limitation of liability determinations on excluded coverage of certain services that are made under section 1879 of the Act. If required by CMS, QIOs must also notify a provider of these determinations. These determinations and further appeals are governed by the reconsideration and appeals procedures in part 405, subpart G of this chapter for Medicare Part A related determinations and part 405, subpart H of this chapter for Medicare Part B related determinations.

(f) A QIO must make its responsibilities under its contract with CMS, primary to all other interests and activities that the QIO undertakes.

§ 476.76 Cooperation with health care facilities.

Before implementation of review, a QIO must make a good faith effort to discuss the QIO's administrative and review procedures with each involved health care facility.

§ 476.78 Responsibilities of health care facilities.

(a) Every hospital seeking payment for services furnished to Medicare beneficiaries must maintain a written agreement with a QIO operating in the area in which the hospital is located. These agreements must provide for the QIO review specified in § 466.71.

(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review. Providers must—

(1) Allocate adequate space to the QIO for its conduct of review at the times the QIO is conducting review.

(2) Provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. The provider must photocopy and deliver to the QIO all required information within 30 days of a request. QIOs pay providers paid under the prospective payment system for the costs of photocopying records requested by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the QIO. When the QIO does postadmission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

(3) Inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to QIO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the facility has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requries inpatient hospital care, it must submit a copy of its determination to the QIO within 3 working days.

(5) Assure, in accordance with the provisions of its agreement with the QIO, that each case subject to preadmission review has been reviewed and approved by the QIO before admission to the hospital or a timely request has been made for QIO review.

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the QIO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a facility, in accordance with its agreement with a QIO, makes a timely request for preadmission review and the QIO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the QIO.

(c) *Photocopying reimbursement methodology for prospective payment system providers.* Providers subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the providers' responsibility to the QIOs to provide photocopies of requested provider records. The payment is in addition to payment already provided for these costs under other provisions of the Social Security Act and is based on a fixed amount per page as determined by CMS as follows:

(1) *Step one.* CMS adds the annual salary of a photocopy machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB Circular A–76.

(2) *Step two.* CMS divides the amount determined in paragraph (c)(1) of this section by the number of pages that can be reasonably expected to be made annually by the photocopy machine operator to establish the labor cost per page.

(3) CMS adds to the per-page labor cost determined in paragraph (c)(2) of this section the per-page costs of supplies.

(4) CMS will periodically review the photocopy reimbursement rate to ensure that it still accurately reflects provider costs. CMS will publish any changes to the rate in a FEDERAL REGISTER notice.

(d) *Appeals.* Reimbursement for the costs of photocopying and mailing records for QIO review is an additional payment to providers under the prospective payment system, as specified in § 412.115, § 413.355, and § 484.265 of this chapter. Thus, appeals concerning these costs are subject to the review

process specified in part 405, subpart R of this chapter.

[50 FR 15330, Apr. 17, 1985, as amended at 57 FR 47787, Oct. 20, 1992; 59 FR 45402, Sept. 1, 1994. Redesignated at 64 FR 66279, Nov. 24, 1999; 68 FR 67960, Dec. 5, 2003]

§ 476.80 Coordination with Medicare fiscal intermediaries and carriers.

(a) *Procedures for agreements.* The Medicare fiscal intermediary or carrier must have a written agreement with the QIO. The QIO must take the initiative with the fiscal intermediary or carrier in developing the agreement. The following steps must be taken in developing the agreement.

(1) The QIO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, CMS will assist them in resolving matters in dispute.

(2) The QIO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from CMS, before it makes conclusive determinations for the Medicare program, unless CMS finds that the fiscal intermediary or carrier has—

(i) Refused to negotiate in good faith or in a timely manner, or

(ii) Insisted on including in the agreement, provisions that are outside the scope of its authority under the Act.

(b) *Content of agreement.* The agreement must include procedures for—

(1) Informing the appropriate Medicare fiscal intermediaries and carriers of—

(i) Changes as a result of DRG validations and revisions as a result of the review of these changes; and

(ii) Initial denial determinations and revisions of these determinations as a result of reconsideration, or reopening all approvals and denials with respect to cases subject to preadmission review, and outlier claims in hospitals under a prospective payment system for health care services and items;

(2) Exchanging data or information;

(3) Modifying the procedures when additional review responsibility is authorized by CMS; and

(4) Any other matters that are necessary for the coordination of functions.

(c) *Action by CMS.* (1) Within the time specified in its contract, the QIO must submit to CMS for approval its agreement with the Medicare fiscal intermediaries and carriers, or if an agreement has not been established, the QIO's proposed administrative procedures, including any comments by the Medicare fiscal intermediaries and carriers.

(2) If CMS approves the agreement or the administrative procedures (after a finding by CMS as specified in paragraph (a)(2) of this section), the QIO may begin to make determinations under its contract with CMS.

(3) If CMS disapproves the agreement or procedures, it will—

(i) Notify the QIO and the appropriate fiscal agents in writing, stating the reasons for disapproval; and

(ii) Require the QIO and fiscal intermediary or carrier to revise its agreements or procedures.

(d) *Modification of agreements.* Agreements or procedures may be modified, with CMS's approval—

(1) Through a revised agreement with the fiscal intermediary or carrier, or

(2) In the case of procedures, by the QIO, after providing opportunity for comment by the fiscal intermediary or carrier.

(e) *Role of the fiscal intermediary.* (1) The fiscal intermediary will not pay any claims for those cases which are subject to preadmission review by the QIO, until it receives notice that the QIO has approved the admission after preadmission or retrospective review.

(2) A QIO's determination that an admission is medically necessary is not a guarantee of payment by the fiscal intermediary. Medicare coverage requirements must also be applied.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.82 Continuation of functions not assumed by QIOs.

Any of the duties and functions under Part B of Title XI of the Act for which a QIO has not assumed responsibility under its contract with CMS must be

performed in the manner and to the extent otherwise provided for under the Act or in regulations.

QIO REVIEW FUNCTIONS

§ 476.83 Initial denial determinations.

A determination by a QIO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under part 473 of this chapter.

§ 476.84 Changes as a result of DRG validation.

A provider or practitioner may obtain a review by a QIO under part 473 of this chapter for changes in diagnostic and procedural coding that resulted in a change in DRG assignment as a result of QIO validation activities.

§ 476.85 Conclusive effect of QIO initial denial determinations and changes as a result of DRG validations.

A QIO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in part 473—

(a) The initial denial determination is reconsidered and revised; or

(b) The change as a result of DRG validation is reviewed and revised.

§ 476.86 Correlation of Title XI functions with Title XVIII functions.

(a) *Payment determinations.* (1) QIO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:

(i) Whether inpatient care furnished in a psychiatric hospital meets the requirements of § 424.14 of this chapter.

(ii) Whether payment for inpatient hospital or SNF care beyond 20 consecutive days is precluded under § 489.50 of this chapter because of failure to perform review of long-stay cases.

(iii) Whether the care furnished was custodial care or care not reasonable and necessary and, as such, excluded under § 405.310(g) or § 405.310(k) of this chapter.

(iv) Whether the care was appropriately furnished in the inpatient or outpatient setting.

(2) Reviews with respect to determinations listed in paragraph (a)(1) of this section must not be conducted, for purposes of payment, by Medicare fiscal intermediaries or carriers except as outlined in paragraph (c) of this section.

(3) QIOs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the QIO determines that it could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

(4) QIO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.

(b) *Utilization review activities.* QIO review activities to determine whether inpatient hospital or SNF care services are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in §§ 405.1035, 405.1042, and 405.1137 of this chapter.

(c) *Coverage.* Nothing in paragraphs (a) (1) and (3) of this section will be construed as precluding CMS or a Medicare fiscal intermediary or carrier, in the proper exercise of its duties and functions, from reviewing claims to determine:

(1) In the case of items or services not reviewed by a QIO, whether they meet coverage requirements of Title XVIII relating to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care. However, if a coverage determination pertains to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care, the fiscal intermediary or carrier

must use a QIO to make a determination on those issues if a QIO is conducting review in the area and must abide by the QIO's determination.

(2) Whether any claim meets coverage requirements of Title XVIII relating to issues other than medical necessity, reasonableness or appropriateness of placement at an acute level of patient care.

(d) *Payment.* Medicare fiscal intermediaries and carriers are not precluded from making payment determinations with regard to coverage determinations made under paragraph (c) of this section.

(e) *Survey, compliance and assistance activities.* QIO review and monitoring activities fulfill the requirements for compliance and assistance activities of State survey agencies under section 1864(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of intermediaries and carriers under §§ 421.100(d) and 421.200(f) of this chapter.

(f) *Appeals.* The requirements and procedures for QIO review of changes as a result of DRG validation and the reconsideration, hearing and judicial review of QIO initial denial determinations are set forth in part 473 of this chapter.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985, as amended at 53 FR 6648, Mar. 2, 1988. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.88 Examination of the operations and records of health care facilities and practitioners.

(a) *Authorization to examine records.* A facility claiming Medicare payment must permit a QIO or its subcontractor to examine its operation and records (including information on charges) that are pertinent to health care services furnished to Medicare beneficiaries and are necessary for the QIO or its subcontractor to—

(1) Perform review functions including, but not limited to—

(i) DRG validation;

(ii) Outlier review in facilities under a prospective payment system; and

(iii) Implementation of corrective action and fraud and abuse prevention activities;

(2) Evaluate cases that have been identified as deviating from the QIO norms and criteria, or standards; and

(3) Evaluate the capability of the facility to perform quality review functions under a subcontract with the QIO.

(b) *Limitations on access to records.* A QIO has access to the records of non-Medicare patients if—

(1) The records relate to review performed under a non-Medicare QIO contract and if authorized by those patients in accordance with State law; or

(2) The QIO needs the records to perform its quality review responsibilities under the Act and receives authorization from the facility or practitioner.

(c) *Conditions of examination.* When examining a facility's operation or records the QIO must—

(1) Examine only those operations and records (including information on charges) required to fulfill the purposes of paragraph (a) of this section;

(2) Cooperate with agencies responsible for other examination functions under Federal or Federally assisted programs in order to minimize duplication of effort;

(3) Conduct the examinations during reasonable hours; and

(4) Maintain in its principal office written records of the results of the examination of the facility.

§ 476.90 Lack of cooperation by a health care facility or practitioner.

(a) If a health care facility or practitioner refuses to allow a QIO to enter and perform the duties and functions required under its contract with CMS, the QIO may—

(1) Determine that the health care facility or practitioner has failed to comply with the requirements of § 474.30(c) of this chapter and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the health care facility, and report the matter to the HHS Inspector General.

(b) If a QIO provides a facility with sufficient notice and a reasonable amount of time to respond to a request for information about a claim, and if

the facility does not respond in a timely manner, the QIO will deny the claim.

§ 476.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.

Before a QIO reaches an initial denial determination or makes a change as a result of a DRG validation, it must—

(a) Promptly notify the provider or supplier and the patient's attending physician (or other attending health care practitioner) of the proposed determination or DRG change; and

(b) Afford an opportunity for the provider or supplier and the physician (or other attending health care practitioner) to discuss the matter with the QIO physician advisor and to explain the nature of the patient's need for health care services, including all factors which preclude treatment of the patient as an outpatient or in an alternative level of inpatient care.

§ 476.94 Notice of QIO initial denial determination and changes as a result of a DRG validation.

(a) *Notice of initial denial determination*—(1) *Parties to be notified.* A QIO must provide written notice of an initial denial determination to—

(i) The patient, or if the patient is expected to be unable to comprehend the notice, the patient's next of kin, guardian or other representative or sponsor;

(ii) The attending physician, or other attending health care practitioner;

(iii) The facility; and

(iv) The fiscal intermediary or carrier.

(2) *Timing of the notice.* The notice must be delivered to beneficiaries in the facility or mailed to those no longer in the facility, within the following time periods—

(i) For admission, on the first working day after the initial denial determination;

(ii) For continued stay (e.g., outliers in facilities under a prospective payment system), by the first working day after the initial denial determination if the beneficiary is still in the facility, and within 3 working days if the beneficiary has been discharged;

(iii) For preprocedure review, before the procedure is performed;

(iv) For preadmission review, before admission;

(v) If identification as a Medicare program patient has been delayed, within three working days of identification;

(vi) For retrospective review, (excluding DRG validation and post procedure review), within 3 working days of the initial denial determination; and

(vii) For post-procedure review, within 3 working days of the initial denial determination.

(3) *Preadmission review.* In the case of preadmission review, the QIO must document that the patient and the facility received notice of the initial denial determination.

(b) *Notice of changes as a result of a DRG validation.* The QIO must notify the provider and practitioner of changes to procedural and diagnostic information that result in a change of DRG assignment, within 30 days of the QIO's decision.

(c) *Content of the notice.* The notice must be understandable and written in plain English and must contain—

(1) The reason for the initial denial determination or change as a result of the DRG validation;

(2) For day outliers in hospitals, the date on which the stay or services in the facility will not be approved as being reasonable and medically necessary or appropriate to the patients' health care needs;

(3) A statement informing each party or his or her representative of the right to request in accordance with the provisions of part 473, subpart B of this chapter—

(i) Review of a change resulting from DRG validation; or

(ii) Reconsideration of the initial denial determination;

(4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;

(5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and

(6) A statement concerning the duties and functions of the QIO under the Act.

(d) *Notice to payers.* The QIO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the

Medicare fiscal intermediary or carrier within the same time periods as the notices to the other parties.

(e) *Record of initial denial determination and changes as a result of a DRG validation.* (1) The QIO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.

(2) The documentary record must include—

(i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and

(ii) A copy of the determination or change in DRG notices sent to all parties and identification of each party and the date on which the notice was mailed or delivered.

§ 476.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.

(a) *General timeframe.* A QIO or its subcontractor—

(1) Within one year of the date of the claim containing the service in question, may review and deny payment; and

(2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.

(b) *Extended timeframes.* (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the claim containing the service in question, if CMS approves.

(2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the QIO's decision if—

(i) Additional information is received on the patient's condition;

(ii) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria;

(iii) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or

(iv) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.

(c) *Fraud and abuse.* (1) A QIO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.

(2) An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

§ 476.98 Reviewer qualifications and participation.

(a) *Peer review by physician.* (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry with active staff privileges in one or more hospitals in the QIO area.

(2) If a QIO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.

(3) For purposes of paragraph (a)(1) of this section, individuals authorized to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands as ''medical officers'' may make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.

(b) *Peer review by health care practitioners other than physicians.* Health care practitioners other than physicians may review services furnished by other practitioners in the same professional field.

(c) *DRG validation review.* Decisions about procedural and diagnostic information must be made by physicians. Technical coding issues must be reviewed by individuals with training and experience in ICD–9–CM coding.

(d) *Persons excluded from review.* (1) A person may not review health care

services or make initial denial determinations or changes as a result of DRG validations if he or she, or a member of his or her family—

(i) Participated in developing or executing the beneficiary's treatment plan;

(ii) Is a member of the beneficiary's family; or

(iii) Is a governing body member, officer, partner, 5 percent or more owner, or managing employee in the health care facility where the services were or are to be furnished.

(2) A member of a reviewer's family is a spouse (other than a spouse who is legally separated under a decree of divorce or separate maintenance), child (including a legally adopted child), grandchild, parent, or grandparent.

§ 476.100 Use of norms and criteria.

(a) *Use of norms.* As specified in its contract, a QIO must use national, or where appropriate, regional norms in conducting review to achieve QIO contract objectives. However, with regard to determining the number of procedures selected for preadmission review, a QIO must use national admission norms.

(b) *Use of criteria.* In assessing the need for and appropriateness of an inpatient health care facility stay, a QIO must apply criteria to determine—

(1) The necessity for facility admission and continued stay (in cases of day outliers in hospitals under prospective payment);

(2) The necessity for surgery and other invasive diagnostic and therapeutic procedures; or

(3) The appropriateness of providing services at a particular health care facility or at a particular level of care. The QIO must determine whether the beneficiary requires the level of care received or whether a lower and less costly level of care would be equally effective.

(c) *Establishment of criteria and standards.* For the conduct of review a QIO must—

(1) Establish written criteria based upon typical patterns of practice in the QIO area, or use national criteria where appropriate; and

(2) Establish written criteria and standards to be used in conducting quality review studies.

(d) *Variant criteria and standards.* A QIO may establish specific criteria and standards to be applied to certain locations and facilities in the QIO area if the QIO determines that—

(1) The patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the QIO area; and

(2) There is a reasonable basis for the difference which makes the variation appropriate.

§ 476.102 Involvement of health care practitioners other than physicians.

(a) *Basic requirement.* Except as provided in paragraph (b) of this section, a QIO must meet the following requirements:

(1) Consult with the peers of the practitioners who furnish the services under review if the QIO reviews care and services delivered by health care practitioners other than physicians.

(2) Assure that in determinations regarding medical necessity of services or the quality of the services they furnish, these practitioners are involved in—

(i) Developing QIO criteria and standards;

(ii) Selecting norms to be used; and

(iii) Developing review mechanisms for care furnished by their peers.

(3) Ensure that an initial denial determination or a change as a result of DRG validation of services provided by a health care practitioner other than a physician is made by a physician only after consultation with a peer of that practitioner. Initial denial determinations and changes as a result of DRG validations must be made only by a physician or dentist.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply if—

(1) The QIO has been unable to obtain a roster of peer practitioners available to perform review; or

(2) The practitioners are precluded from performing review because they participated in the treatment of the patient, the patient is a relative, or the practitioners have a financial interest

in the health care facility as described in § 466.98(d).

(c) *Peer involvement in quality review studies.* Practitioners must be involved in the design of quality review studies, development of criteria, and actual conduct of studies involving their peers.

(d) *Consultation with practitioners other than physicians.* To the extent practicable, a QIO must consult with nurses and other professional health care practitioners (other than physicians defined in 1861(r) (1) and (2) of the Act) and with representatives of institutional and noninstitutional providers and suppliers with respect to the QIO's responsibility for review.

[50 FR 15330, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 476.104 Coordination of activities.

In order to achieve efficient and economical review, a QIO must coordinate its activities (including information exchanges) with the activities of—

(a) Medicare fiscal intermediaries and carriers;

(b) Other QIOs; and

(c) Other public or private review organizations as may be appropriate.

PART 478—RECONSIDERATIONS AND APPEALS

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organization (QIO) Reconsiderations and Appeals

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organization (QIO) Reconsiderations and Appeals

SOURCE: 50 FR 15372, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

§ 478.10 Scope.

This subpart establishes the requirements and procedures for—

(a) Reconsiderations conducted by a Utilization and Quality Control Quality Improvement Organization (QIO) or its subcontractor of initial denial determinations concerning services furnished or proposed to be furnished under Medicare;

(b) Hearings and judicial review of reconsidered determinations; and

(c) QIO review of a change in diagnostic and procedural coding information.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.12 Statutory basis.

(a) Under section 1154 of the Act, a QIO may make an initial determination that services furnished or proposed to be furnished are not reasonable, necessary, or delivered in the most appropriate setting.

(b) Under section 1155 of the Act, the following rules apply:

(1) A Medicare beneficiary, a provider, or an attending practitioner who is dissatisfied with an initial denial determination under paragraph (a) of this section is entitled to a reconsideration by the QIO that made that determination.

(2) The beneficiary is also entitled to the following:

(i) A hearing by an administrative law judge if $200 or more is still in controversy after a reconsidered determination.

(ii) Judicial review if $2000 or more is still in controversy after a final determination by the Department.

(c) Under section 1866(a)(1)(F) of the Act, a hospital that is reimbursed by the Medicare program must maintain an agreement with a QIO under which the QIO reviews the validity of diagnostic information furnished by the hospital.

[50 FR 15372, Apr. 17, 1985, as amended at 60 FR 50442, Sept. 29, 1995. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.14 Applicability.

(a) *Basic provision.* This subpart applies to reconsiderations and hearings of a QIO initial denial determination involving the following issues:

(1) Reasonableness of services.

(2) Medical necessity of services.

(3) Appropriateness of the inpatient setting in which services were furnished or are proposed to be furnished.

(b) *Concurrent appeal.* A reconsideration or hearing provided under this subpart fulfills the requirements of any other review, hearing, or appeal under the Act to which a party may be entitled with respect to the same issues.

(c) *Nonapplicability of rules to related determinations.* (1) A QIO may not reconsider its decision whether to grant grace days.

(2) Limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act. Initial determinations under section 1879 and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B. References in those subparts to initial and reconsidered determinations made by an intermediary, carrier or CMS should be read to mean initial and reconsidered determinations made by a QIO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.15 QIO review of changes resulting from DRG validation.

(a) *General rules.* (1) A provider or practitioner dissatisfied with a change to the diagnostic or procedural coding information made by a QIO as a result of DRG validation under section 1866(a)(1)(F) of the Act is entitled to a review of that change if—

(i) The change caused an assignment of a different DRG; and

(ii) Resulted in a lower payment.

(2) A beneficiary may obtain a review of a QIO DRG coding change only if that change results in noncoverage of a furnished service.

(3) The individual who reviews changes in DRG procedural or diagnostic information must be a physician, and the individual who reviews changes in DRG coding must be qualified through training and experience with ICD–9–CM coding.

(b) *Procedures.* Procedures described in §§ 473.18 through 473.36, and 473.48 (a) and (c) for a QIO reconsideration or reopening also apply to QIO review of a DRG coding change.

(c) *Finality of review.* No additional review or appeal for matters governed by paragraph (a) of this section is available.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.16 Right to reconsideration.

A beneficiary, provider or practitioner who is dissatisfied with a QIO initial denial determination on one of the issues specified in § 473.14(a) has a right to a reconsideration of that determination by the QIO that made the initial denial determination.

§ 478.18 Location for submitting requests for reconsideration.

(a) *Beneficiaries.* Except as provided in paragraph (c) of this section concerning requests for expedited reconsideration, a beneficiary who wishes to

obtain a reconsideration must submit a written request to one of the following:

(1) The QIO or the QIO subcontractor that made the initial determination.

(2) An SSA District Office.

(3) A Railroad Retirement Board Office, if the beneficiary is a railroad retiree.

(b) *Others.* A provider, physician or other practitioner that wishes to obtain reconsideration must submit a written request to the QIO or QIO subcontractor that made the initial determination.

(c) *Expedited reconsideration.* A request for an expedited reconsideration of a preadmission denial determination must be submitted directly to the QIO.

§ 478.20 Time limits for requesting reconsideration.

(a) *Basic rules.* (1) Except for a request for expedited reconsideration as provided in paragraph (c) of this section, or a late request with good cause under § 473.22, a dissatisfied party must file a request for reconsideration within 60 days after receipt of the notice of an initial determination.

(2) The date of receipt of the notice of the initial determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

(b) *Late filing of request.* A QIO will accept a request filed after 60 days after receipt of the notice of the initial determination if the QIO finds under the criteria set forth in § 473.22 that there was good cause for the party's failure to file a timely request.

(c) *Request for expedited reconsideration.* A request for an expedited reconsideration under § 473.18(c) must be submitted within three days after receipt of the notice of the initial denial determination.

§ 478.22 Good cause for late filing of a request for a reconsideration or hearing.

(a) *General Rule.* In determining whether a party has good cause for not filing a request for reconsideration or hearing timely, the QIO or ALJ, respectively, must consider the following:

(1) What circumstances kept the party from making the request on time.

(2) Whether an action by the QIO misled the party.

(3) Whether the party understood the requirements of the Act as affected by amendments to the Act, other legislation, or court decisions.

(b) *Examples.* Examples of circumstances in which good cause may exist include, but are not limited to, the following:

(1) A party was seriously ill and was prevented from requesting a reconsideration in person, through another person, or in writing.

(2) There was a death or serious illness in a party's immediate family.

(3) Important records were accidentally destroyed or damaged by fire or other cause.

(4) A party made a diligent effort but could not find or obtain necessary relevent information within the appropriate time period.

(5) A party requested additional information to further explain the determination within the time limit, and requested reconsideration within 60 days of receiving the explanation (or within 30 days for a Departmental Appeals Board hearing).

(6) The QIO gave the party incorrect or incomplete information about when and how to request a reconsideration or hearing.

(7) A party sent the request to another Government agency in good faith within the time limit, but the request did not reach an office authorized to receive the request until after the time period had expired.

(8) Other unusual or unavoidable circumstances exist that—

(i) Show that a party could not have known of the need to file timely; or

(ii) Prevented a party from filing timely.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.24 Opportunity for a party to obtain and submit information.

(a) Subject to the rules concerning disclosure of QIO information in section 1160 of the Act, at the request of a provider, practitioner or beneficiary,

the QIO must provide an opportunity for examination of the material upon which the initial denial determination was based. The QIO may not furnish a provider, practitioner or beneficiary with—

(1) A record of the QIO deliberation; or

(2) The identity of the QIO review coordinators, physician advisors, or consultants who assisted in the initial denial determination without their consent.

(b) The QIO may require the requester to pay a reasonable fee for the reproduction of the material requested.

(c) The QIO must provide a party with an opportunity to submit new evidence before the reconsidered determination is made.

§ 478.26 Delegation of the reconsideration function.

A QIO may delegate the authority to reconsider an initial determination to a nonfacility subcontractor, including the organization that made the initial determination as a QIO subcontractor.

§ 478.28 Qualifications of a reconsideration reviewer.

A reconsideration reviewer must be someone who is—

(a) Qualified under §466.98 of this chapter to make an initial determination.

(b) Not the individual who made the initial denial determination.

(c) A specialist in the type of services under review, except where meeting this requirement would compromise the effectiveness or efficiency of QIO review.

§ 478.30 Evidence to be considered by the reconsideration reviewer.

A reconsidered determination must be based on—

(a) The information that led to the initial determination;

(b) New information found in the medical records; or

(c) Additional evidence submitted by a party.

§ 478.32 Time limits for issuance of the reconsidered determination.

(a) *Beneficiaries.* If a beneficiary files a timely request for reconsideration of an initial denial determination, the QIO must complete its reconsidered determination and send written notice to the beneficiary within the following time limits—

(1) Within three working days after the QIO receives the request for reconsideration if—

(i) The beneficiary is still an inpatient in a hospital for the stay in question when the QIO receives the request for reconsideration; or

(ii) The initial determination relates to institutional services for which admission to the institution is sought, the initial determination was made before the patient was admitted to the institution; and a request was submitted timely for an expedited reconsideration.

(2) Within 10 working days after the QIO receives the request for reconsideration if the beneficiary is still an inpatient in a SNF for the stay in question when the QIO receives the request for reconsideration.

(3) Within 30 working days after the QIO receives the request for reconsideration if—

(i) The initial determination concerns ambulatory or noninstitutional services;

(ii) The beneficiary is no longer an inpatient in a hospital or SNF for the stay in question; or

(iii) The beneficiary does not submit a request for expedited reconsideration timely.

(b) *Providers or practitioners.* If the provider or practitioner files a request for reconsideration of an initial determination, the QIO must complete its reconsidered determination and send written notice to the provider or practitioner within 30 working days.

§ 478.34 Notice of a reconsidered determination.

(a) *Notice to parties.* A written notice of a QIO reconsidered determination must contain the following;

(1) The basis for the reconsidered determination.

(2) A detailed rationale for the reconsidered determination.

(3) A statement explaining the Medicare payment consequences of the reconsidered determination.

(4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.

(b) *Notice to payers.* (1) A QIO must provide written notice of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.

(2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

§ 478.36 Record of reconsideration.

(a) *QIO requirements.* A QIO must maintain the record of its reconsideration until the later of the following:

(1) Four years after the date on the notice of the QIO's reconsidered determination.

(2) Completion of litigation and the passage of the time period for filing all appeals.

(b) *Contents of the record.* The record of the reconsideration must include:

(1) The initial determination.

(2) The basis for the initial determination.

(3) Documentation of the date of the receipt of the request for reconsideration.

(4) The detailed basis for the reconsidered determination.

(5) Evidence submitted by the parties.

(6) A copy of the notice of the reconsidered determination that was provided to the parties.

(7) Documentation of the delivery or mailing and, if appropriate, the receipt of the notice of the reconsidered determination by the parties.

(c) *Confidentiality.* The record of a QIO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Act.

§ 478.38 Effect of a reconsidered determination.

A QIO reconsidered determination is binding upon all parties to the reconsideration unless—

(a) A hearing is requested in accordance with § 473.40 and a final decision rendered; or

(b) The reconsidered determination is later reopened and revised in accordance with § 473.48.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985, as amended at 62 FR 25855, May 12, 1997; 62 FR 49938, Sept. 24, 1997. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a QIO reconsidered determination may obtain a hearing by an administrative law judge (ALJ) of the Office of Hearings and Appeals of the SSA.

(b) *Subject matter.* A beneficiary has a right to a hearing on the following issues:

(1) Reasonableness of the services.

(2) Medical necessity of the services.

(3) Appropriateness of the setting in which the services were furnished.

(c) *Governing provisions.* The provisions of subpart G, Reconsiderations and Appeals under the Hospital Insurance Program, of part 405 of this chapter apply to hearings and appeals under this subpart unless they are inconsistent with specific provisions in this subpart. References in subpart G to initial and reconsidered determinations made by an intermediary, carrier, or CMS should be read to mean initial and reconsidered determinations made by a QIO.

[50 FR 15372, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 473.40 must submit a written request to one of the following:

(1) The office of the QIO or QIO subcontractor that made the initial determination.

(2) A SSA District Office.

(3) An office of the Office of Hearings and Appeals of SSA.

(4) An office of the Railroad Retirement Board, in the case of a beneficiary who is a railroad retiree.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 days of receipt of the notice of the QIO reconsidered determination, unless the time is extended for good cause as provided in § 473.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(3) A request is considered filed on the date it is postmarked.

§ 478.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ determines the amount in controversy in accordance with § 405.740(a) of this chapter for Part A services or § 405.817(a) of this chapter for Part B services. When two or more appellants submit a request for hearing, the ALJ determines the amount in controversy in accordance with § 405.740(b) of this chapter for Part A services and § 405.817(b) of this chapter for Part B services.

(b) If the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, notifies the parties to the hearing that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least $200.

(c) At the end of the 15-day period, if the ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties to the hearing and the QIO that the QIO reconsidered determination is conclusive for Medicare payment purposes.

[50 FR 15372, Apr. 17, 1985, as amended at 59 FR 12184, Mar. 16, 1994. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.46 Departmental Appeals Board and judicial review.

(a) The circumstances under which the DAB will review an ALJ hearing decision or dismissal are the same as those set forth at 20 CFR 404.970, (''Cases the Appeals Council will review'').

(b) If $2,000 or more is in controversy, a party may obtain judicial review of an Departmental Appeals Board decision, or an ALJ hearing decision if a request for review by the Departmental Appeals Board was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Departmental Appeals Board decision or denial.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996; 62 FR 25855, May 12, 1997. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 478.48 Reopening and revision of a reconsidered determination or a hearing decision.

(a) *QIO reopenings*—(1) *General rule.* A QIO or QIO subcontractor that made a reconsidered determination, or conducted a review of a DRG change as described in § 473.15, that is otherwise binding, may reopen and revise the reconsidered determination or review, either on its own motion or at the request of a party, within one year from the date of the reconsidered determination or review.

(2) *Extension of time limit.* A QIO or QIO subcontractor may reopen and revise its reconsidered determination, or its review of a DRG change as described in § 473.15, that is otherwise binding, after one year but within four years of the date of the determination or review if—

(i) The QIO receives new material evidence;

(ii) The QIO erred in interpretation or application of Medicare coverage policy;

(iii) There is an error apparent on the face of the evidence upon which the reconsidered determination was based; or

(iv) There is a clerical error in the statement of the reconsidered determination.

(b) *ALJ and Departmental Appeals Board Reopening—Applicable procedures.*

The ALJ or the Departmental Appeals Board, whichever made the decision, may reopen and revise the decision in accordance with the procedures set forth in §405.750(b) of this chapter, which concerns reopenings and revisions under subpart G of part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or the Departmental Appeals Board may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

[50 FR 15372, Apr. 17, 1985, as amended at 61 FR 32349, June 24, 1996; 62 FR 25855, May 12, 1997. Redesignated at 64 FR 66279, Nov. 24, 1999]

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE QUALITY IMPROVEMENT ORGANIZATION REVIEW INFORMATION

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organizations (QIOs)

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Utilization and Quality Control Quality Improvement Organizations (QIOs)

SOURCE: 50 FR 15359, Apr. 17, 1985, unless otherwise noted. Redesignated at 64 FR 66279, Nov. 24, 1999.

GENERAL PROVISIONS

§480.101 Scope and definitions.

(a) *Scope.* This subpart sets forth the policies and procedures governing—

(1) Disclosure of information collected, acquired or generated by a Utilization and Quality Control Quality Improvement Organization (QIO) (or

the review component of a QIO subcontractor) in performance of its responsibilities under the Act and these regulations; and

(2) Acquisition and maintenance of information by a QIO to comply with its responsibilities under the Act.

(b) *Definitions.* As used in this part:

Abuse means any unlawful conduct relating to items or services for which payment is sought under Title XVIII of the Act.

Aggregate statistical data means any utilization, admission, discharge or diagnostic related group (DRG) data arrayed on a geographic, institutional or other basis in which the volume and frequency of services are shown without identifying any individual.

Confidential information means any of the following:

(1) Information that explicitly or implicitly identifies an individual patient, practitioner or reviewer.

(2) Sanction reports and recommendations.

(3) Quality review studies which identify patients, practitioners or institutions.

(4) QIO deliberations.

Health care facility or *facility* means an organization involved in the delivery of health care services or items for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Implicitly identify(ies) means data so unique or numbers so small so that identification of an individual patient, practitioners or reviewer would be obvious.

Non-facility organization means a corporate entity that: (1) Is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities in the QIO area.

Patient representative means—(1) an individual designated by the patient, in writing, as authorized to request and receive QIO information that would otherwise be disclosable to that patient; or (2) an individual identified by the QIO in accordance with §480.132(c)(3) when the beneficiary is mentally, physically or legally unable to designate a representative.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

QIO deliberations means discussions or communications (within a QIO or between a QIO and a QIO subcontractor) including, but not limited to, review notes, minutes of meetings and any other records of discussions and judgments involving review matters regarding QIO review responsibilities and appeals from QIO determinations, in which the opinions of, or judgment about, a particular individual or institution can be discerned.

QIO information means any data or information collected, acquired or generated by a QIO in the exercise of its duties and functions under Title XI Part B or Title XVIII of the Act.

QIO interpretations and generalizations on the quality of health care means an assessment of the quality of care furnished by an individual provider or group of providers based on the QIO's knowledge of the area gained from its medical review experience (e.g., quality review studies) and any other information obtained through the QIO's review activities.

QIO review system means the QIO and those organizations and individuals who either assist the QIO or are directly responsible for providing medical care or for making determinations with respect to the medical necessity, appropriate level and quality of health care services that may be reimbursed under the Act. The system includes—

(1) The QIO and its officers, members and employees;

(2) QIO subcontractors;

(3) Health care institutions and practitioners whose services are reviewed;

(4) QIO reviewers and supporting staff; and

(5) Data support organizations.

Public information means information which has been disclosed to the public.

Quality review study means an assessment, conducted by or for a QIO, of a patient care problem for the purpose of improving patient care through peer analysis, intervention, resolution of the problem and follow-up.

Quality review study information means all documentation related to the quality review study process.

Reviewer means review coordinator, physician, or other person authorized to perform QIO review functions.

Sanction report means a report filed pursuant to section 1156 of the Act and part 474 of this chapter documenting the QIO's determination that a practitioner or institution has failed to meet obligations imposed by section 1156 of the Act.

Shared health data system means an agency or other entity authorized by Federal or State law that is used by the QIO review system to provide information or to conduct or arrange for the collection, processing, and dissemination of information on health care services.

Subcontractor means a facility or a non-facility organization under contract with a QIO to perform QIO review functions.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999; 69 FR 49267, Aug. 11, 2004]

§ 480.102 Statutory bases for acquisition and maintenance of information.

(a) Section 1154(a)(7)(C) of the Act requires QIOs to the extent necessary and appropriate to examine the pertinent records of any practitioner or provider of health care services for which payment may be made under Title XVIII of the Act.

(b) Section 1154(a)(9) of the Act requires QIOs to collect and maintain information necessary to carry out their responsibilities under the Act.

(c) Section 1156(a)(3) of the Act requires health care practitioners and providers to maintain evidence of the medical necessity and quality of health care services they provide to Medicare patients as required by QIOs.

§ 480.103 Statutory bases for disclosure of information.

(a) Section 1154(a)(10) of the Act requires QIOs to exchange information with intermediaries and carriers with contracts under sections 1816 and 1842 of the Act, other QIOs, and other public or private review organizations as appropriate.

(b) Section 1160 of the Act provides that QIO information must be held in confidence and not be disclosed except where—

(1) Necessary to carry out the purpose of Title XI Part B of the Act;

(2) Specifically permitted or required under this subpart;

(3) Necessary, and in the manner prescribed under this subpart, to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse;

(4) Necessary, and in the manner prescribed under the subpart to assist Federal or State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health;

(5) Necessary, and in the manner prescribed under this subpart, to assist appropriate State agencies having responsibility for licensing or certification of providers or practitioners; or

(6) Necessary, and in the manner prescribed under this subpart to assist Federal or State health planning agencies by furnishing them aggregate statistical data on a geographical, institutional or other basis.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 480.104 Procedures for disclosure by a QIO.

(a) *Notice to accompany disclosure.* (1) Any disclosure of information under the authority of this subpart is subject to the requirements in § 480.105 relating to the providing of a notice of the disclosure.

(2) Disclosure of confidential information made under the authority of this subpart, except as provided in § 480.106, must be accompanied by a written statement informing the recipient that the information may not be redisclosed except as provided under § 480.107 that limits redisclosure.

(b) *QIO interpretations.* A QIO may provide a statement of comment, analysis, or interpretation to guide the recipient in using information disclosed under this subpart.

(c) *Fees.* A QIO may charge a fee to cover the cost of providing information authorized under this subpart. These

fees may not exceed the amount necessary to recover the cost to the QIO for providing the information.

(d) *Format for disclosure of public information.* A QIO is required to disclose public information (§ 480.120(a)(6)) only in the form in which it is acquired by the QIO or in the form in which it is maintained for QIO use.

(e) *Medicare provider number.* A QIO must include the provider identification number assigned by the Medicare program on information that CMS requests.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.105 Notice of disclosures made by a QIO.

(a) *Notification of the disclosure of nonconfidential information.* Except as permitted under § 480.106, at least 30 calender days before disclosure of nonconfidential information, the QIO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to CMS or Medicare fiscal intermediaries, or to or from QIO subcontractors, or to or from the institution) and provide the institution with a copy of the information. The institution may submit comments to the QIO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) *Notification of the disclosure of confidential information.* (1) A QIO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under § 480.132.

(2) A QIO must notify a practitioner or institution of the QIO's intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§ 480.137 and 480.138) except for cases specified in § 480.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the QIO discloses the identifying information. The QIO must forward with the information any comments submitted by the practitioner or institution in response to the QIO notice if received before disclosure, or forwarded separately if received after disclosure.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.106 Exceptions to QIO notice requirements.

(a) *Imminent danger to individuals or public health.* When the QIO determines that requested information is necessary to protect against an imminent danger to individuals or the public health, the notification required in § 480.105 may be sent simultaneously with the disclosure.

(b) *Fraud or Abuse.* The notification requirement in § 480.105 does not apply if—

(1) The disclosure is made in an investigation of fraud or abuse by the Office of the Inspector General or the General Accounting Office; or

(2) The disclosure is made in an investigation of fraud or abuse by any other Federal or State fraud or abuse agency and the investigative agency specifies in writing that the information is related to a potentially prosecutable criminal offense.

(c) *Other.* The notification requirements in § 480.105(a) and (b)(2) do not apply if:

(1) The institution or practitioner has requested, in writing, that the QIO make the disclosure;

(2) The institution or practitioner has provided, in writing, consent for the disclosure; or

(3) The information is public information as defined in § 480.101(b) and specified under § 480.120.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49266, 49267, Aug. 11, 2004]

§ 480.107 Limitations on redisclosure.

Persons or organizations that obtain confidential QIO information must not further disclose the information to any other person or organization except—

(a) As directed by the QIO to carry out a disclosure permitted or required under a particular provision of this part;

(b) As directed by CMS to carry out specific responsibilities of the Secretary under the Act;

(c) As necessary for CMS to carry out its responsibilities for appeals under section 1155 of the Act or for CMS to process sanctions under section 1156 of the Act;

(d) If the health care services furnished to an individual patient are reimbursed from more than one source, these sources of reimbursement may exchange confidential information as necessary for the payment of claims;

(e) If the information is acquired by the QIO from another source and the receiver of the information is authorized under its own authorities to acquire the information directly from the source, the receiver may disclose the information in accordance with the source's redisclosure rules;

(f) As necessary for the General Accounting Office to carry out its statutory responsibilities;

(g) Information pertaining to a patient or practitioner may be disclosed by that individual provided it does not identify any other patient or practitioner;

(h) An institution may disclose information pertaining to itself provided it does not identify an individual patient or practitioner;

(i) Governmental fraud or abuse agencies and State licensing or certification agencies recognized by CMS may disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency;

(j) State and local public health officials to carry out their responsibilities, as necessary, to protect against a substantial risk to the public health; or

(k) As necessary for the Office of the Inspector General to carry out its statutory responsibilities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 480.108 Penalties for unauthorized disclosure.

A person who discloses information not authorized under Title XI Part B of the Act or the regulations of this part will, upon conviction, be fined no more than $1,000, or be imprisoned for no more than six months, or both, and will pay the costs of prosecution.

§ 480.109 Applicability of other statutes and regulations.

The provisions of 42 U.S.C. 290dd–3 and 290ee–3 governing confidentiality of alcohol and drug abuse patients' records, and the implementing regulations at 42 CFR part 2, are applicable to QIO information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

QIO Access to Information

§ 480.111 QIO access to records and information of institutions and practitioners.

(a) A QIO is authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the QIO area. The QIO may require the institution or practitioner to provide copies of such records or information to the QIO.

(b) A QIO may obtain non-Medicare patient records relating to review performed under a non-Medicare QIO contract if authorized by those patients in accordance with State law.

(c) In accordance with its quality review responsibilities under the Act, a QIO may have access to and obtain information from, the records of non-Medicare patients if authorized by the institution or practitioner.

(d) A QIO may reimburse for requested information at the rate of $.10 per page for photocopying plus first class postage. The photocopying amount includes the cost of labor, supplies, equipment, and overhead.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 65 FR 83154, Dec. 29, 2000]

§ 480.112 QIO access to records and information of intermediaries and carriers.

A QIO is authorized to have access to and require copies of Medicare records or information held by intermediaries or carriers if the QIO determines that

the records or information are necessary to carry out QIO review responsibilities.

§ 480.113 QIO access to information collected for QIO purposes.

(a) Institutions and other entities must disclose to the QIO information collected by them for QIO purposes.

(b) Information collected or generated by institutions or practitioners to carry out quality review studies must be disclosed to the QIO.

§ 480.114 Limitation on data collection.

A QIO or any agent, organization, or institution acting on its behalf, that is collecting information under authority of this part, must collect only that information which is necessary to accomplish the purposes of Title XI Part B of the Act in accordance with 44 U.S.C. Chapter 35, Coordination of Federal Reporting Services Information Policy.

QIO Responsibilities

§ 480.115 Requirements for maintaining confidentiality.

(a) *Responsibilities of QIO officers and employees.* The QIO must provide reasonable physical security measures to prevent unauthorized access to QIO information and to ensure the integrity of the information, including those measures needed to secure computer files. Each QIO must instruct its officers and employees and health care institution employees participating in QIO activities of their responsibility to maintain the confidentiality of information and of the legal penalties that may be imposed for unauthorized disclosure of QIO information.

(b) *Responsible individuals within the QIO.* The QIO must assign a single individual the responsibility for maintaining the system for assuring the confidentiality of information within the QIO review system. That individual must notify CMS of any violations of these regulations.

(c) *Training requirements.* The QIO must train participants of the QIO review system in the proper handling of confidential information.

(d) *Authorized access.* An individual participating in the QIO review system on a routine or ongoing basis must not have authorized access to confidential QIO information unless that individual—

(1) Has completed a training program in the handling of QIO information in accordance with paragraph (c) of this section or has received comparable training from another source; and

(2) Has signed a statement indicating that he or she is aware of the legal penalties for unauthorized disclosure.

(e) *Purging of personal identifiers.* (1) The QIO must purge or arrange for purging computerized information, patient records and other noncomputerized files of all personal identifiers as soon as it is determined by CMS that those identifiers are no longer necessary.

(2) The QIO must destroy or return to the facility from which it was collected confidential information generated from computerized information, patient records and other noncomputerized files when the QIO determines that the maintenance of hard copy is no longer necessary to serve the specific purpose for which it was obtained or generated.

(f) *Data system procedures.* The QIO must assure that organizations and consultants providing data services to the QIO have established procedures for maintaining the confidentiality of QIO information in accordance with requirements defined by the QIO and consistent with procedures established under this part.

§ 480.116 Notice to individuals and institutions under review.

The QIO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information—

(a) The title and address of the person responsible for maintenance of QIO information;

(b) The types of information that will be collected and maintained;

(c) The general rules governing disclosure of QIO information; and

(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves.

DISCLOSURE OF NONCONFIDENTIAL INFORMATION

§ 480.120 Information subject to disclosure.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 480.104 and 480.105, the QIO must disclose—

(a) Nonconfidential information to any person upon request, including—

(1) The norms, criteria, and standards it uses for initial screening of cases, and for other review activities;

(2) Winning technical proposals for contracts from the Department, and winning technical proposals for subcontracts under those contracts (except for proprietary or business information);

(3) Copies of documents describing administrative procedures, agreed to between the QIO and institutions or between a QIO and the Medicare intermediary or Medicare carrier;

(4) Routine reports submitted by the QIO to CMS to the extent that they do not contain confidential information.

(5) Summaries of the proceedings of QIO regular and other meetings of the governing body and general membership except for those portions of the summaries involving QIO deliberations, which are confidential information and subject to the provisions of § 480.139;

(6) Public information in its possession;

(7) Aggregate statiscal information that does not implicitly or explicitly identify individual patients, practitioners or reviewers;

(8) Quality review study information including summaries and conclusions from which the identification of patients, practitioners and institutions has been deleted; and

(9) Information describing the characteristics of a quality review study, including a study design and methodology.

(b) Aggregate statistical information that does not implicitly or explicitly identify individual patients, practitioners or reviewers, to Federal or State health planning agencies (including Health Systems Agencies and State Health Planning and Development Agencies) in carrying out their health care planning and related activities.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.121 Optional disclosure of nonconfidential information.

A QIO may, on its own initiative, subject to the notification requirements in § 480.105, furnish the information available under § 480.120 to any person, agency, or organization.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

DISCLOSURE OF CONFIDENTIAL INFORMATION

§ 480.130 Disclosure to the Department.

Except as limited by §§ 480.139(a) and 480.140 of this subpart, QIOs must disclose all information requested by the Department to it in the manner and form required.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.131 Access to medical records for the monitoring of QIOs.

CMS or any person, organization or agency authorized by the Department or Federal statute to monitor a QIO will have access to medical records maintained by institutions or health care practitioners on Medicare patients. The monitor can require copies of the records.

§ 480.132 Disclosure of information about patients.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, a QIO must—

(1) Disclose patient identified information in its possession to the identified patient or the patient's representative if—

(i) The patient or the patient's representative requests the information in writing;

(ii) The request by a patient's representative includes the designation, by the patient, of the representative; and

(iii) All other patient and practitioner identifiers have been removed.

(2) Seek the advice of the attending practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient 15 days before the QIO provides the requested information. If the attending practitioner states that the released information could harm the patient, the QIO must act in accordance with paragraph (c)(2) of this section. The QIO must make disclosure to the patient or patient's representative within 30 calendar days of receipt of the request.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination under section 1154(a)(3) of the Act, the QIO—

(i) Need not seek the advice of the practitioner that treated the patient regarding the appropriateness of direct disclosure to the patient; and

(ii) Must provide only the information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A QIO must disclose information regarding QIO deliberations only as specified in § 480.139(a).

(3) A QIO must disclose quality review study information only as specified in § 480.140.

(c) *Manner of disclosure.* (1) The QIO must disclose the patient information directly to the patient unless knowledge of the information could harm the patient.

(2) If knowledge of the information could harm the patient, the QIO must disclose the information to the patient's designated representative.

(3) If the patient is mentally, physically or legally unable to designate a representative, the QIO must disclose the information to a person whom the QIO determines is responsible for the patient.

The QIO must first attempt to make that determination based on the medical record. If the responsible person is not named in the medical record, then the QIO may rely on the attending practitioner for the information. If the practitioner is unable to provide a name, then the QIO must make a determination based on other reliable information.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.133 Disclosure of information about practitioners, reviewers and institutions.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the QIO.

(1) *Disclosure to the identified individual or institution.* A QIO must disclose, to particular practitioners, reviewers and institutions, information about themselves, upon request, and may disclose it to them without a request.

(2) *Disclosure to others.* (i) A QIO must disclose to an institution, upon request, information on a practitioner to the extent that the information displays practice or performance patterns of the practitioner in that institution.

(ii) In accordance with section 1160 of the Act, a QIO must disclose information that displays practice or performance patterns of a practitioner or institution in accordance with the procedures for disclosures specified in §§ 480.137 and 480.138 to—

(A) Federal and State agencies that are responsible for the investigation of fraud and abuse of the Medicare or Medicaid programs, and

(B) Federal and State agencies that are responsible for licensing and certification of practitioners and providers.

(iii) A QIO may disclose to any person, agency, or organization information on a particular practitioner or reviewer at the written request of or with the written consent of that practitioner or reviewer. The recipient of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or reviewer as provided under this Subpart B.

(b) *Exceptions.* (1) If the request is in connection with an initial denial determination or a change resulting from a diagnostic related group (DRG) coding validation under Part 466 of this subchapter, the QIO must provide only the

information used to support that determination in accordance with the procedures for disclosure of information relating to determinations under § 473.24.

(2) A QIO must disclose information regarding QIO deliberations only as specified in § 480.139(a).

(3) A QIO must disclose quality review study information only as specified in § 480.140.

[50 FR 15359, Apr. 17, 1885, as amended at 52 FR 37458, Oct. 7, 1987; 52 FR 47004, Dec. 11, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49266, 29267, Aug. 11, 2004]

§ 480.134 Verification and amendment of QIO information.

(a) A QIO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the QIO.

(b) If the QIO agrees with the request for amendment, the QIO must correct the information in its possession. If the information being amended has already been disclosed, the QIO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner or case under review.

(c) If the QIO disagrees with the request for amendment, a notation of the request, reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the information.

[50 FR 15358, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999]

§ 480.135 Disclosure necessary to perform review responsibilities.

(a) *Disclosure to conduct review.* The QIO must disclose or arrange for disclosure of information to individuals and institutions within the QIO review system as necessary to fulfill their particular duties and functions under Title XI Part B of the Act.

(b) *Disclosure to consultants and subcontractors.* The QIO must disclose to consultants or subcontractors the information they need to provide specified services to the QIO.

(c) *Disclosure to other QIO and medical review boards.* The QIO must disclose—

(1) To another QIO, information on patients and practitioners who are subject to review by the other QIO; and

(2) To medical review boards established under section 1881 of the Act, confidential information on patients, practitioners and institutions receiving or furnishing end stage renal disease services.

§ 480.136 Disclosure to intermediaries and carriers.

(a) *Required disclosure.* Except as specified in §§ 480.139(a) and 480.140 relating to disclosure of QIO deliberations and quality review study information, a QIO must disclose to intermediaries and carriers QIO information that relates to, or is necessary for, payment of claims for Medicare as follows:

(1) Review determinations and claims forms for health care services, furnished in the manner and form agreed to by the QIO and the intermediary or carrier.

(2) Upon request, copies of medical records acquired from practitioners or institutions for review purposes.

(3) QIO information about a particular patient or practitioner if the QIO and the intermediary or carrier (or CMS if the QIO and the intermediary or carrier cannot agree) determine that the information is necessary for the administration of the Medicare program.

(b) *Optional disclosure.* The QIO may disclose the information specified in paragraph (a) of this section to intermediaries and carriers without a request.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.137 Disclosure to Federal and State enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs.

(a) *Required disclosure.* Except as specified in §§ 480.139(a) and 480.140 relating to disclosure of QIO deliberations and quality review study information, the QIO must disclose confidential information relevant to an investigation of fraud or abuse of the

Medicare or medicaid programs, including QIO medical necessity determinations and other information that includes patterns of the practice or performance of a practitioner or institution, when a written request is received from a State or Federal enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs that—

(1) Identifies the name and title of the individual initiating the request,

(2) Identifies the physician or institution about which information is requested, and

(3) States affirmatively that the institution or practitioner is currently under investigation for fraud or abuse of the Medicare or Medicaid programs and that the information is needed in furtherance of that investigation.

(b) *Optional disclosure.* The QIO may provide the information specified in paragraph (a) of this section to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse of the Medicare or Medicaid programs, without a request.

[50 FR 15358, Apr. 17, 1985, as amended at 52 FR 37458, Oct. 7, 1987. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.138 Disclosure for other specified purposes.

(a) *General requirements for disclosure.* Except as specified in paragraph (b) of this section, the following provisions are required of the QIO.

(1) *Disclosure to licensing and certification bodies.* (i) A QIO must disclose confidential information upon request, to State or Federal licensing bodies responsible for the professional licensure of a practitioner or a particular institution. Confidential information, including QIO medical necessity determinations that display the practice or performance patterns of that practitioner, must be disclosed by the QIO but only to the extent that it is required by the agency to carry out a function within the jurisdiction of the agency under Federal or State law.

(ii) A QIO may provide the information specified in paragraph (a)(1)(i) of this section to the State or Federal licensing body without request.

(2) *Disclosure to State and local public health officials.* A QIO must disclose QIO information to State and local public health officials whenever the QIO determines that the disclosure of the information is necessary to protect against a substantial risk to the public health.

(3) *Disclosure to the courts.* Patient identified records in the possession of a QIO are not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding.

(b) *Exceptions.* (1) The restriction set forth in paragraph (a)(3) of this section does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

(2) A QIO must disclose information regarding QIO deliberations and quality review study information only as specified in §§ 480.139(a) and 480.140.

[50 FR 15359, Apr. 17, 1985; 50 FR 41887, Oct. 16, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.139 Disclosure of QIO deliberations and decisions.

(a) *QIO deliberations.* (1) A QIO must not disclose its deliberations except to—

(i) CMS, at the QIO office or at a subcontracted organization;

(ii) CMS, to the extent that the deliberations are incorporated in sanction and appeals reports; or

(iii) The Office of the Inspector General, and the General Accounting Office as necessary to carry out statutory responsibilities.

(2) QIO deliberations are not disclosable, either in written form or through oral testimony, in connection with the administrative hearing or review of a beneficiary's claim.

(b) *Reasons for QIO decisions.* (1) A QIO may disclose to those who have access to QIO information under other provisions of this subpart, the reasons

for QIO decisions pertaining to that information provided that the opinions or judgements of a particular individual or practitioner cannot be identified.

(2) A QIO must disclose, if requested in connection with the administrative hearing or review of a beneficiary's claim, the reasons for QIO decisions. The QIO must include the detailed facts, findings and conclusions supporting the QIO's determination. The QIO must insure that the opinions or judgements of a particular individual or practitioner cannot be identified through the materials that are disclosed.

§ 480.140 Disclosure of quality review study information.

(a) A QIO must disclose, onsite, quality review study information with identifiers of patients, practitioners or institutions to—

(1) Representatives of authorized licensure, accreditation or certification agencies as is required by the agencies in carrying out functions which are within the jurisdiction of such agencies under state law; to federal and state agencies responsible for identifying risks to the public health when there is substantial risk to the public health; CMS; or to Federal and State fraud and abuse enforcement agencies;

(2) An institution or practitioner, if the information is limited to health care services furnished by the institution or practitioner; and

(3) A medical review board established under section 1881 of the Act pertaining to end-stage renal disease facilities, if the information is limited to health care services subject to its review.

(b) A QIO must disclose quality review study information with identifiers of patients, practitioners or institutions to the Office of the Inspector General and the General Accounting Office as necessary to carry out statutory responsibilities.

(c) A QIO may disclose information offsite from a particular quality review study to any institution or practitioner involved in that study, provided the disclosed information is limited to that institution or practitioner.

(d) A QIO may disclose quality review study information with identifiers of particular practitioners or institutions, or both, at the written request of, or with the written consent of, the identified practitioner(s) or institution(s).

(1) The consent or request must specify the information that is to be disclosed and the intended recipient of the information.

(2) The recipient of the information has the same redisclosure rights and responsibilities as the requesting or consenting practitioner or institution as provided under this Subpart B.

(e) An institution or group of practitioners may redisclose quality review study information, if the information is limited to health care services they provided.

(f) Quality review study information with patient identifiers is not subject to subpoena or discovery in a civil action, including an administrative, judicial or arbitration proceeding. This restriction does not apply to HHS, including Inspector General, administrative subpoenas issued in the course of audits and investigations of Department programs, in the course of administrative hearings held under the Social Security Act, or to disclosures to the General Accounting Office as necessary to carry out its statutory responsibilities.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49266, Aug. 11, 2004]

§ 480.141 Disclosure of QIO interpretations on the quality of health care.

Subject to the procedures for disclosure and notice of disclosure specified in §§ 480.104 and 480.105, a QIO may disclose to the public QIO interpretations and generalizations on the quality of health care that identify a particular institution.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.142 Disclosure of sanction reports.

(a) The QIO must disclose sanction reports directly to the Office of the Inspector General and, if requested, to CMS.

(b) The QIO must upon request, and may without a request, disclose sanction reports to State and Federal agencies responsible for the identification, investigation or prosecution of cases of fraud or abuse in accordance with § 480.137.

(c) CMS will disclose sanction determinations in accordance with part 474 of this chapter.

[50 FR 15359, Apr. 17, 1985. Redesignated at 64 FR 66279, Nov. 24, 1999, as amended at 69 FR 49267, Aug. 11, 2004]

§ 480.143 QIO involvement in shared health data systems.

(a) *Information collected by a QIO.* Except as prohibited in paragraph (b) of this section, information collected by a QIO may be processed and stored by a cooperative health statistics system established under the Public Health Service Act (42 U.S.C. 242k) or other State or Federally authorized shared data system.

(b) *QIO participation.* A QIO may not participate in a cooperative health statistics system or other shared health data system if the disclosure rules of the system would prevent the QIO from complying with the rules of this part.

(c) *Disclosure of QIO information obtained by a shared health data system.* QIO information must not be disclosed by the shared health data system unless—

(1) The source from which the QIO acquired the information consents to or requests disclosure; or

(2) The QIO requests the disclosure of the information to carry out a disclosure permitted under a provision of this part.

SUBCHAPTER G—STANDARDS AND CERTIFICATION

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 51 FR 22042, June 17, 1986, unless otherwise noted.

Subpart A—General Provisions

§ 482.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1861(e) of the Act provides that—

(i) Hospitals participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.

(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the

distinct part meets the records and staffing requirements that the Secretary finds necessary.

(3) Sections 1861(k) and 1902(a)(30) of the Act provide that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.

(4) Section 1883 of the Act sets forth the requirements for hospitals that provide long term care under an agreement with the Secretary.

(5) Section 1905(a) of the Act provides that ''medical assistance'' (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§ 440.10 and 440.165 of this chapter.).

(b) *Scope.* Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

[51 FR 22042, June 17, 1986, as amended at 60 FR 50442, Sept. 29, 1995]

§ 482.2 Provision of emergency services by nonparticipating hospitals.

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if—

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e) (1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

[51 FR 22042, June 17, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

Subpart B—Administration

§ 482.11 Condition of participation: Compliance with Federal, State and local laws.

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be—

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.

§ 482.12 Condition of participation: Governing body.

The hospital must have an effective governing body legally responsible for the conduct of the hospital as an institution. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon

certification, fellowship, or membership in a specialty body or society.

(b) *Standard: Chief executive officer.* The governing body must appoint a chief executive officer who is responsible for managing the hospital.

(c) *Standard: Care of patients.* In accordance with hospital policy, the governing body must ensure that the following requirements are met:

(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and

(vi) A clinical psychologist as defined in § 410.71 of this chapter, but only with respect to clinical psychologist services as defined in § 410.71 of this chapter and only to the extent permitted by State law.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—

(i) is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

(d) *Standard: Institutional plan and budget.* The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's

patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared—

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) *Standard: Contracted services.* The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) *Standard: Emergency services.* (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of § 482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986, as amended at 53 FR 6549, Mar. 1, 1988; 53 FR 18987, May 26, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 46514, Sept. 8, 1994; 63 FR 20130, Apr. 23, 1998; 63 FR 33874, June 22, 1998; 68 FR 53262, Sept. 9, 2003]

§ 482.13 Condition of participation: Patients' rights.

A hospital must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §489.100 of this part (Definition), §489.102 of this part (Requirements for providers), and §489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

(e) *Standard: Restraint for acute medical and surgical care.* (1) The patient has the right to be free from restraints of any form that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The term ''restraint'' includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

(2) A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint must be—

(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must—

(A) Never be written as a standing or on an as needed basis (that is, PRN); and

(B) Be followed by consultation with the patient's treating physician, as soon as possible, if the restraint is not ordered by the patient's treating physician;

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe and appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

(f) *Standard: Seclusion and restraint for behavior management.* (1) The patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. The term ''restraint'' includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

(2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint or seclusion must be—

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:

(A) Orders for the use of seclusion or a restraint must never be written as a standing order or on an as needed basis (that is, PRN).

(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

(C) A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

(D) Each written order for a physical restraint or seclusion is limited to 4 hours for adults; 2 hours for children and adolescents ages 9 to 17; or 1 hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

(iii) In accordance with a written modification to the patient's plan of care;

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) A restraint and seclusion may not be used simultaneously unless the patient is—

(i) Continually monitored face-to-face by an assigned staff member; or

(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.

(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

(6) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

(7) The hospital must report to CMS any death that occurs while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

[64 FR 36088, July 2, 1999]

Subpart C—Basic Hospital Functions

§ 482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

(2) The hospital must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement and changes that will lead to improvement.

(3) The frequency and detail of data collection must be specified by the hospital's governing body.

(c) *Standard: Program activities.* (1) The hospital must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) *Standard: Executive responsibilities.* The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety,

including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

[68 FR 3454, Jan. 24, 2003]

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Composition of the medical staff.* The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine.

(c) *Standard: Medical staff bylaws.* The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.)

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include a requirement that a physical examination and medical history be done no more than 7 days before or 48 hours after an admission for each patient by a doctor of medicine or osteopathy, or, for patients admitted only for oromaxillofacial surgery, by an oromaxillofacial surgeon who has been granted such privileges by the medical staff in accordance with State law.

(6) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.

(d) *Standard: Autopsies.* The medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. The mechanism for documenting permission to perform an autopsy must be defined. There must be a system for notifying the medical staff, and specifically the attending practitioner, when an autopsy is being performed.

[51 FR 22042, June 17, 1986, as amended at 59 FR 64152, Dec. 13, 1994]

§ 482.23 Condition of participation: Nursing services.

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) *Standard: Organization.* The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

(b) *Standard: Staffing and delivery of care.* The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under § 405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

(c) *Standard: Preparation and administration of drugs.* Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(1) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(2) All orders for drugs and biologicals must be in writing and signed by the practitioner or practitioners responsible for the care of the patient as specified under § 482.12(c) with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment for contraindications. When telephone or oral orders must be used, they must be—

(i) Accepted only by personnel that are authorized to do so by the medical staff policies and procedures, consistent with Federal and State law;

(ii) Signed or initialed by the prescribing practitioner as soon as possible; and

(iii) Used infrequently.

(3) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures. If blood transfusions and intravenous medications are administered by personnel other than doctors of medicine or osteopathy, the personnel must have special training for this duty.

(4) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

[51 FR 22042, June 17, 1986, as amended at 67 FR 61814, Oct. 2, 2002]

§ 482.24 Condition of participation: Medical record services.

The hospital must have a medical record service that has administrative responsibility for medical records. A

medical record must be maintained for every individual evaluated or treated in the hospital.

(a) *Standard: Organization and staffing.* The organization of the medical record service must be appropriate to the scope and complexity of the services performed. The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

(b) *Standard: Form and retention of record.* The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentification and protects the security of all record entries.

(1) Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.

(2) The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.

(3) The hospital must have a procedure for ensuring the confidentiality of patient records. In-formation from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records. Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.

(c) *Standard: Content of record.* The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.

(1) All entries must be legible and complete, and must be authenticated and dated promptly by the person (identified by name and discipline) who is responsible for ordering, providing, or evaluating the service furnished.

(i) The author of each entry must be identifed and must authenticate his or her entry.

(ii) Authentication may include signatures, written initials or computer entry.

(2) All records must document the following, as appropriate:

(i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission.

(ii) Admitting diagnosis.

(iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.

(iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.

(v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

(vi) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.

(vii) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.

(viii) Final diagnosis with completion of medical records within 30 days following discharge.

§ 482.25 Condition of participation: Pharmaceutical services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

(1) A full-time, part-time, or consulting pharmacist must be responsible

for developing, supervising, and coordinating all the activities of the pharmacy services.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.* In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

(1) All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

(2) Drugs and biologicals must be kept in a locked storage area.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.

(5) Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital-wide quality assurance program.

(7) Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.

(8) Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

(9) A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.26 Condition of participation: Radiologic services.

The hospital must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, they, as well as the diagnostic services, must meet professionally approved standards for safety and personnel qualifications.

(a) *Standard: Radiologic services.* The hospital must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precutions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.

(2) The hospital must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.27 Condition of participation: Laboratory services.

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(b) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

(c) *Standard: Potentially infectious blood and blood products*—(1) *Potentially HIV infectious blood and blood products* are prior collections from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to the human immunodeficiency virus (HIV) on a later donation, and the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive and the timing of seroconversion cannot be precisely estimated.

(2) *Services furnished by an outside blood bank.* If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank promptly notify the hospital of the following:

(i) If it supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation; and

(ii) The results of the FDA-licensed, more specific test or other followup testing recommended or required by FDA completed within 30 calendar days after the donor's repeatedly reactive screening test. (FDA regulations concerning HIV testing and lookback procedures are set forth at 21 CFR 610.45- et seq.)

(3) *Quarantine of blood and blood products pending completion of testing.* If the blood bank notifies the hospital of the repeatedly reactive HIV screening test results as required by paragraph (c)(2)(i) of this section, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing recommended or required by FDA is positive, the hospital must dispose of the blood and blood products in accordance with 21 CFR 606.40 and notify patients in accordance with paragraph (c)(4) of this section.

(4) *Patient notification.* If the hospital has administered potentially HIV infectious blood or blood products (either directly through its own blood bank or under an agreement described in paragraph (c)(2) of this section) or released such blood or blood products to another entity or appropriate individual,

the hospital must take the following actions:

(i) Promptly make at least three attempts to notify the patient's attending physician (that is, the physician of record) or the physician who ordered the blood or blood product that potentially HIV infectious blood or blood products were transfused to the patient.

(ii) Ask the physician to immediately notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iii) If the physician is unavailable, declines to make the notification, or later informs the hospital that he or she was unable to notify the patient, promptly make at least three attempts to notify the patient, or other individual as permitted under paragraph (c)(8) of this section, of the need for HIV testing and counseling.

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(5) *Timeframe for notification.* The notification effort begins when the blood bank notifies the hospital that it received potentially HIV infectious blood and blood products and continues for 8 weeks unless—

(i) The patient is located and notified; or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 8 weeks.

(6) *Content of notification.* The notification given under paragraphs (c)(4) (ii) and (iii) of this section must include the following information:

(i) A basic explanation of the need for HIV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV testing and counseling, including any requirements or restrictions the program may impose.

(7) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

(8) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative.

[57 FR 7136, Feb. 28, 1992, as amended at 61 FR 47433, Sept. 9, 1996]

§ 482.28 Condition of participation: Food and dietetic services.

The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. However, a hospital that has a contract with an outside food management company may be found to meet this Condition of participation if the company has a dietitian who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

(a) *Standard: Organization.* (1) The hospital must have a full-time employee who—

(i) Serves as director of the food and dietetic service;

(ii) Is responsible for the daily management of the dietary services; and

(iii) Is qualified by experience or training.

(2) There must be a qualified dietitian, full-time, part-time, or on a consultant basis.

(3) There must be administrative and technical personnel competent in their respective duties.

(b) *Standard: Diets.* Menus must meet the needs of the patients.

(1) Therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients.

(2) Nutritional needs must be met in accordance with recognized dietary practices and in accordance with orders of the practitioner or practitioners responsible for the care of the patients.

(3) A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing, and food service personnel.

§ 482.30 Condition of participation: Utilization review.

The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

(a) *Applicability.* The provisions of this section apply except in either of the following circumstances:

(1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.

(2) CMS has determined that the UR procedures established by the State under title XIX of the Act are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under §§ 456.50 through 456.245 of this chapter.

(b) *Standard: Composition of utilization review committee.* A UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathy. The other members may be any of the other types of practitioners specified in § 482.12(c)(1).

(1) Except as specified in paragraphs (b) (2) and (3) of this section, the UR committee must be one of the following:

(i) A staff committee of the institution;

(ii) A group outside the institution—

(A) Established by the local medical society and some or all of the hospitals in the locality; or

(B) Established in a manner approved by CMS.

(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of this section.

(3) The committee's or group's reviews may not be conducted by any individual who—

(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or

(ii) Was professionally involved in the care of the patient whose case is being reviewed.

(c) *Standard: Scope and frequency of review.* (1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of—

(i) Admissions to the institution;

(ii) The duration of stays; and

(iii) Professional services furnished, including drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of this section, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in Part 412 of this chapter must conduct review of duration of stays and review of professional services as follows:

(i) For duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in § 412.80(a)(1)(i) of this chapter; and

(ii) For professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in § 412.80(a)(1)(ii) of this chapter.

(d) *Standard: Determination regarding admissions or continued stays.* (1) The determination that an admission or continued stay is not medically necessary—

(i) May be made by one member of the UR committee if the practitioner or practitioners responsible for the care of the patient, as specified of

§ 482.12(c), concur with the determination or fail to present their views when afforded the opportunity; and

(ii) Must be made by at least two members of the UR committee in all other cases.

(2) Before making a determination that an admission or continued stay is not medically necessary, the UR committee must consult the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c), and afford the practitioner or practitioners the opportunity to present their views.

(3) If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient, as specified in § 482.12(c);

(e) *Standard: Extended stay review.* (1) In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. The scheduling of the periodic reviews may—

(i) Be the same for all cases; or

(ii) Differ for different classes of cases.

(2) In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because the extended length of stay exceeds the threshold criteria for the diagnosis, as described in § 412.80(a)(1)(i). The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.

(3) The UR committee must make the periodic review no later than 7 days after the day required in the UR plan.

(f) *Standard: Review of professional services.* The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.

§ 482.41 Condition of participation: Physical environment.

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured.

(1) There must be emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(b) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The hospital must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to hospitals.

(2) After consideration of State survey agency findings, CMS may waive

specific provisions of the Life Safety Code which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

(4) Beginning March 13, 2006, a hospital must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to hospitals.

(6) The hospital must have procedures for the proper routine storage and prompt disposal of trash.

(7) The hospital must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, personnel and guests; evacuation; and cooperation with fire fighting authorities.

(8) The hospital must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(9) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(c) *Standard: Facilities.* The hospital must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

[51 FR 22042, June 17, 1986, as amended at 53 FR 11509, Apr. 7, 1988; 68 FR 1386, Jan. 10, 2003; 69 FR 49267, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55340, Sept. 22, 2006, § 482.41 was amended by revising paragraph (b)(9)(iii), by removing the last sentence of paragraph (b)(9)(iv), by removing the period at the end of paragraph (b)(9)(iii) and adding in its place ''; and'', and adding paragraph (b)(9)(v), effective Oct. 23, 2006. For the convenience of the user, the added and revised text is set forth as follows:

§ 482.41 Condition of participation: Physical environment.

* * * * *

(b) * * *

(9) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

§ 482.42 Condition of participation: Infection control.

The hospital must provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. There must be an active program for the prevention, control, and investigation of infections and communicable diseases.

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases.

(1) The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

(2) The infection control officer or officers must maintain a log of incidents related to infections and communicable diseases.

(b) *Standard: Responsibilities of chief executive officer, medical staff, and director of nursing services.* The chief executive officer, the medical staff, and the director of nursing services must—

(1) Ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers; and

(2) Be responsible for the implementation of successful corrective action plans in affected problem areas.

§ 482.43 Condition of participation: Discharge planning.

The hospital must have in effect a discharge planning process that applies to all patients. The hospital's policies and procedures must be specified in writing.

(a) *Standard: Identification of patients in need of discharge planning.* The hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

(b) *Standard: Discharge planning evaluation.* (1) The hospital must provide a discharge planning evaluation to the patients identified in paragraph (a) of this section, and to other patients upon the patient's request, the request of a person acting on the patient's behalf, or the request of the physician.

(2) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, the evaluation.

(3) The discharge planning evaluation must include an evaluation of the likelihood of a patient needing post- hospital services and of the availability of the services.

(4) The discharge planning evaluation must include an evaluation of the likelihood of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the hospital.

(5) The hospital personnel must complete the evaluation on a timely basis so that appropriate arrangements for post-hospital care are made before discharge, and to avoid unnecessary delays in discharge.

(6) The hospital must include the discharge planning evaluation in the patient's medical record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or individual acting on his or her behalf.

(c) *Standard: Discharge plan.* (1) A registered nurse, social worker, or other appropriately qualified personnel must develop, or supervise the development of, a discharge plan if the discharge planning evaluation indicates a need for a discharge plan.

(2) In the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan. In such a case, the hospital must develop a discharge plan for the patient.

(3) The hospital must arrange for the initial implementation of the patient's discharge plan.

(4) The hospital must reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan.

(5) As needed, the patient and family members or interested persons must be counseled to prepare them for post-hospital care.

(6) The hospital must include in the discharge plan a list of HHAs or SNFs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care or post-hospital extended care services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must indicate the availability of home health and posthospital extended care services through individuals and entities that have a contract with the managed care organizations.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the individual acting on the patient's behalf.

(7) The hospital, as part of the discharge planning process, must inform the patient or the patient's family of their freedom to choose among participating Medicare providers of posthospital care services and must, when possible, respect patient and family preferences when they are expressed. The hospital must not specify or otherwise limit the qualified providers that are available to the patient.

(8) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of Part 420, Subpart C, of this chapter.

(d) *Standard: Transfer or referral.* The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for followup or ancillary care.

(e) *Standard: Reassessment.* The hospital must reassess its discharge planning process on an on-going basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

[59 FR 64152, Dec. 13, 1994, as amended at 69 FR 49268, Aug. 11, 2004]

§ 482.45 Condition of participation: Organ, tissue, and eye procurement.

(a) *Standard: Organ procurement responsibilities.* The hospital must have and implement written protocols that:

(1) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose;

(2) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(3) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its options to donate organs, tissues, or eyes or to decline to donate. The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(4) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(5) Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(b) *Standard: Organ transplantation responsibilities.* (1) A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules. The term ''rules of the OPTN'' means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act, or with the requirements of this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing.

(2) For purposes of these standards, the term ''organ'' means a human kidney, liver, heart, lung, or pancreas.

(3) If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs. The hospital must also provide such data directly to the Department when requested by the Secretary.

[63 FR 33875, June 22, 1998]

Subpart D—Optional Hospital Services

§ 482.51 Condition of participation: Surgical services.

If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable standards of practice. If outpatient surgical services are offered the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.

(a) *Standard: Organization and staffing.* The organization of the surgical services must be appropriate to the scope of the services offered.

(1) The operating rooms must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.

(2) Licensed practical nurses (LPNs) and surgical technologists (operating room technicians) may serve as ''scrub nurses'' under the supervision of a registered nurse.

(3) Qualified registered nurses may perform circulating duties in the operating room. In accordance with applicable State laws and approved medical staff policies and procedures, LPNs and surgical technologists may assist in circulatory duties under the surpervision of a qualified registered nurse who is immediately available to respond to emergencies.

(4) Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

(b) *Standard: Delivery of service.* Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

(3) The following equipment must be available to the operating room suites: call-in-system, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.

(4) There must be adequate provisions for immediate post-operative care.

(5) The operating room register must be complete and up-to-date.

(6) An operative report describing techniques, findings, and tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.

§ 482.52 Condition of participation: Anesthesia services.

If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified doctor of medicine or osteopathy. The service is responsible for all anesthesia administered in the hospital.

(a) *Standard: Organization and staffing.* The organization of anesthesia services must be appropriate to the scope of the services offered. Anesthesia must be administered only by—

(1) A qualified anesthesiologist;

(2) A doctor of medicine or osteopathy (other than an anesthesiologist);

(3) A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law;

(4) A certified registered nurse anesthetist (CRNA), as defined in §410.69(b) of this chapter, who, unless exempted in accordance with paragraph (c)of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed; or

(5) An anesthesiologist's assistant, as defined in §410.69(b) of this chapter, who is under the supervision of an anesthesiologist who is immediately available if needed.

(b) *Standard: Delivery of services.* Anesthesia services must be consistent with needs and resources. Policies on anesthesia procedures must include the delineation of preanesthesia and post anesthesia responsibilities. The policies must ensure that the following are provided for each patient:

(1) A preanesthesia evaluation by an individual qualified to administer anesthesia under paragraph (a) of this section performed within 48 hours prior to surgery.

(2) An intraoperative anesthesia record.

(3) With respect to inpatients, a postanesthesia followup report by the individual who administers the anesthesia that is written within 48 hours after surgery.

(4) With respect to outpatients, a postanesthesia evaluation for proper anesthesia recovery performed in accordance with policies and procedures approved by the medical staff.

(c) *Standard: State exemption.* (1) A hospital may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (a)(4) of this section, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision of CRNAs. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[51 FR 22042, June 17, 1986 as amended at 57 FR 33900, July 31, 1992; 66 FR 56769, Nov. 13, 2001]

§ 482.53 Condition of participation: Nuclear medicine services.

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and staffing.* The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions, and responsibilities of nuclear medicine personnel must be specified by the service director and approved by the medical staff.

(b) *Standard: Delivery of service.* Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.

(1) In-house preparation of radiopharmaceuticals is by, or under, the direct supervision of an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

(2) There is proper storage and disposal of radioactive material.

(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in § 482.27.

(c) *Standard: Facilities.* Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance. The equipment must be—

(1) Maintained in safe operating condition; and

(2) Inspected, tested, and calibrated at least annually by qualified personnel.

(d) *Standard: Records.* The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.

(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.

(3) The hospital must maintain records of the receipt and disposition of radiopharmaceuticals.

(4) Nuclear medicine services must be ordered only by practitioner whose scope of Federal or State licensure and whose defined staff privileges allow such referrals.

[51 FR 22042, June 17, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

§ 482.54 Condition of participation: Outpatient services.

If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Organization.* Outpatient services must be appropriately organized and integrated with inpatient services.

(b) *Standard: Personnel.* The hospitals must—

(1) Assign an individual to be responsible for outpatient services; and

(2) Have appropriate professional and nonprofessional personnel available.

§ 482.55 Condition of participation: Emergency services.

The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* If emergency services are provided at the hospital—

(1) The services must be organized under the direction of a qualified member of the medical staff;

(2) The services must be integrated with other departments of the hospital;

(3) The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

(b) *Standard: Personnel.* (1) The emergency services must be supervised by a qualified member of the medical staff.

(2) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§ 482.56 Condition of participation: Rehabilitation services.

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

(a) *Standard: Organization and staffing.* The organization of the service must be appropriate to the scope of the services offered.

(1) The director of the services must have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(2) Physical therapy, occupational therapy, or speech therapy, or audiology services, if provided, must be provided by staff who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of services.* Services must be furnished in accordance with a written plan of treatment. Services must be given in accordance with orders of practitioners who are authorized by the medical staff to order the services, and the orders must be incorporated in the patient's record.

§ 482.57 Condition of participation: Respiratory care services.

The hospital must meet the needs of the patients in accordance with acceptable standards of practice. The following requirements apply if the hospital provides respiratory care service.

(a) *Standard: Organization and Staffing.* The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.

(1) There must be a director of respiratory care services who is a doctor of medicine or osteopathy with the knowledge experience, and capabilities to supervise and administer the service properly. The director may serve on either a full-time or part-time basis.

(2) There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.

(b) *Standard: Delivery of Services.* Services must be delivered in accordance with medical staff directives.

(1) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures must be designated in writing.

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

(3) Services must be provided only on, and in accordance with, the orders of a doctor of medicine or osteopathy.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 57 FR 7136, Feb. 28, 1992]

Subpart E—Requirements for Specialty Hospitals

§ 482.60 Special provisions applying to psychiatric hospitals.

Psychiatric hospital must—

(a) Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;

(b) Meet the conditions of participation specified in §§ 482.1 through 482.23 and §§ 482.25 through 482.57;

(c) Maintain clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries, as specified in § 482.61; and

(d) Meet the staffing requirements specified in § 482.62.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

The medical records maintained by a psychiatric hospital must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

(a) *Standard: Development of assessment/diagnostic data.* Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.

(1) The identification data must include the patient's legal status.

(2) A provisional or admitting diagnosis must be made on every patient at the time of admission, and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(3) The reasons for admission must be clearly documented as stated by the patient and/or others significantly involved.

(4) The social service records, including reports of interviews with patients, family members, and others, must provide an assessment of home plans and

family attitudes, and community resource contacts as well as a social history.

(5) When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.

(b) *Standard: Psychiatric evaluation.* Each patient must receive a psychiatric evaluation that must—

(1) Be completed within 60 hours of admission;

(2) Include a medical history;

(3) Contain a record of mental status;

(4) Note the onset of illness and the circumstances leading to admission;

(5) Describe attitudes and behavior;

(6) Estimate intellectual functioning, memory functioning, and orientation; and

(7) Include an inventory of the patient's assets in descriptive, not interpretative, fashion.

(c) *Standard: Treatment plan.* (1) Each patient must have an individual comprehensive treatment plan that must be based on an inventory of the patient's strengths and disabilities. The written plan must include—

(i) A substantiated diagnosis;

(ii) Short-term and long-range goals;

(iii) The specific treatment modalities utilized;

(iv) The responsibilities of each member of the treatment team; and

(v) Adequate documentation to justify the diagnosis and the treatment and rehabilitation activities carried out.

(2) The treatment received by the patient must be documented in such a way to assure that all active therapeutic efforts are included.

(d) *Standard: Recording progress.* Progress notes must be recorded by the doctor of medicine or osteopathy responsible for the care of the patient as specified in §482.12(c), nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(e) *Standard: Discharge planning and discharge summary.* The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.62 Condition of participation: Special staff requirements for psychiatric hospitals.

The hospital must have adequate numbers of qualified professional and supportive staff to evaluate patients, formulate written, individualized comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.

(a) *Standard: Personnel.* The hospital must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to:

(1) Evaluate patients;

(2) Formulate written individualized, comprehensive treatment plans;

(3) Provide active treatment measures; and

(4) Engage in discharge planning.

(b) *Standard: Director of inpatient psychiatric services; medical staff.* Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program. The number and qualifications of doctors of medicine and osteopathy must be adequate to provide essential psychiatric services.

(1) The clinical director, service chief, or equivalent must meet the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

(2) The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

(c) *Standard: Availability of medical personnel.* Doctors of medicine or osteopathy and other appropriate professional personnel must be available to provide necessary medical and surgical diagnostic and treatment services. If medical and surgical diagnostic and treatment services are not available within the institution, the institution must have an agreement with an outside source of these services to ensure that they are immediately available or a satisfactory agreement must be established for transferring patients to a general hospital that participates in the Medicare program.

(d) *Standard: Nursing services.* The hospital must have a qualified director of psychiatric nursing services. In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each patient's active treatment program and to maintain progress notes on each patient.

(1) The director of psychiatric nursing services must be a registered nurse who has a master's degree in psychiatric or mental health nursing, or its equivalent from a school of nursing accredited by the National League for Nursing, or be qualified by education and experience in the care of the mentally ill. The director must demonstrate competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, monitor, and evaluate the nursing care furnished.

(2) The staffing pattern must insure the availability of a registered professional nurse 24 hours each day. There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each patient's active treatment program.

(e) *Standard: Psychological services.* The hospital must provide or have available psychological services to meet the needs of the patients.

(f) *Standard: Social services.* There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished. The services must be furnished in accordance with accepted standards of practice and established policies and procedures.

(1) The director of the social work department or service must have a master's degree from an accredited school of social work or must be qualified by education and experience in the social services needs of the mentally ill. If the director does not hold a masters degree in social work, at least one staff member must have this qualification.

(2) Social service staff responsibilities must include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate, information with sources outside the hospital.

(g) *Standard: Therapeutic activities.* The hospital must provide a therapeutic activities program.

(1) The program must be appropriate to the needs and interests of patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.

(2) The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each patient's active treatment program.

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986]

§ 482.66 Special requirements for hospital providers of long-term care services ("swing-beds").

A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in § 409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in § 413.114 of this chapter:

(a) *Eligibility.* A hospital must meet the following eligibility requirements:

(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see § 413.24(d)(5) of this chapter).

(2) The hospital is located in a rural area. This includes all areas not delineated as ''urbanized'' areas by the Census Bureau, based on the most recent census.

(3) The hospital does not have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.

(4) The hospital has not had a swing-bed approval terminated within the two years previous to application.

(b) *Skilled nursing facility services.* The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter.

(1) Resident rights (§483.10 (b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)).

(2) Admission, transfer, and discharge rights (§483.12 (a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)).

(3) Resident behavior and facility practices (§483.13).

(4) Patient activities (§483.15(f)).

(5) Social services (§483.15(g)).

(6) Discharge planning (§483.20(e)).

(7) Specialized rehabilitative services (§483.45).

(8) Dental services (§483.55).

[51 FR 22042, June 17, 1986; 51 FR 27848, Aug. 4, 1986, as amended at 51 FR 34833, Sept. 30, 1986; 54 FR 37275, Sept. 7, 1989; 56 FR 54546, Oct. 22, 1991; 59 FR 45403, Sept. 1, 1994; 65 FR 47052, Aug. 1, 2000]

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A [Reserved]

Subpart B—Requirements for Long Term Care Facilities

SOURCE: 54 FR 5359, Feb. 2, 1989, unless otherwise noted.

§ 483.1 Basis and scope.

(a) *Statutory basis.* (1) Sections 1819 (a), (b), (c), and (d) of the Act provide that—

(i) Skilled nursing facilities participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements (see section 1819(d)(4)(B)) if they are necessary for the health and safety of individuals to whom services are furnished in the facilities.

(2) Section 1861(l) of the Act requires the facility to have in effect a transfer agreement with a hospital.

(3) Sections 1919 (a), (b), (c), and (d) of the Act provide that nursing facilities participating in Medicaid must meet certain specific requirements.

(b) *Scope.* The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a SNF in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

[56 FR 48867, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 60 FR 50443, Sept. 29, 1995]

§ 483.5 Definitions.

(a) *Facility defined.* For purposes of this subpart, *facility* means a skilled nursing facility (SNF) that meets the requirements of sections 1819(a), (b), (c), and (d) of the Act, or a nursing facility (NF) that meets the requirements of sections 1919(a), (b), (c), and (d) of the Act. ''Facility'' may include a distinct part of an institution (as defined in paragraph (b) of this section and specified in § 440.40 and § 440.155 of this chapter), but does not include an

institution for the mentally retarded or persons with related conditions described in § 440.150 of this chapter. For Medicare and Medicaid purposes (including eligibility, coverage, certification, and payment), the ''facility'' is always the entity that participates in the program, whether that entity is comprised of all of, or a distinct part of, a larger institution. For Medicare, an SNF (*see* section 1819(a)(1) of the Act), and for Medicaid, an NF (*see* section 1919(a)(1) of the Act) may not be an institution for mental diseases as defined in § 435.1010 of this chapter.

(b) *Distinct part*—(1) *Definition.* A distinct part SNF or NF is physically distinguishable from the larger institution or institutional complex that houses it, meets the requirements of this paragraph and of paragraph (b)(2) of this section, and meets the applicable statutory requirements for SNFs or NFs in sections 1819 or 1919 of the Act, respectively. A distinct part SNF or NF may be comprised of one or more buildings or designated parts of buildings (that is, wings, wards, or floors) that are: In the same physical area immediately adjacent to the institution's main buildings; other areas and structures that are not strictly contiguous to the main buildings but are located within close proximity of the main buildings; and any other areas that CMS determines on an individual basis, to be part of the institution's campus. A distinct part must include all of the beds within the designated area, and cannot consist of a random collection of individual rooms or beds that are scattered throughout the physical plant. The term ''distinct part'' also includes a composite distinct part that meets the additional requirements of paragraph (c) of this section.

(2) *Requirements.* In addition to meeting the participation requirements for long-term care facilities set forth elsewhere in this subpart, a distinct part SNF or NF must meet all of the following requirements:

(i) The SNF or NF must be operated under common ownership and control (that is, common governance) by the institution of which it is a distinct part, as evidenced by the following:

(A) The SNF or NF is wholly owned by the institution of which it is a distinct part.

(B) The SNF or NF is subject to the by-laws and operating decisions of a common governing body.

(C) The institution of which the SNF or NF is a distinct part has final responsibility for the distinct part's administrative decisions and personnel policies, and final approval for the distinct part's personnel actions.

(D) The SNF or NF functions as an integral and subordinate part of the institution of which it is a distinct part, with significant common resource usage of buildings, equipment, personnel, and services.

(ii) The administrator of the SNF or NF reports to and is directly accountable to the management of the institution of which the SNF or NF is a distinct part.

(iii) The SNF or NF must have a designated medical director who is responsible for implementing care policies and coordinating medical care, and who is directly accountable to the management of the institution of which it is a distinct part.

(iv) The SNF or NF is financially integrated with the institution of which it is a distinct part, as evidenced by the sharing of income and expenses with that institution, and the reporting of its costs on that institution's cost report.

(v) A single institution can have a maximum of only one distinct part SNF and one distinct part NF.

(vi) (A) An institution cannot designate a distinct part SNF or NF, but instead must submit a written request with documentation that demonstrates it meets the criteria set forth above to CMS to determine if it may be considered a distinct part.

(B) The effective date of approval of a distinct part is the date that CMS determines all requirements (including enrollment with the fiscal intermediary (FI)) are met for approval, and cannot be made retroactive.

(C) The institution must request approval from CMS for all proposed changes in the number of beds in the approved distinct part.

(c) *Composite distinct part*—(1) *Definition*. A composite distinct part is a distinct part consisting of two or more noncontiguous components that are not located within the same campus, as defined in § 413.65(a)(2) of this chapter.

(2) *Requirements*. In addition to meeting the requirements of paragraph (b) of this section, a composite distinct part must meet all of the following requirements:

(i) A SNF or NF that is a composite of more than one location will be treated as a single distinct part of the institution of which it is a distinct part. As such, the composite distinct part will have only one provider agreement and only one provider number.

(ii) If two or more institutions (each with a distinct part SNF or NF) undergo a change of ownership, CMS must approve the existing SNFs or NFs as meeting the requirements before they are considered a composite distinct part of a single institution. In making such a determination, CMS considers whether its approval or disapproval of a composite distinct part promotes the effective and efficient use of public monies without sacrificing the quality of care.

(iii) If there is a change of ownership of a composite distinct part SNF or NF, the assignment of the provider agreement to the new owner will apply to all of the approved locations that comprise the composite distinct part SNF or NF.

(iv) To ensure quality of care and quality of life for all residents, the various components of a composite distinct part must meet all of the requirements for participation independently in each location.

[68 FR 46071, Aug. 4, 2003, as amended at 71 FR 39229, July 12, 2006]

EFFECTIVE DATE NOTE: At 71 FR 55340, Sept. 22, 2006, § 483.5 was amended by adding paragraphs (d) and (e), effective Oct. 23, 2006. For the convenience of the user, the added text is set forth as follows:

§ 483.5 Definitions.

* * * * *

(d) *Common area*. Common areas are dining rooms, activity rooms, meeting rooms where residents are located on a regular basis, and other areas in the facility where residents may gather together with other residents, visitors, and staff.

(e) *Fully sprinklered*. A fully sprinklered long term care facility is one that has all areas sprinklered in accordance with National Fire Protection Association 13 ''Standard for the Installation of Sprinkler Systems'' without the use of waivers or the Fire Safety Evaluation System.

§ 483.10 Resident rights.

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights:

(a) *Exercise of rights*. (1) The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.

(2) The resident has the right to be free of interference, coercion, discrimination, and reprisal from the facility in exercising his or her rights.

(3) In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf.

(4) In the case of a resident who has not been adjudged incompetent by the State court, any legal-surrogate designated in accordance with State law may exercise the resident's rights to the extent provided by State law.

(b) *Notice of rights and services*. (1) The facility must inform the resident both orally and in writing in a language that the resident understands of his or her rights and all rules and regulations governing resident conduct and responsibilities during the stay in the facility. The facility must also provide the resident with the notice (if any) of the State developed under section 1919(e)(6) of the Act. Such notification must be made prior to or upon admission and during the resident's stay. Receipt of such information, and any amendments to it, must be acknowledged in writing;

(2) The resident or his or her legal representative has the right—

(i) Upon an oral or written request, to access all records pertaining to himself or herself including current clinical records within 24 hours (excluding weekends and holidays); and

(ii) After receipt of his or her records for inspection, to purchase at a cost not to exceed the community standard photocopies of the records or any portions of them upon request and 2 working days advance notice to the facility.

(3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;

(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section; and

(5) The facility must—

(i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of—

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and

(ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.

(6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.

(7) The facility must furnish a written description of legal rights which includes—

(i) A description of the manner of protecting personal funds, under paragraph (c) of this section;

(ii) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment under section 1924(c) which determines the extent of a couple's non-exempt resources at the time of institutionalization and attributes to the community spouse an equitable share of resources which cannot be considered available for payment toward the cost of the institutionalized spouse's medical care in his or her process of spending down to Medicaid eligibility levels;

(iii) A posting of names, addresses, and telephone numbers of all pertinent State client advocacy groups such as the State survey and certification agency, the State licensure office, the State ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit; and

(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, misappropriation of resident property in the facility, and non-compliance with the advance directives requirements.

(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved

of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

(9) The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.

(10) The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

(11) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal respresentative or an interested family member when there is—

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in § 483.12(a).

(ii) The facility must also promptly notify the resident and, if known, the resident's legal representative or interested family member when there is—

(A) A change in room or roommate assignment as specified in § 483.15(e)(2); or

(B) A change in resident rights under Federal or State law or regulations as specified in paragraph (b)(1) of this section.

(iii) The facility must record and periodically update the address and phone number of the resident's legal representative or interested family member.

(12) *Admission to a composite distinct part.* A facility that is a composite distinct part (as defined in § 483.5(c) of this subpart) must disclose in its admission agreement its physical configuration, including the various locations that comprise the composite distinct part, and must specify the policies that apply to room changes between its different locations under § 483.12(a)(8).

(c) *Protection of resident funds.* (1) The resident has the right to manage his or her financial affairs, and the facility may not require residents to deposit their personal funds with the facility.

(2) *Management of personal funds.* Upon written authorization of a resident, the facility must hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility, as specified in paragraphs (c)(3)–(8) of this section.

(3) *Deposit of funds.* (i) *Funds in excess of $50.* The facility must deposit any residents' personal funds in excess of $50 in an interest bearing account (or accounts) that is separate from any of the facility's operating accounts, and that credits all interest earned on resident's funds to that account. (In pooled accounts, there must be a separate accounting for each resident's share.)

(ii) *Funds less than $50.* The facility must maintain a resident's personal funds that do not exceed $50 in a noninterest bearing account, interest-bearing account, or petty cash fund.

(4) *Accounting and records.* The facility must establish and maintain a system that assures a full and complete and separate accounting, according to generally accepted accounting principles, of each resident's personal funds entrusted to the facility on the resident's behalf.

(i) The system must preclude any commingling of resident funds with facility funds or with the funds of any person other than another resident.

(ii) The individual financial record must be available through quarterly statements and on request to the resident or his or her legal representative.

(5) *Notice of certain balances.* The facility must notify each resident that receives Medicaid benefits—

(i) When the amount in the resident's account reaches $200 less than the SSI

resource limit for one person, specified in section 1611(a)(3)(B) of the Act; and

(ii) That, if the amount in the account, in addition to the value of the resident's other nonexempt resources, reaches the SSI resource limit for one person, the resident may lose eligibility for Medicaid or SSI.

(6) *Conveyance upon death.* Upon the death of a resident with a personal fund deposited with the facility, the facility must convey within 30 days the resident's funds, and a final accounting of those funds, to the individual or probate jurisdiction administering the resident's estate.

(7) *Assurance of financial security.* The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(8) *Limitation on charges to personal funds.* The facility may not impose a charge against the personal funds of a resident for any item or service for which payment is made under Medicaid or Medicare (except for applicable deductible and coinsurance amounts). The facility may charge the resident for requested services that are more expensive than or in excess of covered services in accordance with § 489.32 of this chapter. (This does not affect the prohibition on facility charges for items and services for which Medicaid has paid. See § 447.15, which limits participation in the Medicaid program to providers who accept, as payment in full, Medicaid payment plus any deductible, coinsurance, or copayment required by the plan to be paid by the individual.)

(i) *Services included in Medicare or Medicaid payment.* During the course of a covered Medicare or Medicaid stay, facilities may not charge a resident for the following categories of items and services:

(A) Nursing services as required at § 483.30 of this subpart.

(B) Dietary services as required at § 483.35 of this subpart.

(C) An activities program as required at § 483.15(f) of this subpart.

(D) Room/bed maintenance services.

(E) Routine personal hygiene items and services as required to meet the needs of residents, including, but not limited to, hair hygiene supplies, comb, brush, bath soap, disinfecting soaps or specialized cleansing agents when indicated to treat special skin problems or to fight infection, razor, shaving cream, toothbrush, toothpaste, denture adhesive, denture cleaner, dental floss, moisturizing lotion, tissues, cotton balls, cotton swabs, deodorant, incontinence care and supplies, sanitary napkins and related supplies, towels, washcloths, hospital gowns, over the counter drugs, hair and nail hygiene services, bathing, and basic personal laundry.

(F) Medically-related social services as required at § 483.15(g) of this subpart.

(ii) *Items and services that may be charged to residents' funds.* Listed below are general categories and examples of items and services that the facility may charge to residents' funds if they are requested by a resident, if the facility informs the resident that there will be a charge, and if payment is not made by Medicare or Medicaid:

(A) Telephone.

(B) Television/radio for personal use.

(C) Personal comfort items, including smoking materials, notions and novelties, and confections.

(D) Cosmetic and grooming items and services in excess of those for which payment is made under Medicaid or Medicare.

(E) Personal clothing.

(F) Personal reading matter.

(G) Gifts purchased on behalf of a resident.

(H) Flowers and plants.

(I) Social events and entertainment offered outside the scope of the activities program, provided under § 483.15(f) of this subpart.

(J) Noncovered special care services such as privately hired nurses or aides.

(K) Private room, except when therapeutically required (for example, isolation for infection control).

(L) Specially prepared or alternative food requested instead of the food generally prepared by the facility, as required by § 483.35 of this subpart.

(iii) *Requests for items and services.* (A) The facility must not charge a resident (or his or her representative) for any item or service not requested by the resident.

(B) The facility must not require a resident (or his or her representative) to request any item or service as a condition of admission or continued stay.

(C) The facility must inform the resident (or his or her representative) requesting an item or service for which a charge will be made that there will be a charge for the item or service and what the charge will be.

(d) *Free choice.* The resident has the right to—

(1) Choose a personal attending physician;

(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and

(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.

(e) *Privacy and confidentiality.* The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;

(2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;

(3) The resident's right to refuse release of personal and clinical records does not apply when—

(i) The resident is transferred to another health care institution; or

(ii) Record release is required by law.

(f) *Grievances.* A resident has the right to—

(1) Voice grievances without discrimination or reprisal. Such grievances include those with respect to treatment which has been furnished as well as that which has not been furnished; and

(2) Prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(g) *Examination of survey results.* A resident has the right to—

(1) Examine the results of the most recent survey of the facility conducted by Federal or State surveyors and any plan of correction in effect with respect to the facility. The facility must make the results available for examination in a place readily accessible to residents, and must post a notice of their availability; and

(2) Receive information from agencies acting as client advocates, and be afforded the opportunity to contact these agencies.

(h) *Work.* The resident has the right to—

(1) Refuse to perform services for the facility;

(2) Perform services for the facility, if he or she chooses, when—

(i) The facility has documented the need or desire for work in the plan of care;

(ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid;

(iii) Compensation for paid services is at or above prevailing rates; and

(iv) The resident agrees to the work arrangement described in the plan of care.

(i) *Mail.* The resident has the right to privacy in written communications, including the right to—

(1) Send and promptly receive mail that is unopened; and

(2) Have access to stationery, postage, and writing implements at the resident's own expense.

(j) *Access and visitation rights.* (1) The resident has the right and the facility must provide immediate access to any resident by the following:

(i) Any representative of the Secretary;

(ii) Any representative of the State:

(iii) The resident's individual physician;

(iv) The State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965);

(v) The agency responsible for the protection and advocacy system for developmentally disabled individuals (established under part C of the Developmental Disabilities Assistance and Bill of Rights Act);

(vi) The agency responsible for the protection and advocacy system for mentally ill individuals (established under the Protection and Advocacy for Mentally Ill Individuals Act);

(vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and

(viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.

(2) The facility must provide reasonable access to any resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident's right to deny or withdraw consent at any time.

(3) The facility must allow representatives of the State Ombudsman, described in paragraph (j)(1)(iv) of this section, to examine a resident's clinical records with the permission of the resident or the resident's legal representative, and consistent with State law.

(k) *Telephone.* The resident has the right to have reasonable access to the use of a telephone where calls can be made without being overheard.

(l) *Personal property.* The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.

(m) *Married couples.* The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.

(n) *Self-Administration of Drugs.* An individual resident may self-administer drugs if the interdisciplinary team, as defined by § 483.20(d)(2)(ii), has determined that this practice is safe.

(o) *Refusal of certain transfers.* (1) An individual has the right to refuse a transfer to another room within the institution, if the purpose of the transfer is to relocate—

(i) A resident of a SNF from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF, or

(ii) A resident of a NF from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF.

(2) A resident's exercise of the right to refuse transfer under paragraph (o)(1) of this section does not affect the individual's eligibility or entitlement to Medicare or Medicaid benefits.

[56 FR 48867, Sept. 26, 1991, as amended at 57 FR 8202, Mar. 6, 1992; 57 FR 43924, Sept. 23, 1992; 57 FR 53587, Nov. 12, 1992; 60 FR 33293, June 27, 1995; 68 FR 46072, Aug. 4, 2003]

§ 483.12 Admission, transfer and discharge rights.

(a) Transfer and discharge—

(1) *Definition:* Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.

(2) *Transfer and discharge requirements.* The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—

(i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility;

(ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) The safety of individuals in the facility is endangered;

(iv) The health of individuals in the facility would otherwise be endangered;

(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or

(vi) The facility ceases to operate.

(3) *Documentation.* When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by—

(i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and

(ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.

(4) *Notice before transfer.* Before a facility transfers or discharges a resident, the facility must—

(i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand.

(ii) Record the reasons in the resident's clinical record; and

(iii) Include in the notice the items described in paragraph (a)(6) of this section.

(5) *Timing of the notice.* (i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged.

(ii) Notice may be made as soon as practicable before transfer or discharge when—

(A) the safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section;

(B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;

(C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section;

(D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or

(E) A resident has not resided in the facility for 30 days.

(6) *Contents of the notice.* The written notice specified in paragraph (a)(4) of this section must include the following:

(i) The reason for transfer or discharge;

(ii) The effective date of transfer or discharge;

(iii) The location to which the resident is transferred or discharged;

(iv) A statement that the resident has the right to appeal the action to the State;

(v) The name, address and telephone number of the State long term care ombudsman;

(vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and

(vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.

(7) *Orientation for transfer or discharge.* A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

(8) *Room changes in a composite distinct part.* Room changes in a facility that is a composite distinct part (as defined in § 483.5(c)) must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.

(b) *Notice of bed-hold policy and readmission*—(1) *Notice before transfer.* Before a nursing facility transfers a resident to a hospital or allows a resident to go on therapeutic leave, the nursing facility must provide written information to the resident and a family member or legal representative that specifies—

(i) The duration of the bed-hold policy under the State plan, if any, during which the resident is permitted to return and resume residence in the nursing facility; and

(ii) The nursing facility's policies regarding bed-hold periods, which must be consistent with paragraph (b)(3) of this section, permitting a resident to return.

(2) *Bed-hold notice upon transfer.* At the time of transfer of a resident for hospitalization or therapeutic leave, a nursing facility must provide to the

resident and a family member or legal representative written notice which specifies the duration of the bed-hold policy described in paragraph (b)(1) of this section.

(3) *Permitting resident to return to facility.* A nursing facility must establish and follow a written policy under which a resident, whose hospitalization or therapeutic leave exceeds the bed-hold period under the State plan, is readmitted to the facility immediately upon the first availability of a bed in a semi-private room if the resident—

(i) Requires the services provided by the facility; and

(ii) Is eligible for Medicaid nursing facility services.

(4) *Readmission to a composite distinct part.* When the nursing facility to which a resident is readmitted is a composite distinct part (as defined in § 483.5(c) of this subpart), the resident must be permitted to return to an available bed in the particular location of the composite distinct part in which he or she resided previously. If a bed is not available in that location at the time of readmission, the resident must be given the option to return to that location upon the first availability of a bed there.

(c) *Equal access to quality care.* (1) A facility must establish and maintain identical policies and practices regarding transfer, discharge, and the provision of services under the State plan for all individuals regardless of source of payment;

(2) The facility may charge any amount for services furnished to non-Medicaid residents consistent with the notice requirement in § 483.10(b)(5)(i) and (b)(6) describing the charges; and

(3) The State is not required to offer additional services on behalf of a resident other than services provided in the State plan.

(d) *Admissions policy.* (1) The facility must—

(i) Not require residents or potential residents to waive their rights to Medicare or Medicaid; and

(ii) Not require oral or written assurance that residents or potential residents are not eligible for, or will not apply for, Medicare or Medicaid benefits.

(2) The facility must not require a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility. However, the facility may require an individual who has legal access to a resident's income or resources available to pay for facility care to sign a contract, without incurring personal financial liability, to provide facility payment from the resident's income or resources.

(3) In the case of a person eligible for Medicaid, a nursing facility must not charge, solicit, accept, or receive, in addition to any amount otherwise required to be paid under the State plan, any gift, money, donation, or other consideration as a precondition of admission, expedited admission or continued stay in the facility. However,—

(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term ''nursing facility services'' so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and

(ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident.

(4) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.

[56 FR 48869, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 68 FR 46072, Aug. 4, 2003]

§ 483.13 Resident behavior and facility practices.

(a) *Restraints.* The resident has the right to be free from any physical or

chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

(b) *Abuse.* The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

(c) *Staff treatment of residents.* The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

(1) The facility must—

(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

(ii) Not employ individuals who have been—

(A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or

(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and

(iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.

(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

[56 FR 48870, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992]

§ 483.15 Quality of life.

A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

(a) *Dignity.* The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

(b) *Self-determination and participation.* The resident has the right to—

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plans of care;

(2) Interact with members of the community both inside and outside the facility; and

(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

(c) *Participation in resident and family groups.* (1) A resident has the right to organize and participate in resident groups in the facility;

(2) A resident's family has the right to meet in the facility with the families of other residents in the facility;

(3) The facility must provide a resident or family group, if one exists, with private space;

(4) Staff or visitors may attend meetings at the group's invitation;

(5) The facility must provide a designated staff person responsible for providing assistance and responding to written requests that result from group meetings;

(6) When a resident or family group exists, the facility must listen to the views and act upon the grievances and recommendations of residents and families concerning proposed policy and operational decisions affecting resident care and life in the facility.

(d) *Participation in other activities.* A resident has the right to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(e) *Accommodation of needs.* A resident has the right to—

(1) Reside and receive services in the facility with reasonable accommodation of individual needs and preferences, except when the health or safety of the individual or other residents would be endangered; and

(2) Receive notice before the resident's room or roommate in the facility is changed.

(f) *Activities.* (1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident.

(2) The activities program must be directed by a qualified professional who—

(i) Is a qualified therapeutic recreation specialist or an activities professional who—

(A) Is licensed or registered, if applicable, by the State in which practicing; and

(B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or

(ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or

(iii) Is a qualified occupational therapist or occupational therapy assistant; or

(iv) Has completed a training course approved by the State.

(g) *Social Services.* (1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis.

(3) *Qualifications of social worker.* A qualified social worker is an individual with—

(i) A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and

(ii) One year of supervised social work experience in a health care setting working directly with individuals.

(h) *Environment.* The facility must provide—

(1) A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible;

(2) Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior;

(3) Clean bed and bath linens that are in good condition;

(4) Private closet space in each resident room, as specified in § 483.70(d)(2)(iv) of this part;

(5) Adequate and comfortable lighting levels in all areas;

(6) Comfortable and safe temperature levels. Facilities initially certified after October 1, 1990 must maintain a temperature range of 71–81°F; and

(7) For the maintenance of comfortable sound levels.

[56 FR 48871, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992]

§ 483.20 Resident assessment.

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.

(a) *Admission orders.* At the time each resident is admitted, the facility must have physician orders for the resident's immediate care.

(b) *Comprehensive assessments*—(1) *Resident assessment instrument.* A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the State. The assessment must include at least the following:

(i) Identification and demographic information.

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.
(xiii) Activity pursuit.
(xiv) Medications.
(xv) Special treatments and procedures.
(xvi) Discharge potential.
(xvii) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.
(xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

(2) *When required.* Subject to the timeframes prescribed in §413.343(b) of this chapter, a facility must conduct a comprehensive assessment of a resident in accordance with the timeframes specified in paragraphs (b)(2) (i) through (iii) of this section. The timeframes prescribed in §413.343(b) of this chapter do not apply to CAHs.

(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition. (For purposes of this section, ''readmission'' means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.)

(ii) Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a ''significant change'' means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

(iii) Not less often than once every 12 months.

(c) *Quarterly review assessment.* A facility must assess a resident using the quarterly review instrument specified by the State and approved by CMS not less frequently than once every 3 months.

(d) *Use.* A facility must maintain all resident assessments completed within the previous 15 months in the resident's active record and use the results of the assessments to develop, review, and revise the resident's comprehensive plan f care.

(e) *Coordination.* A facility must coordinate assessments with the preadmission screening and resident review program under Medicaid in part 483, subpart C to the maximum extent practicable to avoid duplicative testing and effort.

(f) *Automated data processing requirement*—(1) *Encoding data.* Within 7 days after a facility completes a resident's assessment, a facility must encode the following information for each resident in the facility:

(i) Admission assessment.
(ii) Annual assessment updates.
(iii) Significant change in status assessments.
(iv) Quarterly review assessments.
(v) A subset of items upon a resident's transfer, reentry, discharge, and death.
(vi) Background (face-sheet) information, if there is no admission assessment.

(2) *Transmitting data.* Within 7 days after a facility completes a resident's assessment, a facility must be capable of transmitting to the State information for each resident contained in the MDS in a format that conforms to standard record layouts and data dictionaries, and that passes standardized edits defined by CMS and the State.

(3) *Monthly transmittal requirements.* A facility must electronically transmit, at least monthly, encoded, accurate, complete MDS data to the State for all assessments conducted during the previous month, including the following:

(i) Admission assessment.
(ii) Annual assessment.
(iii) Significant change in status assessment.
(iv) Significant correction of prior full assessment.
(v) Significant correction of prior quarterly assessment.
(vi) Quarterly review.
(vii) A subset of items upon a resident's transfer, reentry, discharge, and death.

(viii) Background (face-sheet) information, for an initial transmission of MDS data on a resident that does not have an admission assessment.

(4) *Data format.* The facility must transmit data in the format specified by CMS or, for a State which has an alternate RAI approved by CMS, in the format specified by the State and approved by CMS.

(5) *Resident-identifiable information.* (i) A facility may not release information that is resident-identifiable to the public.

(ii) The facility may release information that is resident-identifiable to an agent only in accordance with a contract under which the agent agrees not to use or disclose the information except to the extent the facility itself is permitted to do so.

(g) *Accuracy of assessments.* The assessment must accurately reflect the resident's status.

(h) *Coordination.* A registered nurse must conduct or coordinate each assessment with the appropriate participation of health professionals.

(i) *Certification.* (1) A registered nurse must sign and certify that the assessment is completed.

(2) Each individual who completes a portion of the assessment must sign and certify the accuracy of that portion of the assessment.

(j) *Penalty for falsification.* (1) Under Medicare and Medicaid, an individual who willfully and knowingly—

(i) Certifies a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 for each assessment; or

(ii) Causes another individual to certify a material and false statement in a resident assessment is subject to a civil money penalty of not more than $5,000 for each assessment.

(2) Clinical disagreement does not constitute a material and false statement.

(k) *Comprehensive care plans.* (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following—

(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under § 483.25; and

(ii) Any services that would otherwise be required under § 483.25 but are not provided due to the resident's exercise of rights under § 483.10, including the right to refuse treatment under § 483.10(b)(4).

(2) A comprehensive care plan must be—

(i) Developed within 7 days after completion of the comprehensive assessment;

(ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and

(iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

(3) The services provided or arranged by the facility must—

(i) Meet professional standards of quality; and

(ii) Be provided by qualified persons in accordance with each resident's written plan of care.

(l) *Discharge summary.* When the facility anticipates discharge a resident must have a discharge summary that includes—

(1) A recapitulation of the resident's stay;

(2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and

(3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.

(m) *Preadmission screening for mentally ill individuals and individuals with mental retardation.* (1) A nursing facility

must not admit, on or after January 1, 1989, any new resident with—

(i) Mental illness as defined in paragraph (f)(2)(i) of this section, unless the State mental health authority has determined, based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority, prior to admission,

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services; or

(ii) Mental retardation, as defined in paragraph (f)(2)(ii) of this section, unless the State mental retardation or developmental disability authority has determined prior to admission—

(A) That, because of the physical and mental condition of the individual, the individual requires the level of services provided by a nursing facility; and

(B) If the individual requires such level of services, whether the individual requires specialized services for mental retardation.

(2) *Definition.* For purposes of this section—

(i) An individual is considered to have *mental illness* if the individual has a serious mental illness as defined in § 483.102(b)(1).

(ii) An individual is considered to be *mentally retarded* if the individual is mentally retarded as defined in § 483.102(b)(3) or is a person with a related condition as described in 42 CFR 435.1010 of this chapter.

[56 FR 48871, Sept. 26, 1991, as amended at 57 FR 43924, Sept. 23, 1992; 62 FR 67211, Dec. 23, 1997; 63 FR 53307, Oct. 5, 1998; 64 FR 41543, July 30, 1999; 68 FR 46072, Aug. 4, 2003; 71 FR 39229, July 12, 2006]

§ 483.25 Quality of care.

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

(a) *Activities of daily living.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that diminution was unavoidable. This includes the resident's ability to—

(i) Bathe, dress, and groom;

(ii) Transfer and ambulate;

(iii) Toilet;

(iv) Eat; and

(v) Use speech, language, or other functional communication systems.

(2) A resident is given the appropriate treatment and services to maintain or improve his or her abilities specified in paragraph (a)(1) of this section; and

(3) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

(b) *Vision and hearing.* To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(1) In making appointments, and

(2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(c) *Pressure sores.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

(d) *Urinary Incontinence.* Based on the resident's comprehensive assessment, the facility must ensure that—

(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

(e) *Range of motion.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who enters the facility without a limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(f) *Mental and Psychosocial functioning.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem, and

(2) A resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that such a pattern was unavoidable.

(g) *Naso-gastric tubes.* Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who has been able to eat enough alone or with assistance is not fed by naso-gastric tube unless the resident's clinical condition demonstrates that use of a naso-gastric tube was unavoidable; and

(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.

(h) *Accidents.* The facility must ensure that—

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

(i) *Nutrition.* Based on a resident's comprehensive assessment, the facility must ensure that a resident—

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and

(2) Receives a therapeutic diet when there is a nutritional problem.

(j) *Hydration.* The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

(k) *Special needs.* The facility must ensure that residents receive proper treatment and care for the following special services:

(1) Injections;

(2) Parenteral and enteral fluids;

(3) Colostomy, ureterostomy, or ileostomy care;

(4) Tracheostomy care;

(5) Tracheal suctioning;

(6) Respiratory care;

(7) Foot care; and

(8) Prostheses.

(l) *Unnecessary drugs*—(1) *General.* Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate drug therapy); or

(ii) For excessive duration; or

(iii) Without adequate monitoring; or

(iv) Without adequate indications for its use; or

(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(vi) Any combinations of the reasons above.

(2) *Antipsychotic Drugs.* Based on a comprehensive assessment of a resident, the facility must ensure that—

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

(m) *Medication Errors.* The facility must ensure that—

(1) It is free of medication error rates of five percent or greater; and

(2) Residents are free of any significant medication errors.

(n) *Influenza and pneumococcal immunizations*—(1) *Influenza.* The facility must develop policies and procedures that ensure that—

(i) Before offering the influenza immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered an influenza immunization October 1 through March 31 annually, unless the immunization is medically contraindicated or the resident has already been immunized during this time period;

(iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of influenza immunization; and

(B) That the resident either received the influenza immunization or did not receive the influenza immunization due to medical contraindications or refusal.

(2) *Pneumococcal disease.* The facility must develop policies and procedures that ensure that—

(i) Before offering the pneumococcal immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;

(ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;

(iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and

(iv) The resident's medical record includes documentation that indicates, at a minimum, the following:

(A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and

(B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.

(v) *Exception.* As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

[56 FR 48873, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992; 70 FR 58851, Oct. 7, 2005]

§ 483.30 Nursing services.

The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

(a) *Sufficient staff.* (1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:

(i) Except when waived under paragraph (c) of this section, licensed nurses; and

(ii) Other nursing personnel.

(2) Except when waived under paragraph (c) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

(b) *Registered nurse.* (1) Except when waived under paragraph (c) or (d) of this section, the facility must use the services of a registered nurse for at least 8 consecutive hours a day, 7 days a week.

(2) Except when waived under paragraph (c) or (d) of this section, the facility must designate a registered nurse to serve as the director of nursing on a full time basis.

(3) The director of nursing may serve as a charge nurse only when the facility has an average daily occupancy of 60 or fewer residents.

(c) *Nursing facilities: Waiver of requirement to provide licensed nurses on a 24-hour basis.* To the extent that a facility is unable to meet the requirements of paragraphs (a)(2) and (b)(1) of this section, a State may waive such requirements with respect to the facility if—

(1) The facility demonstrates to the satisfaction of the State that the facility has been unable, despite diligent efforts (including offering wages at the community prevailing rate for nursing facilities), to recruit appropriate personnel;

(2) The State determines that a waiver of the requirement will not endanger the health or safety of individuals staying in the facility;

(3) The State finds that, for any periods in which licensed nursing services are not available, a registered nurse or a physician is obligated to respond immediately to telephone calls from the facility;

(4) A waiver granted under the conditions listed in paragraph (c) of this section is subject to annual State review;

(5) In granting or renewing a waiver, a facility may be required by the State to use other qualified, licensed personnel;

(6) The State agency granting a waiver of such requirements provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(7) The nursing facility that is granted such a waiver by a State notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(d) *SNFs: Waiver of the requirement to provide services of a registered nurse for more than 40 hours a week.* (1) The Secretary may waive the requirement that a SNF provide the services of a registered nurse for more than 40 hours a week, including a director of nursing specified in paragraph (b) of this section, if the Secretary finds that—

(i) The facility is located in a rural area and the supply of skilled nursing facility services in the area is not sufficient to meet the needs of individuals residing in the area;

(ii) The facility has one full-time registered nurse who is regularly on duty at the facility 40 hours a week; and

(iii) The facility either—

(A) Has only patients whose physicians have indicated (through physicians' orders or admission notes) that they do not require the services of a registered nurse or a physician for a 48-hours period, or

(B) Has made arrangements for a registered nurse or a physician to spend time at the facility, as determined necessary by the physician, to provide necessary skilled nursing services on days when the regular full-time registered nurse is not on duty;

(iv) The Secretary provides notice of the waiver to the State long term care ombudsman (established under section 307(a)(12) of the Older Americans Act of 1965) and the protection and advocacy system in the State for the mentally ill and mentally retarded; and

(v) The facility that is granted such a waiver notifies residents of the facility (or, where appropriate, the guardians or legal representatives of such residents) and members of their immediate families of the waiver.

(2) A waiver of the registered nurse requirement under paragraph (d)(1) of this section is subject to annual renewal by the Secretary.

(e) *Nurse staffing information*—(1) *Data requirements.* The facility must post the following information on a daily basis:

(i) Facility name.

(ii) The current date.

(iii) The total number and the actual hours worked by the following categories of licensed and unlicensed nursing staff directly responsible for resident care per shift:

(A) Registered nurses.

(B) Licensed practical nurses or licensed vocational nurses (as defined under State law).

(C) Certified nurse aides.

(iv) Resident census.

(2) *Posting requirements.* (i) The facility must post the nurse staffing data

specified in paragraph (e)(1) of this section on a daily basis at the beginning of each shift.

(ii) Data must be posted as follows:

(A) Clear and readable format.

(B) In a prominent place readily accessible to residents and visitors.

(3) *Public access to posted nurse staffing data.* The facility must, upon oral or written request, make nurse staffing data available to the public for review at a cost not to exceed the community standard.

(4) *Facility data retention requirements.* The facility must maintain the posted daily nurse staffing data for a minimum of 18 months, or as required by State law, whichever is greater.

[56 FR 48873, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992; 70 FR 62073, Oct. 28, 2005]

§ 483.35 Dietary services.

The facility must provide each resident with a nourishing, palatable, well-balanced diet that meets the daily nutritional and special dietary needs of each resident.

(a) *Staffing.* The facility must employ a qualified dietitian either full-time, part-time, or on a consultant basis.

(1) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian.

(2) A qualified dietitian is one who is qualified based upon either registration by the Commission on Dietetic Registration of the American Dietetic Association, or on the basis of education, training, or experience in identification of dietary needs, planning, and implementation of dietary programs.

(b) *Sufficient staff.* The facility must employ sufficient support personnel competent to carry out the functions of the dietary service.

(c) *Menus and nutritional adequacy.* Menus must—

(1) Meet the nutritional needs of residents in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences;

(2) Be prepared in advance; and

(3) Be followed.

(d) *Food.* Each resident receives and the facility provides—

(1) Food prepared by methods that conserve nutritive value, flavor, and appearance;

(2) Food that is palatable, attractive, and at the proper temperature;

(3) Food prepared in a form designed to meet individual needs; and

(4) Substitutes offered of similar nutritive value to residents who refuse food served.

(e) *Therapeutic diets.* Therapeutic diets must be prescribed by the attending physician.

(f) *Frequency of meals.* (1) Each resident receives and the facility provides at least three meals daily, at regular times comparable to normal mealtimes in the community.

(2) There must be no more than 14 hours between a substantial evening meal and breakfast the following day, except as provided in (4) below.

(3) The facility must offer snacks at bedtime daily.

(4) When a nourishing snack is provided at bedtime, up to 16 hours may elapse between a substantial evening meal and breakfast the following day if a resident group agrees to this meal span, and a nourishing snack is served.

(g) *Assistive devices.* The facility must provide special eating equipment and utensils for residents who need them.

(h) *Paid feeding assistants*—(1) *State-approved training course.* A facility may use a paid feeding assistant, as defined in § 488.301 of this chapter, if—

(i) The feeding assistant has successfully completed a State-approved training course that meets the requirements of § 483.160 before feeding residents; and

(ii) The use of feeding assistants is consistent with State law.

(2) *Supervision.* (i) A feeding assistant must work under the supervision of a registered nurse (RN) or licensed practical nurse (LPN).

(ii) In an emergency, a feeding assistant must call a supervisory nurse for help on the resident call system.

(3) *Resident selection criteria.* (i) A facility must ensure that a feeding assistant feeds only residents who have no complicated feeding problems.

(ii) Complicated feeding problems include, but are not limited to, difficulty

swallowing, recurrent lung aspirations, and tube or parenteral/IV feedings.

(iii) The facility must base resident selection on the charge nurse's assessment and the resident's latest assessment and plan of care.

(i) *Sanitary conditions.* The facility must—

(1) Procure food from sources approved or considered satisfactory by Federal, State, or local authorities;

(2) Store, prepare, distribute, and serve food under sanitary conditions; and

(3) Dispose of garbage and refuse properly.

[56 FR 48874, Sept. 26, 1991, as amended at 68 FR 55539, Sept. 26, 2003]

§ 483.40 Physician services.

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

(a) *Physician supervision.* The facility must ensure that—

(1) The medical care of each resident is supervised by a physician; and

(2) Another physician supervises the medical care of residents when their attending physician is unavailable.

(b) *Physician visits.* The physician must—

(1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;

(2) Write, sign, and date progress notes at each visit; and

(3) Sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

(c) *Frequency of physician visits.* (1) The resident must be seen by a physician at least once every 30 days for the first 90 days after admission, and at least once every 60 days thereafter.

(2) A physician visit is considered timely if it occurs not later than 10 days after the date the visit was required.

(3) Except as provided in paragraphs (c)(4) and (f) of this section, all required physician visits must be made by the physician personally.

(4) At the option of the physician, required visits in SNFs after the initial visit may alternate between personal visits by the physician and visits by a physician assistant, nurse practitioner, or clinical nurse specialist in accordance with paragraph (e) of this section.

(d) *Availability of physicians for emergency care.* The facility must provide or arrange for the provision of physician services 24 hours a day, in case of an emergency.

(e) *Physician delegation of tasks in SNFs.* (1) Except as specified in paragraph (e)(2) of this section, a physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist who—

(i) Meets the applicable definition in § 491.2 of this chapter or, in the case of a clinical nurse specialist, is licensed as such by the State;

(ii) Is acting within the scope of practice as defined by State law; and

(iii) Is under the supervision of the physician.

(2) A physician may not delegate a task when the regulations specify that the physician must perform it personally, or when the delegation is prohibited under State law or by the facility's own policies.

(f) *Performance of physician tasks in NFs.* At the option of the State, any required physician task in a NF (including tasks which the regulations specify must be performed personally by the physician) may also be satisfied when performed by a nurse practitioner, clinical nurse specialist, or physician assistant who is not an employee of the facility but who is working in collaboration with a physician.

[56 FR 48875, Sept. 26, 1991, as amended at 67 FR 61814, Oct. 2, 2002]

§ 483.45 Specialized rehabilitative services.

(a) *Provision of services.* If specialized rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services; or

(2) Obtain the required services from an outside resource (in accordance with § 483.75(h) of this part) from a provider of specialized rehabilitative services.

(b) *Qualifications.* Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.

[56 FR 48875, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

§ 483.55 Dental services.

The facility must assist residents in obtaining routine and 24-hour emergency dental care.

(a) *Skilled nursing facilities.* A facility (1) Must provide or obtain from an outside resource, in accordance with § 483.75(h) of this part, routine and emergency dental services to meet the needs of each resident;

(2) May charge a Medicare resident an additional amount for routine and emergency dental services;

(3) Must if necessary, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(4) Promptly refer residents with lost or damaged dentures to a dentist.

(b) *Nursing facilities.* The facility (1) Must provide or obtain from an outside resource, in accordance with § 483.75(h) of this part, the following dental services to meet the needs of each resident:

(i) Routine dental services (to the extent covered under the State plan); and

(ii) Emergency dental services;

(2) Must, if necessary, assist the resident—

(i) In making appointments; and

(ii) By arranging for transportation to and from the dentist's office; and

(3) Must promptly refer residents with lost or damaged dentures to a dentist.

[56 FR 48875, Sept. 26, 1991]

§ 483.60 Pharmacy services.

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) *Procedures.* A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) *Service consultation.* The facility must employ or obtain the services of a licensed pharmacist who—

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) *Drug regimen review.* (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) The pharmacist must report any irregularities to the attending physician and the director of nursing, and these reports must be acted upon.

(d) *Labeling of drugs and biologicals.* Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(e) *Storage of drugs and biologicals.* (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

[56 FR 48875, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

§ 483.65 Infection control.

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

(a) *Infection control program.* The facility must establish an infection control program under which it—

(1) Investigates, controls, and prevents infections in the facility;

(2) Decides what procedures, such as isolation, should be applied to an individual resident; and

(3) Maintains a record of incidents and corrective actions related to infections.

(b) *Preventing spread of infection.* (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

(c) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

[56 FR 48876, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992]

§ 483.70 Physical environment.

The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

(a) *Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to long-term care facilities.

(2) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety ode which, if rigidly applied, would result in unreasonable hardship upon the facility, but only if the waiver does not adversely affect the health and safety of the patients.

(3) The provisions of the Life safety Code do not apply in a State where CMS finds, in accordance with applicable provisions of sections 1819(d)(2)(B)(ii) and 1919(d)(2)(B)(ii) of the Act, that a fire and safety code imposed by State law adequately protects patients, residents and personnel in long term care facilities.

(4) Beginning March 13, 2006, a long-term care facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

(5) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to long-term care facilities.

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a long-term care facility may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(7) A long-term care facility must:

(i) Install battery-operated smoke detectors in resident sleeping rooms and public areas by May 24, 2006.

(ii) Have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors.

(iii) Exception:

(A) The facility has a hard-wired AC smoke detection system in patient rooms and public areas that is installed, tested, and maintained in accordance with NFPA 72, *National Fire Alarm Code,* for hard-wired AC systems; or

(B) The facility has a sprinkler system throughout that is installed, tested, and maintained in accordance with NFPA 13, *Automatic Sprinklers.*

(b) *Emergency power.* (1) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted.

(2) When life support systems are used, the facility must provide emergency electrical power with an emergency generator (as defined in NFPA 99, Health Care Facilities) that is located on the premises.

(c) *Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, health services, recreation, and program areas to enable staff to provide residents with needed services as required by these standards and as identified in each resident's plan of care; and

(2) Maintain all essential mechanical, electrical, and patient care equipment in safe operating condition.

(d) *Resident rooms.* Resident rooms must be designed and equipped for adequate nursing care, comfort, and privacy of residents.

(1) Bedrooms must—

(i) Accommodate no more than four residents;

(ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;

(iii) Have direct access to an exit corridor;

(iv) Be designed or equipped to assure full visual privacy for each resident;

(v) In facilities initially certified after March 31, 1992, except in private rooms, each bed must have ceiling suspended curtains, which extend around the bed to provide total visual privacy in combination with adjacent walls and curtains;

(vi) Have at least one window to the outside; and

(vii) Have a floor at or above grade level.

(2) The facility must provide each resident with—

(i) A separate bed of proper size and height for the convenience of the resident;

(ii) A clean, comfortable mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the resident's needs, and individual closet space in the resident's bedroom with clothes racks and shelves accessible to the resident.

(3) CMS, or in the case of a nursing facility the survey agency, may permit

variations in requirements specified in paragraphs (d)(1) (i) and (ii) of this section relating to rooms in individual cases when the facility demonstrates in writing that the variations—

(i) Are in accordance with the special needs of the residents; and

(ii) Will not adversely affect residents' health and safety.

(e) *Toilet facilities.* Each resident room must be equipped with or located near toilet and bathing facilities.

(f) *Resident call system.* The nurse's station must be equipped to receive resident calls through a communication system from—

(1) Resident rooms; and

(2) Toilet and bathing facilities.

(g) *Dining and resident activities.* The facility must provide one or more rooms designated for resident dining and activities. These rooms must—

(1) Be well lighted;

(2) Be well ventilated, with nonsmoking areas identified;

(3) Be adequately furnished; and

(4) Have sufficient space to accommodate all activities.

(h) *Other environmental conditions.* The facility must provide a safe, functional, sanitary, and comfortable environment for the residents, staff and the public. The facility must—

(1) Establish procedures to ensure that water is available to essential areas when there is a loss of normal water supply;

(2) Have adequate outside ventilation by means of windows, or mechanical ventilation, or a combination of the two;

(3) Equip corridors with firmly secured handrails on each side; and

(4) Maintain an effective pest control program so that the facility is free of pests and rodents.

[56 FR 48876, Sept. 26, 1991, as amended at 57 FR 43925, Sept. 23, 1992; 68 FR 1386, Jan. 10, 2003; 69 FR 49268, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55340, Sept. 22, 2006, § 483.70 was amended by revising paragraph (a)(6)(iii), by removing the last sentence of paragraph (a)(6)(iv), by removing the period at the end of the paragraph (a)(6)(iv) and adding in its place ''; and'', by adding paragraph (a)(6)(v), and revising paragraph (a)(7), effective Oct. 23, 2006. For the convenience of the user, the added and revised text is set forth as follows:

§ 483.70 Physical environment.

(a) * * *

(6) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(7) A long term care facility must:

(i) Install, at least, battery-operated single station smoke alarms in accordance with the manufacturer's recommendations in resident sleeping rooms and common areas.

(ii) Have a program for inspection, testing, maintenance, and battery replacement that conforms to the manufacturer's recommendations and that verifies correct operation of the smoke alarms.

(iii) Exception:

(A) The facility has system-based smoke detectors in patient rooms and common areas that are installed, tested, and maintained in accordance with NFPA 72, *National Fire Alarm Code*, for system-based smoke detectors; or

(B) The facility is fully sprinklered in accordance with NFPA 13, *Standard for the Installation of Sprinkler Systems*.

* * * * *

§ 483.75 Administration.

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

(a) *Licensure.* A facility must be licensed under applicable State and local law.

(b) *Compliance with Federal, State, and local laws and professional standards.* The facility must operate and provide services in compliance with all applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility.

(c) *Relationship to other HHS regulations.* In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national

origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.

(d) *Governing body.* (1) The facility must have a governing body, or designated persons functioning as a governing body, that is legally responsible for establishing and implementing policies regarding the management and operation of the facility; and

(2) The governing body appoints the administrator who is—

(i) Licensed by the State where licensing is required; and

(ii) Responsible for management of the facility.

(e) *Required training of nursing aides*—(1) *Definitions.*

Licensed health professional means a physician; physician assistant; nurse practitioner; physical, speech, or occupational therapist; physical or occupational therapy assistant; registered professional nurse; licensed practical nurse; or licensed or certified social worker.

Nurse aide means any individual providing nursing or nursing-related services to residents in a facility who is not a licensed health professional, a registered dietitian, or someone who volunteers to provide such services without pay. Nurse aides do not include those individuals who furnish services to residents only as paid feeding assistants as defined in § 488.301 of this chapter.

(2) *General rule.* A facility must not use any individual working in the facility as a nurse aide for more than 4 months, on a full-time basis, unless:

(i) That individual is competent to provide nursing and nursing related services; and

(ii)(A) That individual has completed a training and competency evaluation program, or a competency evaluation program approved by the State as meeting the requirements of §§ 483.151–483.154 of this part; or

(B) That individual has been deemed or determined competent as provided in § 483.150 (a) and (b).

(3) *Non-permanent employees.* A facility must not use on a temporary, per diem, leased, or any basis other than a permanent employee any individual who does not meet the requirements in paragraphs (e)(2) (i) and (ii) of this section.

(4) *Competency.* A facility must not use any individual who has worked less than 4 months as a nurse aide in that facility unless the individual—

(i) Is a full-time employee in a State-approved training and competency evaluation program;

(ii) Has demonstrated competence through satisfactory participation in a State-approved nurse aide training and competency evaluation program or competency evaluation program; or

(iii) Has been deemed or determined competent as provided in § 483.150 (a) and (b).

(5) *Registry verification.* Before allowing an individual to serve as a nurse aide, a facility must receive registry verification that the individual has met competency evaluation requirements unless—

(i) The individual is a full-time employee in a training and competency evaluation program approved by the State; or

(ii) The individual can prove that he or she has recently successfully completed a training and competency evaluation program or competency evaluation program approved by the State and has not yet been included in the registry. Facilities must follow up to ensure that such an individual actually becomes registered.

(6) *Multi-State registry verification.* Before allowing an individual to serve as a nurse aide, a facility must seek information from every State registry established under sections 1819(e)(2)(A) or 1919(e)(2)(A) of the Act the facility believes will include information on the individual.

(7) *Required retraining.* If, since an individual's most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual provided nursing or nursing-related services for

monetary compensation, the individual must complete a new training and competency evaluation program or a new competency evaluation program.

(8) *Regular in-service education.* The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. The in-service training must—

(i) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year;

(ii) Address areas of weakness as determined in nurse aides' performance reviews and may address the special needs of residents as determined by the facility staff; and

(iii) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

(f) *Proficiency of Nurse aides.* The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

(g) *Staff qualifications.* (1) The facility must employ on a full-time, part-time or consultant basis those professionals necessary to carry out the provisions of these requirements.

(2) Professional staff must be licensed, certified, or registered in accordance with applicable State laws.

(h) *Use of outside resources.* (1) If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility under an arrangement described in section 1861(w) of the Act or (with respect to services furnished to NF residents and dental services furnished to SNF residents) an agreement described in paragraph (h)(2) of this section.

(2) Arrangements as described in section 1861(w) of the Act or agreements pertaining to services furnished by outside resources must specify in writing that the facility assumes responsibility for—

(i) Obtaining services that meet professional standards and principles that apply to professionals providing services in such a facility; and

(ii) The timeliness of the services.

(i) *Medical director.* (1) The facility must designate a physician to serve as medical director.

(2) The medical director is responsible for—

(i) Implementation of resident care policies; and

(ii) The coordination of medical care in the facility.

(j) Level B requirement: Laboratory services. (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

(2) The facility must—

(i) Provide or obtain laboratory services only when ordered by the attending physician;

(ii) Promptly notify the attending physican of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs asistance; and

(iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

(k) *Radiology and other diagnostic services.* (1) The facility must provide or obtain radiology and other diagnostic

services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own diagnostic services, the services must meet the applicable conditions of participation for hospitals contained in § 482.26 of this subchapter.

(ii) If the facility does not provide its own diagnostic services, it must have an agreement to obtain these services from a provider or supplier that is approved to provide these services under Medicare.

(2) The facility must—

(i) Provide or obtain radiology and other diagnostic services only when ordered by the attending physician;

(ii) Promptly notify the attending physician of the findings;

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance; and

(iv) File in the resident's clinical record signed and dated reports of x-ray and other diagnostic services.

(l) *Clinical records.* (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are—

(i) Complete;

(ii) Accurately documented;

(iii) Readily accessible; and

(iv) Systematically organized.

(2) Clinical records must be retained for—

(i) The period of time required by State law; or

(ii) Five years from the date of discharge when there is no requirement in State law; or

(iii) For a minor, three years after a resident reaches legal age under State law.

(3) The facility must safeguard clinical record information against loss, destruction, or unauthorized use;

(4) The facility must keep confidential all information contained in the resident's records, regardless of the form or storage method of the records, except when release is required by—

(i) Transfer to another health care institution;

(ii) Law;

(iii) Third party payment contract; or

(iv) The resident.

(5) The clinical record must contain—

(i) Sufficient information to identify the resident;

(ii) A record of the resident's assessments;

(iii) The plan of care and services provided;

(iv) The results of any preadmission screening conducted by the State; and

(v) Progress notes.

(m) *Disaster and emergency preparedness.* (1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

(2) The facility must train all employees in emergency procedures when they begin to work in the facility, periodically review the procedures with existing staff, and carry out unannounced staff drills using those procedures.

(n) *Transfer agreement.* (1) In accordance with section 1861(l) of the Act, the facility (other than a nursing facility which is located in a State on an Indian reservation) must have in effect a written transfer agreement with one or more hospitals approved for participation under the Medicare and Medicaid programs that reasonably assures that—

(i) Residents will be transferred from the facility to the hospital, and ensured of timely admission to the hospital when transfer is medically appropriate as determined by the attending physician; and

(ii) Medical and other information needed for care and treatment of residents, and, when the transferring facility deems it appropriate, for determining whether such residents can be adequately cared for in a less expensive setting than either the facility or the hospital, will be exchanged between the institutions.

(2) The facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.

(o) *Quality assessment and assurance.* (1) A facility must maintain a quality

assessment and assurance committee consisting of—

(i) The director of nursing services;

(ii) A physician designated by the facility; and

(iii) At least 3 other members of the facility's staff.

(2) The quality assessment and assurance committee—

(i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and

(ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A State or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

(p) *Disclosure of ownership.* (1) The facility must comply with the disclosure requirements of §§ 420.206 and 455.104 of this chapter.

(2) The facility must provide written notice to the State agency responsible for licensing the facility at the time of change, if a change occurs in—

(i) Persons with an ownership or control interest, as defined in §§ 420.201 and 455.101 of this chapter;

(ii) The officers, directors, agents, or managing employees;

(iii) The corporation, association, or other company responsible for the management of the facility; or

(iv) The facility's administrator or director of nursing.

(3) The notice specified in paragraph (p)(2) of this section must include the identity of each new individual or company.

(q) *Required training of feeding assistants.* A facility must not use any individual working in the facility as a paid feeding assistant unless that individual has successfully completed a State-approved training program for feeding assistants, as specified in § 483.160 of this part.

[56 FR 48877, Sept. 26, 1991, as amended at 56 FR 48918, Sept. 26, 1991; 57 FR 7136, Feb. 28, 1992; 57 FR 43925, Sept. 23, 1992; 59 FR 56237, Nov. 10, 1994; 63 FR 26311, May 12, 1998; 68 FR 55539, Sept. 26, 2003]

Subpart C—Preadmission Screening and Annual Review of Mentally Ill and Mentally Retarded Individuals

SOURCE: 57 FR 56506, Nov. 30, 1992, unless otherwise noted.

§ 483.100 Basis.

The requirements of §§ 483.100 through 483.138 governing the State's responsibility for preadmission screening and annual resident review (PASARR) of individuals with mental illness and mental retardation are based on section 1919(e)(7) of the Act.

§ 483.102 Applicability and definitions.

(a) This subpart applies to the screening or reviewing of all individuals with mental illness or mental retardation who apply to or reside in Medicaid certified NFs regardless of the source of payment for the NF services, and regardless of the individual's or resident's known diagnoses.

(b) *Definitions.* As used in this subpart—

(1) An individual is considered to have a serious mental illness (MI) if the individual meets the following requirements on diagnosis, level of impairment and duration of illness:

(i) *Diagnosis.* The individual has a major mental disorder diagnosable under the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987.

Incorporation of the 1987 edition of the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporation by reference.[1]

[1]The Diagnostic and Statistical Manual of Mental Disorders is available for inspection at the Centers for Medicare & Medicaid Services, room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland, or

This mental disorder is—

(A) A schizophrenic, mood, paranoid, panic or other severe anxiety disorder; somatoform disorder; personality disorder; other psychotic disorder; or another mental disorder that may lead to a chronic disability; but

(B) Not a primary diagnosis of dementia, including Alzheimer's disease or a related disorder, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.

(ii) *Level of impairment.* The disorder results in functional limitations in major life activities within the past 3 to 6 months that would be appropriate for the individual's developmental stage. An individual typically has at least one of the following characteristics on a continuing or intermittent basis:

(A) *Interpersonal functioning.* The individual has serious difficulty interacting appropriately and communicating effectively with other persons, has a possible history of altercations, evictions, firing, fear of strangers, avoidance of interpersonal relationships and social isolation;

(B) *Concentration, persistence, and pace.* The individual has serious difficulty in sustaining focused attention for a long enough period to permit the completion of tasks commonly found in work settings or in work-like structured activities occurring in school or home settings, manifests difficulties in concentration, inability to complete simple tasks within an established time period, makes frequent errors, or requires assistance in the completion of these tasks; and

(C) *Adaptation to change.* The individual has serious difficulty in adapting to typical changes in circumstances associated with work, school, family, or social interaction, manifests agitation, exacerbated signs and symptoms associated with the illness, or withdrawal from the situation, or requires intervention by the mental health or judicial system.

(iii) *Recent treatment.* The treatment history indicates that the individual has experienced at least one of the following:

(A) Psychiatric treatment more intensive than outpatient care more than once in the past 2 years (e.g., partial hospitalization or inpatient hospitalization); or

(B) Within the last 2 years, due to the mental disorder, experienced an episode of significant disruption to the normal living situation, for which supportive services were required to maintain functioning at home, or in a residential treatment environment, or which resulted in intervention by housing or law enforcement officials.

(2) An individual is considered to have dementia if he or she has a primary diagnosis of dementia, as described in the Diagnostic and Statistical Manual of Mental Disorders, 3rd edition, revised in 1987, or a non-primary diagnosis of dementia unless the primary diagnosis is a major mental disorder as defined in paragraph (b)(1)(i)(A) of this section.

(3) An individual is considered to have mental retardation (MR) if he or she has—

(i) A level of retardation (mild, moderate, severe or profound) described in the American Association on Mental Retardation's Manual on Classification in Mental Retardation (1983). Incorporation by reference of the 1983 edition of the American Association on Mental Retardation's Manual on Classification in Mental Retardation was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 that govern the use of incorporations by reference;[2] or

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at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. Copies may be obtained from the American Psychiatric Association, Division of Publications and Marketing, 1400 K Street, NW., Washington, DC 20005.

[2]The American Association on Mental Retardation's Manual on Classification in Mental Retardation is available for inspection at the Centers for Medicare & Medicaid Services, Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA,

Continued

(ii) A related condition as defined by § 435.1010 of this chapter.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993; 71 FR 39229, July 12, 2006]

§ 483.104 State plan requirement.

As a condition of approval of the State plan, the State must operate a preadmission screening and annual resident review program that meets the requirements of §§ 483.100 through 438.138.

§ 483.106 Basic rule.

(a) *Requirement.* The State PASARR program must require—(1) Preadmission screening of all individuals with mental illness or mental retardation who apply as new admissions to Medicaid NFs on or after January 1, 1989;

(2) Initial review, by April 1, 1990, of all current residents with mental retardation or mental illness who entered Medicaid NFs prior to January 1, 1989; and

(3) At least annual review, as of April 1, 1990, of all residents with mental illness or mental retardation, regardless of whether they were first screened under the preadmission screening or annual resident review requirements.

(b) *Admissions, readmissions and interfacility transfers*—(1) *New admission.* An individual is a new admission if he or she is admitted to any NF for the first time or does not qualify as a readmission. With the exception of certain hospital discharges described in paragraph (b)(2) of this section, new admissions are subject to preadmission screening.

(2) *Exempted hospital discharge.* (i) An exempted hospital discharge means an individual—

(A) Who is admitted to any NF directly from a hospital after receiving acute inpatient care at the hospital;

(B) Who requires NF services for the condition for which he or she received care in the hospital; and

(C) Whose attending physician has certified before admission to the facility that the individual is likely to require less than 30 days nursing facility services.

(ii) If an individual who enters a NF as an exempted hospital discharge is later found to require more than 30 days of NF care, the State mental health or mental retardation authority must conduct an annual resident review within 40 calendar days of admission.

(3) *Readmissions.* An individual is a readmission if he or she was readmitted to a facility from a hospital to which he or she was transferred for the purpose of receiving care. Readmissions are subject to annual resident review rather than preadmission screening.

(4) *Interfacility transfers*—(i) An interfacility transfer occurs when an individual is transferred from one NF to another NF, with or without an intervening hospital stay. Interfacility transfers are subject to annual resident review rather than preadmission screening.

(ii) In cases of transfer of a resident with MI or MR from a NF to a hospital or to another NF, the transferring NF is responsible for ensuring that copies of the resident's most recent PASARR and resident assessment reports accompany the transferring resident.

(c) *Purpose.* The preadmission screening and annual resident review process must result in determinations based on a physical and mental evaluation of each individual with mental illness or mental retardation, that are described in §§ 483.112 and 483.114.

(d) *Responsibility for evaluations and determinations.* The PASARR determinations of whether an individual requires the level of services provided by a NF and whether specialized services are needed—

(1) For individuals with mental illness, must be made by the State mental health authority and be based on an independent physical and mental evaluation performed by a person or entity other than the State mental health authority; and

(2) For individuals with mental retardation, must be made by the State

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call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the American Association on Mental Retardation, 1719 Kalorama Rd., NW., Washington, DC 20009.

mental retardation or developmental disabilities authority.

(e) *Delegation of responsibility*—(1) The State mental health and mental retardation authorities may delegate by subcontract or otherwise the evaluation and determination functions for which they are responsible to another entity only if—

(i) The State mental health and mental retardation authorities retain ultimate control and responsibility for the performance of their statutory obligations;

(ii) The two determinations as to the need for NF services and for specialized services are made, based on a consistent analysis of the data; and

(iii) The entity to which the delegation is made is not a NF or an entity that has a direct or indirect affiliation or relationship with a NF.

(2) The State mental retardation authority has responsibility for both the evaluation and determination functions for individuals with MR whereas the State mental health authority has responsibility only for the determination function.

(3) The evaluation of individuals with MI cannot be delegated by the State mental health authority because it does not have responsibility for this function. The evaluation function must be performed by a person or entity other than the State mental health authority. In designating an independent person or entity to perform MI evaluations, the State must not use a NF or an entity that has a direct or indirect affiliation or relationship with a NF.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.108 Relationship of PASARR to other Medicaid processes.

(a) PASARR determinations made by the State mental health or mental retardation authorities cannot be countermanded by the State Medicaid agency, either in the claims process or through other utilization control/review processes or by the State survey and certification agency. Only appeals determinations made through the system specified in subpart E of this part may overturn a PASARR determination made by the State mental health or mental retardation authorities.

(b) In making their determinations, however, the State mental health and mental retardation authorities must not use criteria relating to the need for NF care or specialized services that are inconsistent with this regulation and any supplementary criteria adopted by the State Medicaid agency under its approved State plan.

(c) To the maximum extent practicable, in order to avoid duplicative testing and effort, the PASARR must be coordinated with the routine resident assessments required by § 483.20(b).

§ 483.110 Out-of-State arrangements.

(a) *Basic rule.* The State in which the individual is a State resident (or would be a State resident at the time he or she becomes eligible for Medicaid), as defined in § 435.403 of this chapter, must pay for the PASARR and make the required determinations, in accordance with § 431.52(b).

(b) *Agreements.* A State may include arrangements for PASARR in its provider agreements with out-of-State facilities or reciprocal interstate agreements.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.112 Preadmission screening of applicants for admission to NFs.

(a) *Determination of need for NF services.* For each NF applicant with MI or MR, the State mental health or mental retardation authority (as appropriate) must determine, in accordance with § 483.130, whether, because of the resident's physical and mental condition, the individual requires the level of services provided by a NF.

(b) *Determination of need for specialized services.* If the individual with mental illness or mental retardation is determined to require a NF level of care, the State mental health or mental retardation authority (as appropriate) must also determine, in accordance with § 483.130, whether the individual requires specialized services for the mental illness or mental retardation, as defined in § 483.120.

(c) *Timeliness*—(1) Except as specified in paragraph (c)(4) of this section, a preadmission screening determination must be made in writing within an annual average of 7 to 9 working days of

referral of the individual with MI or MR by whatever agent performs the Level I identification, under § 483.128(a) of this part, to the State mental health or mental retardation authority for screening. (See § 483.128(a) for discussion of Level I evaluation.)

(2) The State may convey determinations verbally to nursing facilities and the individual and confirm them in writing.

(3) The State may compute separate annual averages for the mentally ill and the mentally retarded/developmentally disabled populations.

(4) The Secretary may grant an exception to the timeliness standard in paragraph (c)(1) of this section when the State—

(i) Exceeds the annual average; and

(ii) Provides justification satisfactory to the Secretary that a longer time period was necessary.

§ 483.114 Annual review of NF residents.

(a) *Individuals with mental illness.* For each resident of a NF who has mental illness, the State mental health authority must determine in accordance with § 483.130 whether, because of the resident's physical and mental condition, the resident requires—

(1) The level of services provided by—

(i) A NF;

(ii) An inpatient psychiatric hospital for individuals under age 21, as described in section 1905(h) of the Act; or

(iii) An institution for mental diseases providing medical assistance to individuals age 65 or older; and

(2) Specialized services for mental illness, as defined in § 483.120.

(b) *Individuals with mental retardation.* For each resident of a NF who has mental retardation, the State mental retardation or developmental disability authority must determine in accordance with § 483.130 whether, because of his or her physical or mental condition, the resident requires—

(1) The level of services provided by a NF or an intermediate care facility for the mentally retarded; and

(2) Specialized services for mental retardation as defined in § 483.120.

(c) *Frequency of review*—(1) A review and determination must be conducted for each resident of a Medicaid NF who has mental illness or mental retardation not less often than annually.

(2) ''Annually'' is defined as occurring within every fourth quarter after the previous preadmission screen or annual resident review.

(d) *April 1, 1990 deadline for initial reviews.* The first set of annual reviews on residents who entered the NF prior to January 1, 1989, must be completed by April 1, 1990.

§ 483.116 Residents and applicants determined to require NF level of services.

(a) *Individuals needing NF services.* If the State mental health or mental retardation authority determines that a resident or applicant for admission to a NF requires a NF level of services, the NF may admit or retain the individual.

(b) *Individuals needing NF services and specialized services.* If the State mental health or mental retardation authority determines that a resident or applicant for admission requires both a NF level of services and specialized services for the mental illness or mental retardation—

(1) The NF may admit or retain the individual; and

(2) The State must provide or arrange for the provision of the specialized services needed by the individual while he or she resides in the NF.

§ 483.118 Residents and applicants determined not to require NF level of services.

(a) *Applicants who do not require NF services.* If the State mental health or mental retardation authority determines that an applicant for admission to a NF does not require NF services, the applicant cannot be admitted. NF services are not a covered Medicaid service for that individual, and further screening is not required.

(b) *Residents who require neither NF services nor specialized services for MI or MR.* If the State mental health or mental retardation authority determines that a resident requires neither the level of services provided by a NF nor specialized services for MI or MR, regardless of the length of stay in the facility, the State must—

(1) Arrange for the safe and orderly discharge of the resident from the facility in accordance with § 483.12(a); and

(2) Prepare and orient the resident for discharge.

(c) *Residents who do not require NF services but require specialized services for MI or MR*—(1) *Long term residents.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, for any resident who has continuously resided in a NF for at least 30 months before the date of the determination, and who requires only specialized services as defined in § 483.120, the State must, in consultation with the resident's family or legal representative and caregivers—

(i) Offer the resident the choice of remaining in the facility or of receiving services in an alternative appropriate setting;

(ii) Inform the resident of the institutional and noninstitutional alternatives covered under the State Medicaid plan for the resident;

(iii) Clarify the effect on eligibility for Medicaid services under the State plan if the resident chooses to leave the facility, including its effect on readmission to the facility; and

(iv) Regardless of the resident's choice, provide for, or arrange for the provision of specialized services for the mental illness or mental retardation.

(2) *Short term residents.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, for any resident who requires only specialized services, as defined in § 483.120, and who has not continuously resided in a NF for at least 30 months before the date of the determination, the State must, in consultation with the resident's family or legal representative and caregivers—

(i) Arrange for the safe and orderly discharge of the resident from the facility in accordance with § 483.12(a);

(ii) Prepare and orient the resident for discharge; and

(iii) Provide for, or arrange for the provision of, specialized services for the mental illness or mental retardation.

(3) For the purpose of establishing length of stay in a NF, the 30 months of continuous residence in a NF or longer—

(i) Is calculated back from the date of the first annual resident review determination which finds that the individual is not in need of NF level of services;

(ii) May include temporary absences for hospitalization or therapeutic leave; and

(iii) May consist of consecutive residences in more than one NF.

§ 483.120 Specialized services.

(a) *Definition*—(1) For mental illness, specialized services means the services specified by the State which, combined with services provided by the NF, results in the continuous and aggressive implementation of an individualized plan of care that—

(i) Is developed and supervised by an interdisciplinary team, which includes a physician, qualified mental health professionals and, as appropriate, other professionals.

(ii) Prescribes specific therapies and activities for the treatment of persons experiencing an acute episode of serious mental illness, which necessitates supervision by trained mental health personnel; and

(iii) Is directed toward diagnosing and reducing the resident's behavioral symptoms that necessitated institutionalization, improving his or her level of independent functioning, and achieving a functioning level that permits reduction in the intensity of mental health services to below the level of specialized services at the earliest possible time.

(2) For mental retardation, specialized services means the services specified by the State which, combined with services provided by the NF or other service providers, results in treatment which meets the requirements of § 483.440(a)(1).

(b) *Who must receive specialized services.* The State must provide or arrange for the provision of specialized services, in accordance with this subpart, to all NF residents with MI or MR whose needs are such that continuous supervision, treatment and training by qualified mental health or mental retardation personnel is necessary, as

identified by the screening provided in § 483.130 or §§ 483.134 and 483.136.

(c) *Services of lesser intensity than specialized services.* The NF must provide mental health or mental retardation services which are of a lesser intensity than specialized services to all residents who need such services.

§ 483.122 FFP for NF services.

(a) *Basic rule.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, FFP is available in State expenditures for NF services provided to a Medicaid eligible individual subject to the requirements of this part only if the individual has been determined—

(1) To need NF care under § 483.116(a) or

(2) Not to need NF services but to need specialized services, meets the requirements of § 483.118(c)(1), and elects to stay in the NF.

(b) *FFP for late reviews.* When a preadmission screening has not been performed prior to admission or an annual review is not performed timely, in accordance with § 483.114(c), but either is performed at a later date, FFP is available only for services furnished after the screening or review has been performed, subject to the provisions of paragraph (a) of this section.

§ 483.124 FFP for specialized services.

FFP is not available for specialized services furnished to NF residents as NF services.

§ 483.126 Appropriate placement.

Placement of an individual with MI or MR in a NF may be considered appropriate only when the individual's needs are such that he or she meets the minimum standards for admission and the individual's needs for treatment do not exceed the level of services which can be delivered in the NF to which the individual is admitted either through NF services alone or, where necessary, through NF services supplemented by specialized services provided by or arranged for by the State.

§ 483.128 PASARR evaluation criteria.

(a) *Level I: Identification of individuals with MI or MR.* The State's PASARR program must identify all individuals who are suspected of having MI or MR as defined in § 483.102. This identification function is termed Level I. Level II is the function of evaluating and determining whether NF services and specialized services are needed. The State's performance of the Level I identification function must provide at least, in the case of first time identifications, for the issuance of written notice to the individual or resident and his or her legal representative that the individual or resident is suspected of having MI or MR and is being referred to the State mental health or mental retardation authority for Level II screening.

(b) *Adaptation to culture, language, ethnic origin.* Evaluations performed under PASARR and PASARR notices must be adapted to the cultural background, language, ethnic origin and means of communication used by the individual being evaluated.

(c) *Participation by individual and family.* PASARR evaluations must involve—

(1) The individual being evaluated;

(2) The individual's legal representative, if one has been designated under State law; and

(3) The individual's family if—

(i) Available; and

(ii) The individual or the legal representative agrees to family participation.

(d) *Interdisciplinary coordination.* When parts of a PASARR evaluation are performed by more than one evaluator, the State must ensure that there is interdisciplinary coordination among the evaluators.

(e) The State's PASARR program must use at least the evaluative criteria of § 483.130 (if one or both determinations can easily be made categorically as described in § 483.130) or of §§ 483.132 and 483.134 or § 483.136 (or, in the case of individuals with both MI and MR, §§ 483.132, 483.134 and 483.136 if a more extensive individualized evaluation is required).

(f) *Data.* In the case of individualized evaluations, information that is necessary for determining whether it is appropriate for the individual with MI or MR to be placed in an NF or in another appropriate setting should be

gathered throughout all applicable portions of the PASARR evaluation (§§483.132 and 483.134 and/or §483.136). The two determinations relating to the need for NF level of care and specialized services are interrelated and must be based upon a comprehensive analysis of all data concerning the individual.

(g) *Preexisting data.* Evaluators may use relevant evaluative data, obtained prior to initiation of preadmission screening or annual resident review, if the data are considered valid and accurate and reflect the current functional status of the individual. However, in the case of individualized evaluations, to supplement and verify the currency and accuracy of existing data, the State's PASARR program may need to gather additional information necessary to assess proper placement and treatment.

(h) *Findings.* For both categorical and individualized determinations, findings of the evaluation must correspond to the person's current functional status as documented in medical and social history records.

(i) *Evaluation report: Individualized determinations.* For individualized PASARR determinations, findings must be issued in the form of a written evaluative report which—

(1) Identifies the name and professional title of person(s) who performed the evaluation(s) and the date on which each portion of the evaluation was administered;

(2) Provides a summary of the medical and social history, including the positive traits or developmental strengths and weaknesses or developmental needs of the evaluated individual;

(3) If NF services are recommended, identifies the specific services which are required to meet the evaluated individual's needs, including services required in paragraph (i)(5) of this section;

(4) If specialized services are not recommended, identifies any specific mental retardation or mental health services which are of a lesser intensity than specialized services that are required to meet the evaluated individual's needs;

(5) If specialized services are recommended, identifies the specific mental retardation or mental health services required to meet the evaluated individual's needs; and

(6) Includes the bases for the report's conclusions.

(j) *Evaluation report: Categorical determinations.* For categorical PASARR determinations, findings must be issued in the form of an abbreviated written evaluative report which—

(1) Identifies the name and professional title of the person applying the categorical determination and the data on which the application was made;

(2) Explains the categorical determination(s) that has (have) been made and, if only one of the two required determinations can be made categorically, describes the nature of any further screening which is required;

(3) Identifies, to the extent possible, based on the available data, NF services, including any mental health or specialized psychiatric rehabilitative services, that may be needed; and

(4) Includes the bases for the report's conclusions.

(k) *Interpretation of findings to individual.* For both categorical and individualized determinations, findings of the evaluation must be interpreted and explained to the individual and, where applicable, to a legal representative designated under State law.

(l) *Evaluation report.* The evaluator must send a copy of the evaluation report to the—

(1) Individual or resident and his or her legal representative;

(2) Appropriate State authority in sufficient time for the State authorities to meet the times identified in §483.112(c) for PASs and §483.114(c) for ARRs;

(3) Admitting or retaining NF;

(4) Individual's attending physician; and

(5) The discharging hospital if the individual is seeking NF admission from a hospital.

(m) The evaluation may be terminated if the evaluator finds at any time during the evaluation that the individual being evaluated—

(1) Does not have MI or MR; or

(2) Has—

(i) A primary diagnosis of dementia (including Alzheimer's Disease or a related disorder); or

(ii) A non-primary diagnosis of dementia without a primary diagnosis that is a serious mental illness, and does not have a diagnosis of MR or a related condition.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.130 PASARR determination criteria.

(a) *Basis for determinations.* Determinations made by the State mental health or mental retardation authority as to whether NF level of services and specialized services are needed must be based on an evaluation of data concerning the individual, as specified in paragraph (b) of this section.

(b) *Types of determinations.* Determinations may be—

(1) Advance group determinations, in accordance with this section, by category that take into account that certain diagnoses, levels of severity of illness, or need for a particular service clearly indicate that admission to or residence in a NF is normally needed, or that the provision of specialized services is not normally needed; or

(2) Individualized determinations based on more extensive individualized evaluations as required in § 483.132, § 483.134, or § 483.136 (or, in the case of an individual having both MR and MI, §§ 483.134 and 483.136).

(c) *Group determinations by category.* Advance group determinations by category developed by the State mental health or mental retardation authorities may be made applicable to individuals by the NF or other evaluator following Level I review only if existing data on the individual appear to be current and accurate and are sufficient to allow the evaluator readily to determine that the individual fits into the category established by the State authorities (see § 483.132(c)). Sources of existing data on the individual that could form the basis for applying a categorical determination by the State authorities would be hospital records, physician's evaluations, election of hospice status, records of community mental health centers or community mental retardation or developmental disability providers.

(d) *Examples of categories.* Examples of categories for which the State mental health or mental retardation authority may make an advance group determination that NF services are needed are—

(1) Convalescent care from an acute physical illness which—

(i) Required hospitalization; and

(ii) Does not meet all the criteria for an exempt hospital discharge, which is not subject to preadmission screening, as specified in § 483.106(b)(2).

(2) Terminal illness, as defined for hospice purposes in § 418.3 of this chapter;

(3) Severe physical illnesses such as coma, ventilator dependence, functioning at a brain stem level, or diagnoses such as chronic obstructive pulmonary disease, Parkinson's disease, Huntington's disease, amyotrophic lateral sclerosis, and congestive heart failure which result in a level of impairment so severe that the individual could not be expected to benefit from specialized services;

(4) Provisional admissions pending further assessment in cases of delirium where an accurate diagnosis cannot be made until the delirium clears;

(5) Provisional admissions pending further assessment in emergency situations requiring protective services, with placement in a nursing facility not to exceed 7 days; and

(6) Very brief and finite stays of up to a fixed number of days to provide respite to in-home caregivers to whom the individual with MI or MR is expected to return following the brief NF stay.

(e) *Time limits.* The State may specify time limits for categorical determinations that NF services are needed and in the case of paragraphs (d)(4), (5) and (6) of this section, must specify a time limit which is appropriate for provisional admissions pending further assessment and for emergency situations and respite care. If an individual is later determined to need a longer stay than the State's limit allows, the individual must be subjected to an annual resident review before continuation of the stay may be permitted and payment made for days of NF care beyond the State's time limit.

(f) The State mental health and mental retardation authorities may make categorical determinations that specialized services are not needed in the provisional, emergency and respite admission situations identified in §483.130(d)(4)–(6). In all other cases, except for §483.130(h), a determination that specialized services are not needed must be based on a more extensive individualized evaluation under §483.134 or §483.136.

(g) *Categorical determinations: No positive specialized treatment determinations.* The State mental health and mental retardation authorities must not make categorical determinations that specialized services are needed. Such a determination must be based on a more extensive individualized evaluation under §483.134 or §483.136 to determine the exact nature of the specialized services that are needed.

(h) *Categorical determinations: Dementia and MR.* The State mental retardation authority may make categorical determinations that individuals with dementia, which exists in combination with mental retardation or a related condition, do not need specialized services.

(i) If a State mental health or mental retardation authority determines NF needs by category, it may not waive the specialized services determination. The appropriate State authority must also determine whether specialized services are needed either by category (if permitted) or by individualized evaluations, as specified in §483.134 or §483.136.

(j) *Recording determinations.* All determinations made by the State mental health and mental retardation authority, regardless of how they are arrived at, must be recorded in the individual's record.

(k) *Notice of determination.* The State mental health or mental retardation authority must notify in writing the following entities of a determination made under this subpart:

(1) The evaluated individual and his or her legal representative;

(2) The admitting or retaining NF;

(3) The individual or resident's attending physician; and

(4) The discharging hospital, unless the individual is exempt from preadmission screening as provided for at §483.106(b)(2).

(l) *Contents of notice.* Each notice of the determination made by the State mental health or mental retardation authority must include—

(1) Whether a NF level of services is needed;

(2) Whether specialized services are needed;

(3) The placement options that are available to the individual consistent with these determinations; and

(4) The rights of the individual to appeal the determination under subpart E of this part.

(m) *Placement options.* Except as otherwise may be provided in an alternative disposition plan adopted under section 1919(e)(7)(E) of the Act, the placement options and the required State actions are as follows:

(1) *Can be admitted to a NF.* Any applicant for admission to a NF who has MI or MR and who requires the level of services provided by a NF, regardless of whether specialized services are also needed, may be admitted to a NF, if the placement is appropriate, as determined in §483.126. If specialized services are also needed, the State is responsible for providing or arranging for the provision of the specialized services.

(2) *Cannot be admitted to a NF.* Any applicant for admission to a NF who has MI or MR and who does not require the level of services provided by a NF, regardless of whether specialized services are also needed, is inappropriate for NF placement and must not be admitted.

(3) *Can be considered appropriate for continued placement in a NF.* Any NF resident with MI or MR who requires the level of services provided by a NF, regardless of the length of his or her stay or the need for specialized services, can continue to reside in the NF, if the placement is appropriate, as determined in §483.126.

(4) *May choose to remain in the NF even though the placement would otherwise be inappropriate.* Any NF resident with MI or MR who does not require the level of services provided by a NF but does require specialized services and who has continuously resided in a NF for at least 30 consecutive months

before the date of determination may choose to continue to reside in the facility or to receive covered services in an alternative appropriate institutional or noninstitutional setting. Wherever the resident chooses to reside, the State must meet his or her specialized services needs. The determination notice must provide information concerning how, when, and by whom the various placement options available to the resident will be fully explained to the resident.

(5) *Cannot be considered appropriate for continued placement in a NF and must be discharged (short-term residents).* Any NF resident with MI or MR who does not require the level of services provided by a NF but does require specialized services and who has resided in a NF for less than 30 consecutive months must be discharged in accordance with §483.12(a) to an appropriate setting where the State must provide specialized services. The determination notice must provide information on how, when, and by whom the resident will be advised of discharge arrangements and of his/her appeal rights under both PASARR and discharge provisions.

(6) *Cannot be considered appropriate for continued placement in a NF and must be discharged (short or long-term residents).* Any NF resident with MI or MR who does not require the level of services provided by a NF and does not require specialized services regardless of his or her length of stay, must be discharged in accordance with §483.12(a). The determination notice must provide information on how, when, and by whom the resident will be advised of discharge arrangements and of his or her appeal rights under both PASARR and discharge provisions.

(n) *Specialized services needed in a NF.* If a determination is made to admit or allow to remain in a NF any individual who requires specialized services, the determination must be supported by assurances that the specialized services that are needed can and will be provided or arranged for by the State while the individual resides in the NF.

(o) *Record retention.* The State PASARR system must maintain records of evaluations and determinations, regardless of whether they are performed categorically or individually, in order to support its determinations and actions and to protect the appeal rights of individuals subjected to PASARR; and

(p) *Tracking system.* The State PASARR system must establish and maintain a tracking system for all individuals with MI or MR in NFs to ensure that appeals and future reviews are performed in accordance with this subpart and subpart E.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.132 Evaluating the need for NF services and NF level of care (PASARR/NF).

(a) *Basic rule.* For each applicant for admission to a NF and each NF resident who has MI or MR, the evaluator must assess whether—

(1) The individual's total needs are such that his or her needs can be met in an appropriate community setting;

(2) The individual's total needs are such that they can be met only on an inpatient basis, which may include the option of placement in a home and community-based services waiver program, but for which the inpatient care would be required;

(3) If inpatient care is appropriate and desired, the NF is an appropriate institutional setting for meeting those needs in accordance with §483.126; or

(4) If the inpatient care is appropriate and desired but the NF is not the appropriate setting for meeting the individual's needs in accordance with §483.126, another setting such as an ICF/MR (including small, community-based facilities), an IMD providing services to individuals aged 65 or older, or a psychiatric hospital is an appropriate institutional setting for meeting those needs.

(b) *Determining appropriate placement.* In determining appropriate placement, the evaluator must prioritize the physical and mental needs of the individual being evaluated, taking into account the severity of each condition.

(c) *Data.* At a minimum, the data relied on to make a determination must include:

(1) Evaluation of physical status (for example, diagnoses, date of onset, medical history, and prognosis);

(2) Evaluation of mental status (for example, diagnoses, date of onset, medical history, likelihood that the individual may be a danger to himself/herself or others); and

(3) Functional assessment (activities of daily living).

(d) Based on the data compiled in § 483.132 and, as appropriate, in §§ 483.134 and 483.136, the State mental health or mental retardation authority must determine whether an NF level of services is needed.

§ 483.134 Evaluating whether an individual with mental illness requires specialized services (PASARR/MI).

(a) *Purpose.* The purpose of this section is to identify the minimum data needs and process requirements for the State mental health authority, which is responsible for determining whether or not the applicant or resident with MI, as defined in § 483.102(b)(1) of this part, needs a specialized services program for mental illness as defined in § 483.120.

(b) *Data.* Minimum data collected must include—(1) A comprehensive history and physical examination of the person. The following areas must be included (if not previously addressed):

(i) Complete medical history;

(ii) Review of all body systems;

(iii) Specific evaluation of the person's neurological system in the areas of motor functioning, sensory functioning, gait, deep tendon reflexes, cranial nerves, and abnormal reflexes; and

(iv) In case of abnormal findings which are the basis for an NF placement, additional evaluations conducted by appropriate specialists.

(2) A comprehensive drug history including current or immediate past use of medications that could mask symptoms or mimic mental illness.

(3) A psychosocial evaluation of the person, including current living arrangements and medical and support systems.

(4) A comprehensive psychiatric evaluation including a complete psychiatric history, evaluation of intellectual functioning, memory functioning, and orientation, description of current attitudes and overt behaviors, affect, suicidal or homicidal ideation, paranoia, and degree of reality testing (presence and content of delusions) and hallucinations.

(5) A functional assessment of the individual's ability to engage in activities of daily living and the level of support that would be needed to assist the individual to perform these activities while living in the community. The assessment must determine whether this level of support can be provided to the individual in an alternative community setting or whether the level of support needed is such that NF placement is required.

(6) The functional assessment must address the following areas: Self-monitoring of health status, self-administering and scheduling of medical treatment, including medication compliance, or both, self-monitoring of nutritional status, handling money, dressing appropriately, and grooming.

(c) *Personnel requirements.* (1) If the history and physical examination are not performed by a physician, then a physician must review and concur with the conclusions.

(2) The State may designate the mental health professionals who are qualified—

(i) To perform the evaluations required under paragraph (b) (2)–(6) of this section including the—

(A) Comprehensive drug history;

(B) Psychosocial evaluation;

(C) Comprehensive psychiatric evaluation;

(D) Functional assessment; and

(ii) To make the determination required in paragraph (d) of this section.

(d) *Data interpretation.* Based on the data compiled, a qualified mental health professional, as designated by the State, must validate the diagnosis of mental illness and determine whether a program of psychiatric specialized services is needed.

§ 483.136 Evaluating whether an individual with mental retardation requires specialized services (PASARR/MR).

(a) *Purpose.* The purpose of this section is to identify the minimum data needs and process requirements for the State mental retardation authority to determine whether or not the applicant or resident with mental retardation, as defined in § 483.102(b)(3) of this part, needs a continuous specialized services

program, which is analogous to active treatment, as defined in § 435.1010 of this chapter and § 483.440.

(b) *Data.* Minimum data collected must include the individual's comprehensive history and physical examination results to identify the following information or, in the absence of data, must include information that permits a reviewer specifically to assess:

(1) The individual's medical problems;

(2) The level of impact these problems have on the individual's independent functioning;

(3) All current medications used by the individual and the current response of the individual to any prescribed medications in the following drug groups:

(i) Hypnotics,

(ii) Antipsychotics (neuroleptics),

(iii) Mood stabilizers and antidepressants,

(iv) Antianxiety-sedative agents, and

(v) Anti-Parkinson agents.

(4) Self-monitoring of health status;

(5) Self-administering and scheduling of medical treatments;

(6) Self-monitoring of nutritional status;

(7) Self-help development such as toileting, dressing, grooming, and eating;

(8) Sensorimotor development, such as ambulation, positioning, transfer skills, gross motor dexterity, visual motor perception, fine motor dexterity, eye-hand coordination, and extent to which prosthetic, orthotic, corrective or mechanical supportive devices can improve the individual's functional capacity;

(9) Speech and language (communication) development, such as expressive language (verbal and nonverbal), receptive language (verbal and nonverbal), extent to which non-oral communication systems can improve the individual's function capacity, auditory functioning, and extent to which amplification devices (for example, hearing aid) or a program of amplification can improve the individual's functional capacity;

(10) Social development, such as interpersonal skills, recreation-leisure skills, and relationships with others;

(11) Academic/educational development, including functional learning skills;

(12) Independent living development such as meal preparation, budgeting and personal finances, survival skills, mobility skills (orientation to the neighborhood, town, city), laundry, housekeeping, shopping, bedmaking, care of clothing, and orientation skills (for individuals with visual impairments);

(13) Vocational development, including present vocational skills;

(14) Affective development such as interests, and skills involved with expressing emotions, making judgments, and making independent decisions; and

(15) The presence of identifiable maladaptive or inappropriate behaviors of the individual based on systematic observation (including, but not limited to, the frequency and intensity of identified maladaptive or inappropriate behaviors).

(c) *Data interpretation*—(1) The State must ensure that a licensed psychologist identifies the intellectual functioning measurement of individuals with MR or a related condition.

(2) Based on the data compiled in paragraph (b) of this section, the State mental retardation authority, using appropriate personnel, as designated by the State, must validate that the individual has MR or is a person with a related condition and must determine whether specialized services for mental retardation are needed. In making this determination, the State mental retardation authority must make a qualitative judgment on the extent to which the person's status reflects, singly and collectively, the characteristics commonly associated with the need for specialized services, including—

(i) Inability to—

(A) Take care of the most personal care needs;

(B) Understand simple commands;

(C) Communicate basic needs and wants;

(D) Be employed at a productive wage level without systematic long term supervision or support;

(E) Learn new skills without aggressive and consistent training;

(F) Apply skills learned in a training situation to other environments or settings without aggressive and consistent training;

(G) Demonstrate behavior appropriate to the time, situation or place without direct supervision; and

(H) Make decisions requiring informed consent without extreme difficulty;

(ii) Demonstration of severe maladaptive behavior(s) that place the person or others in jeopardy to health and safety; and

(iii) Presence of other skill deficits or specialized training needs that necessitate the availability of trained MR personnel, 24 hours per day, to teach the person functional skills.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993, as amended at 71 FR 39229, July 12, 2006]

§ 483.138 Maintenance of services and availability of FFP.

(a) *Maintenance of services.* If a NF mails a 30 day notice of its intent to transfer or discharge a resident, under § 483.12(a) of this chapter, the agency may not terminate or reduce services until—

(1) The expiration of the notice period; or

(2) A subpart E appeal, if one has been filed, has been resolved.

(b) *Availability of FFP.* FFP is available for expenditures for services provided to Medicaid recipients during—

(1) The 30 day notice period specified in § 483.12(a) of this chapter; or

(2) During the period an appeal is in progress.

Subpart D—Requirements That Must Be Met by States and State Agencies: Nurse Aide Training and Competency Evaluation, and Paid Feeding Assistants

SOURCE: 56 FR 48919, Sept. 26, 1991, unless otherwise noted.

§ 483.150 Statutory basis; Deemed meeting or waiver of requirements.

(a) *Statutory basis.* This subpart is based on sections 1819(b)(5) and 1919(b)(5) of the Act, which establish standards for training nurse-aides and for evaluating their competency.

(b) *Deemed meeting of requirements.* A nurse aide is deemed to satisfy the requirement of completing a training and competency evaluation approved by the State if he or she successfully completed a training and competency evaluation program before July 1, 1989 if—

(1) The aide would have satisfied this requirement if—

(i) At least 60 hours were substituted for 75 hours in sections 1819(f)(2) and 1919(f)(2) of the Act, and

(ii) The individual has made up at least the difference in the number of hours in the program he or she completed and 75 hours in supervised practical nurse aide training or in regular in-service nurse aide education;

or

(2) The individual was found to be competent (whether or not by the State) after the completion of nurse aide training of at least 100 hours duration.

(c) *Waiver of requirements.* A State may—

(1) Waive the requirement for an individual to complete a competency evaluation program approved by the State for any individual who can demonstrate to the satisfaction of the State that he or she has served as a nurse aide at one or more facilities of the same employer in the state for at least 24 consecutive months before December 19, 1989; or

(2) Deem an individual to have completed a nurse aide training and competency evaluation program approved by the State if the individual completed, before July 1, 1989, such a program that the State determines would have met the requirements for approval at the time it was offered.

[56 FR 48919, Sept. 26, 1991; 56 FR 59331, Nov. 25, 1991, as amended at 60 FR 50443, Sept. 29, 1995]

§ 483.151 State review and approval of nurse aide training and competency evaluation programs and competency evaluation programs.

(a) *State review and administration.* (1) The State—

(i) Must specify any nurse aide training and competency evaluation programs that the State approves as meeting the requirements of § 483.152 and/or competency evaluations programs that the State approves as meeting the requirements of § 483.154; and

(ii) May choose to offer a nurse aide training and competency evaluation program that meets the requirements of § 483.152 and/or a competency evaluation program that meets the requirements of § 483.154.

(2) If the State does not choose to offer a nurse aide training and competency evaluation program or competency evaluation program, the State must review and approve or disapprove nurse aide training and competency evaluation programs and nurse aide competency evaluation programs upon request.

(3) The State survey agency must in the course of all surveys, determine whether the nurse aide training and competency evaluation requirements of § 483.75(e) are met.

(b) *Requirements for approval of programs.* (1) Before the State approves a nurse aide training and competency evaluation program or competency evaluation program, the State must—

(i) Determine whether the nurse aide training and competency evaluation program meets the course requirements of §§ 483.152:

(ii) Determine whether the nurse aide competency evaluation program meets the requirements of § 483.154; and

(iii) In all reviews other than the initial review, visit the entity providing the program.

(2) The State may not approve a nurse aide training and competency evaluation program or competency evaluation program offered by or in a facility which, in the previous two years—

(i) In the case of a skilled nursing facility, has operated under a waiver under section 1819(b)(4)(C)(ii)(II) of the Act;

(ii) In the case of a nursing facility, has operated under a waiver under section 1919(b)(4)(C)(ii) of the Act that was granted on the basis of a demonstration that the facility is unable to provide nursing care required under section 1919(b)(4)(C)(i) of the Act for a period in excess of 48 hours per week;

(iii) Has been subject to an extended (or partial extended) survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act;

(iv) Has been assessed a civil money penalty described in section 1819(h)(2)(B)(ii) of 1919(h)(2)(A)(ii) of the Act of not less than $5,000; or

(v) Has been subject to a remedy described in sections 1819(h)(2)(B) (i) or (iii), 1819(h)(4), 1919(h)(1)(B)(i), or 1919(h)(2)(A) (i), (iii) or (iv) of the Act.

(3) A State may not, until two years since the assessment of the penalty (or penalties) has elapsed, approve a nurse aide training and competency evaluation program or competency evaluation program offered by or in a facility that, within the two-year period beginning October 1, 1988—

(i) Had its participation terminated under title XVIII of the Act or under the State plan under title XIX of the Act;

(ii) Was subject to a denial of payment under title XVIII or title XIX;

(iii) Was assessed a civil money penalty of not less than $5,000 for deficiencies in nursing facility standards;

(iv) Operated under temporary management appointed to oversee the operation of the facility and to ensure the health and safety of its residents; or

(v) Pursuant to State action, was closed or had its residents transferred.

(c) *Time frame for acting on a request for approval.* The State must, within 90 days of the date of a request under paragraph (a)(3) of this section or receipt of additional information from the requester—

(1) Advise the requester whether or not the program has been approved; or

(2) Request additional information form the requesting entity.

(d) *Duration of approval.* The State may not grant approval of a nurse aide training and competency evaluation program for a period longer than 2 years. A program must notify the State and the State must review that program when there are substantive changes made to that program within the 2-year period.

(e) *Withdrawal of approval.* (1) The State must withdraw approval of a nurse aide training and competency

evaluation program or nurse aide competency evaluation program offered by or in a facility described in paragraph (b)(2) of this section.

(2) The State may withdraw approval of a nurse aide training and competency evaluation program or nurse aide competency evaluation program if the State determines that any of the applicable requirements of §§ 483.152 or 483.154 are not met by the program.

(3) The State must withdraw approval of a nurse aide training and competency evaluation program or a nurse aide competency evaluation program if the entity providing the program refuses to permit unannounced visits by the State.

(4) If a State withdraws approval of a nurse aide training and competency evaluation program or competency evaluation program—

(i) The State must notify the program in writing, indicating the reason(s) for withdrawal of approval of the program.

(ii) Students who have started a training and competency evaluation program from which approval has been withdrawn must be allowed to complete the course.

§ 483.152 Requirements for approval of a nurse aide training and competency evaluation program.

(a) For a nurse aide training and competency evaluation program to be approved by the State, it must, at a minimum—

(1) Consist of no less than 75 clock hours of training;

(2) Include at least the subjects specified in paragraph (b) of this section;

(3) Include at least 16 hours of supervised practical training. *Supervised practical training* means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or a licensed practical nurse;

(4) Ensure that—

(i) Students do not perform any services for which they have not trained and been found proficient by the instructor; and

(ii) Students who are providing services to residents are under the general supervision of a licensed nurse or a registered nurse;

(5) Meet the following requirements for instructors who train nurse aides;

(i) The training of nurse aides must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of long term care facility services;

(ii) Instructors must have completed a course in teaching adults or have experience in teaching adults or supervising nurse aides;

(iii) In a facility-based program, the training of nurse aides may be performed under the general supervision of the director of nursing for the facility who is prohibited from performing the actual training; and

(iv) Other personnel from the health professions may supplement the instructor, including, but not limited to, registered nurses, licensed practical/vocational nurses, pharmacists, dietitians, social workers, sanitarians, fire safety experts, nursing home administrators, gerontologists, psychologists, physical and occupational therapists, activities specialists, speech/language/hearing therapists, and resident rights experts. Supplemental personnel must have at least 1 year of experience in their fields;

(6) Contain competency evaluation procedures specified in § 483.154.

(b) The curriculum of the nurse aide training program must include—

(1) At least a total of 16 hours of training in the following areas prior to any direct contact with a resident:

(i) Communication and interpersonal skills;

(ii) Infection control;

(iii) Safety/emergency procedures, including the Heimlich maneuver;

(iv) Promoting residents' independence; and

(v) Respecting residents' rights.

(2) Basic nursing skills;

(i) Taking and recording vital signs;

(ii) Measuring and recording height and weight;

(iii) Caring for the residents' environment;

(iv) Recognizing abnormal changes in body functioning and the importance of

reporting such changes to a supervisor; and

(v) Caring for residents when death is imminent.

(3) Personal care skills, including, but not limited to—

(i) Bathing;

(ii) Grooming, including mouth care;

(iii) Dressing;

(iv) Toileting;

(v) Assisting with eating and hydration;

(vi) Proper feeding techniques;

(vii) Skin care; and

(viii) Transfers, positioning, and turning.

(4) Mental health and social service needs:

(i) Modifying aide's behavior in response to residents' behavior;

(ii) Awareness of developmental tasks associated with the aging process;

(iii) How to respond to resident behavior;

(iv) Allowing the resident to make personal choices, providing and reinforcing other behavior consistent with the resident's dignity; and

(v) Using the resident's family as a source of emotional support.

(5) Care of cognitively impaired residents:

(i) Techniques for addressing the unique needs and behaviors of individual with dementia (Alzheimer's and others);

(ii) Communicating with cognitively impaired residents;

(iii) Understanding the behavior of cognitively impaired residents;

(iv) Appropriate responses to the behavior of cognitively impaired residents; and

(v) Methods of reducing the effects of cognitive impairments.

(6) Basic restorative services:

(i) Training the resident in self care according to the resident's abilities;

(ii) Use of assistive devices in transferring, ambulation, eating, and dressing;

(iii) Maintenance of range of motion;

(iv) Proper turning and positioning in bed and chair;

(v) Bowel and bladder training; and

(vi) Care and use of prosthetic and orthotic devices.

(7) Residents' Rights.

(i) Providing privacy and maintenance of confidentiality;

(ii) Promoting the residents' right to make personal choices to accommodate their needs;

(iii) Giving assistance in resolving grievances and disputes;

(iv) Providing needed assistance in getting to and participating in resident and family groups and other activities;

(v) Maintaining care and security of residents' personal possessions;

(vi) Promoting the resident's right to be free from abuse, mistreatment, and neglect and the need to report any instances of such treatment to appropriate facility staff;

(vii) Avoiding the need for restraints in accordance with current professional standards.

(c) Prohibition of charges. (1) No nurse aide who is employed by, or who has received an offer of employment from, a facility on the date on which the aide begins a nurse aide training and competency evaluation program may be charged for any portion of the program (including any fees for textbooks or other required course materials).

(2) If an individual who is not employed, or does not have an offer to be employed, as a nurse aide becomes employed by, or receives an offer of employment from, a facility not later than 12 months after completing a nurse aide training and competency evaluation program, the State must provide for the reimbursement of costs incurred in completing the program on a pro rata basis during the period in which the individual is employed as a nurse aide.

§ 483.154 Nurse aide competency evaluation.

(a) *Notification to Individual.* The State must advise in advance any individual who takes the competency evaluation that a record of the successful completion of the evaluation will be included in the State's nurse aid registry.

(b) *Content of the competency evaluation program*—(1) *Written or oral examinations.* The competency evaluation must—

(i) Allow an aide to choose between a written and an oral examination;

(ii) Address each course requirement specified in § 483.152(b);

(iii) Be developed from a pool of test questions, only a portion of which is used in any one examination;

(iv) Use a system that prevents disclosure of both the pool of questions and the individual competency evaluations; and

(v) If oral, must be read from a prepared text in a neutral manner.

(2) *Demonstration of skills.* The skills demonstration must consist of a demonstration of randomly selected items drawn from a pool consisting of the tasks generally performed by nurse aides. This pool of skills must include all of the personal care skills listed in § 483.152(b)(3).

(c) *Administration of the competency evaluation.* (1) The competency examination must be administered and evaluated only by—

(i) The State directly; or

(ii) A State approved entity which is neither a skilled nursing facility that participates in Medicare nor a nursing facility that participates in Medicaid.

(2) No nurse aide who is employed by, or who has received an offer of employment from, a facility on the date on which the aide begins a nurse aide competency evaluation program may be charged for any portion of the program.

(3) If an individual who is not employed, or does not have an offer to be employed, as a nurse aide becomes employed by, or receives an offer of employment from, a facility not later than 12 months after completing a nurse aide competency evaluation program, the State must provide for the reimbursement of costs incurred in completing the program on a pro rata basis during the period in which the individual is employed as a nurse aide.

(4) The skills demonstration part of the evaluation must be—

(i) Performed in a facility or laboratory setting comparable to the setting in which the individual will function as a nurse aide; and

(ii) Administered and evaluated by a registered nurse with at least one year's experience in providing care for the elderly or the chronically ill of any age.

(d) *Facility proctoring of the competency evaluation.* (1) The competency evaluation may, at the nurse aide's option, be conducted at the facility in which the nurse aide is or will be employed unless the facility is described in § 483.151(b)(2).

(2) The State may permit the competency evaluation to be proctored by facility personnel if the State finds that the procedure adopted by the facility assures that the competency evaluation program—

(i) Is secure from tampering;

(ii) Is standardized and scored by a testing, educational, or other organization approved by the State; and

(iii) Requires no scoring by facility personnel.

(3) The State must retract the right to proctor nurse aide competency evaluations from facilities in which the State finds any evidence of impropriety, including evidence of tampering by facility staff.

(e) *Successful completion of the competency evaluation program.* (1) The State must establish a standard for satisfactory completion of the competency evaluation. To complete the competency evaluation successfully an individual must pass both the written or oral examination and the skills demonstration.

(2) A record of successful completion of the competency evaluation must be included in the nurse aide registry provided in § 483.156 within 30 days of the date if the individual is found to be competent.

(f) *Unsuccessful completion of the competency evaluation program.* (1) If the individual does not complete the evaluation satisfactorily, the individual must be advised—

(i) Of the areas which he or she; did not pass; and

(ii) That he or she has at least three opportunities to take the evaluation.

(2) The State may impose a maximum upon the number of times an individual upon the number of times an individual may attempt to complete the competency evaluation successfully, but the maximum may be no less than three.

§ 483.156 Registry of nurse aides.

(a) *Establishment of registry.* The State must establish and maintain a registry of nurse aides that meets the requirement of this section. The registry—

(1) Must include as a minimum the information contained in paragraph (c) of this section:

(2) Must be sufficiently accessible to meet the needs of the public and health care providers promptly;

(3) May include home health aides who have successfully completed a home health aide competency evaluation program approved by the State if home health aides are differentiated from nurse aides; and

(4) Must provide that any response to an inquiry that includes a finding of abuse, neglect, or misappropriation of property also include any statement disputing the finding made by the nurse aide, as provided under paragraph (c)(1)(ix) of this section.

(b) *Registry operation.* (1) The State may contract the daily operation and maintenance of the registry to a non-State entity. However, the State must maintain accountability for overall operation of the registry and compliance with these regulations.

(2) Only the State survey and certification agency may place on the registry findings of abuse, neglect, or misappropriation of property.

(3) The State must determine which individuals who (i) have successfully completed a nurse aide training and competency evaluation program or nurse aide competency evaluation program; (ii) have been deemed as meeting these requirements; or (iii) have had these requirements waived by the State do not qualify to remain on the registry because they have performed no nursing or nursing-related services for a period of 24 consecutive months.

(4) The State may not impose any charges related to registration on individuals listed in the registry.

(5) The State must provide information on the registry promptly.

(c) *Registry Content.* (1) The registry must contain at least the following information on each individual who has successfully completed a nurse aide training and competency evaluation program which meets the requirements of § 483.152 or a competency evaluation which meets the requirements of § 483.154 and has been found by the State to be competent to function as a nurse aide or who may function as a nurse aide because of meeting criteria in § 483.150:

(i) The individual's full name.

(ii) Information necessary to identify each individual;

(iii) The date the individual became eligible for placement in the registry through successfully completing a nurse aide training and competency evaluation program or competency evaluation program or by meeting the requirements of § 483.150; and

(iv) The following information on any finding by the State survey agency of abuse, neglect, or misappropriation of property by the individual:

(A) Documentation of the State's investigation, including the nature of the allegation and the evidence that led the State to conclude that the allegation was valid;

(B) The date of the hearing, if the individual chose to have one, and its outcome; and

(C) A statement by the individual disputing the allegation, if he or she chooses to make one; and

(D) This information must be included in the registry within 10 working days of the finding and must remain in the registry permanently, unless the finding was made in error, the individual was found not guilty in a court of law, or the State is notified of the individual's death.

(2) The registry must remove entries for individuals who have performed no nursing or nursing-related services for a period of 24 consecutive months, unless the individual's registry entry includes documented findings of abuse, neglect, or misappropriation of property.

(d) *Disclosure of information.* The State must—

(1) Disclose all of the information in § 483.156(c)(1) (iii) and (iv) to all requesters and may disclose additional information it deems necessary; and

(2) Promptly provide individuals with all information contained in the registry on them when adverse findings are placed on the registry and upon request. Individuals on the registry must have sufficient opportunity to correct

any misstatements or inaccuracies contained in the registry.

[56 FR 48919, Sept. 26, 1991; 56 FR 59331, Nov. 25, 1991]

§ 483.158 FFP for nurse aide training and competency evaluation.

(a) State expenditures for nurse aide training and competency evaluation programs and competency evaluation programs are administrative costs. They are matched as indicated in § 433.15(b)(8) of this chapter.

(b) FFP is available for State expenditures associated with nurse aide training and competency evaluation programs and competency evaluation programs only for—

(1) Nurse aides employed by a facility;

(2) Nurse aides who have an offer of employment from a facility;

(3) Nurse aides who become employed by a facility not later than 12 months after completing a nurse aide training and competency evaluation program or competency evaluation program; or

(4) Nurse aides who receive an offer of employment from a facility not later than 12 months after completing a nurse aide training and competency evaluation program or competency evaluation program.

§ 483.160 Requirements for training of paid feeding assistants.

(a) Minimum training course contents. A State-approved training course for paid feeding assistants must include, at a minimum, 8 hours of training in the following:

(1) Feeding techniques.

(2) Assistance with feeding and hydration.

(3) Communication and interpersonal skills.

(4) Appropriate responses to resident behavior.

(5) Safety and emergency procedures, including the Heimlich maneuver.

(6) Infection control.

(7) Resident rights.

(8) Recognizing changes in residents that are inconsistent with their normal behavior and the importance of reporting those changes to the supervisory nurse.

(b) Maintenance of records. A facility must maintain a record of all individuals, used by the facility as feeding assistants, who have successfully completed the training course for paid feeding assistants.

[68 FR 55539, Sept. 26, 2003]

Subpart E—Appeals of Discharges, Transfers, and Preadmission Screening and Annual Resident Review (PASARR) Determinations

SOURCE: 57 FR 56514, Nov. 30, 1992, unless otherwise noted.

§ 483.200 Statutory basis.

This subpart is based on sections 1819(e)(3) and (f)(3) and 1919(e)(3) and (f)(3) of the Act, which require States to make available, to individuals who are discharged or transferred from SNFs or NFs, an appeals process that complies with guidelines issued by the Secretary.

[60 FR 50443, Sept. 29, 1995]

§ 483.202 Definitions.

For purposes of this subpart and subparts B and C—

Discharge means movement from an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing facility, or a Medicaid certified distinct part to a noninstitutional setting when the discharging facility ceases to be legally responsible for the care of the resident.

Individual means an individual or any legal representative of the individual.

Resident means a resident of a SNF or NF or any legal representative of the resident.

Transfer means movement from an entity that participates in Medicare as a skilled nursing facility, a Medicare certified distinct part, an entity that participates in Medicaid as a nursing facility or a Medicaid certified distinct part to another institutional setting when the legal responsibility for the care of the resident changes from the transferring facility to the receiving facility.

§ 483.204 Provision of a hearing and appeal system.

(a) Each State must provide a system for:

(1) A resident of a SNF or a NF to appeal a notice from the SNF or NF of intent to discharge or transfer the resident; and

(2) An individual who has been adversely affected by any PASARR determination made by the State in the context of either a preadmission screening or an annual resident review under subpart C of part 483 to appeal that determination.

(b) The State must provide an appeals system that meets the requirements of this subpart, § 483.12 of this part, and part 431 subpart E of this chapter.

[57 FR 56506, Nov. 30, 1992; 58 FR 25784, Apr. 28, 1993]

§ 483.206 Transfers, discharges and relocations subject to appeal.

(a) ''Facility'' means a certified entity, either a Medicare SNF or a Medicaid NF (see §§ 483.5 and 483.12(a)(1)).

(b) A resident has appeal rights when he or she is transferred from—

(1) A certified bed into a noncertified bed; and

(2) A bed in a certified entity to a bed in an entity which is certified as a different provider.

(c) A resident has no appeal rights when he or she is moved from one bed in the certified entity to another bed in the same certified entity.

Subpart F—Requirements That Must be Met by States and State Agencies, Resident Assessment

§ 483.315 Specification of resident assessment instrument.

(a) *Statutory basis.* Sections 1819(e)(5) and 1919(e)(5) of the Act require that a State specify the resident assessment instrument (RAI) to be used by long term care facilities in the State when conducting initial and periodic assessments of each resident's functional capacity, in accordance with § 483.20.

(b) *State options in specifying an RAI.* The RAI that the State specifies must be one of the following:

(1) The instrument designated by CMS.

(2) An alternate instrument specified by the State and approved by CMS, using the criteria specified in the State Operations Manual issued by CMS (CMS Pub. 7) which is available for purchase through the National Technical Information Service, 5285 Port Royal Rd., Springfield, VA 22151.

(c) *State requirements in specifying an RAI.* (1) Within 30 days after CMS notifies the State of the CMS-designated RAI or changes to it, the State must do one of the following:

(i) Specify the CMS-designated RAI.

(ii) Notify CMS of its intent to specify an alternate instrument.

(2) Within 60 days after receiving CMS approval of an alternate RAI, the State must specify the RAI for use by all long term care facilities participating in the Medicare and Medicaid programs.

(3) After specifying an instrument, the State must provide periodic educational programs for facility staff to assist with implementation of the RAI.

(4) A State must audit implementation of the RAI through the survey process.

(5) A State must obtain approval from CMS before making any modifications to its RAI.

(6) A State must adopt revisions to the RAI that are specified by CMS.

(d) *CMS-designated RAI.* The CMS-designated RAI is published in the State Operations Manual issued by CMS (CMS Pub. 7), as updated periodically, and consists of the following:

(1) The minimum data set (MDS) and common definitions.

(2) The resident assessment protocols (RAPs) and triggers that are necessary to accurately assess residents, established by CMS.

(3) The quarterly review, based on a subset of the MDS specified by CMS.

(4) The requirements for use of the RAI that appear at § 483.20.

(e) *Minimum data set (MDS).* The MDS includes assessment in the following areas:

(1) Identification and demographic information, which includes information to identify the resident and facility, the resident's residential history,

education, the reason for the assessment, guardianship status and information regarding advance directives, and information regarding mental health history.

(2) Customary routine, which includes the resident's lifestyle prior to admission to the facility.

(3) Cognitive patterns, which include memory, decision making, consciousness, behavioral measures of delirium, and stability of condition.

(4) Communication, which includes scales for measuring hearing and communication skills, information on how the resident expresses himself or herself, and stability of communicative ability.

(5) Vision pattern, which includes a scale for measuring vision and vision problems.

(6) Mood and behavior patterns, which include scales for measuring behavioral indicators and symptoms, and stability of condition.

(7) Psychosocial well-being, which includes the resident's interpersonal relationships and adjustment factors.

(8) Physical functioning and structural problems, which contains scales for measuring activities of daily living, mobility, potential for improvement, and stability of functioning.

(9) Continence, which includes assessment scales for bowel and bladder incontinence, continence patterns, interventions, and stability of continence status.

(10) Disease diagnoses and health conditions, which includes active medical diagnoses, physical problems, pain assessment, and stability of condition.

(11) Dental and nutritional status, which includes information on height and weight, nutritional problems and accommodations, oral care and problems, and measure of nutritional intake.

(12) Skin condition, which includes current and historical assessment of skin problems, treatments, and information regarding foot care.

(13) Activity pursuit, which gathers information on the resident's activity preferences and the amount of time spent participating in activities.

(14) Medications, which contains information on the types and numbers of medications the resident receives.

(15) Special treatments and procedures, which includes measurements of therapies, assessment of rehabilitation/restorative care, special programs and interventions, and information on hospital visits and physician involvement.

(16) Discharge potential, which assesses the possibility of discharging the resident and discharge status.

(17) Documentation of summary information regarding the additional assessment performed through the resident assessment protocols.

(18) Documentation of participation in assessment.

(f) *Resident assessment protocols (RAPs).* At a minimum, the RAPs address the following domains:

(1) Delirium.

(2) Cognitive loss.

(3) Visual function.

(4) Communication.

(5) ADL functional/rehabilitation potential.

(6) Urinary incontinence and indwelling catheter.

(7) Psychosocial well-being.

(8) Mood state.

(9) Behavioral symptoms.

(10) Activities.

(11) Falls.

(12) Nutritional status.

(13) Feeding tubes.

(14) Dehydration/fluid maintenance.

(15) Dental care.

(16) Pressure ulcers.

(17) Psychotropic drug use.

(18) Physical restraints.

(g) *Criteria for CMS approval of alternate instrument.* To receive CMS approval, a State's alternate instrument must use the standardized format, organization, item labels and definitions, and instructions specified by CMS in the latest issuance of the State Operations Manual issued by CMS (CMS Pub. 7).

(h) *State MDS collection and data base requirements.* (1) As part of facility survey responsibilities, the State must establish and maintain an MDS Database, and must do the following:

(i) Use a system to collect, store, and analyze data that is developed or approved by CMS.

(ii) Obtain CMS approval before modifying any parts of the CMS standard system other than those listed in

paragraph (h)(2) of this section (which may not be modified).

(iii) Specify to a facility the method of transmission of data to the State, and instruct the facility on this method.

(iv) Upon receipt of data from a facility, edit the data, as specified by CMS, and ensure that a facility resolves errors.

(v) At least monthly, transmit to CMS all edited MDS records received during that period, according to formats specified by CMS, and correct and retransmit rejected data as needed.

(vi) Analyze data and generate reports, as specified by CMS.

(2) The State may not modify any aspect of the standard system that pertains to the following:

(i) Standard approvable RAI criteria specified in the State Operations Manual issued by CMS (CMS Pub. 7) (MDS item labels and definitions, RAPs and utilization guidelines).

(ii) Standardized record formats and validation edits specified in the State Operations Manual issued by CMS (CMS Pub. 7).

(iii) Standard facility encoding and transmission methods specified in the State Operations Manual issued by CMS (CMS Pub. 7).

(i) *State identification of agency that collects RAI data.* The State must identify the component agency that collects RAI data, and ensure that this agency restricts access to the data except for the following:

(1) Reports that contain no resident-identifiable data.

(2) Transmission of data and reports to CMS.

(3) Transmission of data and reports to the State agency that conducts surveys to ensure compliance with Medicare and Medicaid participation requirements, for purposes related to this function.

(4) Transmission of data and reports to the State Medicaid agency for purposes directly related to the administration of the State Medicaid plan.

(5) Transmission of data and reports to other entities only when authorized as a routine use by CMS.

(j) *Resident-identifiable data.* (1) The State may not release information that is resident-identifiable to the public.

(2) The State may not release RAI data that is resident-identifiable except in accordance with a written agreement under which the recipient agrees to be bound by the restrictions described in paragraph (i) of this section.

[62 FR 67212, Dec. 23, 1997]

Subpart G—Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

SOURCE: 66 FR 7161, Jan. 22, 2001, unless otherwise noted.

§ 483.350 Basis and scope.

(a) *Statutory basis.* Sections 1905(a)(16) and (h) of the Act provide that inpatient psychiatric services for individuals under age 21 include only inpatient services that are provided in an institution (or distinct part thereof) that is a psychiatric hospital as defined in section 1861(f) of the Act or in another inpatient setting that the Secretary has specified in regulations. Additionally, the Children's Health Act of 2000 (Pub. L. 106–310) imposes procedural reporting and training requirements regarding the use of restraints and involuntary seclusion in facilities, specifically including facilities that provide inpatient psychiatric services for children under the age of 21 as defined by sections 1905(a)(16) and (h) of the Act.

(b) *Scope.* This subpart imposes requirements regarding the use of restraint or seclusion in psychiatric residential treatment facilities, that are not hospitals, providing inpatient psychiatric services to individuals under age 21.

§ 483.352 Definitions.

For purposes of this subpart, the following definitions apply:

Drug used as a restraint means any drug that—

(1) Is administered to manage a resident's behavior in a way that reduces the safety risk to the resident or others;

(2) Has the temporary effect of restricting the resident's freedom of movement; and

(3) Is not a standard treatment for the resident's medical or psychiatric condition.

Emergency safety intervention means the use of restraint or seclusion as an immediate response to an emergency safety situation.

Emergency safety situation means unanticipated resident behavior that places the resident or others at serious threat of violence or injury if no intervention occurs and that calls for an emergency safety intervention as defined in this section.

Mechanical restraint means any device attached or adjacent to the resident's body that he or she cannot easily remove that restricts freedom of movement or normal access to his or her body.

Minor means a minor as defined under State law and, for the purpose of this subpart, includes a resident who has been declared legally incompetent by the applicable State court.

Personal restraint means the application of physical force without the use of any device, for the purposes of restraining the free movement of a resident's body. The term personal restraint does not include briefly holding without undue force a resident in order to calm or comfort him or her, or holding a resident's hand to safely escort a resident from one area to another.

Psychiatric Residential Treatment Facility means a facility other than a hospital, that provides psychiatric services, as described in subpart D of part 441 of this chapter, to individuals under age 21, in an inpatient setting.

Restraint means a ''personal restraint,'' ''mechanical restraint,'' or ''drug used as a restraint'' as defined in this section.

Seclusion means the involuntary confinement of a resident alone in a room or an area from which the resident is physically prevented from leaving.

Serious injury means any significant impairment of the physical condition of the resident as determined by qualified medical personnel. This includes, but is not limited to, burns, lacerations, bone fractures, substantial hematoma, and injuries to internal organs, whether self-inflicted or inflicted by someone else.

Staff means those individuals with responsibility for managing a resident's health or participating in an emergency safety intervention and who are employed by the facility on a full-time, part-time, or contract basis.

Time out means the restriction of a resident for a period of time to a designated area from which the resident is not physically prevented from leaving, for the purpose of providing the resident an opportunity to regain self-control.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28116, May 22, 2001]

§ 483.354 General requirements for psychiatric residential treatment facilities.

A psychiatric residential treatment facility must meet the requirements in § 441.151 through § 441.182 of this chapter.

§ 483.356 Protection of residents.

(a) *Restraint and seclusion policy for the protection of residents.* (1) Each resident has the right to be free from restraint or seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation.

(2) An order for restraint or seclusion must not be written as a standing order or on an as-needed basis.

(3) Restraint or seclusion must not result in harm or injury to the resident and must be used only—

(i) To ensure the safety of the resident or others during an emergency safety situation; and

(ii) Until the emergency safety situation has ceased and the resident's safety and the safety of others can be ensured, even if the restraint or seclusion order has not expired.

(4) Restraint and seclusion must not be used simultaneously.

(b) *Emergency safety intervention.* An emergency safety intervention must be performed in a manner that is safe, proportionate, and appropriate to the severity of the behavior, and the resident's chronological and developmental age; size; gender; physical, medical, and psychiatric condition; and personal history (including any history of physical or sexual abuse).

(c) *Notification of facility policy.* At admission, the facility must—

(1) Inform both the incoming resident and, in the case of a minor, the resident's parent(s) or legal guardian(s) of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that may occur while the resident is in the program;

(2) Communicate its restraint and seclusion policy in a language that the resident, or his or her parent(s) or legal guardian(s) understands (including American Sign Language, if appropriate) and when necessary, the facility must provide interpreters or translators;

(3) Obtain an acknowledgment, in writing, from the resident, or in the case of a minor, from the parent(s) or legal guardian(s) that he or she has been informed of the facility's policy on the use of restraint or seclusion during an emergency safety situation. Staff must file this acknowledgment in the resident's record; and

(4) Provide a copy of the facility policy to the resident and in the case of a minor, to the resident's parent(s) or legal guardian(s).

(d) *Contact information.* The facility's policy must provide contact information, including the phone number and mailing address, for the appropriate State Protection and Advocacy organization.

§ 483.358 Orders for the use of restraint or seclusion.

(a) Orders for restraint or seclusion must be by a physician, or other licensed practitioner permitted by the State and the facility to order restraint or seclusion and trained in the use of emergency safety interventions. Federal regulations at 42 CFR 441.151 require that inpatient psychiatric services for recipients under age 21 be provided under the direction of a physician.

(b) If the resident's treatment team physician is available, only he or she can order restraint or seclusion.

(c) A physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must order the least restrictive emergency safety intervention that is most likely to be effective in resolving the emergency safety situation based on consultation with staff.

(d) If the order for restraint or seclusion is verbal, the verbal order must be received by a registered nurse or other licensed staff such as a licensed practical nurse, while the emergency safety intervention is being initiated by staff or immediately after the emergency safety situation ends. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must verify the verbal order in a signed written form in the resident's record. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must be available to staff for consultation, at least by telephone, throughout the period of the emergency safety intervention.

(e) Each order for restraint or seclusion must:

(1) Be limited to no longer than the duration of the emergency safety situation; and

(2) Under no circumstances exceed 4 hours for residents ages 18 to 21; 2 hours for residents ages 9 to 17; or 1 hour for residents under age 9.

(f) Within 1 hour of the initiation of the emergency safety intervention a physician, or other licensed practitioner trained in the use of emergency safety interventions and permitted by the state and the facility to assess the physical and psychological well being of residents, must conduct a face-to-face assessment of the physical and psychological well being of the resident, including but not limited to—

(1) The resident's physical and psychological status;

(2) The resident's behavior;

(3) The appropriateness of the intervention measures; and

(4) Any complications resulting from the intervention.

(g) Each order for restraint or seclusion must include—

(1) The name of the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion;

(2) The date and time the order was obtained; and

(3) The emergency safety intervention ordered, including the length of

time for which the physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion authorized its use.

(h) Staff must document the intervention in the resident's record. That documentation must be completed by the end of the shift in which the intervention occurs. If the intervention does not end during the shift in which it began, documentation must be completed during the shift in which it ends. Documentation must include all of the following:

(1) Each order for restraint or seclusion as required in paragraph (g) of this section.

(2) The time the emergency safety intervention actually began and ended.

(3) The time and results of the 1-hour assessment required in paragraph (f) of this section.

(4) The emergency safety situation that required the resident to be restrained or put in seclusion.

(5) The name of staff involved in the emergency safety intervention.

(i) The facility must maintain a record of each emergency safety situation, the interventions used, and their outcomes.

(j) The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must sign the restraint or seclusion order in the resident's record as soon as possible.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28116, May 22, 2001]

§ 483.360 Consultation with treatment team physician.

If a physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion orders the use of restraint or seclusion, that person must contact the resident's treatment team physician, unless the ordering physician is in fact the resident's treatment team physician. The person ordering the use of restraint or seclusion must—

(a) Consult with the resident's treatment team physician as soon as possible and inform the team physician of the emergency safety situation that required the resident to be restrained or placed in seclusion; and

(b) Document in the resident's record the date and time the team physician was consulted.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28117, May 22, 2001]

§ 483.362 Monitoring of the resident in and immediately after restraint.

(a) Clinical staff trained in the use of emergency safety interventions must be physically present, continually assessing and monitoring the physical and psychological well-being of the resident and the safe use of restraint throughout the duration of the emergency safety intervention.

(b) If the emergency safety situation continues beyond the time limit of the order for the use of restraint, a registered nurse or other licensed staff, such as a licensed practical nurse, must immediately contact the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

(c) A physician, or other licensed practitioner permitted by the state and the facility to evaluate the resident's well-being and trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the restraint is removed.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28117, May 22, 2001]

§ 483.364 Monitoring of the resident in and immediately after seclusion.

(a) Clinical staff, trained in the use of emergency safety interventions, must be physically present in or immediately outside the seclusion room, continually assessing, monitoring, and evaluating the physical and psychological well-being of the resident in seclusion. Video monitoring does not meet this requirement.

(b) A room used for seclusion must—

(1) Allow staff full view of the resident in all areas of the room; and

(2) Be free of potentially hazardous conditions such as unprotected light fixtures and electrical outlets.

(c) If the emergency safety situation continues beyond the time limit of the order for the use of seclusion, a registered nurse or other licensed staff, such as a licensed practical nurse,

must immediately contact the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

(d) A physician, or other licensed practitioner permitted by the state and the facility to evaluate the resident's well-being and trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the resident is removed from seclusion.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28117, May 22, 2001]

§ 483.366 Notification of parent(s) or legal guardian(s).

If the resident is a minor as defined in this subpart:

(a) The facility must notify the parent(s) or legal guardian(s) of the resident who has been restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention.

(b) The facility must document in the resident's record that the parent(s) or legal guardian(s) has been notified of the emergency safety intervention, including the date and time of notification and the name of the staff person providing the notification.

§ 483.368 Application of time out.

(a) A resident in time out must never be physically prevented from leaving the time out area.

(b) Time out may take place away from the area of activity or from other residents, such as in the resident's room (exclusionary), or in the area of activity or other residents (inclusionary).

(c) Staff must monitor the resident while he or she is in time out.

§ 483.370 Postintervention debriefings.

(a) Within 24 hours after the use of restraint or seclusion, staff involved in an emergency safety intervention and the resident must have a face-to-face discussion. This discussion must include all staff involved in the intervention except when the presence of a particular staff person may jeopardize the well-being of the resident. Other staff and the resident's parent(s) or legal guardian(s) may participate in the disussion when it is deemed appropriate by the facility. The facility must conduct such discussion in a language that is understood by the resident's parent(s) or legal guardian(s). The discussion must provide both the resident and staff the opportunity to discuss the circumstances resulting in the use of restraint or seclusion and strategies to be used by the staff, the resident, or others that could prevent the future use of restraint or seclusion.

(b) Within 24 hours after the use of restraint or seclusion, all staff involved in the emergency safety intervention, and appropriate supervisory and administrative staff, must conduct a debriefing session that includes, at a minimum, a review and discussion of—

(1) The emergency safety situation that required the intervention, including a discussion of the precipitating factors that led up to the intervention;

(2) Alternative techniques that might have prevented the use of the restraint or seclusion;

(3) The procedures, if any, that staff are to implement to prevent any recurrence of the use of restraint or seclusion; and

(4) The outcome of the intervention, including any injuries that may have resulted from the use of restraint or seclusion.

(c) Staff must document in the resident's record that both debriefing sessions took place and must include in that documentation the names of staff who were present for the debriefing, names of staff that were excused from the debriefing, and any changes to the resident's treatment plan that result from the debriefings.

§ 483.372 Medical treatment for injuries resulting from an emergency safety intervention.

(a) Staff must immediately obtain medical treatment from qualified medical personnel for a resident injured as a result of an emergency safety intervention.

(b) The psychiatric residential treatment facility must have affiliations or written transfer agreements in effect with one or more hospitals approved for participation under the Medicaid program that reasonably ensure that—

(1) A resident will be transferred from the facility to a hospital and admitted in a timely manner when a transfer is medically necessary for medical care or acute psychiatric care;

(2) Medical and other information needed for care of the resident in light of such a transfer, will be exchanged between the institutions in accordance with State medical privacy law, including any information needed to determine whether the appropriate care can be provided in a less restrictive setting; and

(3) Services are available to each resident 24 hours a day, 7 days a week.

(c) Staff must document in the resident's record, all injuries that occur as a result of an emergency safety intervention, including injuries to staff resulting from that intervention.

(d) Staff involved in an emergency safety intervention that results in an injury to a resident or staff must meet with supervisory staff and evaluate the circumstances that caused the injury and develop a plan to prevent future injuries.

§ 483.374 Facility reporting.

(a) *Attestation of facility compliance.* Each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 must attest, in writing, that the facility is in compliance with CMS's standards governing the use of restraint and seclusion. This attestation must be signed by the facility director.

(1) A facility with a current provider agreement with the Medicaid agency must provide its attestation to the State Medicaid agency by July 21, 2001.

(2) A facility enrolling as a Medicaid provider must meet this requirement at the time it executes a provider agreement with the Medicaid agency.

(b) *Reporting of serious occurrences.* The facility must report each serious occurrence to both the State Medicaid agency and, unless prohibited by State law, the State-designated Protection and Advocacy system. Serious occurrences that must be reported include a resident's death, a serious injury to a resident as defined in § 483.352 of this part, and a resident's suicide attempt.

(1) Staff must report any serious occurrence involving a resident to both the State Medicaid agency and the State-designated Protection and Advocacy system by no later than close of business the next business day after a serious occurrence. The report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

(2) In the case of a minor, the facility must notify the resident's parent(s) or legal guardian(s) as soon as possible, and in no case later than 24 hours after the serious occurrence.

(3) Staff must document in the resident's record that the serious occurrence was reported to both the State Medicaid agency and the State-designated Protection and Advocacy system, including the name of the person to whom the incident was reported. A copy of the report must be maintained in the resident's record, as well as in the incident and accident report logs kept by the facility.

(c) *Reporting of deaths.* In addition to the reporting requirements contained in paragraph (b) of this section, facilities must report the death of any resident to the Centers for Medicare & Medicaid Services (CMS) regional office.

(1) Staff must report the death of any resident to the CMS regional office by no later than close of business the next business day after the resident's death.

(2) Staff must document in the resident's record that the death was reported to the CMS regional office.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28117, May 22, 2001]

§ 483.376 Education and training.

(a) The facility must require staff to have ongoing education, training, and demonstrated knowledge of—

(1) Techniques to identify staff and resident behaviors, events, and environmental factors that may trigger emergency safety situations;

(2) The use of nonphysical intervention skills, such as de-escalation, mediation conflict resolution, active listening, and verbal and observational methods, to prevent emergency safety situations; and

(3) The safe use of restraint and the safe use of seclusion, including the

ability to recognize and respond to signs of physical distress in residents who are restrained or in seclusion.

(b) Certification in the use of cardiopulmonary resuscitation, including periodic recertification, is required.

(c) Individuals who are qualified by education, training, and experience must provide staff training.

(d) Staff training must include training exercises in which staff members successfully demonstrate in practice the techniques they have learned for managing emergency safety situations.

(e) Staff must be trained and demonstrate competency before participating in an emergency safety intervention.

(f) Staff must demonstrate their competencies as specified in paragraph (a) of this section on a semiannual basis and their competencies as specified in paragraph (b) of this section on an annual basis.

(g) The facility must document in the staff personnel records that the training and demonstration of competency were successfully completed. Documentation must include the date training was completed and the name of persons certifying the completion of training.

(h) All training programs and materials used by the facility must be available for review by CMS, the State Medicaid agency, and the State survey agency.

Subpart H [Reserved]

Subpart I—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

SOURCE: 53 FR 20496, June 3, 1988, unless otherwise noted. Redesignated at 56 FR 48918, Sept. 26, 1991.

§ 483.400 Basis and purpose.

This subpart implements section 1905 (c) and (d) of the Act which gives the Secretary authority to prescribe regulations for intermediate care facility services in facilities for the mentally retarded or persons with related conditions.

§ 483.405 Relationship to other HHS regulations.

In addition to compliance with the regulations set forth in this subpart, facilities are obliged to meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color, or national origin (45 CFR Part 80), nondiscrimination on the basis of handicap (45 CFR Part 84), nondiscrimination on the basis of age (45 CFR Part 91), protection of human subjects of research (45 CFR Part 46), and fraud and abuse (42 CFR Part 455). Although those regulations are not in themselves considered conditions of participation under this Part, their violation may result in the termination or suspension of, or the refusal to grant or continue, Federal financial assistance.

§ 483.410 Condition of participation: Governing body and management.

(a) *Standard: Governing body.* The facility must identify an individual or individuals to constitute the governing body of the facility. The governing body must—

(1) Exercise general policy, budget, and operating direction over the facility;

(2) Set the qualifications (in addition to those already set by State law, if any) for the administrator of the facility; and

(3) Appoint the administrator of the facility.

(b) *Standard: Compliance with Federal, State, and local laws.* The facility must be in compliance with all applicable provisions of Federal, State and local laws, regulations and codes pertaining to health, safety, and sanitation.

(c) *Standard: Client records.* (1) The facility must develop and maintain a recordkeeping system that includes a separate record for each client and that documents the client's health care, active treatment, social information, and protection of the client's rights.

(2) The facility must keep confidential all information contained in the clients' records, regardless of the form or storage method of the records.

(3) The facility must develop and implement policies and procedures governing the release of any client information, including consents necessary from the client, or parents (if the client is a minor) or legal guardian.

(4) Any individual who makes an entry in a client's record must make it legibly, date it, and sign it.

(5) The facility must provide a legend to explain any symbol or abbreviation used in a client's record.

(6) The facility must provide each identified residential living unit with appropriate aspects of each client's record.

(d) *Standard: Services provided under agreements with outside sources.* (1) If a service required under this subpart is not provided directly, the facility must have a written agreement with an outside program, resource, or service to furnish the necessary service, including emergency and other health care.

(2) The agreement must—

(i) Contain the responsibilities, functions, objectives, and other terms agreed to by both parties; and

(ii) Provide that the facility is responsible for assuring that the outside services meet the standards for quality of services contained in this subpart.

(3) The facility must assure that outside services meet the needs of each client.

(4) If living quarters are not provided in a facility owned by the ICF/MR, the ICF/MR remains directly responsible for the standards relating to physical environment that are specified in § 483.470 (a) through (g), (j) and (k).

(e) *Standard: Licensure.* The facility must be licensed under applicable State and local law.

[53 FR 20496, June 3, 1988. Redesignated at 56 FR 48918, Sept. 26, 1991, and amended at 57 FR 43925, Sept. 23, 1992]

§ 483.420 Condition of participation: Client protections.

(a) *Standard: Protection of clients' rights.* The facility must ensure the rights of all clients. Therefore, the facility must—

(1) Inform each client, parent (if the client is a minor), or legal guardian, of the client's rights and the rules of the facility;

(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

(3) Allow and encourage individual clients to exercise their rights as clients of the facility, and as citizens of the United States, including the right to file complaints, and the right to due process;

(4) Allow individual clients to manage their financial affairs and teach them to do so to the extent of their capabilities;

(5) Ensure that clients are not subjected to physical, verbal, sexual or psychological abuse or punishment;

(6) Ensure that clients are free from unnecessary drugs and physical restraints and are provided active treatment to reduce dependency on drugs and physical restraints;

(7) Provide each client with the opportunity for personal privacy and ensure privacy during treatment and care of personal needs;

(8) Ensure that clients are not compelled to perform services for the facility and ensure that clients who do work for the facility are compensated for their efforts at prevailing wages and commensurate with their abilities;

(9) Ensure clients the opportunity to communicate, associate and meet privately with individuals of their choice, and to send and receive unopened mail;

(10) Ensure that clients have access to telephones with privacy for incoming and outgoing local and long distance calls except as contraindicated by factors identified within their individual program plans;

(11) Ensure clients the opportunity to participate in social, religious, and community group activities;

(12) Ensure that clients have the right to retain and use appropriate personal possessions and clothing, and ensure that each client is dressed in his or her own clothing each day; and

(13) Permit a husband and wife who both reside in the facility to share a room.

(b) *Standard: Client finances.* (1) The facility must establish and maintain a system that—

(i) Assures a full and complete accounting of clients' personal funds entrusted to the facility on behalf of clients; and

(ii) Precludes any commingling of client funds with facility funds or with the funds of any person other than another client.

(2) The client's financial record must be available on request to the client, parents (if the client is a minor) or legal guardian.

(c) *Standard: Communication with clients, parents, and guardians.* The facility must—

(1) Promote participation of parents (if the client is a minor) and legal guardians in the process of providing active treatment to a client unless their participation is unobtainable or inappropriate;

(2) Answer communications from clients' families and friends promptly and appropriately;

(3) Promote visits by individuals with a relationship to the client (such as family, close friends, legal guardians and advocates) at any reasonable hour, without prior notice, consistent with the right of that client's and other clients' privacy, unless the interdisciplinary team determines that the visit would not be appropriate;

(4) Promote visits by parents or guardians to any area of the facility that provides direct client care services to the client, consistent with the right of that client's and other clients' privacy;

(5) Promote frequent and informal leaves from the facility for visits, trips, or vacations; and

(6) Notify promptly the client's parents or guardian of any significant incidents, or changes in the client's condition including, but not limited to, serious illness, accident, death, abuse, or unauthorized absence.

(d) *Standard: Staff treatment of clients.* (1) The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect or abuse of the client.

(i) Staff of the facility must not use physical, verbal, sexual or psychological abuse or punishment.

(ii) Staff must not punish a client by withholding food or hydration that contributes to a nutritionally adequate diet.

(iii) The facility must prohibit the employment of individuals with a conviction or prior employment history of child or client abuse, neglect or mistreatment.

(2) The facility must ensure that all allegations of mistreatment, neglect or abuse, as well as injuries of unknown source, are reported immediately to the administrator or to other officials in accordance with State law through established procedures.

(3) The facility must have evidence that all alleged violations are thoroughly investigated and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or designated representative or to other officials in accordance with State law within five working days of the incident and, if the alleged violation is verified, appropriate corrective action must be taken.

§ 483.430 Condition of participation: Facility staffing.

(a) *Standard: Qualified mental retardation professional.* Each client's active treatment program must be integrated, coordinated and monitored by a qualified mental retardation professional who—

(1) Has at least one year of experience working directly with persons with mental retardation or other developmental disabilities; and

(2) Is one of the following:

(i) A doctor of medicine or osteopathy.

(ii) A registered nurse.

(iii) An individual who holds at least a bachelor's degree in a professional category specified in paragraph (b)(5) of this section.

(b) *Standard: Professional program services.* (1) Each client must receive the professional program services needed to implement the active treatment program defined by each client's individual program plan. Professional program staff must work directly with clients and with paraprofessional, nonprofessional and other professional program staff who work with clients.

(2) The facility must have available enough qualified professional staff to carry out and monitor the various professional interventions in accordance with the stated goals and objectives of every individual program plan.

(3) Professional program staff must participate as members of the interdisciplinary team in relevant aspects of the active treatment process.

(4) Professional program staff must participate in on-going staff development and training in both formal and informal settings with other professional, paraprofessional, and nonprofessional staff members.

(5) Professional program staff must be licensed, certified, or registered, as applicable, to provide professional services by the State in which he or she practices. Those professional program staff who do not fall under the jurisdiction of State licensure, certification, or registration requirements, specified in §483.410(b), must meet the following qualifications:

(i) To be designated as an occupational therapist, an individual must be eligible for certification as an occupational therapist by the American Occupational Therapy Association or another comparable body.

(ii) To be designated as an occupational therapy assistant, an individual must be eligible for certification as a certified occupational therapy assistant by the American Occupational Therapy Association or another comparable body.

(iii) To be designated as a physical therapist, an individual must be eligible for certification as a physical therapist by the American Physical Therapy Association or another comparable body.

(iv) To be designated as a physical therapy assistant, an individual must be eligible for registration by the American Physical Therapy Association or be a graduate of a two year college-level program approved by the American Physical Therapy Association or another comparable body.

(v) To be designated as a psychologist, an individual must have at least a master's degree in psychology from an accredited school.

(vi) To be designated as a social worker, an individual must—

(A) Hold a graduate degree from a school of social work accredited or approved by the Council on Social Work Education or another comparable body; or

(B) Hold a Bachelor of Social Work degree from a college or university accredited or approved by the Council on Social Work Education or another comparable body.

(vii) To be designated as a speech-language pathologist or audiologist, an individual must—

(A) Be eligible for a Certificate of Clinical Competence in Speech-Language Pathology or Audiology granted by the American Speech-Language-Hearing Association or another comparable body; or

(B) Meet the educational requirements for certification and be in the process of accumulating the supervised experience required for certification.

(viii) To be designated as a professional recreation staff member, an individual must have a bachelor's degree in recreation or in a specialty area such as art, dance, music or physical education.

(ix) To be designated as a professional dietitian, an individual must be eligible for registration by the American Dietetics Association.

(x) To be designated as a human services professional an individual must have at least a bachelor's degree in a human services field (including, but not limited to: sociology, special education, rehabilitation counseling, and psychology).

(xi) If the client's individual program plan is being successfully implemented by facility staff, professional program staff meeting the qualifications of paragraph (b)(5) (i) through (x) of this section are not required—

(A) Except for qualified mental retardation professionals;

(B) Except for the requirements of paragraph (b)(2) of this section concerning the facility's provision of enough qualified professional program staff; and

(C) Unless otherwise specified by State licensure and certification requirements.

(c) *Standard: Facility staffing.* (1) The facility must not depend upon clients

or volunteers to perform direct care services for the facility.

(2) There must be responsible direct care staff on duty and awake on a 24-hour basis, when clients are present, to take prompt, appropriate action in case of injury, illness, fire or other emergency, in each defined residential living unit housing—

(i) Clients for whom a physician has ordered a medical care plan;

(ii) Clients who are aggressive, assaultive or security risks;

(iii) More than 16 clients; or

(iv) Fewer than 16 clients within a multi-unit building.

(3) There must be a responsible direct care staff person on duty on a 24 hour basis (when clients are present) to respond to injuries and symptoms of illness, and to handle emergencies, in each defined residential living unit housing—

(i) Clients for whom a physician has not ordered a medical care plan;

(ii) Clients who are not aggressive, assaultive or security risks; and

(iii) Sixteen or fewer clients,

(4) The facility must provide sufficient support staff so that direct care staff are not required to perform support services to the extent that these duties interfere with the exercise of their primary direct client care duties.

(d) *Standard: Direct care (residential living unit) staff.* (1) The facility must provide sufficient direct care staff to manage and supervise clients in accordance with their individual program plans.

(2) Direct care staff are defined as the present on-duty staff calculated over all shifts in a 24-hour period for each defined residential living unit.

(3) Direct care staff must be provided by the facility in the following minimum ratios of direct care staff to clients:

(i) For each defined residential living unit serving children under the age of 12, severely and profoundly retarded clients, clients with severe physical disabilities, or clients who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the staff to client ratio is 1 to 3.2.

(ii) For each defined residential living unit serving moderately retarded clients, the staff to client ratio is 1 to 4.

(iii) For each defined residential living unit serving clients who function within the range of mild retardation, the staff to client ratio is 1 to 6.4.

(4) When there are no clients present in the living unit, a responsible staff member must be available by telephone.

(e) *Standard: Staff training program.* (1) The facility must provide each employee with initial and continuing training that enables the employee to perform his or her duties effectively, efficiently, and competently.

(2) For employees who work with clients, training must focus on skills and competencies directed toward clients' developmental, behavioral, and health needs.

(3) Staff must be able to demonstrate the skills and techniques necessary to administer interventions to manage the inappropriate behavior of clients.

(4) Staff must be able to demonstrate the skills and techniques necessary to implement the individual program plans for each client for whom they are responsible.

§ 483.440 Condition of participation: Active treatment services.

(a) *Standard: Active treatment.* (1) Each client must receive a continuous active treatment program, which includes aggressive, consistent implementation of a program of specialized and generic training, treatment, health services and related services described in this subpart, that is directed toward—

(i) The acquisition of the behaviors necessary for the client to function with as much self determination and independence as possible; and

(ii) The prevention or deceleration of regression or loss of current optimal functional status.

(2) Active treatment does not include services to maintain generally independent clients who are able to function with little supervision or in the absence of a continuous active treatment program.

(b) *Standard: Admissions, transfers, and discharge.* (1) Clients who are admitted by the facility must be in need

of and receiving active treatment services.

(2) Admission decisions must be based on a preliminary evaluation of the client that is conducted or updated by the facility or by outside sources.

(3) A preliminary evaluation must contain background information as well as currently valid assessments of functional developmental, behavioral, social, health and nutritional status to determine if the facility can provide for the client's needs and if the client is likely to benefit from placement in the facility.

(4) If a client is to be either transferred or discharged, the facility must—

(i) Have documentation in the client's record that the client was transferred or discharged for good cause; and

(ii) Provide a reasonable time to prepare the client and his or her parents or guardian for the transfer or discharge (except in emergencies).

(5) At the time of the discharge, the facility must—

(i) Develop a final summary of the client's developmental, behavioral, social, health and nutritional status and, with the consent of the client, parents (if the client is a minor) or legal guardian, provide a copy to authorized persons and agencies; and

(ii) Provide a post-discharge plan of care that will assist the client to adjust to the new living environment.

(c) *Standard: Individual program plan.* (1) Each client must have an individual program plan developed by an interdisciplinary team that represents the professions, disciplines or service areas that are relevant to—

(i) Identifying the client's needs, as described by the comprehensive functional assessments required in paragraph (c)(3) of this section; and

(ii) Designing programs that meet the client's needs.

(2) Appropriate facility staff must participate in interdisciplinary team meetings. Participation by other agencies serving the client is encouraged. Participation by the client, his or her parent (if the client is a minor), or the client's legal guardian is required unless that participation is unobtainable or inappropriate.

(3) Within 30 days after admission, the interdisciplinary team must perform accurate assessments or reassessments as needed to supplement the preliminary evaluation conducted prior to admission. The comprehensive functional assessment must take into consideration the client's age (for example, child, young adult, elderly person) and the implications for active treatment at each stage, as applicable, and must—

(i) Identify the presenting problems and disabilities and where possible, their causes;

(ii) Identify the client's specific developmental strengths;

(iii) Identify the client's specific developmental and behavioral management needs;

(iv) Identify the client's need for services without regard to the actual availability of the services needed; and

(v) Include physical development and health, nutritional status, sensorimotor development, affective development, speech and language development and auditory functioning, cognitive development, social development, adaptive behaviors or independent living skills necessary for the client to be able to function in the community, and as applicable, vocational skills.

(4) Within 30 days after admission, the interdisciplinary team must prepare for each client an individual program plan that states the specific objectives necessary to meet the client's needs, as identified by the comprehensive assessment required by paragraph (c)(3) of this section, and the planned sequence for dealing with those objectives. These objectives must—

(i) Be stated separately, in terms of a single behavioral outcome;

(ii) Be assigned projected completion dates;

(iii) Be expressed in behavioral terms that provide measurable indices of performance;

(iv) Be organized to reflect a developmental progression appropriate to the individual; and

(v) Be assigned priorities.

(5) Each written training program designed to implement the objectives in the individual program plan must specify:

(i) The methods to be used;

(ii) The schedule for use of the method;

(iii) The person responsible for the program;

(iv) The type of data and frequency of data collection necessary to be able to assess progress toward the desired objectives;

(v) The inappropriate client behavior(s), if applicable; and

(vi) Provision for the appropriate expression of behavior and the replacement of inappropriate behavior, if applicable, with behavior that is adaptive or appropriate.

(6) The individual program plan must also:

(i) Describe relevant interventions to support the individual toward independence.

(ii) Identify the location where program strategy information (which must be accessible to any person responsible for implementation) can be found.

(iii) Include, for those clients who lack them, training in personal skills essential for privacy and independence (including, but not limited to, toilet training, personal hygiene, dental hygiene, self-feeding, bathing, dressing, grooming, and communication of basic needs), until it has been demonstrated that the client is developmentally incapable of acquiring them.

(iv) Identify mechanical supports, if needed, to achieve proper body position, balance, or alignment. The plan must specify the reason for each support, the situations in which each is to be applied, and a schedule for the use of each support.

(v) Provide that clients who have multiple disabling conditions spend a major portion of each waking day out of bed and outside the bedroom area, moving about by various methods and devices whenever possible.

(vi) Include opportunities for client choice and self-management.

(7) A copy of each client's individual program plan must be made available to all relevant staff, including staff of other agencies who work with the client, and to the client, parents (if the client is a minor) or legal guardian.

(d) *Standard: Program implementation.* (1) As soon as the interdisciplinary team has formulated a client's individual program plan, each client must receive a continuous active treatment program consisting of needed interventions and services in sufficient number and frequency to support the achievement of the objectives identified in the individual program plan.

(2) The facility must develop an active treatment schedule that outlines the current active treatment program and that is readily available for review by relevant staff.

(3) Except for those facets of the individual program plan that must be implemented only by licensed personnel, each client's individual program plan must be implemented by all staff who work with the client, including professional, paraprofessional and nonprofessional staff.

(e) *Standard: Program documentation.* (1) Data relative to accomplishment of the criteria specified in client individual program plan objectives must be documented in measureable terms.

(2) The facility must document significant events that are related to the client's individual program plan and assessments and that contribute to an overall understanding of the client's ongoing level and quality of functioning.

(f) *Standard: Program monitoring and change.* (1) The individual program plan must be reviewed at least by the qualified mental retardation professional and revised as necessary, including, but not limited to situations in which the client—

(i) Has successfully completed an objective or objectives identified in the individual program plan;

(ii) Is regressing or losing skills already gained;

(iii) Is failing to progress toward identified objectives after reasonable efforts have been made; or

(iv) Is being considered for training towards new objectives.

(2) At least annually, the comprehensive functional assessment of each client must be reviewed by the interdisciplinary team for relevancy and updated as needed, and the individual program plan must be revised, as appropriate, repeating the process set forth in paragraph (c) of this section.

(3) The facility must designate and use a specially constituted committee or committees consisting of members of facility staff, parents, legal guardians, clients (as appropriate), qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior, and persons with no ownership or controlling interest in the facility to—

(i) Review, approve, and monitor individual programs designed to manage inappropriate behavior and other programs that, in the opinion of the committee, involve risks to client protection and rights;

(ii) Insure that these programs are conducted only with the written informed consent of the client, parent (if the client is a minor), or legal guardian; and

(iii) Review, monitor and make suggestions to the facility about its practices and programs as they relate to drug usage, physical restraints, time-out rooms, application of painful or noxious stimuli, control of inappropriate behavior, protection of client rights and funds, and any other area that the committee believes need to be addressed.

(4) The provisions of paragraph (f)(3) of this section may be modified only if, in the judgment of the State survey agency, Court decrees, State law or regulations provide for equivalent client protection and consultation.

§ 483.450 Condition of participation: Client behavior and facility practices.

(a) *Standard: Facility practices—Conduct toward clients.* (1) The facility must develop and implement written policies and procedures for the management of conduct between staff and clients. These policies and procedures must—

(i) Promote the growth, development and independence of the client;

(ii) Address the extent to which client choice will be accommodated in daily decision-making, emphasizing self-determination and self-management, to the extent possible;

(iii) Specify client conduct to be allowed or not allowed; and

(iv) Be available to all staff, clients, parents of minor children, and legal guardians.

(2) To the extent possible, clients must participate in the formulation of these policies and procedures.

(3) Clients must not discipline other clients, except as part of an organized system of self-government, as set forth in facility policy.

(b) *Standard: Management of inappropriate client behavior.* (1) The facility must develop and implement written policies and procedures that govern the management of inappropriate client behavior. These policies and procedures must be consistent with the provisions of paragraph (a) of this section. These procedures must—

(i) Specify all facility approved interventions to manage inappropriate client behavior;

(ii) Designate these interventions on a hierarchy to be implemented, ranging from most positive or least intrusive, to least positive or most intrusive;

(iii) Insure, prior to the use of more restrictive techniques, that the client's record documents that programs incorporating the use of less intrusive or more positive techniques have been tried systematically and demonstrated to be ineffective; and

(iv) Address the following:

(A) The use of time-out rooms.

(B) The use of physical restraints.

(C) The use of drugs to manage inappropriate behavior.

(D) The application of painful or noxious stimuli.

(E) The staff members who may authorize the use of specified interventions.

(F) A mechanism for monitoring and controlling the use of such interventions.

(2) Interventions to manage inappropriate client behavior must be employed with sufficient safeguards and supervision to ensure that the safety, welfare and civil and human rights of clients are adequately protected.

(3) Techniques to manage inappropriate client behavior must never be used for disciplinary purposes, for the convenience of staff or as a substitute for an active treatment program.

(4) The use of systematic interventions to manage inappropriate client

behavior must be incorporated into the client's individual program plan, in accordance with § 483.440(c) (4) and (5) of this subpart.

(5) Standing or as needed programs to control inappropriate behavior are not permitted.

(c) *Standard: Time-out rooms.* (1) A client may be placed in a room from which egress is prevented only if the following conditions are met:

(i) The placement is a part of an approved systematic time-out program as required by paragraph (b) of this section. (Thus, emergency placement of a client into a time-out room is not allowed.)

(ii) The client is under the direct constant visual supervision of designated staff.

(iii) The door to the room is held shut by staff or by a mechanism requiring constant physical pressure from a staff member to keep the mechanism engaged.

(2) Placement of a client in a time-out room must not exceed one hour.

(3) Clients placed in time-out rooms must be protected from hazardous conditions including, but not limited to, presence of sharp corners and objects, uncovered light fixtures, unprotected electrical outlets.

(4) A record of time-out activities must be kept.

(d) *Standard: Physical restraints.* (1) The facility may employ physical restraint only—

(i) As an integral part of an individual program plan that is intended to lead to less restrictive means of managing and eliminating the behavior for which the restraint is applied;

(ii) As an emergency measure, but only if absolutely necessary to protect the client or others from injury; or

(iii) As a health-related protection prescribed by a physician, but only if absolutely necessary during the conduct of a specific medical or surgical procedure, or only if absolutely necessary for client protection during the time that a medical condition exists.

(2) Authorizations to use or extend restraints as an emergency must be:

(i) In effect no longer than 12 consecutive hours; and

(ii) Obtained as soon as the client is restrained or stable.

(3) The facility must not issue orders for restraint on a standing or as needed basis.

(4) A client placed in restraint must be checked at least every 30 minutes by staff trained in the use of restraints, released from the restraint as quickly as possible, and a record of these checks and usage must be kept.

(5) Restraints must be designed and used so as not to cause physical injury to the client and so as to cause the least possible discomfort.

(6) Opportunity for motion and exercise must be provided for a period of not less than 10 minutes during each two hour period in which restraint is employed, and a record of such activity must be kept.

(7) Barred enclosures must not be more than three feet in height and must not have tops.

(e) *Standard: Drug usage.* (1) The facility must not use drugs in doses that interfere with the individual client's daily living activities.

(2) Drugs used for control of inappropriate behavior must be approved by the interdisciplinary team and be used only as an integral part of the client's individual program plan that is directed specifically towards the reduction of and eventual elimination of the behaviors for which the drugs are employed.

(3) Drugs used for control of inappropriate behavior must not be used until it can be justified that the harmful effects of the behavior clearly outweigh the potentially harmful effects of the drugs.

(4) Drugs used for control of inappropriate behavior must be—

(i) Monitored closely, in conjunction with the physician and the drug regimen review requirement at § 483.460(j), for desired responses and adverse consequences by facility staff; and

(ii) Gradually withdrawn at least annually in a carefully monitored program conducted in conjunction with the interdisciplinary team, unless clinical evidence justifies that this is contraindicated.

§483.460 Condition of participation: Health care services.

(a) *Standard: Physician services.* (1) The facility must ensure the availability of physician services 24 hours a day.

(2) The physician must develop, in coordination with licensed nursing personnel, a medical care plan of treatment for a client if the physician determines that an individual client requires 24-hour licensed nursing care. This plan must be integrated in the individual program plan.

(3) The facility must provide or obtain preventive and general medical care as well as annual physical examinations of each client that at a minimum include the following:

(i) Evaluation of vision and hearing.

(ii) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Commitee on Immunization Practices or of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics.

(iii) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed.

(iv) Tuberculosis control, appropriate to the facility's population, and in accordance with the recommendations of the American College of Chest Physicians or the section of diseases of the chest of the American Academy of Pediatrics, or both.

(4) To the extent permitted by State law, the facility may utilize physician assistants and nurse practitioners to provide physician services as described in this section.

(b) *Standard: Physician participation in the individual program plan.* A physician must participate in—

(1) The establishment of each newly admitted client's initial individual program plan as required by §456.380 of this chapter that specified plan of care requirements for ICFs; and

(2) If appropriate, physicians must participate in the review and update of an individual program plan as part of the interdisciplinary team process either in person or through written report to the interdisciplinary team.

(c) *Standard: Nursing services.* The facility must provide clients with nursing services in accordance with their needs. These services must include—

(1) Participation as appropriate in the development, review, and update of an individual program plan as part of the interdisciplinary team process;

(2) The development, with a physician, of a medical care plan of treatment for a client when the physician has determined that an individual client requires such a plan;

(3) For those clients certified as not needing a medical care plan, a review of their health status which must—

(i) Be by a direct physical examination;

(ii) Be by a licensed nurse;

(iii) Be on a quarterly or more frequent basis depending on client need;

(iv) Be recorded in the client's record; and

(v) Result in any necessary action (including referral to a physician to address client health problems).

(4) Other nursing care as prescribed by the physician or as identified by client needs; and

(5) Implementing, with other members of the interdisciplinary team, appropriate protective and preventive health measures that include, but are not limited to—

(i) Training clients and staff as needed in appropriate health and hygiene methods;

(ii) Control of communicable diseases and infections, including the instruction of other personnel in methods of infection control; and

(iii) Training direct care staff in detecting signs and symptoms of illness or dysfunction, first aid for accidents or illness, and basic skills required to meet the health needs of the clients.

(d) *Standard: Nursing staff.* (1) Nurses providing services in the facility must have a current license to practice in the State.

(2) The facility must employ or arrange for licensed nursing services sufficient to care for clients health needs including those clients with medical care plans.

(3) The facility must utilize registered nurses as appropriate and required by State law to perform the health services specified in this section.

(4) If the facility utilizes only licensed practical or vocational nurses to provide health services, it must have a formal arrangement with a registered nurse to be available for verbal or onsite consultation to the licensed practical or vocational nurse.

(5) Non-licensed nursing personnel who work with clients under a medical care plan must do so under the supervision of licensed persons.

(e) *Standard: Dental services.* (1) The facility must provide or make arrangements for comprehensive diagnostic and treatment services for each client from qualified personnel, including licensed dentists and dental hygienists either through organized dental services in-house or through arrangement.

(2) If appropriate, dental professionals must participate, in the development, review and update of an individual program plan as part of the interdisciplinary process either in person or through written report to the interdisciplinary team.

(3) The facility must provide education and training in the maintenance of oral health.

(f) *Standard: Comprehensive dental diagnostic services.* Comprehensive dental diagnostic services include—

(1) A complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the client's oral condition, not later than one month after admission to the facility (unless the examination was completed within twelve months before admission);

(2) Periodic examination and diagnosis performed at least annually, including radiographs when indicated and detection of manifestations of systemic disease; and

(3) A review of the results of examination and entry of the results in the client's dental record.

(g) *Standard: Comprehensive dental treatment.* The facility must ensure comprehensive dental treatment services that include—

(1) The availability for emergency dental treatment on a 24-hour-a-day basis by a licensed dentist; and

(2) Dental care needed for relief of pain and infections, restoration of teeth, and maintenance of dental health.

(h) *Standard: Documentation of dental services.* (1) If the facility maintains an in-house dental service, the facility must keep a permanent dental record for each client, with a dental summary maintained in the client's living unit.

(2) If the facility does not maintain an in-house dental service, the facility must obtain a dental summary of the results of dental visits and maintain the summary in the client's living unit.

(i) *Standard: Pharmacy services.* The facility must provide or make arrangements for the provision of routine and emergency drugs and biologicals to its clients. Drugs and biologicals may be obtained from community or contract pharmacists or the facility may maintain a licensed pharmacy.

(j) *Standard: Drug regimen review.* (1) A pharmacist with input from the interdisciplinary team must review the drug regimen of each client at least quarterly.

(2) The pharmacist must report any irregularities in clients' drug regimens to the prescribing physician and interdisciplinary team.

(3) The pharmacist must prepare a record of each client's drug regimen reviews and the facility must maintain that record.

(4) An individual medication administration record must be maintained for each client.

(5) As appropriate the pharmacist must participate in the development, implementation, and review of each client's individual program plan either in person or through written report to the interdisciplinary team.

(k) *Standard: Drug administration.* The facility must have an organized system for drug administration that identifies each drug up to the point of administration. The system must assure that—

(1) All drugs are administered in compliance with the physician's orders;

(2) All drugs, including those that are self-administered, are administered without error;

(3) Unlicensed personnel are allowed to administer drugs only if State law permits;

(4) Clients are taught how to administer their own medications if the interdisciplinary team determines that self administration of medications is

an appropriate objective, and if the physician does not specify otherwise;

(5) The client's physician is informed of the interdisciplinary team's decision that self-administration of medications is an objective for the client;

(6) No client self-administers medications until he or she demonstrates the competency to do so;

(7) Drugs used by clients while not under the direct care of the facility are packaged and labeled in accordance with State law; and

(8) Drug administration errors and adverse drug reactions are recorded and reported immediately to a physician.

(l) *Standard: Drug storage and recordkeeping.* (1) The facility must store drugs under proper conditions of sanitation, temperature, light, humidity, and security.

(2) The facility must keep all drugs and biologicals locked except when being prepared for administration. Only authorized persons may have access to the keys to the drug storage area. Clients who have been trained to self administer drugs in accordance with §483.460(k)(4) may have access to keys to their individual drug supply.

(3) The facility must maintain records of the receipt and disposition of all controlled drugs.

(4) The facility must, on a sample basis, periodically reconcile the receipt and disposition of all controlled drugs in schedules II through IV (drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 801 *et seq.*, as implemented by 21 CFR part 308).

(5) If the facility maintains a licensed pharmacy, the facility must comply with the regulations for controlled drugs.

(m) *Standard: Drug labeling.* (1) Labeling of drugs and biologicals must—

(i) Be based on currently accepted professional principles and practices; and

(ii) Include the appropriate accessory and cautionary instructions, as well as the expiration date, if applicable.

(2) The facility must remove from use—

(i) Outdated drugs; and

(ii) Drug containers with worn, illegible, or missing labels.

(3) Drugs and biologicals packaged in containers designated for a particular client must be immediately removed from the client's current medication supply if discontinued by the physician.

(n) *Standard: Laboratory services.* (1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.

(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialities of service in accordance with the requirements of part 493 of this chapter.

[53 FR 20496, June 3, 1988, as amended at 57 FR 7136, Feb. 28, 1992]

§483.470 Condition of participation: Physical environment.

(a) *Standard: Client living environment.* (1) The facility must not house clients of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(2) The facility must not segregate clients solely on the basis of their physical disabilities. It must integrate clients who have ambulation deficits or who are deaf, blind, or have seizure disorders, etc., with others of comparable social and intellectual development.

(b) *Standard: Client bedrooms.* (1) Bedrooms must—

(i) Be rooms that have at least one outside wall;

(ii) Be equipped with or located near toilet and bathing facilities;

(iii) Accommodate no more than four clients unless granted a variance under paragraph (b)(3) of this section;

(iv) Measure at least 60 square feet per client in multiple client bedrooms and at least 80 square feet in single client bedrooms; and

(v) In all facilities initially certified, or in buildings constructed or with major renovations or conversions on or after October 3, 1988, have walls that extend from floor to ceiling.

(2) If a bedroom is below grade level, it must have a window that—

(i) Is usable as a second means of escape by the client(s) occupying the room; and

(ii) Is no more than 44 inches (measured to the window sill) above the floor unless the facility is surveyed under the Health Care Occupancy Chapter of the Life Safety Code, in which case the window must be no more than 36 inches (measured to the window sill) above the floor.

(3) The survey agency may grant a variance from the limit of four clients per room only if a physician who is a member of the interdisciplinary team and who is a qualified mental retardation professional—

(i) Certifies that each client to be placed in a bedroom housing more than four persons is so severely medically impaired as to require direct and continuous monitoring during sleeping hours; and

(ii) Documents the reasons why housing in a room of only four or fewer persons would not be medically feasible.

(4) The facility must provide each client with—

(i) A separate bed of proper size and height for the convenience of the client;

(ii) A clean, comfortable, mattress;

(iii) Bedding appropriate to the weather and climate; and

(iv) Functional furniture appropriate to the client's needs, and individual closet space in the client's bedroom with clothes racks and shelves accessible to the client.

(c) *Standard: Storage space in bedroom.* The facility must provide—

(1) Space and equipment for daily out-of-bed activity for all clients who are not yet mobile, except those who have a short-term illness or those few clients for whom out-of-bed activity is a threat to health and safety; and

(2) Suitable storage space, accessible to clients, for personal possessions, such as TVs, radios, prosthetic equipment and clothing.

(d) *Standard: Client bathrooms.* The facility must—

(1) Provide toilet and bathing facilities appropriate in number, size, and design to meet the needs of the clients;

(2) Provide for individual privacy in toilets, bathtubs, and showers; and

(3) In areas of the facility where clients who have not been trained to regulate water temperature are exposed to hot water, ensure that the temperature of the water does not exceed 110° Fahrenheit.

(e) *Standard: Heating and ventilation.* (1) Each client bedroom in the facility must have—

(i) At least one window to the outside; and

(ii) Direct outside ventilation by means of windows, air conditioning, or mechanical ventilation.

(2) The facility must—

(i) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(ii) Ensure that the heating apparatus does not constitute a burn or smoke hazard to clients.

(f) *Standard: Floors.* The facility must have—

(1) Floors that have a resilient, nonabrasive, and slip-resistant surface;

(2) Nonabrasive carpeting, if the area used by clients is carpeted and serves clients who lie on the floor or ambulate with parts of their bodies, other than feet, touching the floor; and

(3) Exposed floor surfaces and floor coverings that promote mobility in areas used by clients, and promote maintenance of sanitary conditions.

(g) *Standard: Space and equipment.* The facility must—

(1) Provide sufficient space and equipment in dining, living, health services, recreation, and program areas (including adequately equipped and sound treated areas for hearing and other evaluations if they are conducted in the facility) to enable staff to provide clients with needed services as required by this subpart and as identified in each client's individual program plan.

(2) Furnish, maintain in good repair, and teach clients to use and to make informed choices about the use of dentures, eyeglasses, hearing and other communications aids, braces, and other devices identified by the interdisciplinary team as needed by the client.

(3) Provide adequate clean linen and dirty linen storage areas.

(h) *Standard: Emergency plan and procedures.* (1) The facility must develop

and implement detailed written plans and procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing clients.

(2) The facility must communicate, periodically review, make the plan available, and provide training to the staff.

(i) *Standard: Evacuation drills.* (1) The facility must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to—

(i) Ensure that all personnel on all shifts are trained to perform assigned tasks;

(ii) Ensure that all personnel on all shifts are familiar with the use of the facility's fire protection features; and

(iii) Evaluate the effectiveness of emergency and disaster plans and procedures.

(2) The facility must—

(i) Actually evacuate clients during at least one drill each year on each shift;

(ii) Make special provisions for the evacuation of clients with physical disabilities;

(iii) File a report and evaluation on each evacuation drill;

(iv) Investigate all problems with evacuation drills, including accidents, and take corrective action; and

(v) During fire drills, clients may be evacuated to a safe area in facilities certified under the Health Care Occupancies Chapter of the Life Safety Code.

(3) Facilities must meet the requirements of paragraphs (i)(1) and (2) of this section for any live-in and relief staff they utilize.

(j) *Standard: Fire protection*—(1) *General.* Except as otherwise provided in this section—

(i) The facility must meet the applicable provisions of either the Health Care Occupancies Chapters or the Residential Board and Care Occupancies Chapter of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted LSC does not apply to a facility.

(2) The State survey agency may apply a single chapter of the LSC to the entire facility or may apply different chapters to different buildings or parts of buildings as permitted by the LSC.

(3) A facility that meets the LSC definition of a residential board and care occupancy must have its evacuation capability evaluated in accordance with the Evacuation Difficulty Index of the Fire Safety Evaluation System for Board and Care facilities (FSES/BC).

(4) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects a facility's clients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(5) Beginning March 13, 2006, a facility must be in compliance with Chapter 19.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to a facility.

(7) *Facilities that meet the LSC definition of a health care occupancy.* (i) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

(A) The waiver would not adversely affect the health and safety of the clients.

(B) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(ii) Notwithstanding any provisions of the 2000 edition of the Life Safety

Code to the contrary, a facility may install alcohol-based hand rub dispensers if—

(A) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(B) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(C) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(D) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(k) *Standard: Paint.* The facility must—

(1) Use lead-free paint inside the facility; and

(2) Remove or cover interior paint or plaster containing lead so that it is not accessible to clients.

(l) *Standard: Infection control.* (1) The facility must provide a sanitary environment to avoid sources and transmission of infections. There must be an active program for the prevention, control, and investigation of infection and communicable diseases.

(2) The facility must implement successful corrective action in affected problem areas.

(3) The facility must maintain a record of incidents and corrective actions related to infections.

(4) The facility must prohibit employees with symptoms or signs of a communicable disease from direct contact with clients and their food.

[53 FR 20496, June 3, 1988. Redesignated at 56 FR 48918, Sept. 26, 1991, as amended at 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55340, Sept. 22, 2006, § 483.470 was amended by revising paragraph (j)(7)(ii)(C), by removing the last sentence of paragraph (j)(7)(ii)(D), by removing the period at the end of the paragraph (j)(7)(ii)(D) and adding in its place ''; and'', and adding paragraph (j)(7)(ii)(E), effective Oct. 23, 2006. For the convenience of the user, the revised and added text is set forth as follows:

§ 483.470 Condition of participation: Physical environment.

* * * * *

(j) * * *

(7) * * *

(ii) * * *

(C) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(E) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

* * * * *

§ 483.480 Condition of participation: Dietetic services.

(a) *Standard: Food and nutrition services.* (1) Each client must receive a nourishing, well-balanced diet including modified and specially-prescribed diets.

(2) A qualified dietitian must be employed either full-time, part-time, or on a consultant basis at the facility's discretion.

(3) If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food services.

(4) The client's interdisciplinary team, including a qualified dietitian and physician, must prescribe all modified and special diets including those

used as a part of a program to manage inappropriate client behavior.

(5) Foods proposed for use as a primary reinforcement of adaptive behavior are evaluated in light of the client's nutritional status and needs.

(6) Unless otherwise specified by medical needs, the diet must be prepared at least in accordance with the latest edition of the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, disability and activity.

(b) *Standard: Meal services.* (1) Each client must receive at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(i) Not more than 14 hours between a substantial evening meal and breakfast of the following day, except on weekends and holidays when a nourishing snack is provided at bedtime, 16 hours may elapse between a substantial evening meal and breakfast; and

(ii) Not less than 10 hours between breakfast and the evening meal of the same day, except as provided under paragraph (b)(1)(i) of this section.

(2) Food must be served—

(i) In appropriate quantity;

(ii) At appropriate temperature;

(iii) In a form consistent with the developmental level of the client; and

(iv) With appropriate utensils.

(3) Food served to clients individually and uneaten must be discarded.

(c) *Standard: Menus.* (1) Menus must—

(i) Be prepared in advance;

(ii) Provide a variety of foods at each meal;

(iii) Be different for the same days of each week and adjusted for seasonal changes; and

(iv) Include the average portion sizes for menu items.

(2) Menus for food actually served must be kept on file for 30 days.

(d) *Standard: Dining areas and service.* The facility must—

(1) Serve meals for all clients, including persons with ambulation deficits, in dining areas, unless otherwise specified by the interdisciplinary team or a physician;

(2) Provide table service for all clients who can and will eat at a table, including clients in wheelchairs;

(3) Equip areas with tables, chairs, eating utensils, and dishes designed to meet the developmental needs of each client;

(4) Supervise and staff dining rooms adequately to direct self-help dining procedure, to assure that each client receives enough food and to assure that each client eats in a manner consistent with his or her developmental level: and

(5) Ensure that each client eats in an upright position, unless otherwise specified by the interdisciplinary team or a physician.

PART 484—HOME HEALTH SERVICES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

SOURCE: 54 FR 33367, Aug. 14, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 484.1 Basis and scope.

(a) *Basis and scope.* This part is based on the indicated provisions of the following sections of the Act:

(1) Sections 1861(o) and 1891 establish the conditions that an HHA must meet in order to participate in Medicare.

(2) Section 1861(z) specifies the Institutional planning standards that HHAs must meet.

(3) Section 1895 provides for the establishment of a prospective payment system for home health services covered under Medicare.

(b) This part also sets forth additional requirements that are considered necessary to ensure the health and safety of patients.

[60 FR 50443, Sept. 29, 1995, as amended at 65 FR 41211, July 3, 2000]

§ 484.2 Definitions.

As used in this part, unless the context indicates otherwise—*Bylaws or equivalent* means a set of rules adopted by an HHA for governing the agency's operation.

Branch office means a location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the home health agency and is located sufficiently close to share administration, supervision, and services in a manner that renders it unnecessary for the branch independently to meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition.

HHA stands for home health agency.

Nonprofit agency means an agency exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954.

Parent home health agency means the agency that develops and maintains administrative controls of subunits and/or branch offices.

Primary home health agency means the agency that is responsible for the services furnished to patients and for implementation of the plan of care.

Progress note means a written notation, dated and signed by a member of the health team, that summarizes facts about care furnished and the patient's response during a given period of time.

Proprietary agency means a private profit-making agency licensed by the State.

Public agency means an agency operated by a State or local government.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets

the conditions of participation for HHAs. A subdivision that has subunits or branch offices is considered a parent agency.

Subunit means a semi-autonomous organization that—

(1) Serves patients in a geographic area different from that of the parent agency; and

(2) Must independently meet the conditions of participation for HHAs because it is too far from the parent agency to share administration, supervision, and services on a daily basis.

Summary report means the compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician.

Supervision means authoritative procedural guidance by a qualified person for the accomplishment of a function or activity. Unless otherwise specified in this part, the supervisor must be on the premises to supervise an individual who does not meet the qualifications specified in § 484.4.

§ 484.4 Personnel qualifications.

Staff required to meet the conditions set forth in this part are staff who meet the qualifications specified in this section.

Administrator, home health agency. A person who:

(a) Is a licensed physician; or

(b) Is a registered nurse; or

(c) Has training and experience in health service administration and at least 1 year of supervisory or administrative experience in home health care or related health programs.

Audiologist. A person who:

(a) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(b) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

Home health aide. Effective for services furnished after August 14, 1990, a person who has successfully completed a State-established or other training program that meets the requirements of § 484.36(a) and a competency evaluation program or State licensure program that meets the requirements of § 484.36 (b) or (e), or a competency evaluation program or State licensure program that meets the requirements of § 484.36 (b) or (e). An individual is not considered to have completed a training and competency evaluation program, or a competency evaluation program if, since the individual's most recent completion of this program(s), there has been a continuous period of 24 consecutive months during none of which the individual furnished services described in § 409.40 of this chapter for compensation.

Occupational therapist. A person who:

(a) Is a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(b) Is eligible for the National Registration Examination of the American Occupational Therapy Association; or

(c) Has 2 years of appropriate experience as an occupational therapist, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.

Occupational therapy assistant. A person who:

(a) Meets the requirements for certification as an occupational therapy assistant established by the American Occupational Therapy Association; or

(b) Has 2 years of appropriate experience as an occupational therapy assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapy assistant after December 31, 1977.

Physical therapist. A person who is licensed as a physical therapist by the State in which practicing, and

(a) Has graduated from a physical therapy curriculum approved by:

(1) The American Physical Therapy Association, or

(2) The Committee on Allied Health Education and Accreditation of the American Medical Association, or

(3) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association; or

(b) Prior to January 1, 1966,

(1) Was admitted to membership by the American Physical Therapy Association, or

(2) Was admitted to registration by the American Registry of Physical Therapist, or

(3) Has graduated from a physical therapy curriculum in a 4-year college or university approved by a State department of education; or

(c) Has 2 years of appropriate experience as a physical therapist, and has achieved a satifactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service except that such determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking qualification as a physical therapist after December 31, 1977; or

(d) Was licensed or registered prior to January 1, 1966, and prior to January 1, 1970, had 15 years of full-time experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy; or

(e) If trained outside the United States,

(1) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization of the World Confederation for Physical Therapy.

(2) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy,

Physical therapist assistant. A person who is licensed as a physical therapist assistant, if applicable, by the State in which practicing, and

(1) Has graduated from a 2-year college-level program approved by the American Physical Therapy Association; or

(2) Has 2 years of appropriate experience as a physical therapist assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a physical therapy assistant after December 31, 1977.

Physician. A doctor of medicine, osteophathy or podiatry legally authorized to practice medicine and surgery by the State in which such function or action is performed.

Practical (vocational) nurse. A person who is licensed as a practical (vocational) nurse by the State in which practicing.

Public health nurse. A registered nurse who has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or postregistered nurse study that includes content aproved by the National League for Nursing for public health nursing preparation.

Registered nurse (RN). A graduate of an approved school of professional nursing, who is licensed as a registered nurse by the State in which practicing.

Social work assistant. A person who:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that these determinations of proficiency do not apply with respect to persons initially licensed by a State or seeking initial qualification as a social work assistant after December 31, 1977.

Social worker. A person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of

social work experience in a health care setting.

Speech-language pathologist. A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in (speech pathology or audiology) granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 69 FR 66426, Nov. 15, 2004]

Subpart B—Administration

§ 484.10 Condition of participation: Patient rights.

The patient has the right to be informed of his or her rights. The HHA must protect and promote the exercise of these rights.

(a) *Standard: Notice of rights.* (1) The HHA must provide the patient with a written notice of the patient's rights in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The HHA must maintain documentation showing that it has complied with the requirements of this section.

(b) *Standard: Exercise of rights and respect for property and person.* (1) The patient has the right to exercise his or her rights as a patient of the HHA.

(2) The patient's family or guardian may exercise the patient's rights when the patient has been judged incompetent.

(3) The patient has the right to have his or her property treated with respect.

(4) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the HHA and must not be subjected to discrimination or reprisal for doing so.

(5) The HHA must investigate complaints made by a patient or the patient's family or guardian regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the HHA, and must document both the existence of the complaint and the resolution of the complaint.

(c) *Standard: Right to be informed and to participate in planning care and treatment.* (1) The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished.

(i) The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(ii) The HHA must advise the patient in advance of any change in the plan of care before the change is made.

(2) The patient has the right to participate in the planning of the care.

(i) The HHA must advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(ii) The HHA complies with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. The HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(d) *Standard: Confidentiality of medical records.* The patient has the right to confidentiality of the clinical records maintained by the HHA. The HHA must advise the patient of the agency's policies and procedures regarding disclosure of clinical records.

(e) *Standard: Patient liability for payment.* (1) The patient has the right to be advised, before care is initiated, of the extent to which payment for the HHA services may be expected from Medicare or other sources, and the extent to which payment may be required from the patient. Before the care is initiated, the HHA must inform the patient, orally and in writing, of—

(i) The extent to which payment may be expected from Medicare, Medicaid,

or any other Federally funded or aided program known to the HHA;

(ii) The charges for services that will not be covered by Medicare; and

(iii) The charges that the individual may have to pay.

(2) The patient has the right to be advised orally and in writing of any changes in the information provided in accordance with paragraph (e)(1) of this section when they occur. The HHA must advise the patient of these changes orally and in writing as soon as possible, but no later than 30 calendar days from the date that the HHA becomes aware of a change.

(f) *Standard: Home health hotline.* The patient has the right to be advised of the availability of the toll-free HHA hotline in the State. When the agency accepts the patient for treatment or care, the HHA must advise the patient in writing of the telephone number of the home health hotline established by the State, the hours of its operation, and that the purpose of the hotline is to receive complaints or questions about local HHAs. The patient also has the right to use this hotline to lodge complaints concerning the implementation of the advance directives requirements.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 57 FR 8203, Mar. 6, 1992; 60 FR 33293, June 27, 1995]

§ 484.11 Condition of participation: Release of patient identifiable OASIS information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

[64 FR 3763, Jan. 25, 1999]

§ 484.12 Condition of participation: Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles.

(a) *Standard: Compliance with Federal, State, and local laws and regulations.* The HHA and its staff must operate and furnish services in compliance with all applicable Federal, State, and local laws and regulations. If State or applicable local law provides for the licensure of HHAs, an agency not subject to licensure is approved by the licensing authority as meeting the standards established for licensure.

(b) *Standard: Disclosure of ownership and management information.* The HHA must comply with the requirements of Part 420, Subpart C of this chapter. The HHA also must disclose the following information to the State survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(1) The name and address of all persons with an ownership or control interest in the HHA as defined in §§ 420.201, 420.202, and 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent or a managing employee of the HHA as defined in §§ 420.201, 420.202, and 420.206 of this chapter.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the HHA, and the name and address of the chief executive officer and the chairman of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(c) *Standard: Compliance with accepted professional standards and principles.* The HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA.

§ 484.14 Condition of participation: Organization, services, and administration.

Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level are clearly set forth in writing and are readily identifiable. Administrative and supervisory functions are not delegated to another agency or organization and all services not furnished directly, including services provided through subunits are monitored and controlled by the parent agency. If an

agency has subunits, appropriate administrative records are maintained for each subunit.

(a) *Standard: Services furnished.* Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the qualifying services directly through agency employees, but may provide the second qualifying service and additional services under arrangements with another agency or organization.

(b) *Standard: Governing body.* A governing body (or designated persons so functioning) assumes full legal authority and responsibility for the operation of the agency. The governing body appoints a qualified administrator, arranges for professional advice as required under §484.16, adopts and periodically reviews written bylaws or an acceptable equivalent, and oversees the management and fiscal affairs of the agency.

(c) *Standard: Administrator.* The administrator, who may also be the supervising physician or registered nurse required under paragraph (d) of this section, organizes and directs the agency's ongoing functions; maintains ongoing liaison among the governing body, the group of professional personnel, and the staff; employs qualified personnel and ensures adequate staff education and evaluations; ensures the accuracy of public information materials and activities; and implements an effective budgeting and accounting system. A qualified person is authorized in writing to act in the absence of the administrator.

(d) *Standard: Supervising physician or registered nurse.* The skilled nursing and other therapeutic services furnished are under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person, or similarly qualified alternate, is available at all times during operating hours and participates in all activities relevant to the professional services furnished, including the development of qualifications and the assignment of personnel.

(e) *Standard: Personnel policies.* Personnel practices and patient care are supported by appropriate, written personnel policies. Personnel records include qualifications and licensure that are kept current.

(f) *Standard: Personnel under hourly or per visit contracts.* If personnel under hourly or per visit contracts are used by the HHA, there is a written contract between those personnel and the agency that specifies the following:

(1) Patients are accepted for care only by the primary HHA.

(2) The services to be furnished.

(3) The necessity to conform to all applicable agency policies, including personnel qualifications.

(4) The responsibility for participating in developing plans of care.

(5) The manner in which services will be controlled, coordinated, and evaluated by the primary HHA.

(6) The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation.

(7) The procedures for payment for services furnished under the contract.

(g) *Standard: Coordination of patient services.* All personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. The clinical record or minutes of case conferences establish that effective interchange, reporting, and coordination of patient care does occur. A written summary report for each patient is sent to the attending physician at least every 60 days.

(h) *Standard: Services under arrangements.* Services furnished under arrangements are subject to a written contract conforming with the requirements specified in paragraph (f) of this section and with the requirements of section 1861(w) of the Act (42 U.S.C. 1495x(w)).

(i) *Standard: Institutional planning.* The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

(1) *Annual operating budget.* There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

(2) *Capital expenditure plan.* (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health and Crippled Children's Services) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to comform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a–1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

(3) *Preparation of plan and budget.* The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) *Annual review of plan and budget.* The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

(j) *Standard: Laboratory services.* (1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32973, July 18, 1991; 56 FR 51334, Oct. 11, 1991; 57 FR 7136, Feb. 28, 1992; 66 FR 32778, June 18, 2001]

§ 484.16 Condition of participation: Group of professional personnel.

A group of professional personnel, which includes at least one physician and one registered nurse (preferably a

public health nurse), and with appropriate representation from other professional disciplines, establishes and annually reviews the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of care, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group is neither an owner nor an employee of the agency.

(a) *Standard: Advisory and evaluation function.* The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program, and to assist the agency in maintaining liaison with other health care providers in the community and in the agency's community information program. The meetings are documented by dated minutes.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.18 Condition of participation: Acceptance of patients, plan of care, and medical supervision.

Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

(a) *Standard: Plan of care.* The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

(b) *Standard: Periodic review of plan of care.* The total plan of care is reviewed by the attending physician and HHA personnel as often as the severity of the patient's condition requires, but at least once every 60 days or more frequently when there is a beneficiary elected transfer; a significant change in condition resulting in a change in the case-mix assignment; or a discharge and return to the same HHA during the 60-day episode. Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

(c) *Standard: Conformance with physician orders.* Drugs and treatments are administered by agency staff only as ordered by the physician with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per agency policy developed in consultation with a physician, and after an assessment for contraindications. Verbal orders are put in writing and signed and dated with the date of receipt by the registered nurse or qualified therapist (as defined in § 484.4 of this chapter) responsible for furnishing or supervising the ordered services. Verbal orders are only accepted by personnel authorized to do so by applicable State and Federal laws and regulations as well as by the HHA's internal policies.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991; 64 FR 3784, Jan. 25, 1999; 65 FR 41211, July 3, 2000; 67 FR 61814, Oct. 2, 2002]

§ 484.20 Condition of participation: Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with § 484.55.

(a) *Standard: Encoding and transmitting OASIS data.* An HHA must encode and electronically transmit each completed OASIS assessment to the State agency or the CMS OASIS contractor, regarding each beneficiary with respect to which such information is required to be transmitted (as determined by

the Secretary), within 30 days of completing the assessment of the beneficiary.

(b) *Standard: Accuracy of encoded OASIS data.* The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

(c) *Standard: Transmittal of OASIS data.* An HHA must—

(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

(2) Successfully transmit test data to the State agency or CMS OASIS contractor.

(3) Transmit data using electronics communications software that provides a direct telephone connection from the HHA to the State agency or CMS OASIS contractor.

(4) Transmit data that includes the CMS-assigned branch identification number, as applicable.

(d) *Standard: Data Format.* The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

[64 FR 3763, Jan. 25, 1999, as amended at 70 FR 76208, Dec. 23, 2005]

Subpart C—Furnishing of Services

§ 484.30 Condition of participation: Skilled nursing services.

The HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care.

(a) *Standard: Duties of the registered nurse.* The registered nurse makes the initial evaluation visit, regularly reevaluates the patient's nursing needs, initiates the plan of care and necessary revisions, furnishes those services requiring substantial and specialized nursing skill, initiates appropriate preventive and rehabilitative nursing procedures, prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs, counsels the patient and family in meeting nursing and related needs, participates in in-service programs, and supervises and teaches other nursing personnel.

(b) *Standard: Duties of the licensed practical nurse.* The licensed practical nurse furnishes services in accordance with agency policies, prepares clinical and progress notes, assists the physician and registered nurse in performing specialized procedures, prepares equipment and materials for treatments observing aseptic technique as required, and assists the patient in learning appropriate self-care techniques.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.32 Condition of participation: Therapy services.

Any therapy services offered by the HHA directly or under arrangement are given by a qualified therapist or by a qualified therapy assistant under the supervision of a qualified therapist and in accordance with the plan of care. The qualified therapist assists the physician in evaluating level of function, helps develop the plan of care (revising it as necessary), prepares clinical and progress notes, advises and consults with the family and other agency personnel, and participates in in-service programs.

(a) *Standard: Supervision of physical therapy assistant and occupational therapy assistant.* Services furnished by a qualified physical therapy assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapy assistant or occupational therapy assistant performs services planned, delegated, and supervised by the therapist, assists in preparing clinical notes and progress reports, and participates in educating the patient and family, and in in-service programs.

(b) *Standard: Supervision of speech therapy services.* Speech therapy services are furnished only by or under supervision of a qualified speech pathologist or audiologist.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991]

§ 484.34 Condition of participation: Medical social services.

If the agency furnishes medical social services, those services are given

by a qualified social worker or by a qualified social work assistant under the supervision of a qualified social worker, and in accordance with the plan of care. The social worker assists the physician and other team members in understanding the significant social and emotional factors related to the health problems, participates in the development of the plan of care, prepares clinical and progress notes, works with the family, uses appropriate community resources, participates in discharge planning and in-service programs, and acts as a consultant to other agency personnel.

§ 484.36 Condition of participation: Home health aide services.

Home health aides are selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. They are closely supervised to ensure their competence in providing care. For home health services furnished (either directly or through arrangements with other organizations) after August 14, 1990, the HHA must use individuals who meet the personnel qualifications specified in § 484.4 for ''home health aide''.

(a) *Standard: Home health aide training*—(1) *Content and duration of training.* The aide training program must address each of the following subject areas through classroom and supervised practical training totalling at least 75 hours, with at least 16 hours devoted to supervised practical training. The individual being trained must complete at least 16 hours of classroom training before beginning the supervisied practical training.

(i) Communications skills.

(ii) Observation, reporting and documentation of patient status and the care or service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and knowledge of emergency procedures.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy and his or her property.

(ix) Appropriate and safe techniques in personal hygiene and grooming that include—

(A) Bed bath.

(B) Sponge, tub, or shower bath.

(C) Shampoo, sink, tub, or bed.

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(x) Safe transfer techniques and ambulation.

(xi) Normal range of motion and positioning.

(xii) Adequate nutrition and fluid intake.

(xiii) Any other task that the HHA may choose to have the home health aide perform.

''Supervised practical training'' means training in a laboratory or other setting in which the trainee demonstrates knowledge while performing tasks on an individual under the direct supervision of a registered nurse or licensed practical nurse.

(2) *Conduct of training*—(i) *Organizations.* A home health aide training program may be offered by any organization except an HHA that, within the previous 2 years has been found—

(A) Out of compliance with requirements of this paragraph (a) or paragraph (b) of this section;

(B) To permit an individual that does not meet the definition of ''home health aide'' as specified in § 484.4 to furnish home health aide services (with the exception of licensed health professionals and volunteers);

(C) Has been subject to an extended (or partial extended) survey as a result of having been found to have furnished substandard care (or for other reasons at the discretion of the CMS or the State);

(D) Has been assessed a civil monetary penalty of not less than $5,000 as an intermediate sanction;

(E) Has been found to have compliance deficiencies that endanger the health and safety of the HHA's patients and has had a temporary management appointed to oversee the management of the HHA;

(F) Has had all or part of its Medicare payments suspended; or

(G) Under any Federal or State law within the 2-year period beginning on October 1, 1988—

(*1*) Has had its participation in the Medicare program terminated;

(*2*) Has been assessed a penalty of not less than $5,000 for deficiencies in Federal or State standards for HHAs;

(*3*) Was subject to a suspension of Medicare payments to which it otherwise would have been entitled;

(*4*) Had operated under a temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(*5*) Was closed or had it's residents transferred by the State.

(ii) *Qualifications for instructors.* The training of home health aides and the supervision of home health aides during the supervised practical portion of the training must be performed by or under the general supervision of a registered nurse who possesses a minimum of 2 years of nursing experience, at least 1 year of which must be in the provision of home health care. Other individuals may be used to provide instruction under the supervision of a qualified registered nurse.

(3) *Documentation of training.* The HHA must maintain sufficient documentation to demonstrate that the requirements of this standard are met.

(b) *Standard: Competency evaluation and in-service training*—(1) *Applicability.* An individual may furnish home health aide services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this paragraph. The HHA is responsible for ensuring that the individuals who furnish home health aide services on its behalf meet the competency evaluation requirements of this section.

(2) *Content and frequency of evaluations and amount of in-service training.* (i) The competency evaluation must address each of the subjects listed in paragraph (a)(1) (ii) through (xiii) of this section.

(ii) The HHA must complete a performance review of each home health aide no less frequently than every 12 months.

(iii) The home health aide must receive at least 12 hours of in-service training during each 12-month period. The in-service training may be furnished while the aide is furnishing care to the patient.

(3) *Conduct of evaluation and training*—(i) *Organizations.* A home health aide competency evaluation program may be offered by any organization except as specified in paragraph (a)(2)(i) of this section.

The in-service training may be offered by any organization.

(ii) *Evaluators and instructors.* The competency evaluation must be performed by a registered nurse. The in-service training generally must be supervised by a registered nurse who possesses a minimum of 2 years of nursing experience at least 1 year of which must be in the provision of home health care.

(iii) *Subject areas.* The subject areas listed at paragraphs (a)(1) (iii), (ix), (x), and (xi) of this section must be evaluated after observation of the aide's performance of the tasks with a patient. The other subject areas in paragraph (a)(1) of this section may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(4) *Competency determination.* (i) A home health aide is not considered competent in any task for which he or she is evaluated as ''unsatisfactory''. The aide must not perform that task without direct supervision by a licensed nurse until after he or she receives training in the task for which he or she was evaluated as ''unsatisfactory'' and passes a subsequent evaluation with ''satisfactory''.

(ii) A home health aide is not considered to have successfully passed a competency evaluation if the aide has an ''unsatisfactory'' rating in more than one of the required areas.

(5) *Documentation of competency evaluation.* The HHA must maintain documentation which demonstrates that

the requirements of this standard are met.

(6) *Effective date.* The HHA must implement a competency evaluation program that meets the requirements of this paragraph before February 14, 1990. The HHA must provide the preparation necessary for the individual to successfully complete the competency evaluation program. After August 14, 1990, the HHA may use only those aides that have been found to be competent in accordance with § 484.36(b).

(c) *Standard: Assignment and duties of the home health aide*—(1) *Assignment.* The home health aide is assigned to a specific patient by the registered nurse. Written patient care instructions for the home health aide must be prepared by the registered nurse or other appropriate professional who is responsible for the supervision of the home health aide under paragraph (d) of this section.

(2) *Duties.* The home health aide provides services that are ordered by the physician in the plan of care and that the aide is permitted to perform under State law. The duties of a home health aide include the provision of hands-on personal care, performance of simple procedures as an extension of therapy or nursing services, assistance in ambulation or exercises, and assistance in administering medications that are ordinarily self-administered. Any home health aide services offered by an HHA must be provided by a qualified home health aide.

(d) *Standard: Supervision.* (1) If the patient receives skilled nursing care, the registered nurse must perform the supervisory visit required by paragraph (d)(2) of this section. If the patient is not receiving skilled nursing care, but is receiving another skilled service (that is, physical therapy, occupational therapy, or speech-language pathology services), supervision may be provided by the appropriate therapist.

(2) The registered nurse (or another professional described in paragraph (d)(1) of this section) must make an onsite visit to the patient's home no less frequently than every 2 weeks.

(3) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy or speech-language pathology services, the registered nurse must make a supervisory visit to the patient's home no less frequently than every 60 days. In these cases, to ensure that the aide is properly caring for the patient, each supervisory visit must occur while the home health aide is providing patient care.

(4) If home health aide services are provided by an individual who is not employed directly by the HHA (or hospice), the services of the home health aide must be provided under arrangements, as defined in section 1861(w)(1) of the Act. If the HHA (or hospice) chooses to provide home health aide services under arrangements with another organization, the HHA's (or hospice's) responsibilities include, but are not limited to—

(i) Ensuring the overall quality of the care provided by the aide;

(ii) Supervision of the aide's services as described in paragraphs (d)(1) and (d)(2) of this section; and

(iii) Ensuring that home health aides providing services under arrangements have met the training requirements of paragraphs (a) and (b) of this section.

(e) *Personal care attendant: Evaluation requirements*—(1) *Applicability.* This paragraph applies to individuals who are employed by HHAs exclusively to furnish personal care attendant services under a Medicaid personal care benefit.

(2) *Rule.* An individual may furnish personal care services, as defined in § 440.170 of this chapter, on behalf of an HHA after the individual has been found competent by the State to furnish those services for which a competency evaluation is required by paragraph (b) of this section and which the individual is required to perform. The individual need not be determined competent in those services listed in paragraph (a) of this section that the individual is not required to furnish.

[54 FR 33367, August 14, 1989, as amended at 56 FR 32974, July 18, 1991; 56 FR 51334, Oct. 11, 1991; 59 FR 65498, Dec. 20, 1994; 60 FR 39123, Aug. 1, 1995; 66 FR 32778, June 18, 2001]

§ 484.38 Condition of participation: Qualifying to furnish outpatient physical therapy or speech pathology services.

An HHA that wishes to furnish outpatient physical therapy or speech pathology services must meet all the pertinent conditions of this part and also meet the additional health and safety requirements set forth in §§ 485.711, 485.713, 485.715, 485.719, 485.723, and 485.727 of this chapter to implement section 1861(p) of the Act.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 2329, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995]

§ 484.48 Condition of participation: Clinical records.

A clinical record containing pertinent past and current findings in accordance with accepted professional standards is maintained for every patient receiving home health services. In addition to the plan of care, the record contains appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary. The HHA must inform the attending physician of the availability of a discharge summary. The discharge summary must be sent to the attending physician upon request and must include the patient's medical and health status at discharge.

(a) *Standards: Retention of records.* Clinical records are retained for 5 years after the month the cost report to which the records apply is filed with the intermediary, unless State law stipulates a longer period of time. Policies provide for retention even if the HHA discontinues operations. If a patient is transferred to another health facility, a copy of the record or abstract is sent with the patient.

(b) *Standards: Protection of records.* Clinical record information is safeguarded against loss or unauthorized use. Written procedures govern use and removal of records and the conditions for release of information. Patient's written consent is required for release of information not authorized by law.

[54 FR 33367, Aug. 14, 1989, as amended at 60 FR 65498, Dec. 20, 1994]

§ 484.52 Condition of participation: Evaluation of the agency's program.

The HHA has written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), HHA staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation consists of an overall policy and administrative review and a clinical record review. The evaluation assesses the extent to which the agency's program is appropriate, adequate, effective, and efficient. Results of the evaluation are reported to and acted upon by those responsible for the operation of the agency and are maintained separately as administrative records.

(a) *Standard: Policy and administrative review.* As a part of the evaluation process the policies and administrative practices of the agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient. Mechanisms are established in writing for the collection of pertinent data to assist in evaluation.

(b) *Standard: Clinical record review.* At least quarterly, appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care.

[54 FR 33367, Aug. 14, 1989; 66 FR 32778, June 18, 2001]

§ 484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement

of desired outcomes. The comprehensive assessment must identify the patient's continuing need for home care and meet the patient's medical, nursing, rehabilitative, social, and discharge planning needs. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment. The comprehensive assessment must also incorporate the use of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary.

(a) *Standard: Initial assessment visit.* (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate rehabilitation skilled professional.

(b) *Standard: Completion of the comprehensive assessment.* (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) *Standard: Drug regimen review.* The comprehensive assessment must include a review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

(d) *Standard: Update of the comprehensive assessment.* The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than—

(1) The last five days of every 60 days beginning with the start-of-care date, unless there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition resulting in a new case-mix assignment; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests;

(3) At discharge.

(e) *Standard: Incorporation of OASIS data items.* The OASIS data items determined by the Secretary must be incorporated into the HHA's own assessment and must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data

items collected at inpatient facility admission or discharge only.

[64 FR 3784, Jan. 25, 1999, as amended at 65 FR 41211, July 3, 2000]

Subpart D [Reserved]

Subpart E—Prospective Payment System for Home Health Agencies

SOURCE: 65 FR 41212, July 3, 2000, unless otherwise noted.

§ 484.200 Basis and scope.

(a) *Basis.* This subpart implements section 1895 of the Act, which provides for the implementation of a prospective payment system (PPS) for HHAs for portions of cost reporting periods occurring on or after October 1, 2000.

(b) *Scope.* This subpart sets forth the framework for the HHA PPS, including the methodology used for the development of the payment rates, associated adjustments, and related rules.

§ 484.202 Definitions.

As used in this subpart—

Case-mix index means a scale that measures the relative difference in resource intensity among different groups in the clinical model.

Discipline means one of the six home health disciplines covered under the Medicare home health benefit (skilled nursing services, home health aide services, physical therapy services, occupational therapy services, speech-language pathology services, and medical social services).

Home health market basket index means an index that reflects changes over time in the prices of an appropriate mix of goods and services included in home health services.

Rural area means, with respect to home health episodes ending on or after January 1, 2006, an area defined in § 412.64(b)(1)(ii)(C) of this chapter.

Urban area means, with respect to home health episodes ending on or after January 1, 2006, an area defined in § 412.64(b)(1)(ii)(A) and (B) of this chapter.

[70 FR 68142, Nov. 9, 2005]

§ 484.205 Basis of payment.

(a) *Method of payment.* An HHA receives a national prospective 60-day episode payment of a predetermined rate for a home health service previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national 60-day episode payment is determined in accordance with § 484.215. The national prospective 60-day episode payment is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in § 484.230.

(2) A partial episode payment (PEP) adjustment due to an intervening event defined as a beneficiary elected transfer or a discharge and return to the same HHA during the 60-day episode, that warrants a new 60-day episode payment during an existing 60-day episode, that initiates the start of a new 60-day episode payment and a new physician certification of the new plan of care. The PEP adjustment is determined in accordance with § 484.235.

(3) A significant change in condition (SCIC) payment adjustment due to the intervening event defined as a significant change in the patient's condition during an existing 60-day episode. The SCIC adjustment occurs when a beneficiary experiences a significant change in condition during a 60-day episode that was not envisioned in the original plan of care. The SCIC adjustment is determined in accordance with § 484.237.

(4) An outlier payment is determined in accordance with § 484.240.

(b) *Episode payment.* The national prospective 60-day episode payment represents payment in full for all costs associated with furnishing home health services previously paid on a reasonable cost basis (except the osteoporosis drug listed in section 1861(m) of the Act as defined in section 1861(kk) of the Act) as of August 5, 1997 unless the national 60-day episode payment is subject to a low-utilization payment adjustment set forth in § 484.230, a partial episode payment adjustment set forth at § 484.235, a significant change in condition payment set forth at § 484.237, or an additional outlier payment set forth in § 484.240. All payments under this

system may be subject to a medical review adjustment reflecting beneficiary eligibility, medical necessity determinations, and HHRG assignment. DME provided as a home health service as defined in section 1861(m) of the Act continues to be paid the fee schedule amount.

(1) *Split percentage payment for initial episodes.* The initial percentage payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(2) *Split percentage payment for subsequent episodes.* The initial percentage payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage adjusted 60-day episode rate. The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage adjusted 60-day episode rate. Split percentage payments are made in accordance with requirements at § 409.43(c) of this chapter.

(c) *Low-utilization payment.* An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless CMS determines at the end of the 60-day episode that the HHA furnished minimal services to a patient during the 60-day episode. A low- utilization payment adjustment is determined in accordance with § 484.230.

(d) *Partial episode payment adjustment.* An HHA receives a national 60-day episode payment of a predetermined rate for home health services previously paid on a reasonable cost basis as of August 5, 1997, unless CMS determines an intervening event, defined as a beneficiary elected transfer, or discharge and return to the same HHA during a 60-day episode, warrants a new 60-day episode payment. The PEP adjustment would not apply in situations of transfers among HHAs of common ownership as defined in § 424.22 of this chapter. Those situations would be considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode. The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA. The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid. The discharge and return to the same HHA during the 60-day episode is only recognized in those circumstances when a beneficiary reached the goals in the original plan of care. The original plan of care must have been terminated with no anticipated need for additional home health services for the balance of the 60-day episode. If the intervening event warrants a new 60-day episode payment and the new physician certification of a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care. A partial episode payment adjustment is determined in accordance with § 484.235.

(e) *Significant change in condition adjustment.* The HHA receives a national 60-day episode payment of a predetermined rate for home health services paid on a reasonable cost basis as of August 5, 1997, unless CMS determines an intervening event defined as a beneficiary experiencing a significant change in condition during a 60-day episode that was not envisioned in the original plan of care occurred. In order to receive a new case-mix assignment for purposes of payment during the 60-day episode, the HHA must complete an OASIS assessment and obtain the necessary physician change orders reflecting the significant change in the treatment approach in the patient's plan of care. The total significant change in condition payment adjustment is a proportional payment adjustment reflecting the time both prior and after the patient experienced a significant change in condition during the 60-day episode. A SCIC adjustment is determined in accordance with § 484.237.

(f) *Outlier payment.* An HHA receives a national 60-day episode payment of a predetermined rate for a home health service paid on a reasonable cost basis as of August 5, 1997, unless the imputed cost of the 60-day episode exceeds a threshold amount. The outlier payment is defined to be a proportion of the imputed costs beyond the threshold. An outlier payment is a payment in addition to the national 60-day episode payment. The total of all outlier payments is limited to 5 percent of total outlays under the HHA PPS. An outlier payment is determined in accordance with § 484.240.

§ 484.210 Data used for the calculation of the national prospective 60-day episode payment.

To calculate the national prospective 60-day episode payment, CMS uses the following:

(a) Medicare cost data on the most recent audited cost report data available.

(b) Utilization data based on Medicare claims.

(c) An appropriate wage index to adjust for area wage differences.

(d) The most recent projections of increases in costs from the HHA market basket index.

(e) OASIS assessment data and other data that account for the relative resource utilization for different HHA Medicare patient case-mix.

§ 484.215 Initial establishment of the calculation of the national 60-day episode payment.

(a) *Determining an HHA's costs.* In calculating the initial unadjusted national 60-day episode payment applicable for a service furnished by an HHA using data on the most recent available audited cost reports, CMS determines each HHA's costs by summing its allowable costs for the period. CMS determines the national mean cost per visit.

(b) *Determining HHA utilization.* In calculating the initial unadjusted national 60-day episode payment, CMS determines the national mean utilization for each of the six disciplines using home health claims data.

(c) *Use of the market basket index.* CMS uses the HHA market basket index to adjust the HHA cost data to reflect cost increases occurring between October 1, 1996 through September 30, 2001.

(d) *Calculation of the unadjusted national average prospective payment amount for the 60-day episode.* CMS calculates the unadjusted national 60-day episode payment in the following manner:

(1) By computing the mean national cost per visit.

(2) By computing the national mean utilization for each discipline.

(3) By multiplying the mean national cost per visit by the national mean utilization summed in the aggregate for the six disciplines.

(4) By adding to the amount derived in paragraph (d)(3) of this section, amounts for nonroutine medical supplies, an OASIS adjustment for estimated ongoing reporting costs, an OASIS adjustment for the one time implementation costs associated with assessment scheduling form changes and amounts for Part B therapies that could have been unbundled to Part B prior to October 1, 2000. The resulting amount is the unadjusted national 60-day episode rate.

(e) *Standardization of the data for variation in area wage levels and case-mix.* CMS standardizes—

(1) The cost data described in paragraph (a) of this section to remove the effects of geographic variation in wage levels and variation in case-mix;

(2) The cost data for geographic variation in wage levels using the hospital wage index; and

(3) The cost data for HHA variation in case-mix using the case-mix indices and other data that indicate HHA case-mix.

§ 484.220 Calculation of the adjusted national prospective 60-day episode payment rate for case-mix and area wage levels.

CMS adjusts the national prospective 60-day episode payment rate to account for—

(a) HHA case-mix using a case-mix index to explain the relative resource utilization of different patients; and

(b) Geographic differences in wage levels using an appropriate wage index based on the site of service of the beneficiary.

§ 484.225 Annual update of the unadjusted national prospective 60-day episode payment rate.

(a) CMS updates the unadjusted national 60-day episode payment rate on a fiscal year basis.

(b) For fiscal year 2001, the unadjusted national 60-day episode payment rate is adjusted using the latest available home health market basket index factors.

(c) For fiscal years 2002 and 2003, the unadjusted national prospective 60-day episode payment rate is updated by a factor equal to the applicable home health market basket minus 1.1 percentage points.

(d) For the last calendar quarter of 2003 and the first calendar quarter of 2004, the unadjusted national prospective 60-day episode payment rate is equal to the rate from the previous fiscal year (FY 2003) increased by the applicable home health market basket index amount.

(e) For the last the 3 calendar quarters of 2004, the unadjusted national prospective 60-day episode payment rate is equal to the rate from the previous fiscal year (FY 2003) increased by the applicable home health market basket minus 0.8 percentage points.

(f) For each calendar year of 2005 and 2006, the unadjusted national prospective 60-day episode payment rate is equal to the rate from the previous calendar year, increased by the applicable home health market basket minus 0.8 percentage points.

(g) For 2007 and subsequent calendar years, the unadjusted national rate is equal to the rate for the previous calendar year increased by the applicable home health market basket index amount.

[65 FR 41212, July 3, 2000, as amended at 69 FR 62138, Oct. 22, 2004]

§ 484.230 Methodology used for the calculation of the low-utilization payment adjustment.

An episode with four or fewer visits is paid the national per-visit amount by discipline updated annually by the applicable market basket for each visit type. The national per-visit amount is determined by using cost data set forth in § 484.210(a) and adjusting by the appropriate wage index based on the site of service for the beneficiary.

§ 484.235 Methodology used for the calculation of the partial episode payment adjustment.

(a) CMS makes a PEP adjustment to the original 60-day episode payment that is interrupted by an intervening event described in § 484.205(d).

(b) The original 60-day episode payment is adjusted to reflect the length of time the beneficiary remained under the care of the original HHA based on the first billable visit date through and including the last billable visit date.

(c) The partial episode payment is calculated by determining the actual days served by the original HHA as a proportion of 60 multiplied by the initial 60-day episode payment.

§ 484.237 Methodology used for the calculation of the significant change in condition payment adjustment.

(a) CMS makes a SCIC payment adjustment to the original 60-day episode payment that is interrupted by the intervening event defined in § 484.205(e).

(b) The SCIC payment adjustment is calculated in two parts.

(1) The first part of the SCIC payment adjustment reflects the adjustment to the level of payment prior to the significant change in the patient's condition during the 60-day episode. The first part of the SCIC adjustment is determined by taking the span of days (the first billable visit date through and including the last billable visit date) prior to the patient's significant change in condition as a proportion of 60 multiplied by the original episode amount.

(2) The second part of the SCIC payment adjustment reflects the adjustment to the level of payment after the significant change in the patient's condition occurs during the 60-day episode. The second part of the SCIC adjustment is calculated by using the span of days (the first billable visit date through and including the last billable visit date) through the balance of the 60-day episode.

(c) The initial percentage payment provided at the start of the 60-day episode will be adjusted at the end of the episode to reflect the first and second

parts of the total SCIC adjustment determined at the end of the 60-day episode.

§ 484.240 Methodology used for the calculation of the outlier payment.

(a) CMS makes an outlier payment for an episode whose estimated cost exceeds a threshold amount for each case-mix group.

(b) The outlier threshold for each case-mix group is the episode payment amount for that group, the PEP adjustment amount for the episode or the total significant change in condition adjustment amount for the episode plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of estimated cost beyond the threshold.

(d) CMS imputes the cost for each episode by multiplying the national per-visit amount of each discipline by the number of visits in the discipline and computing the total imputed cost for all disciplines.

(e) The fixed dollar loss amount and the loss sharing proportion are chosen so that the estimated total outlier payment is no more than 5 percent of total payment under home health PPS.

§ 484.245 Accelerated payments for home health agencies.

(a) *General rule.* Upon request, an accelerated payment may be made to an HHA that is receiving payment under the home health prospective payment system if the HHA is experiencing financial difficulties because there is a delay by the intermediary in making payment to the HHA.

(b) *Approval of payment.* An HHA's request for an accelerated payment must be approved by the intermediary and CMS.

(c) *Amount of payment.* The amount of the accelerated payment is computed as a percentage of the net payment for unbilled or unpaid covered services.

(d) *Recovery of payment.* Recovery of the accelerated payment is made by recoupment as HHA bills are processed or by direct payment by the HHA.

§ 484.250 Patient assessment data.

An HHA must submit to CMS the OASIS data described at § 484.55(b)(1) and (d)(1) in order for CMS to administer the payment rate methodologies described in §§ 484.215, 484.230, 484.235, and 484.237.

§ 484.260 Limitation on review.

An HHA is not entitled to judicial or administrative review under sections 1869 or 1878 of the Act, or otherwise, with regard to the establishment of the payment unit, including the national 60-day prospective episode payment rate, adjustments and outlier payments. An HHA is not entitled to the review regarding the establishment of the transition period, definition and application of the unit of payments, the computation of initial standard prospective payment amounts, the establishment of the adjustment for outliers, and the establishment of case-mix and area wage adjustment factors.

§ 484.265 Additional payment.

QIO photocopy and mailing costs. An additional payment is made to a home health agency in accordance with § 476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

[68 FR 67960, Dec. 5, 2003]

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

SOURCE: 48 FR 56293, Dec. 15, 1982, unless otherwise noted. Redesignated at 50 FR 33034, Aug. 16, 1985.

Subpart A [Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

§ 485.50 Basis and scope.

This subpart sets forth the conditions that facilities must meet to be certified as comprehensive outpatient rehabilitation facilities (CORFs) under section 1861(cc)(2) of the Social Security Act and be accepted for participation in Medicare in accordance with part 489 of this chapter.

§ 485.51 Definition.

As used in this subpart, unless the context indicates otherwise, ''*comprehensive outpatient rehabilitation facility*'', ''*CORF*'', or ''*facility*'' means a nonresidential facility that—

(a) Is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician; and

(b) Meets all the requirements of this subpart.

§ 485.54 Condition of participation: Compliance with State and local laws.

The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.

(a) *Standard: Licensure of facility.* If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.

(b) *Standard: Licensure of personnel.* Personnel that provide service must be licensed, certified, or registered in accordance with applicable State and local laws.

§ 485.56 Condition of participation: Governing body and administration.

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

(a) *Standard: Disclosure of ownership.* The facility must comply with the provisions of part 420, subpart C of this chapter that require health care providers and fiscal agents to disclose certain information about ownership and control.

(b) *Standard: Administrator.* The governing body must appoint an administrator who—

(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;

(2) Implements and enforces the facility's policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

(c) *Standard: Group of professional personnel.* The facility must have a group of professional personnel associated with the facility that—

(1) Develops and periodically reviews policies to govern the services provided by the facility; and

(2) Consists of at least one physician and one professional representing each of the services provided by the facility.

(d) *Standard: Institutional budget plan.* The facility must have an institutional budget plan that meets the following conditions:

(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff.

(2) It provides for—

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A 3-year capital expenditure plan if expenditures in excess of $100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings, and equipment; and the replacement, modernization, and expansion of buildings and equipment; and

(iii) Annual review and updating by the governing body.

(e) *Standard: Patient care policies.* The facility must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services the facility furnishes through employees and those furnished under arrangements.

(2) Rules for and personnel responsibilities in handling medical emergencies.

(3) Rules for the storage, handling, and administration of drugs and biologicals.

(4) Criteria for patient admission, continuing care, and discharge.

(5) Procedures for preparing and maintaining clinical records on all patients.

(6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.

(7) A procedure to assist the referring physician in locating another level of care for—patients whose treatment has terminated and who are discharged.

(8) A requirement that patients accepted by the facility must be under the care of a physician.

(9) A requirement that there be a plan of treatment established by a physician for each patient.

(10) A procedure to ensure that the group of professional personnel reviews

and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

(f) *Standard: Delegation of authority.* The responsibility for overall administration, management, and operation must be retained by the facility itself and not delegated to others.

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services:

(i) Bookkeeping.

(ii) Assistance in the development of procedures for billing and accounting systems.

(iii) Assistance in the development of an operating budget.

(iv) Purchase of supplies in bulk form.

(v) The preparation of financial statements.

(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and:

(i) May not be for a term of more than 5 years;

(ii) Must be subject to termination within 60 days of written notice by either party;

(iii) Must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised or amended Federal regulation or law;

(iv) Must state that only the facility may bill the Medicare program; and

(v) May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, mangement, or operations of the facility.

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services, and social or psychological services. The services must be furnished by personnel that meet the qualifications set forth in § 485.70 and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

(a) *Standard: Physician services.* (1) A facility physician must be present in the facility for a sufficient time to—

(i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, and consultation;

(ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;

(iii) Assist in establishing and implementing the facility's patient care policies; and

(iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.

(2) The facility must provide for emergency physician services during the facility operating hours.

(b) *Standard: Plan of treatment.* For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.

(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.

(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.

(4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.

(5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.

(c) *Standard: Coordination of services.* The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their

related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—

(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;

(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the recommendation of one of the professionals providing services.

(d) *Standard: Provision of services.* (1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history.

(ii) Current medical findings.

(iii) Diagnosis(es) and contraindications to any treatment modality.

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility.

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes, in the plan, if necessary.

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours.

(7) All services must be provided consistent with accepted professional standards and practice.

(e) *Standard: Scope and site of services*—(1) *Basic requirements.* The facility must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises.

(2) *Exceptions.* Physical therapy, occupational therapy, and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single home visit is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals.

(f) *Standard: Patient assessment.* Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—

(1) Carry out an initial patient assessment; and

(2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

(g) *Standard: Laboratory services.* (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in

the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

[48 FR 56293, Dec. 15, 1982, as amended at 56 FR 8852, Mar. 1, 1991; 57 FR 7137, Feb. 28, 1992]

§ 485.60 Condition of participation: Clinical records.

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) *Standard: Content.* Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is necessary to insure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—

(1) The initial assessment and subsequent reassessments of the patient's needs;

(2) Current plan of treatment;

(3) Identification data and consent or authorization forms;

(4) Pertinent medical history, past and present;

(5) A report of pertinent physical examinations if any;

(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and

(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) *Standard: Protection of clinical record information.* The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required to be released by law.

(c) *Standard: Retention and preservation.* The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

§ 485.62 Condition of participation: Physical environment.

The facility must provide a physical environment that protects the health and safety or patients, personnel, and the public.

(a) *Standard: Safety and comfort of patients.* The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire, and safety codes must be met.

(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.

(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.

(4) Lights, supported by an emergency power source, must be placed at exits.

(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.

(7) Safe and sufficient space must be available for the scope of services offered.

(b) *Standard: Sanitary environment.* The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections.

(1) The facility must establish written policies and procedures designed to

control and prevent infection in the facility and to investigate and identify possible causes of infection.

(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field.

(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a mannner that prevents the spread of infection.

(4) Provisions must be in effect to ensure that the facility's premises are maintained free of rodent and insect infestation.

(c) *Standard: Maintenance of equipment, physical location, and grounds.* The facility must establish a written preventive maintenance program to ensure that—

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

(d) *Standard: Access for the physically impaired.* The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are—

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

(ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and nonambulatory individuals.

(3) At least one entrance is usable by individuals in wheelchairs.

(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.

(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.

§ 485.64 Condition of participation: Disaster procedures.

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

(a) *Standard: Disaster plan.* The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other appropriate experts. The plan must include—

(1) Procedures for prompt transfer of casualties and records;

(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);

(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and

(4) Specification of evacuation routes and procedures for leaving the facility.

(b) *Standard: Drills and staff training.* (1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.

(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within two weeks of their first workday.

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

(a) *Standard: Utilization review committee.* The utilization review committee, consisting of the group of professional personnel specified in § 485.56(c), a committee of this group, or

a group of similar composition, comprised by professional personnel not associated with the facility, must carry out the utilization review plan.

(b) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating—

(1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;

(2) The applicability of the plan of treatment to established goals; and

(3) The adequacy of clinical records with regard to—

(i) Assessing the quality of services provided; and

(ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.

§ 485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under § 485.58, and as a condition of coverage of services under § 410.100 of this chapter.

(a) A facility physician must be a doctor of medicine or osteopathy who—

(1) Is licensed under State law to practice medicine or surgery; and

(2) Has had, subsequent to completing a 1-year hospital internship, at least 1 year of training in the medical management of patients requiring rehabilitation services; or

(3) Has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physicians' services similar to those required in this subpart.

(b) A licensed practical nurse must be licensed as a practical or vocational nurse by the State in which practicing, if applicable.

(c) An occupational therapist and an occupational therapist assistant must meet the qualifications set forth in § 405.1202(f) and (g) of this chapter.

(d) An orthotist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in orthotics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in orthotics.

(e) A *physical therapist* and a *physical therapist assistant* must meet the qualifications set forth in paragraphs (b) and (c) of § 485.705.

(f) A *prosthetist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in prosthetics.

(g) A *psychologist* must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must hold a masters degree in psychology from and educational institution approved by the State in which the institution is located.

(h) A *registered nurse* must be a graduate of an approved school of nursing and be licensed as a registered nurse by the State in which practicing, if applicable.

(i) A *rehabilitation counselor* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree; and

(3) Be eligible to take the certification examination administered by the Commission on Rehabilitation Counselor Certification.

(j) A *respiratory therapist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committee on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the registry examination for respiratory therapists administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(k) A *respiratory therapy technician* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc,; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A *social worker* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(m) A *speech-language pathologist* must meet the qualifications set forth in § 485.705(f) of this chapter.

[48 FR 56293, Dec. 15, 1982. Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986; 60 FR 2327, Jan. 9, 1995]

§ 485.74 Appeal rights.

The appeal provisions set forth in part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORF.

[48 FR 56293, Dec. 15, 1982, as amended at 52 FR 22454, June 12, 1987]

Subparts C–E [Reserved]

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

SOURCE: 58 FR 30671, May 26, 1993, unless otherwise noted.

§ 485.601 Basis and scope.

(a) *Statutory basis.* This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) *Scope.* This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.602 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by employed staff of the CAH, not services provided through arrangements or agreements.

[59 FR 45403, Sept. 1, 1994, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network when applicable;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46035, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who performs the services of a clinical nurse specialist as authorized by the State, in accordance with State law or the State regulatory mechanism provided by State law.

(b) *Nurse practitioner.* A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) *Physician assistant.* A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that—

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.606 Designation and certification of CAHs.

(a) *Criteria for State designation.* (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in § 482.66 of this chapter.

(b) Criteria for CMS certification. CMS certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this Part and all other applicable requirements for participation in Part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a

CAH by the State under the rules in this subpart.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26359, May 12, 1998]

§ 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Standard: Compliance with Federal laws and regulations.* The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

(b) *Standard: Compliance with State and local laws and regulations.* All patient care services are furnished in accordance with applicable State and local laws and regulations.

(c) *Standard: Licensure of CAH.* The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

(d) *Standard: Licensure, certification or registration of personnel.* Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.610 Condition of participation: Status and location.

(a) *Standard:* Status. The facility is—

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility—

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that—

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

(b) *Standard: Location in a rural area or treatment as rural.* The CAH meets the requirements of either paragraph (b)(1) or (b)(2) or (b)(3) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under § 412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under § 412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under § 412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with § 412.103 of this chapter.

(3) Effective only for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

(c) *Standard: Location relative to other facilities or necessary provider certification.* The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

(d) *Standard: Relocation of CAHs with a necessary provider designation.* A CAH

that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location—

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in § 489.52(b)(3).

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47490, Aug. 12, 2005; 71 FR 48143, Aug. 18, 2006]

§ 485.612 Condition of participation: Compliance with hospital requirements at the time of application.

Except for recently closed facilities as described in § 485.610(a)(2), or health clinics or health centers as described in § 485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

§ 485.616 Condition of participation: Agreements.

(a) *Standard: Agreements with network hospitals.* In the case of a CAH that is a member of a rural health network as defined in § 485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for—

(1) Patient referral and transfer;

(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) *Standard: Agreements for credentialing and quality assurance.* Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[62 FR 46036, Aug. 29, 1997]

§ 485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) *Standard: Availability.* Emergency services are available on a 24-hours a day basis.

(b) *Standard: Equipment, supplies, and medication.* Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) *Drugs and biologicals* commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) *Equipment and supplies* commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric

tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

(c) *Standard: Blood and blood products.* The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) *Standard: Personnel.* (1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care on call and immediately available by telephone or radio contact, and available onsite within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if—

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(2)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(3) The request, as specified in paragraph(d)(2)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

(e) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately

available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999; 67 FR 80041, Dec. 31, 2002; 69 FR 49271, Aug. 11, 2004]

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) *Standard: Number of beds.* Except as permitted for CAHs having distinct part units under § 485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

(b) *Standard: Length of stay.* The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

§ 485.623 Condition of participation: Physical plant and environment.

(a) *Standard: Construction.* The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Standard: Maintenance.* The CAH has housekeeping and preventive maintenance programs to ensure that—

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) *Standard: Emergency procedures.* The CAH assures the safety of patients in non-medical emergencies by—

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) *Standard: Life safety from fire.* (1) Except as otherwise provided in this section—

(i) The CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not

adversely affect the health and safety of patients.

(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

(5) Beginning March 13, 2006, a critical access hospital must be in compliance with Chapter 9.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to critical access hospitals.

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the FEDERAL REGISTER to announce the change.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005]

EFFECTIVE DATE NOTE: At 71 FR 55341, Sept. 22, 2006, § 485.623 was amended by revising paragraph (d)(7)(iii), by removing the last sentence in paragraph (d)(7)(iv), by removing the period at the end of paragraph (d)(7)(iv) and adding in its place ''; and'', and adding paragraph (d)(7)(v), effective Oct. 23, 2006. For the convenience of the user, the revised and added text is set forth as follows:

§ 485.623 Condition of participation: Physical plant and environment.

* * * * *

(d) * * *

(7) * * *

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

* * * * *

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

§ 485.627 Condition of participation: Organizational structure.

(a) *Standard: Governing body or responsible individual.* The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) *Standard: Disclosure.* The CAH discloses the names and addresses of—

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

(2) The person principally responsible for the operation of the CAH; and

(3) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.631 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Staffing*—(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

(b) *Standard: Responsibilities of the doctor of medicine or osteopathy*. (1) The doctor of medicine or osteopathy—

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants.

(v) Periodically, but not less than every 2 weeks, reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants according to the policies of the CAH and according to current standards of practice where State law requires record reviews or co-signatures, or both, by a collaborating physician.

(vi) Is not required to review and sign outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants where State law does not require record reviews or co-signatures, or both, by a collaborating physician.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff—

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 70 FR 68728, Nov. 10, 2005]

§ 485.635 Condition of participation: Provision of services.

(a) *Standard: Patient care policies.* (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1); at least one member is not a member of the CAH staff.

(3) The policies include the following:

(i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) *Standard: Direct services*—(1) *General.* The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory services.* The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose:

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Radiology services.* Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

(4) *Emergency procedures.* In accordance with the requirements of § 485.618, the CAH provides as direct services

medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) *Standard: Services provided through agreements or arrangements.* (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

(i) Inpatient hospital care;

(ii) Services of doctors of medicine or osteopathy; and

(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.

(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under § 485.627(b)(2) of this chapter is also responsible for the following:

(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.

(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(d) *Standard: Nursing services.* Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997]

§ 485.638 Conditions of participation: Clinical records.

(a) *Standard: Records system*—(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information*—(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) *Designation of qualified practitioners.* The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by—

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) *Anesthetic risk and evaluation.* (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only—

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) *Standard: State exemption.* (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related

to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001]

§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) *Standard: Periodic evaluation*—(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—

(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

(ii) A representative sample of both active and closed clinical records; and

(iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) *Standard: Quality assurance.* The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that—

(1) All patient care services and other services affecting patient health and safety, are evaluated;

(2) Nosocomial infections and medication therapy are evaluated;

(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity; or

(iii) One other appropriate and qualified entity identified in the State rural health care plan; and

(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual

designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(f) For purposes of these standards, the term ''organ'' means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[65 FR 47110, Aug. 1, 2000, as amended at 66 FR 39938, Aug. 1, 2001]

§ 485.645 Special requirements for CAH providers of long-term care services ("swing-beds")

A CAH must meet the following requirements in order to be granted an approval from CMS to provided post-hospital SNF care, as specified in § 409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

(a) *Eligibility*. A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under § 485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) *Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997*. These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions and limitations that were applicable at the time those approvals were granted.

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

(c) *Payment*. Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with § 413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in § 413.114 of this chapter.

(d) *SNF services*. The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Residents rights (§ 483.10(b)(3) through (b)(6), (d) (e), (h), (i), (j)(1)(vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§ 483.12(a) of this chapter).

(3) Resident behavior and facility practices (§ 483.13 of this chapter).

(4) Patient activities (§ 483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of § 485.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§ 483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment

instrument (RAI) specified by the State that is required under § 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in § 413.343(b) of this chapter).

(7) Specialized rehabilitative services (§ 483.45 of this chapter).

(8) Dental services (§ 483.55 of this chapter).

(9) Nutrition (§ 483.25(i) of this chapter).

[63 FR 26359, May 12, 1998 as amended at 64 FR 41544, July 30, 1999; 67 FR 50120, Aug. 1, 2002; 69 FR 49272, Aug. 11, 2004]

§ 485.647 Condition of participation: psychiatric and rehabilitation distinct part units.

(a) *Conditions.* (1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of § 412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of § 412.27 of Part 412 of this chapter for excluded psychiatric units.

(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of § 412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payments systems, and the additional requirements of §§ 412.29 and § 412.30 of Part 412 of this chapter related specifically to rehabilitation units.

(b) *Eligibility requirements.* (1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in § 485.620(a).

(3) The average annual 96-hour length of stay requirement specified under § 485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in § 485.620.

[69 FR 49272, Aug. 11, 2004]

Subpart G [Reserved]

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

§ 485.701 Basis and scope.

This subpart implements section 1861(p)(4) of the Act, which—

(a) Defines outpatient physical therapy and speech pathology services;

(b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and

(c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

§ 485.703 Definitions.

Clinic. A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

(1) The medical services are furnished by a group of three or more physicians practicing medicine together.

(2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

Organization. A clinic, rehabilitation agency, or public health agency.

Public health agency. An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

Rehabilitation agency. An agency that—

(1) Provides an integrated interdisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and

(2) Provides at least the following services:

(i) Physical therapy or speech-language pathology services.

(ii) Social or vocational adjustment services.

Supervision. Authoritative procedural guidance that is for the accomplishment of a function or activity and that—

(1) Includes initial direction and periodic observation of the actual performance of the function or activity; and

(2) Is furnished by a qualified person—

(i) Whose sphere of competence encompasses the particular function or activity; and

(ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in § 485.705.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.705 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

(1) For a physician, the qualifications and conditions as defined in section 1861(r) of the Act and the requirements in part 484 of this chapter.

(2) *For a speech-language pathologist,* the qualifications specified in section 1861(11)(1) of the Act and the requirements in part 484 of this chapter.

(c) *Exceptions when no State Licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—

(1) An *administrator* is a person who has a bachelor's degree and:

(i) Has experience or specialized training in the administration of health institutions or agencies; or

(ii) Is qualified and has experience in one of the professional health disciplines.

(2) An *occupational therapist* must meet the requirements in part 484 of this chapter.

(3) *An occupational therapy assistant* must meet the requirements in part 484 of this chapter.

(4) A *physical therapist* must meet the requirements in part 484 of this chapter.

(5) A *physical therapist assistant* must meet the requirements in part 484 of this chapter.

(6) A *social worker* must meet the requirements in part 484 of this chapter.

(7) A *vocational specialist* is a person who has a baccalaureate degree and—

(i) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(ii) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(iii) A master's degree in vocational counseling.

(8) A nurse practitioner is a person who must:

(i) Be a registered professional nurse who is authorized by the State in which the services are furnished to

practice as a nurse practitioner in accordance with State law; *and*

(ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*

(iii) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; *or*

(iv) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (c)(8)(i) and (c)(8)(ii) of this section; *or*

(v) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.

(9) *A clinical nurse specialist* is a person who must:

(i) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(ii) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and,

(iii) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

(10) *A physician assistant* is a person who:

(i) Has graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; or

(ii) Has passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and

(iii) Is licensed by the State to practice as a physician assistant.

[63 FR 58912, Nov. 2, 1998; 64 FR 25457, May 12, 1999; 64 FR 59442, Nov. 2, 1999]

§ 485.707 Condition of participation: Compliance with Federal, State, and local laws.

The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of organization.* In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) *Standard: Licensure or registration of personnel.* Staff of the organization are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

§ 485.709 Condition of participation: Administrative management.

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body.* There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator.* The governing body—

(1) Appoints a qualified full-time administrator;

(2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;

(3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and

(4) Designates a competent individual to act during temporary absence of the administrator.

(c) *Standard: Personnel policies.* Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

(d) *Standard: Patient care policies.* Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.711 Condition of participation: Plan of care and physician involvement.

For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The organization has a physician available to furnish necessary medical care in case of emergency.

(a) *Standard: Medical history and prior treatment.* The following are obtained by the organization before or at the time of initiation of treatment:

(1) The patient's significant past history.

(2) Current medical findings, if any.

(3) Diagnosis(es), if established.

(4) Physician's orders, if any.

(5) Rehabilitation goals, if determined.

(6) Contraindications, if any.

(7) The extent to which the patient is aware of the diagnosis(es) and prognosis.

(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) *Standard: Plan of care.* (1) For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—

(i) Type;

(ii) Amount;

(iii) Frequency; and

(iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken. (For Medicare patients, the plan must be reviewed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant at least every 30 days, in accordance with § 410.61(e) of this chapter.)

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

(c) *Standard: Emergency care.* The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 63 FR 58913, Nov. 2, 1998]

§ 485.713 Condition of participation: Physical therapy services.

If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* (1) The organization is considered to have an adequate outpatient physical therapy program if it can:

(i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;

(ii) Conduct patient evaluations; and

(iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.

(i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.

(ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

(c) *Standard: Personnel qualified to provide physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) *Standard: Supportive personnel.* If personnel are available to assist qualified physical therapists by performing services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.715 Condition of participation: Speech pathology services.

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

(c) *Standard: Personnel qualified to provide speech pathology services.* Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.717 Condition of participation: Rehabilitation program.

This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff

furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.

(a) *Standard: Qualification of staff.* The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologists, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

(b) *Standard: Arrangements for social or vocational adjustment services.* (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.

(2) The contract must specify the term of the contract and the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

(a) *Conditions.* If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains of professional and administrative responsibility for, and control and supervision of, the services.

(b) *Standard: Contract provisions.* The contract—

(1) Specifies the term of the contract and the manner of termination or renewal;

(2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and

(3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that—

(i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and

(ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.

[56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.721 Condition of participation: Clinical records.

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of

an appropriate plan of care, and of the care and services furnished.

(2) Identification data and consent forms.

(3) Medical history.

(4) Report of physical examinations, if any.

(5) Observations and progress notes.

(6) Reports of treatments and clinical findings.

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State; or

(2) In the absence of a State statute—

(i) Five years after the date of discharge; or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.723 Condition of participation: Physical environment.

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

(a) *Standard: Safety of patients.* The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) *Standard: Maintenance of equipment, building, and grounds.* The organization establishes a written preventive-maintenance program to ensure that—

(1) The equipment is operative, and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

(c) *Standard: Other environmental considerations.* The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through

windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by nonambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.725 Condition of participation: Infection control.

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection-control committee.* The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

(c) *Standard: Housekeeping.* (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization's premises are maintained free from insects and rodents through operation of a pest-control program.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.727 Condition of participation: Disaster preparedness.

The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

(a) *Standard: Disaster plan.* The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

(1) Transfer of casualties and records;

(2) The location and use of alarm systems and signals;

(3) Methods of containing fire;

(4) Notification of appropriate persons; and

(5) Evacuation routes and procedures.

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

§ 485.729 Condition of participation: Program evaluation.

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate

utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

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AUTHORITY: Secs. 1102, 1138, and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, and 1395hh) and section 371 of the Public Health Service Act (42 U.S.C 273).

Subpart A—General Provisions

§ 486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act:

1102 and 1138(b), 1871 of the Social Security Act, section 371(b) of the Public Health Service Act—for coverage of organ procurement services.

1861(p)—for coverage of outpatient physical therapy services furnished by physical therapists in independent practice.

1861(s) (3), (15), and (17)—for coverage of portable X-ray services.

(b) *Scope.* (1) This part sets forth the conditions for coverage of certain specialized services that are furnished by suppliers and that are not specified in other portions of this chapter.

(2) The conditions for coverage of other specialized services furnished by suppliers are set forth in the following regulations which, unless otherwise indicated, are part of this chapter:

(i) Ambulatory surgical center (ASC) services—Part 416.

(ii) Ambulance services—Part 410, subpart B.

(iii) ESRD services—Part 405, subpart U.

(iv) Laboratory services—Part 493.

(v) Mammography services—Part 410, subpart B (§ 410.34) and 21 CFR Part 900, subpart B, of the Food and Drug Administration regulations.

(vi) Rural health clinic and Federally qualified health center services—Part 491, subpart A.

[60 FR 50447, Sept. 29, 1995, as amended at 71 FR 31046, May 31, 2006]

Subpart B [Reserved]

Subpart C—Conditions for Coverage: Portable X-Ray Services

AUTHORITY: Secs. 1102, 1861(s) (3), (11) and (12), 1864, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x(s) (3), (11), and (12), 1395aa and 1395hh).

SOURCE: 34 FR 388, Jan. 10, 1969, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977, and further redesignated and amended at 60 FR 2326, Jan. 9, 1995.

§ 486.100 Condition for coverage: Compliance with Federal, State, and local laws and regulations.

The supplier of portable X-ray services is in conformity with all applicable Federal, State, and local laws and regulations.

(a) *Standard—licensure or registration of supplier.* In any State in which State or applicable local law provides for the licensure or registration of suppliers of X-ray services, the supplier is (1) licensed or registered pursuant to such law, or (2) approved by the agency of the State or locality responsible for licensure or registration as meeting the standards established for such licensure or registration.

(b) *Standard—licensure or registration of personnel.* All personnel engaged in operating portable X-ray equipment are currently licensed or registered in accordance with all applicable State and local laws.

(c) *Standard—licensure or registration of equipment.* All portable X-ray equipment used in providing portable X-ray services is licensed or registered in accordance with all applicable State and local laws.

(d) *Standard—conformity with other Federal, State, and local laws and regulations.* The supplier of portable X-ray services agrees to render such services in conformity with Federal, State, and local laws relating to safety standards.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.102 Condition for coverage: Supervision by a qualified physician.

Portable X-ray services are provided under the supervision of a qualified physician.

(a) *Standard—physician supervision.* The performance of the roentgenologic procedures is subject to the supervision of a physician who meets the requirements of paragraph (b) of this section and one of the following requirements is met:

(1) The supervising physician owns the equipment and it is operated only by his employees, or

(2) The supervising physician certifies annually that he periodically

checks the procedural manuals and observes the operators' performance, that he has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements and that safe operating procedures are used.

(b) *Standard—qualifications of the physician supervisor.* Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of X-rays for diagnostic purposes, i.e., he (1) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or possesses qualifications which are equivalent to those required for such certification, or (2) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes, or (3) specializes in radiology and is recognized by the medical community as a specialist in radiology.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.104 Condition for coverage: Qualifications, orientation and health of technical personnel.

Portable X-ray services are provided by qualified technologists.

(a) *Standard—qualifications of technologists.* All operators of the portable X-ray equipment meet the requirements of paragraph (a) (1), (2), or (3) of this section:

(1) Successful completion of a program of formal training in X-ray technology of not less than 24 months' duration in a school approved by the Council on Education of the American Medical Association or by the American Osteopathic Association, or have earned a bachelor's or associate degree in radiologic technology from an accredited college or university.

(2) For those whose training was completed prior to July 1, 1966, but on or after July 1, 1960: Successful completion of 24 full months of training and/or experience under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.

(3) For those whose training was completed prior to July 1, 1960: Successful completion of 24 full months of training and/or experience of which at least 12 full months were under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable X-ray equipment operation experience in the 5 years prior to January 1, 1968.

(b) *Standard—personnel orientation.* The supplier of portable X-ray services has an orientation program for personnel, based on a procedural manual which is: Available to all members of the staff, incorporates relevant portions of professionally recognized documents, and includes instruction in all of the following:

(1) Precautions to be followed to protect the patient from unnecessary exposure to radiation;

(2) Precautions to be followed to protect an individual supporting the patient during X-ray procedures from unnecessary exposure to radiation;

(3) Precautions to be followed to protect other individuals in the surrounding environment from exposure to radiation;

(4) Precautions to be followed to protect the operator of portable X-ray equipment from unnecessary exposure to radiation;

(5) Considerations in determining the area which will receive the primary beam;

(6) Determination of the time interval at which to check personnel radiation monitors;

(7) Use of the personnel radiation monitor in providing an additional check on safety of equipment;

(8) Proper use and maintenance of equipment;

(9) Proper maintenance of records;

(10) Technical problems which may arise and methods of solution;

(11) Protection against electrical hazards;

(12) Hazards of excessive exposure to radiation.

(c) *Standard: Employee records.* Records are maintained and include evidence that—

(1) Each employee is qualified for his or her position by means of training and experience; and

(2) Employees receive adequate health supervision.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 60 FR 45086, Aug. 30, 1995]

§ 486.106 Condition for coverage: Referral for service and preservation of records.

All portable X-ray services performed for Medicare beneficiaries are ordered by a doctor of medicine or doctor of osteopathy and records are properly preserved.

(a) *Standard—referral by a physician.* Portable X-ray examinations are performed only on the order of a doctor of medicine or doctor of osteopathy licensed to practice in the State. The supplier's records show that:

(1) The X-ray test was ordered by a licensed doctor of medicine or doctor of osteopathy, and

(2) Such physician's written, signed order specifies the reason an X-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable X-ray services are necessary.

(b) *Standard—records of examinations performed.* The supplier makes for each patient a record of the date of the X-ray examination, the name of the patient, a description of the procedures ordered and performed, the referring physician, the operator(s) of the portable X-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

(c) *Standard—preservation of records.* Such reports are maintained for a period of at least 2 years, or for the period of time required by State law for such records (as distinguished from requirements as to the radiograph itself), whichever is longer.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.108 Condition for coverage: Safety standards.

X-ray examinations are conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

(a) *Standard—tube housing and devices to restrict the useful beam.* The tube housing is of diagnostic type. Diaphragms, cones, or adjustable collimators capable of restricting the useful beam to the area of clinical interest are used and provide the same degree of protection as is required of the housing.

(b) *Standard—total filtration.* (1) The aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table except when contraindicated for a particular diagnostic procedure.

Operating kVp	Total filtration (inherent plus added)
Below 50 kVp	0.5 millimeters aluminum.
50–70 kVp	1.5 millimeters aluminum.
Above 70 kVp	2.5 millimeters aluminum.

(2) If the filter in the machine is not accessible for examination or the total filtration is unknown, it can be assumed that the requirements are met if the half-value layer is not less than that shown in the following table:

Operating kVp	Half-value layer
50 kVp	0.6 millimeters aluminum.
70 kVp	1.6 millimeters aluminum.
90 kVp	2.6 millimeters aluminum.
100 kVp	2.8 millimeters aluminum.
110 kVp	3.0 millimeters aluminum.
120 kVp	3.3 millimeters aluminum.

(c) *Standard—termination of exposure.* A device is provided to terminate the exposure after a preset time or exposure.

(d) *Standard—control panel.* The control panel provides a device (usually a milliammeter or a means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel includes appropriate indicators (labelled control settings and/or meters) which show the physical factors (such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

(e) *Standard—exposure control switch.* The exposure control switch is of the dead-man type and is so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

(f) *Standard—protection against electrical hazards.* Only shockproof equipment is used. All electrical equipment is grounded.

(g) *Standard—mechanical supporting or restraining devices.* Mechanical supporting or restraining devices are provided so that such devices can be used when a patient must be held in position for radiography.

(h) *Standard—protective gloves and aprons.* Protective gloves and aprons are provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.

(i) *Standard—restriction of the useful beam.* Diaphragms, cones, or adjustable collimators are used to restrict the useful beam to the area of clinical interest.

(j) *Standard—personnel monitoring.* A device which can be worn to monitor radiation exposure (e.g., a film badge) is provided to each individual who operates portable X-ray equipment. The device is evaluated for radiation exposure to the operator at least monthly and appropriate records are maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.

(k) *Standard—personnel and public protection.* No individual occupationally exposed to radiation is permitted to hold patients during exposures except during emergencies, nor is any other individual regularly used for this service. Care is taken to assure that pregnant women do not assist in portable X-ray examinations.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995]

§ 486.110 Condition for coverage: Inspection of equipment.

Inspections of all X-ray equipment and shielding are made by qualified individuals at intervals not greater than every 24 months.

(a) *Standard—qualified inspectors.* Inspections are made at least every 24 months by a radiation health specialist who is on the staff of or approved by an appropriate State or local government agency.

(b) *Standard—records of inspection and scope of inspection.* The supplier maintains records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in § 486.108.

[34 FR 388, Jan. 10, 1969. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, Jan. 9, 1995; 60 FR 45086, Aug. 30, 1995; 60 FR 50447, Sept. 29, 1995]

Subparts D–F [Reserved]

Subpart G—Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations

SOURCE: 71 FR 31046, May 31, 2006, unless otherwise noted.

§ 486.301 Basis and scope.

(a) *Statutory basis.* (1) Section 1138(b) of the Act sets forth the requirements that an organ procurement organization (OPO) must meet to have its organ procurement services to hospitals covered under Medicare and Medicaid. These include certification as a ''qualified'' OPO and designation as the OPO for a particular service area.

(2) Section 371(b) of the Public Health Service Act sets forth the requirements for certification and the functions that a qualified OPO is expected to perform.

(3) Section 1102 of the Act authorizes the Secretary of Health and Human

Services to make and publish rules and regulations necessary to the efficient administration of the functions that are assigned to the Secretary under the Act.

(4) Section 1871 of the Act authorizes the Secretary to prescribe regulations as may be necessary to carry out the administration of the Medicare program under title XVIII.

(b) *Scope.* This subpart sets forth—

(1) The conditions and requirements that an OPO must meet;

(2) The procedures for certification and designation of OPOs; and

(3) The terms of the agreement with CMS and the basis for and the effect of de-certification.

(4) The requirements for an OPO to be re-certified.

§ 486.302 Definitions.

As used in this subpart, the following definitions apply:

Adverse event means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. As applied to OPOs, adverse events include but are not limited to transmission of disease from a donor to a recipient, avoidable loss of a medically suitable potential donor for whom consent for donation has been obtained, or delivery to a transplant center of the wrong organ or an organ whose blood type does not match the blood type of the intended recipient.

Agreement cycle refers to the time period of at least 4 years when an agreement is in effect between CMS and an OPO.

Certification means a CMS determination that an OPO meets the requirements for certification at § 486.303.

Death record review means an assessment of the medical chart of a deceased patient to evaluate potential for organ donation.

Decertification means a CMS determination that an OPO no longer meets the requirements for certification at § 486.303.

Designated requestor or effective requestor is an individual (generally employed by a hospital), who is trained to handle or participate in the donation consent process. The designated requestor may request consent for donation from the family of a potential donor or from the individual(s) responsible for making the donation decision in circumstances permitted under State law, provide information about donation to the family or decision-maker(s), or provide support to or collaborate with the OPO in the donation consent process.

Designation means CMS assignment of a geographic service area to an OPO. Once an OPO is certified and assigned a geographic service area, organ procurement costs of the OPO are eligible for Medicare and Medicaid payment under section 1138(b)(1)(F) of the Act.

Donation service area (DSA) means a geographical area of sufficient size to ensure maximum effectiveness in the procurement and equitable distribution of organs and that either includes an entire metropolitan statistical area or does not include any part of such an area and that meets the standards of this subpart.

Donor means a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is recovered for the purpose of transplantation.

Donor after cardiac death (DCD) means an individual who donates after his or her heart has irreversibly stopped beating. A donor after cardiac death may be termed a non-heartbeating or asystolic donor.

Donor document is any documented indication of an individual's choice in regard to donation that meets the requirements of the governing state law.

Eligible death for organ donation means the death of a patient 70 years old or younger, who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

(1) Active infections (specific diagnoses).

(i) Bacterial:

(A) Tuberculosis.

(B) Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis.

(ii) Viral:

(A) HIV infection by serologic or molecular detection.

(B) Rabies.

(C) Reactive Hepatitis B Surface Antigen.

(D) Retroviral infections including HTLV I/II.

(E) Viral Encephalitis or Meningitis.

(F) Active Herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia.

(G) Acute Epstein Barr Virus (mononucleosis).

(H) West Nile Virus infection.

(I) Severe acute respiratory syndrome (SARS).

(iii) Fungal:

(A) Active infection with Cryptococcus, Aspergillus, Histoplasma, Coccidioides.

(B) Active candidemia or invasive yeast infection.

(iv) Parasites: active infection with Trypanosoma cruzi (Chagas'), Leishmania, Strongyloides, or Malaria (Plasmodium sp.).

(v) Prion: Creutzfeldt-Jacob Disease.

(2) General:

(i) Aplastic Anemia.

(ii) Agranulocytosis.

(iii) Extreme Immaturity (<500 grams or gestational age of <32 weeks).

(iv) Current malignant neoplasms except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease.

(v) Previous malignant neoplasms with current evident metastatic disease.

(vi) A history of melanoma.

(vii) Hematologic malignancies: Leukemia, Hodgkin's Disease, Lymphoma, Multiple Myeloma.

(viii) Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation.

(ix) Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis.

(3) The number of eligible deaths is the denominator for the donation rate outcome performance measure as described at § 486.318(a)(1).

Eligible donor means any donor that meets the eligible death criteria. The number of eligible donors is the numerator of the donation rate outcome performance measure.

Entire metropolitan statistical area means a metropolitan statistical area (MSA), a consolidated metropolitan statistical area (CMSA), or a primary metropolitan statistical area (PMSA) listed in the State and Metropolitan Area Data Book published by the U.S. Bureau of the Census. CMS does not recognize a CMSA as a metropolitan area for the purposes of establishing a geographical area for an OPO.

Expected donation rate means the donation rate expected for an OPO based on the national experience for OPOs serving similar hospitals and donation service areas. This rate is adjusted for the following hospital characteristics: Level I or Level II trauma center, Metropolitan Statistical Area size, MS Case Mix Index, total bed size, number of intensive care unit (ICU) beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

Observed donation rate is the number of donors meeting the eligibility criteria per 100 deaths.

Open area means an OPO service area for which CMS has notified the public that it is accepting applications for designation.

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (or multivisceral organs when transplanted at the same time as an intestine).

Organ procurement organization (OPO) means an organization that performs or coordinates the procurement, preservation, and transport of organs and maintains a system for locating prospective recipients for available organs.

Re-certification cycle means the 4-year cycle during which an OPO is certified.

Standard criteria donor (SCD) means a donor that meets the eligibility criteria for an eligible donor and does not meet the criteria to be a donor after cardiac death or expanded criteria donor.

Transplant hospital means a hospital that provides organ transplants and other medical and surgical specialty services required for the care of transplant patients. There may be one or

more types of organ transplant centers operating within the same transplant hospital.

Urgent need occurs when an OPO's noncompliance with one or more conditions for coverage has caused, or is likely to cause, serious injury, harm, impairment, or death to a potential or actual donor or an organ recipient.

REQUIREMENTS FOR CERTIFICATION AND DESIGNATION

§ 486.303 Requirements for certification.

In order to be certified as a qualified organ procurement organization, an organ procurement organization must:

(a) Have received a grant under 42 U.S.C. 273(a) or have been certified or re-certified by the Secretary within the previous 4 years as being a qualified OPO.

(b) Be a non-profit entity that is exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1986.

(c) Have accounting and other fiscal procedures necessary to assure the fiscal stability of the organization, including procedures to obtain payment for kidneys and non-renal organs provided to transplant hospitals.

(d) Have an agreement with CMS, as the Secretary's designated representative, to be reimbursed under title XVIII for the procurement of kidneys.

(e) Have been re-certified as an OPO under the Medicare program from January 1, 2002 through December 31, 2005.

(f) Have procedures to obtain payment for non-renal organs provided to transplant centers.

(g) Agree to enter into an agreement with any hospital or critical access hospital in the OPO's service area, including a transplant hospital that requests an agreement.

(h) Meet the conditions for coverage for organ procurement organizations, which include both outcome and process performance measures.

(i) Meet the provisions of titles XI, XVIII, and XIX of the Act, section 371(b) of the Public Health Services Act, and any other applicable Federal regulations.

§ 486.304 Requirements for designation.

(a) Designation is a condition for payment. Payment may be made under the Medicare and Medicaid programs for organ procurement costs attributable to payments made to an OPO by a hospital only if the OPO has been designated by CMS as an OPO.

(b) An OPO must be certified as a qualified OPO by CMS under 42 U.S.C. 273(b) and § 486.303 to be eligible for designation.

(c) An OPO must enter into an agreement with CMS in order for the organ procurement costs attributable to the OPO to be reimbursed under Medicare and Medicaid.

§ 486.306 OPO service area size designation and documentation requirements.

(a) *General documentation requirement.* An OPO must make available to CMS documentation verifying that the OPO meets the requirements of paragraphs (b) through (d) of this section at the time of application and throughout the period of its designation.

(b) *Service area designation.* The defined service area either includes an entire metropolitan statistical area or a New England county metropolitan statistical area as specified by the Director of the Office of Management and Budget or does not include any part of such an area.

(c) *Service area location and characteristics.* An OPO must define and document a proposed service area's location through the following information:

(1) The names of counties (or parishes in Louisiana) served or, if the service area includes an entire State, the name of the State.

(2) Geographic boundaries of the service area.

(3) The number and the names of all hospitals and critical access hospitals in the service area that have both a ventilator and an operating room.

§ 486.308 Designation of one OPO for each service area.

(a) CMS designates only one OPO per service area. A service area is open for competition when the OPO for the

service area is de-certified and all administrative appeals under §486.314 are exhausted.

(b) Designation periods—

(1) *General.* An OPO is normally designated for a 4-year agreement cycle. The period may be shorter, for example, if an OPO has voluntarily terminated its agreement with CMS and CMS selects a successor OPO for the balance of the 4-year agreement cycle. In rare situations, a designation period may be longer, for example, a designation may be extended if additional time is needed to select a successor OPO to an OPO that has been de-certified.

(2) *Re-Certification.* Re-certification must occur not more frequently than once every 4 years.

(c) Unless CMS has granted a hospital a waiver under paragraphs

(d) through (f) of this section, the hospital must enter into an agreement only with the OPO designated to serve the area in which the hospital is located.

(d) If CMS changes the OPO designated for an area, hospitals located in that area must enter into agreements with the newly designated OPO or submit a request for a waiver in accordance with paragraph (e) of this section within 30 days of notice of the change in designation.

(e) A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located. To qualify for a waiver, the hospital must submit data to CMS establishing that—

(1) The waiver is expected to increase organ donations; and

(2) The waiver will ensure equitable treatment of patients listed for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.

(f) In making a determination on waiver requests, CMS considers—

(1) Cost effectiveness;

(2) Improvements in quality;

(3) Changes in a hospital's designated OPO due to changes in the definitions of metropolitan statistical areas, if applicable; and

(4) The length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO.

(g) A hospital may continue to operate under its existing agreement with an out-of-area OPO while CMS is processing the waiver request. If a waiver request is denied, a hospital must enter into an agreement with the designated OPO within 30 days of notification of the final determination.

§486.309 Re-certification from August 1, 2006 through July 31, 2010.

An OPO will be considered to be re-certified for the period of August 1, 2006 through July 31, 2010 if an OPO met the standards to be a qualified OPO within a 4-year period ending December 31, 2001 and has an agreement with the Secretary that is scheduled to terminate on July 31, 2006. Agreements based on the August 1, 2006 through July 31, 2010 re-certification cycle will end on January 31, 2011.

§486.310 Changes in control or ownership or service area.

(a) *OPO requirements.*

(1) A designated OPO considering a change in control (see §413.17(b)(3)) or ownership or in its service area must notify CMS before putting it into effect. This notification is required to ensure that the OPO, if changed, will continue to satisfy Medicare and Medicaid requirements. The merger of one OPO into another or the consolidation of one OPO with another is considered a change in control or ownership.

(2) A designated OPO considering a change in its service area must obtain prior CMS approval. In the case of a service area change that results from a change of control or ownership due to merger or consolidation, the OPOs must resubmit the information required in an application for designation. The OPO must provide information specific to the board structure of the new organization, as well as operating budgets, financial information, and other written documentation CMS determines to be necessary for designation.

(b) *CMS requirements.*

(1) If CMS finds that the OPO has changed to such an extent that it no longer satisfies the requirements for OPO designation, CMS may de-certify the OPO and declare the OPO's service area to be an open area. An OPO may appeal such a de-certification as set forth in § 486.314. The OPO's service area is not opened for competition until the conclusion of the administrative appeals process.

(2) If CMS finds that the changed OPO continues to satisfy the requirements for OPO designation, the period of designation of the changed OPO is the remaining portion of the 4-year term of the OPO that was reorganized. If more than one designated OPO is involved in the reorganization, the remaining designation term is the longest of the remaining periods unless CMS determines that a shorter period is in the best interest of the Medicare and Medicaid programs. The changed OPO must continue to meet the requirements for certification at § 486.303 throughout the remaining period.

RE-CERTIFICATION AND DE-CERTIFICATION

§ 486.312 De-certification.

(a) *Voluntary termination of agreement.* If an OPO wishes to terminate its agreement, the OPO must send CMS written notice of its intention to terminate its agreement and the proposed effective date. CMS may approve the proposed date, set a different date no later than 6 months after the proposed effective date, or set a date less than 6 months after the proposed effective date if it determines that a different date would not disrupt services to the service area. If CMS determines that a designated OPO has ceased to furnish organ procurement services to its service area, the cessation of services is deemed to constitute a voluntary termination by the OPO, effective on a date determined by CMS. CMS will de-certify the OPO as of the effective date of the voluntary termination.

(b) *Involuntary termination of agreement.* During the term of the agreement, CMS may terminate an agreement with an OPO if the OPO no longer meets the requirements for certification at § 486.303. CMS may also terminate an agreement immediately in cases of urgent need, such as the discovery of unsound medical practices. CMS will de-certify the OPO as of the effective date of the involuntary termination.

(c) *Non-renewal of agreement.* CMS will not voluntarily renew its agreement with an OPO if the OPO fails to meet the requirements for certification at § 486.318, based on findings from the most recent re-certification cycle, or the other requirements for certification at § 486.303. CMS will de-certify the OPO as of the ending date of the agreement.

(d) *Notice to OPO.* Except in cases of urgent need, CMS gives written notice of de-certification to an OPO at least 90 days before the effective date of the de-certification. In cases of urgent need, CMS gives written notice of de-certification to an OPO at least 3 calendar days prior to the effective date of the de-certification. The notice of de-certification states the reasons for de-certification and the effective date.

(e) *Public notice.* Once CMS approves the date for a voluntary termination, the OPO must provide prompt public notice of the date of de-certification and such other information as CMS may require through publication in local newspapers in the service area. In the case of involuntary termination or non-renewal of an agreement, CMS provides public notice of the date of de-certification through publication in local newspapers in the service area. No payment under titles XVIII or XIX of the Act will be made with respect to organ procurement costs attributable to the OPO on or after the effective date of de-certification.

§ 486.314 Appeals.

If an OPO's de-certification is due to involuntary termination or non-renewal of its agreement with CMS, the OPO may appeal the de-certification on substantive and procedural grounds.

(a) *Notice of initial determination.* CMS mails notice to the OPO of an initial de-certification determination. The notice contains the reasons for the determination, the effect of the determination, and the OPO's right to seek reconsideration.

(b) *Reconsideration.* (1) Filing request. If the OPO is dissatisfied with the de-certification determination, it has 15 business days from receipt of the notice of de-certification to seek reconsideration from CMS. The request for reconsideration must state the issues or findings of fact with which the OPO disagrees and the reasons for disagreement.

(2) An OPO must seek reconsideration before it is entitled to seek a hearing before a hearing officer. If an OPO does not request reconsideration or its request is not made timely, the OPO has no right to further administrative review.

(3) *Reconsideration determination.* CMS makes a written reconsidered determination within 10 business days of receipt of the request for reconsideration, affirming, reversing, or modifying the initial determination and the findings on which it was based. CMS augments the administrative record to include any additional materials submitted by the OPO, and a copy of the reconsideration decision and sends the supplemented administrative record to the CMS hearing officer.

(c) *Request for hearing.* An OPO dissatisfied with the CMS reconsideration decision, must file a request for a hearing before a CMS hearing officer within 40 business days of receipt of the notice of the reconsideration determination. If an OPO does not request a hearing or its request is not received timely, the OPO has no right to further administrative review.

(d) *Administrative record.* The hearing officer sends the administrative record to both parties within 10 business days of receipt of the request for a hearing.

(1) The administrative record consists of, but is not limited to, the following:

(i) Factual findings from the survey(s) on the OPO conditions for coverage.

(ii) Data from the outcome measures.

(iii) Rankings of OPOs based on the outcome data.

(iv) Correspondence between CMS and the affected OPO.

(2) The administrative record will not include any privileged information.

(e) *Pre-Hearing conference.* At any time before the hearing, the CMS hearing officer may call a pre-hearing conference if he or she believes that a conference would more clearly define the issues. At the pre-hearing conference, the hearing officer may establish the briefing schedule, sets the hearing date, and addresses other administrative matters. The hearing officer will issue an order reflecting the results of the pre-hearing conference.

(f) *Date of hearing.* The hearing officer sets a date for the hearing that is no more than 60 calendar days following the receipt of the request for a hearing.

(g) *Conduct of hearing.* (1) The hearing is open to both parties, CMS and the OPO.

(2) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(3) The hearing officer provides the parties with an opportunity to enter an objection to the inclusion of any document. The hearing officer will consider the objection and will rule on the document's admissibility.

(4) The hearing officer decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(5) The hearing officer rules on the admissibility of evidence and may admit evidence that would be inadmissible under rules applicable to court procedures.

(6) The hearing officer rules on motions and other procedural items.

(7) The hearing officer regulates the course of the hearing and conduct of counsel.

(8) The hearing officer may examine witnesses.

(9) The hearing officer takes any action authorized by the rules in this subpart.

(h) Parties' rights. CMS and the OPO may:

(1) Appear by counsel or other authorized representative, in all hearing proceedings.

(2) Participate in any pre-hearing conference held by the hearing officer.

(3) Agree to stipulations as to facts which will be made a part of the record.

(4) Make opening statements at the hearing.

(5) Present relevant evidence on the issues at the hearing.

(6) Present witnesses, who then must be available for cross-examination, and cross-examine witnesses presented by the other party.

(7) Present oral arguments at the hearing.

(i) Hearing officer's decision. The hearing officer renders a decision on the appeal of the notice of de-certification within 20 business days of the hearing.

(1) *Reversal of de-certification.* If the hearing officer reverses CMS' determination to de-certify an OPO in a case involving the involuntary termination of the OPO's agreement, CMS will not terminate the OPO's agreement and will not de-certify the OPO.

(2) *De-certification is upheld.* If the de-certification determination is upheld by the hearing officer, the OPO is de-certified and it has no further administrative appeal rights.

(j) *Extension of agreement.* If there is insufficient time prior to expiration of an agreement with CMS to allow for competition of the service area and, if necessary, transition of the service area to a successor OPO, CMS may choose to extend the OPO's agreement with CMS.

(k) *Effects of de-certification.* Medicare and Medicaid payments may not be made for organ procurement services the OPO furnishes on or after the effective date of de-certification. CMS will then open the de-certified OPO's service area for competition as set forth in § 486.316(c).

§ 486.316 Re-certification and competition processes.

(a) *Re-Certification of OPOs.* An OPO is re-certified for an additional 4 years and its service area is not opened for competition when the OPO:

(1) Meets all 3 outcome measure requirements at § 486.318; and

(2) Has been shown by survey to be in compliance with the requirements for certification at § 486.303, including the conditions for coverage at § 486.320 through § 486.348.

(b) *De-certification and competition.* If an OPO does not meet all 3 outcome measures as described in paragraph (a)(1) of this section or the requirements described in paragraph (a)(2) of this section, the OPO is de-certified. If the OPO does not appeal or the OPO appeals and the reconsideration official and CMS hearing officer uphold the de-certification, the OPO's service area is opened for competition from other OPOs. The de-certified OPO is not permitted to compete for its open area or any other open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(c) *Criteria to compete.* To compete for an open service area, an OPO must meet the criteria in paragraph (a) of this section and the following additional criteria:

(1) The OPO's performance on the donation rate outcome measure and yield outcome measure is at or above 100 percent of the mean national rate averaged over the 4 years of the re-certification cycle; and

(2) The OPO's donation rate is at least 15 percentage points higher than the donation rate of the OPO currently designated for the service area.

(3) The OPO must compete for the entire service area.

(d) *Criteria for selection.* CMS will designate an OPO for an open service area based on the following criteria:

(1) Performance on the outcome measures at § 486.318;

(2) Relative success in meeting the process performance measures and other conditions at §§ 486.320 through 486.348;

(3) Contiguity to the open service area.

(4) Success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area. An OPO competing for an open service area must submit information and data that describe the barriers in its service area, how they affected organ donation, what steps the OPO took to overcome them, and the results.

(e) *No OPO applies.* If no OPO applies to compete for a de-certified OPO's

open area, CMS may select a single OPO to take over the entire open area or may adjust the service area boundaries of two or more contiguous OPOs to incorporate the open area. CMS will make its decision based on the criteria in paragraph (d) of this section.

ORGAN PROCUREMENT ORGANIZATION OUTCOME REQUIREMENTS

§ 486.318 Condition: Outcome measures.

(a) With the exception of OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, or possessions, an OPO must meet all 3 of the following outcome measures:

(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

(3) At least 2 out of the 3 following yield measures are no more than 1 standard deviation below the national mean, averaged over the 4 years of the re-certification cycle:

(i) The number of organs transplanted per standard criteria donor, including pancreata used for islet cell transplantation;

(ii) The number of organs transplanted per expanded criteria donor, including pancreata used for islet cell transplantation; and

(iii) The number of organs used for research per donor, including pancreata used for islet cell research.

(b) For OPOs operating exclusively in non-contiguous U.S. states, commonwealths, territories, and possessions, the OPO outcome measures are as follows:

(1) The OPO's donation rate of eligible donors as a percentage of eligible deaths is no more than 1.5 standard deviations below the mean national donation rate of eligible donors as a percentage of eligible deaths, averaged over the 4 years of the re-certification cycle. Both the numerator and denominator of an individual OPO's donation rate ratio are adjusted by adding a 1 for each donation after cardiac death donor and each donor over the age of 70;

(2) The observed donation rate is not significantly lower than the expected donation rate for 18 or more months of the 36 months of data used for re-certification, as calculated by the SRTR;

(3) At least 2 out of the 3 following are no more than 1 standard deviation below the national mean:

(i) The number of kidneys transplanted per standard criteria donor;

(ii) The number of kidneys transplanted per expanded criteria donor; and

(iii) The number of organs used for research per donor, including pancreata recovered for islet cell transplantation.

(c) Data for the outcome measures.

(1) An OPO's performance on the outcome measures is based on 36 months of data, beginning with January 1 of the first full year of the re-certification cycle and ending 36 months later on December 31, 7 months prior to the end of the re-certification cycle.

(2) If an OPO takes over another OPO's service area on a date later than January 1 of the first full year of the re-certification cycle so that 36 months of data are not available to evaluate the OPO's performance in its new service area, we will not hold the OPO accountable for its performance in the new area until the end of the following re-certification cycle when 36 months of data are available.

ORGAN PROCUREMENT ORGANIZATION PROCESS PERFORMANCE MEASURES

§ 486.320 Condition: Participation in Organ Procurement and Transplantation Network.

After being designated, an OPO must become a member of, participate in,

and abide by the rules and requirements of the OPTN established and operated in accordance with section 372 of the Public Health Service Act (42 U.S.C. 274). The term ''rules and requirements of the OPTN'' means those rules and requirements approved by the Secretary. No OPO is considered out of compliance with section 1138(b)(1)(D) of the Act or this section until the Secretary approves a determination that the OPO failed to comply with the rules and requirements of the OPTN. The Secretary may impose sanctions under section 1138 only after such noncompliance has been determined in this manner.

§ 486.322 Condition: Relationships with hospitals, critical access hospitals, and tissue banks.

(a) *Standard:* Hospital agreements. An OPO must have a written agreement with 95 percent of the Medicare and Medicaid participating hospitals and critical access hospitals in its service area that have both a ventilator and an operating room and have not been granted a waiver by CMS to work with another OPO. The agreement must describe the responsibilities of both the OPO and hospital or critical access hospital in regard to donation after cardiac death (if the OPO has a protocol for donation after cardiac death) and the requirements for hospitals at § 482.45 or § 485.643. The agreement must specify the meaning of the terms ''timely referral'' and ''imminent death.''

(b) *Standard:* Designated requestor training for hospital staff. The OPO must offer to provide designated requestor training on at least an annual basis for hospital and critical access hospital staff.

(c) *Standard:* Cooperation with tissue banks.

(1) The OPO must have arrangements to cooperate with tissue banks that have agreements with hospitals and critical access hospitals with which the OPO has agreements. The OPO must cooperate in the following activities, as may be appropriate, to ensure that all usable tissues are obtained from potential donors:

(i) Screening and referral of potential tissue donors.

(ii) Obtaining informed consent from families of potential tissue donors.

(iii) Retrieval, processing, preservation, storage, and distribution of tissues.

(iv) Providing designated requestor training.

(2) An OPO is not required to have an arrangement with a tissue bank that is unwilling to have an arrangement with the OPO.

§ 486.324 Condition: Administration and governing body.

(a) While an OPO may have more than one board, the OPO must have an advisory board that has both the authority described in paragraph (b) of this section and the following membership:

(1) Members who represent hospital administrators, either intensive care or emergency room personnel, tissue banks, and voluntary health associations in the OPO's service area.

(2) Individuals who represent the public residing in the OPO's service area.

(3) A physician with knowledge, experience, or skill in the field of human histocompatibility, or an individual with a doctorate degree in a biological science and with knowledge, experience, or skills in the field of human histocompatibility.

(4) A neurosurgeon or other physician with knowledge or skills in the neurosciences.

(5) A transplant surgeon representing each transplant hospital in the service area with which the OPO has arrangements to coordinate its activities. The transplant surgeon must have practicing privileges and perform transplants in the transplant hospital represented.

(6) An organ donor family member.

(b) The OPO board described in paragraph (a) of this section has the authority to recommend policies for the following:

(1) Procurement of organs.

(2) Effective agreements to identify potential organ donors with a substantial majority of hospitals in its service area that have facilities for organ donation.

(3) Systematic efforts, including professional education, to acquire all useable organs from potential donors.

(4) Arrangements for the acquisition and preservation of donated organs and provision of quality standards for the acquisition of organs that are consistent with the standards adopted by the OPTN, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immunodeficiency syndrome (AIDS).

(5) Appropriate tissue typing of organs.

(6) A system for allocation of organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in §486.320 of this part.

(7) Transportation of organs to transplant hospitals.

(8) Coordination of activities with transplant hospitals in the OPO's service area.

(9) Participation in the OPTN.

(10) Arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors.

(11) Annual evaluation of the effectiveness of the OPO in acquiring organs.

(12) Assistance to hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) The advisory board described in paragraph (a) of this section has no authority over any other activity of the OPO and may not serve as the OPO's governing body or board of directors. Members of the advisory board described in paragraph (a) of this section are prohibited from serving on any other OPO board.

(d) The OPO must have bylaws for each of its board(s) that address potential conflicts of interest, length of terms, and criteria for selecting and removing members. (e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(e) A governing body must have full legal authority and responsibility for the management and provision of all OPO services and must develop and oversee implementation of policies and procedures considered necessary for the effective administration of the OPO, including fiscal operations, the OPO's quality assessment and performance improvement (QAPI) program, and services furnished under contract or arrangement, including agreements for these services. The governing body must appoint an individual to be responsible for the day-to-day operation of the OPO.

(f) The OPO must have procedures to address potential conflicts of interest for the governing body described in paragraph (d) of this section.

(g) The OPO's policies must state whether the OPO recovers organs from donors after cardiac death.

§486.326 Condition: Human resources.

All OPOs must have a sufficient number of qualified staff, including a director, a medical director, organ procurement coordinators, and hospital development staff to obtain all usable organs from potential donors, and to ensure that required services are provided to families of potential donors, hospitals, tissue banks, and individuals and facilities that use organs for research.

(a) *Standard: Qualifications.* (1) The OPO must ensure that all individuals who provide services and/or supervise services, including services furnished under contract or arrangement, are qualified to provide or supervise the services.

(2) The OPO must develop and implement a written policy that addresses potential conflicts of interest for the OPO's director, medical director, senior management, and procurement coordinators.

(3) The OPO must have credentialing records for physicians and other practitioners who routinely recover organs in

hospitals under contract or arrangement with the OPO and ensure that all physicians and other practitioners who recover organs in hospitals with which the OPO has agreements are qualified and trained.

(b) *Standard: Staffing.*

(1) The OPO must provide sufficient coverage, either by its own staff or under contract or arrangement, to assure both that hospital referral calls are screened for donor potential and that potential donors are evaluated for medical suitability for organ and/or tissue donation in a timely manner.

(2) The OPO must have a sufficient number of qualified staff to provide information and support to potential organ donor families; request consent for donation; ensure optimal maintenance of the donor, efficient placement of organs, and adequate oversight of organ recovery; and conduct QAPI activities, such as death record reviews and hospital development.

(3) The OPO must provide a sufficient number of recovery personnel, either from its own staff or under contract or arrangement, to ensure that all usable organs are recovered in a manner that, to the extent possible, preserves them for transplantation.

(c) *Standard: Education, training, and performance evaluation.* The OPO must provide its staff with the education, training, and supervision necessary to furnish required services. Training must include but is not limited to performance expectations for staff, applicable organizational policies and procedures, and QAPI activities. OPOs must evaluate the performance of their staffs and provide training, as needed, to improve individual and overall staff performance and effectiveness.

(d) *Standard: Medical director.* The OPO's medical director is a physician licensed in at least one of the States or territories within the OPO's service area or as required by State or territory law or by the jurisdiction in which the OPO is located. The medical director is responsible for implementation of the OPO's protocols for donor evaluation and management and organ recovery and placement. The medical director is responsible for oversight of the clinical management of potential donors, including providing assistance in managing a donor case when the surgeon on call is unavailable.

§ 486.328 Condition: Reporting of data.

(a) An OPO must provide individually-identifiable, hospital-specific organ donation and transplantation data and other information to the Organ Procurement and Transplantation Network, the Scientific Registry of Transplant Recipients, and DHHS, as requested by the Secretary. The data may include, but are not limited to:

(1) Number of hospital deaths;

(2) Results of death record reviews;

(3) Number and timeliness of referral calls from hospitals;

(4) Number of eligible deaths;

(5) Data related to non-recovery of organs;

(6) Data about consents for donation;

(7) Number of eligible donors;

(8) Number of organs recovered, by type of organ; and

(9) Number of organs transplanted, by type of organ.

(b) An OPO must provide hospital-specific organ donation data annually to the transplant hospitals with which it has agreements.

(c) Data to be used for OPO re-certification purposes must be reported to the OPTN and must include data for all deaths in all hospitals and critical access hospitals in the OPO's donation service area, unless a hospital or critical access hospital has been granted a waiver to work with a different OPO.

(d) Data reported by the OPO to the OPTN must be reported within 30 days after the end of the month in which a death occurred. If an OPO determines through death record review or other means that the data it reported to the OPTN was incorrect, it must report the corrected data to the OPTN within 30 days of the end of the month in which the error is identified.

(e) For the purpose of determining the information to be collected under paragraph (a) of this section, the following definitions apply:

(1) *Kidneys procured.* Each kidney recovered will be counted individually. En bloc kidneys recovered will count as two kidneys procured.

(2) *Kidneys transplanted.* Each kidney transplanted will be counted individually. En bloc kidney transplants will be counted as two kidneys transplanted.

(3) *Extra-renal organs procured.* Each organ recovered is counted individually.

(4) *Extra-renal organs transplanted.* Each organ or part thereof transplanted will be counted individually. For example, a single liver is counted as one organ procured and each portion that is transplanted will count as one transplant. Further, a heart and double lung transplant will be counted as three organs transplanted. A kidney/pancreas transplant will count as one kidney transplanted and one extra-renal organ transplanted.

§ 486.330 Condition: Information management.

An OPO must establish and use an electronic information management system to maintain the required medical, social and identifying information for every donor and transplant recipient and develop and follow procedures to ensure the confidentiality and security of the information.

(a) *Donor information.* The OPO must maintain a record for every donor. The record must include, at a minimum, information identifying the donor (for example, name, address, date of birth, social security number or other unique identifier, such as Medicare health insurance claim number), organs and (when applicable) tissues recovered, date of the organ recovery, donor management data, all test results, current hospital history, past medical and social history, the pronouncement of death, and consent and next-of-kin information.

(b) *Disposition of organs.* The OPO must maintain records showing the disposition of each organ recovered for the purpose of transplantation, including information identifying transplant recipients.

(c) *Data retention.* Donor and transplant recipient records must be maintained in a human readable and reproducible paper or electronic format for 7 years.

(d) *Format of records.* The OPO must maintain data in a format that can readily be transferred to a successor OPO and in the event of a transfer must provide to CMS copies of all records, data, and software necessary to ensure uninterrupted service by a successor OPO. Records and data subject to this requirement include donor and transplant recipient records and procedural manuals and other materials used in conducting OPO operations.

§ 486.342 Condition: Requesting consent.

An OPO must encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of potential donor families.

(a) An OPO must have a written protocol to ensure that, in the absence of a donor document, the individual(s) responsible for making the donation decision are informed of their options to donate organs or tissues (when the OPO is making a request for tissues) or to decline to donate. The OPO must provide to the individual(s) responsible for making the donation decision, at a minimum, the following:

(1) A list of the organs and/or tissues that may be recovered.

(2) The most likely uses for the donated organs or tissues.

(3) A description of the screening and recovery processes.

(4) Information about the organizations that will recover, process, and distribute the tissue.

(5) Information regarding access to and release of the donor's medical records.

(6) An explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body.

(7) Contact information for individual(s) with questions or concerns.

(8) A copy of the signed consent form if a donation is made.

(b) If an OPO does not request consent to donation because a potential donor consented to donation before his or her death in a manner that satisfied applicable State law requirements in the potential donor's State of residence, the OPO must provide information about the donation to the family of the potential donor, as requested.

§ 486.344 Condition: Evaluation and management of potential donors and organ placement and recovery.

The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

(a) *Potential donor protocol management.* (1) The medical director is responsible for ensuring that potential donor evaluation and management protocols are implemented correctly and appropriately to ensure that potential donors are thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

(2) The OPO must implement a system that ensures that a qualified physician or other qualified individual is available to assist in the medical management of a potential donor when the surgeon on call is unavailable.

(b) *Potential donor evaluation.* The OPO must do the following:

(1) Verify that death has been pronounced according to applicable local, State, and Federal laws.

(2) Determine whether there are conditions that may influence donor acceptance.

(3) If possible, obtain the potential donor's medical and social history.

(4) Review the potential donor's medical chart and perform a physical examination of the donor.

(5) Obtain the potential donor's vital signs and perform all pertinent tests.

(c) *Testing.* The OPO must do the following:

(1) Arrange for screening and testing of the potential donor for infectious disease according to current standards of practice, including testing for the human immunodeficiency virus.

(2) Ensure that screening and testing of the potential donor (including point-of-care testing and blood typing) are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(3) Ensure that the potential donor's blood is typed using two separate blood samples.

(4) Document potential donor's record with all test results, including blood type, before organ recovery.

(d) *Standard: Collaboration with transplant programs.*

(1) The OPO must establish protocols in collaboration with transplant programs that define the roles and responsibilities of the OPO and the transplant program for all activities associated with the evaluation and management of potential donors, organ recovery, and organ placement, including donation after cardiac death, if the OPO has implemented a protocol for donation after cardiac death.

(2) The protocol must ensure that:

(i) The OPO is responsible for two separate determinations of the donor's blood type;

(ii) If the identify of the intended recipient is known, the OPO has a procedure to ensure that prior to organ recovery, an individual from the OPO's staff compares the blood type of the donor with the blood type of the intended recipient, and the accuracy of the comparison is verified by a different individual;

(iii) Documentation of the donor's blood type accompanies the organ to the hospital where the transplant will take place.

(3) The established protocols must be reviewed regularly with the transplant programs to incorporate practices that have been shown to maximize organ donation and transplantation.

(e) *Documentation of recipient information.* If the intended recipient has been identified prior to recovery of an organ for transplantation, the OPO must have written documentation from the OPTN showing, at a minimum, the intended organ recipient's ranking in relation to other suitable candidates and the recipient's OPTN identification number and blood type.

(f) *Donation after cardiac death.* If an OPO recovers organs from donors after cardiac death, the OPO must have protocols that address the following:

(1) Criteria for evaluating patients for donation after cardiac death;

(2) Withdrawal of support, including the relationship between the time of consent to donation and the withdrawal of support;

(3) Use of medications and interventions not related to withdrawal of support;

(4) Involvement of family members prior to organ recovery;

(5) Criteria for declaration of death and the time period that must elapse prior to organ recovery.

(g) *Organ allocation.* The OPO must have a system to allocate donated organs among transplant patients that is consistent with the rules and requirements of the OPTN, as defined in § 486.320 of this part.

(h) *Organ placement.* The OPO must develop and implement a protocol to maximize placement of organs for transplantation.

§ 486.346 Condition: Organ preparation and transport.

(a) The OPO must arrange for testing of organs for infectious disease and tissue typing of organs according to current standards of practice. The OPO must ensure that testing and tissue typing of organs are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.

(b) The OPO must send complete documentation of donor information to the transplant center with the organ, including donor evaluation, the complete record of the donor's management, documentation of consent, documentation of the pronouncement of death, and documentation for determining organ quality. Two individuals, one of whom must be an OPO employee, must verify that the documentation that accompanies an organ to a transplant center is correct.

(c) The OPO must develop and follow a written protocol for packaging, labeling, handling, and shipping organs in a manner that ensures their arrival without compromise to the quality of the organ. The protocol must include procedures to check the accuracy and integrity of labels, packaging, and contents prior to transport, including verification by two individuals, one of whom must be an OPO employee, that information listed on the labels is correct.

(d) All packaging in which an organ is transported must be marked with the identification number, specific contents, and donor's blood type.

§ 486.348 Condition: Quality assessment and performance improvement (QAPI).

The OPO must develop, implement, and maintain a comprehensive, data-driven QAPI program designed to monitor and evaluate performance of all donation services, including services provided under contract or arrangement.

(a) *Standard: Components of a QAPI program.* The OPO's QAPI program must include objective measures to evaluate and demonstrate improved performance with regard to OPO activities, such as hospital development, designated requestor training, donor management, timeliness of on-site response to hospital referrals, consent practices, organ recovery and placement, and organ packaging and transport. The OPO must take actions that result in performance improvements and track performance to ensure that improvements are sustained.

(b) *Standard: Death record reviews.* As part of its ongoing QAPI efforts, an OPO must conduct at least monthly death record reviews in every Medicare and Medicaid participating hospital in its service area that has a Level I or Level II trauma center or 150 or more beds, a ventilator, and an intensive care unit (unless the hospital has a waiver to work with another OPO), with the exception of psychiatric and rehabilitation hospitals. When missed opportunities for donation are identified, the OPO must implement actions to improve performance.

(c) *Standard: Adverse events.*

(1) An OPO must establish written policies to address, at a minimum, the process for identification, reporting, analysis, and prevention of adverse events that occur during the organ donation process.

(2) The OPO must conduct a thorough analysis of any adverse event and must use the analysis to affect changes in the OPO's policies and practices to prevent repeat incidents.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

SOURCE: 53 FR 22859, June 17, 1988, unless otherwise noted.

Subpart A—General Provisions

§ 488.1 Definitions.

As used in this part—

Accredited provider or supplier means a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by CMS in accordance with § 488.5 or § 488.6.

Act means the Social Security Act.

AOA stands for the American Osteopathic Association.

Certification is a recommendation made by the State survey agency on the compliance of providers and suppliers with the conditions of participation, requirements (for SNFs and NFs), and conditions of coverage.

Conditions for coverage means the requirements suppliers must meet to participate in the Medicare program.

Conditions of participation means the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics.

Full review means a survey of a hospital for compliance with all conditions of participation for hospitals.

JCAHO stands for the Joint Commission on Accreditation of Healthcare Organizations.

Medicare condition means any condition of participation or for coverage, including any long term care requirements.

Provider of services or *provider* means a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or provider of outpatient physical therapy or speech pathology services.

Rate of disparity means the percentage of all sample validation surveys for which a State survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization's most recent surveys of providers or suppliers of the same type.

Example: Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield ((60–22)/200) a rate of disparity of 19 percent.

Reasonable assurance means that an accreditation organization has demonstrated to CMS's satisfaction that its requirements, taken as a whole, are at least as stringent as those established by CMS, taken as a whole.

State includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

State survey agency means the State health agency or other appropriate State or local agency used by HFCA to perform survey and review functions for Medicare.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would affect the health and safety of patients and raises doubts as to a provider's or supplier's noncompliance with any Medicare condition.

Supplier means any of the following: Independent laboratory; portable X-ray services physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; or chiropractor.

Validation review period means the one year period during which CMS conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by the accreditation organization.

[53 FR 22859, June 17, 1988, as amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 57 FR 24982, June 12, 1992; 58 FR 30676, May 26, 1993; 58 FR 61838, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997]

§ 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

1128—Exclusion of entities from participation in Medicare.
1128A—Civil money penalties.
1814—Conditions for, and limitations on, payment for Part A services.
1819—Requirements for SNFs.
1861(f)—Requirements for psychiatric hospitals.
1861(z)—Institutional planning standards that hospitals and SNFs must meet.
1861(ee)—Discharge planning guidelines for hospitals.
1861(ss)(2)—Accreditation of religious nonmedical health care institutions.
1864—Use of State survey agencies.
1865—Effect of accreditation.
1880—Requirements for hospitals and SNFs of the Indian Health Service.
1883—Requirements for hospitals that provide SNF care.
1902—Requirements for participation in the Medicaid program.
1913—Medicaid requirements for hospitals that provide NF care.
1919—Medicaid requirements for NFs.

[60 FR 50443, Sept. 29, 1995, as amended at 64 FR 67052, Nov. 30, 1999]

§ 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) *Basic rules.* In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must:

(1) Meet the applicable statutory definition in section 1138(b), 1819, 1832(a)(2)(F), 1861, 1881, or 1919 of the Act; and

(2) Be in compliance with the applicable conditions or long-term care requirements prescribed in subpart N, Q or U of part 405, part 416, subpart C of part 418, part 482, part 483, part 484, part 485, subpart A of part 491, or part 494 of this chapter.

(b) *Special Conditions.* (1) The Secretary, after consultation with the JCAHO or AOA, may issue conditions of participation for hospitals higher or more precise than those of either those accrediting bodies.

(2) The Secretary may, at a State's request, approve health and safety requirements for providers and suppliers in that State, which are higher than those otherwise applied in the Medicare program.

(3) If a State or political subdivision imposes higher requirements on institutions as a condition for the purchase of health services under a State Medicaid Plan approved under Title XIX of the Act, (or if Guam, Puerto Rico, or the Virgin Islands does so under a State plan for Old Age Assistance under Title I of the Act, or for Aid to the Aged, Blind, and Disabled under the original Title XVI of the Act), the Secretary is required to impose similar requirements as a condition for payment under Medicare in that State or political subdivision.

[53 FR 22859, June 17, 1988, as amended at 58 FR 61838, Nov. 23, 1993]

§ 488.4 Application and reapplication procedures for accreditation organizations.

(a) A national accreditation organization applying for approval of deeming authority for Medicare requirements under § 488.5 or 488.6 of this subpart must furnish to CMS the information and materials specified in paragraphs (a)(1) through (10) of this section. A national accreditation organization reapplying for approval must furnish to CMS whatever information and materials from paragraphs (a)(1) through (10) of this section that CMS requests. The materials and information are—

(1) The types of providers and suppliers for which the organization is requesting approval;

(2) A detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare requirements (for example, a crosswalk);

(3) A detailed description of the organization's survey process, including—

(i) Frequency of the surveys performed;

(ii) Copies of the organization's survey forms, guidelines and instructions to surveyors;

(iii) Accreditation survey review process and the accreditation status decision-making process;

(iv) Procedures used to notify accredited facilities of deficiencies and the procedures used to monitor the correction of deficiencies in accredited facilities; and

(v) Whether surveys are announced or unannounced;

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of provider and supplier accredited;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Policies and procedures with respect to an individual's participation in the survey or accreditation decision process of any facility with which the individual is professionally or financially affiliated;

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system;

(6) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs;

(7) The organization's policies and procedures with respect to the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements;

(8) A description of all types (for example, full, partial, type of facility, etc.) and categories (provisional, conditional, temporary, etc.) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement specifying the types and categories of accreditation for which approval of deeming authority is sought;

(9) A list of all currently accredited facilities, the type and category of accreditation currently held by each facility, and the expiration date of each facility's current accreditation; and

(10) A list of all full and partial accreditation surveys scheduled to be performed by the organization.

(b) The accreditation organization must also submit the following supporting documentation—

(1) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code;

(2) A resource analysis that demonstrates that the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities; and

(3) A statement acknowledging that as a condition for approval of deeming authority, the organization will agree to—

(i) Notify CMS in writing of any facility that has had its accreditation revoked, withdrawn, or revised, or that has had any other remedial or adverse action taken against it by the accreditation organization within 30 days of any such action taken;

(ii) Notify all accredited facilities within 10 days of CMS's withdrawal of the organization's approval of deeming authority;

(iii) Notify CMS in writing at least 30 days in advance of the effective date of any proposed changes in accreditation requirements;

(iv) Within 30 days of a change in CMS requirements, submit to CMS an acknowledgement of CMS's notification of the change as well as a revised crosswalk reflecting the new requirements and inform CMS about how the organization plans to alter its requirements to conform to CMS's new requirements;

(v) Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings;

(vi) [Reserved]

(vii) Notify CMS in writing within ten days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's patients or residents or a hazard to the general public; and

(viii) Conform accreditation requirements to changes in Medicare requirements.

(c) If CMS determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for deeming authority, the organization will be notified and afforded an opportunity to provide the additional information.

(d) CMS may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) The accreditation organization will receive a formal notice from CMS stating whether the request for deeming authority has been approved or denied, the rationale for any denial, and reconsideration and reapplication procedures.

(f) An accreditation organization may withdraw its application for approval of deeming authority at any time before the formal notice provided for in paragraph (e) of this section is received.

(g) Except as provided in paragraph (i) of this section, an accreditation organization that has been notified that its request for deeming authority has been denied may request a reconsideration of that determination in accordance with subpart D of this part.

(h) Except as provided in paragraph (i) of this section, any accreditation organization whose request for approval of deeming authority has been denied may resubmit its application if the organization—

(1) Has revised its accreditation program to address the rationale for denial of its previous request;

(2) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet applicable Medicare requirements; and

(3) Resubmits the application in its entirety.

(i) If an accreditation organization has requested, in accordance with part 488, subpart D of this chapter, a reconsideration of CMS's determination that its request for deeming approval is denied, it may not submit a new application for deeming authority for the type of provider or supplier that is at issue in the reconsideration until the reconsideration is administratively final.

[58 FR 61838, Nov. 23, 1993]

§ 488.5 Effect of JCAHO or AOA accreditation of hospitals.

(a) *Deemed to meet.* Institutions accredited as hospitals by the JCAHO or AOA are deemed to meet all of the Medicare conditions of participation for hospitals, except—

(1) The requirement for utilization review as specified in section 1861(e)(6) of the Act and in § 482.30 of this chapter;

(2) The additional special staffing and medical records requirements that are considered necessary for the provision of active treatment in psychiatric hospitals (section 1861(f) of the Act) and implementing regulations; and

(3) Any requirements under section 1861(e) of the Act and implementing

regulations that CMS, after consulting with JCAHO or AOA, identifies as being higher or more precise than the requirements for accreditation (section 1865(a)(4) of the Act).

(b) *Deemed status for providers and suppliers that participate in the Medicaid program.* Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider r supplier type.

(c) *Release and use of hospital accreditation surveys.* (1) A hospital deemed to meet program requirements must authorize its accreditation organization to release to CMS and the State survey agency a copy of its most current accreditation survey together with any other information related to the survey that CMS may require (including corrective action plans).

(2) CMS may use a validation survey, an accreditation survey or other information related to the survey to determine that a hospital does not meet the Medicare conditions of participation.

(3) CMS may disclose the survey and information related to the survey to the extent that the accreditation survey and related survey information are related to an enforcement action taken by CMS.

[58 FR 61840, Nov. 23, 1993]

§ 488.6 Other national accreditation programs for hospitals and other providers and suppliers.

(a) In accordance with the requirements of this subpart, a national accreditation program for hospitals; psychiatric hospitals; SNFs; HHAs; ASCs; RHCs; CORFs; hospices; religious nonmedical health care institutions; screening mammography services; critical access hospitals; or clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy, occupational therapy or speech pathology services may provide reasonable assurance to CMS that it requires the providers or suppliers it accredits to meet requirements that are at least as stringent as the Medicare conditions when taken as a whole. In such a case, CMS may deem the providers or suppliers the program accredits to be in compliance with the appropriate Medicare conditions. These providers and suppliers are subject to validation surveys under § 488.7 of this subpart. CMS will publish notices in the FEDERAL REGISTER in accordance with § 488.8(b) identifying the programs and deeming authority of any national accreditation program and the providers or suppliers it accredits. The notice will describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. (See § 488.5 for requirements concerning hospitals accredited by JCAHO or AOA.)

(b) Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c)(1) A provider or supplier deemed to meet program requirements under paragraph (a) of this section must authorize its accreditation organization to release to CMS and the State survey agency a copy of its most current accreditation survey, together with any information related to the survey that CMS may require (including corrective action plans).

(2) CMS may determine that a provider or supplier does not meet the Medicare conditions on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(3) Upon written request, CMS may disclose the survey and information related to the survey—

(i) Of any HHA; or

(ii) Of any other provider or supplier specified at paragraph (a) of this section if the accreditation survey and related survey information relate to an enforcement action taken by CMS.

[58 FR 61840, Nov. 23, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 67052, Nov. 30, 1999]

§ 488.7 Validation survey.

(a) *Basis for survey.* CMS may require a survey of an accredited provider or supplier to validate its organization's

accreditation process. These surveys will be conducted on a representative sample basis, or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the survey is comprehensive and addresses all Medicare conditions or is focused on a specific condition or conditions.

(2) When conducted in response to a substantial allegation, the State survey agency surveys for any condition that CMS determines is related to the allegations.

(3) If the State survey agency substantiates a deficiency and CMS determines that the provider or supplier is out of compliance with any Medicare condition, the State survey agency conducts a full Medicare survey.

(b) *Effect of selection for survey.* A provider or supplier selected for a validation survey must—

(1) Authorize the validation survey to take place; and

(2) Authorize the State survey agency to monitor the correction of any deficiencies found through the validation survey.

(c) *Refusal to cooperate with survey.* If a provider or supplier selected for a validation survey fails to comply with the requirements specified in paragraph (b) of this section, it will no longer be deemed to meet the Medicare conditions but will be subject to full review by the State survey agency in accordance with § 488.11 and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(d) *Consequences of finding of noncompliance.* If a validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet any Medicare conditions. Specifically, the provider or supplier will be subject to the participation and enforcement requirements applied to all providers or suppliers that are found out of compliance following a State agency survey under § 488.24 and to full review by a State agency survey in accordance with § 488.11 and may be subject to termination of the provider agreement under § 439.53 of this chapter and any other applicable intermediate sanctions and remedies.

(e) *Reinstating effect of accreditation.* An accredited provider or supplier will again be deemed to meet the Medicare conditions in accordance with this section if—

(1) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the provider's or supplier's current accreditation survey;

(2) It withdraws any prior refusal to allow a validation survey; and

(3) CMS finds that the provider or supplier meets all the applicable Medicare conditions. If CMS finds that an accredited facility meets the Life Safety Code Standard by virtue of a plan of correction, the State survey agency will continue to monitor the facility until it is in compliance with the Life Safety Code Standard.

[58 FR 61840, Nov. 23, 1993]

§ 488.8 Federal review of accreditation organizations.

(a) *Review and approval of national accreditation organization.* CMS's review and evaluation of a national accreditation organization will be conducted in accordance with, but will not necessarily be limited to, the following general criteria—

(1) The equivalency of an accreditation organization's accreditation requirements of an entity to the comparable CMS requirements for the entity;

(2) The organization's survey process to determine—

(i) The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training;

(ii) The comparability of survey procedures to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

(iii) The organization's procedures for monitoring providers or suppliers found by the organization to be out of compliance with program requirements. These monitoring procedures

are to be used only when the organization identifies noncompliance. If noncompliance is identified through validation surveys, the State survey agency monitors corrections as specified at § 488.7(b)(3);

(iv) The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;

(v) The ability of the organization to provide CMS with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization survey process;

(vi) The adequacy of staff and other resources;

(vii) The organization's ability to provide adequate funding for performing required surveys; and

(viii) The organization's policies with respect to whether surveys are announced or unannounced; and

(3) The accreditation organization's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans).

(b) *Notice and comment.* (1) CMS will publish a proposed notice in the FEDERAL REGISTER whenever it contemplates approving an accreditation organization's application for deeming authority. The proposed notice will specify the basis for granting approval of deeming authority and the types of providers and suppliers accredited by the organization for which deeming authority would be approved. The proposed notice will also describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. The proposed notice will also provide opportunity for public comment.

(2) CMS will publish a final notice in the FEDERAL REGISTER whenever it grants deeming authority to a national accreditation organization. Publication of the final notice will follow publication of the proposed notice by at least six months. The final notice will specify the effective date of the approval of deeming authority and the term of approval (which will not exceed six years).

(c) *Effects of approval of an accreditation organization.* CMS will deem providers and suppliers accredited by an approved accreditation organization to meet the Medicare conditions for which the approval of deeming authority has specifically been granted. The deeming authority will take effect 90 days following the publication of the final notice.

(d) *Continuing Federal oversight of equivalency of an accreditation organization and removal of deeming authority.* This paragraph establishes specific criteria and procedures for continuing oversight and for removing the approval of deeming authority of a national accreditation organization.

(1) *Comparability review.* CMS will compare the equivalency of an accreditation organization's accreditation requirements to the comparable CMS requirements if—

(i) CMS imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new requirements or change its survey process. An accreditation organization must provide written notification to CMS at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process; and

(iii) An accreditation organization's approval has been in effect for the maximum term specified by CMS in the final notice.

(2) *Validation review.* Following the end of a validation review period, CMS will identify any accreditation programs for which—

(i) Validation survey results indicate a rate of disparity between certifications of the accreditation organization and certification of the State agency of 20 percent or more; or

(ii) Validation survey results, irrespective of the rate of disparity, indicate widespread or systematic problems in an organization's accreditation process that provide evidence that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

(3) *Reapplication procedures.* (i) Every six years, or sooner as determined by

CMS, an approved accreditation organization must reapply for continued approval of deeming authority. CMS will notify the organization of the materials the organization must submit as part of the reapplication procedure.

(ii) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish CMS, upon request and at any time, with the reapplication materials CMS requests. CMS will establish a deadline by which the materials are to be submitted.

(e) *Notice.* If a comparability or validation review reveals documentation that an accreditation organization is not meeting the requirements of this subpart, CMS will provide written notice to the organization indicating that its deeming authority approval may be in jeopardy and that a deeming authority review is being initiated. The notice provides the following information—

(1) A statement of the requirements, instances, rates or patterns of discrepancies that were found as well as other related documentation;

(2) An explanation of CMS's deeming authority review on which the final determination is based;

(3) A description of the process available if the accreditation organization wishes an opportunity to explain or justify the findings made during the comparability or validation review;

(4) A description of the possible actions that may be imposed by CMS based on the findings from the validation review; and

(5) The reapplication materials the organization must submit and the deadline for their submission.

(f) *Deeming authority review.* (1) CMS will conduct a review of an accreditation organization's accreditation program if the comparability or validation review produces findings as described at paragraph (d)(1) or (2), respectively, of this section. CMS will review as appropriate either or both—

(i) The requirements of the accreditation organization; or

(ii) The criteria described in paragraph (a)(1) of this section to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) If CMS determines, following the deeming authority review, that the accreditation organization has failed to adopt requirements comparable to CMS's or submit new requirements timely, the accreditation organization may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements.

(3) If CMS determines, following the deeming authority review, that the rate of disparity identified during the validation review meets either of the criteria set forth in paragraph (d)(2) of this section CMS—

(i) May give the accreditation organization conditional approval of its deeming authority during a probationary period of up to one year (whether or not there are also noncomparable requirements) that will be effective 30 days following the date of this determination;

(ii) Will require the accreditation organization to release to CMS upon its request any facility-specific data that is required by CMS for continued monitoring:

(iii) Will require the accreditation organization to provide CMS with a survey schedule for the purpose of intermittent onsite monitoring by CMS staff, State surveyors, or both; and

(iv) Will publish in the Medicare Annual Report to Congress the name of any accreditation organization given a probationary period by CMS.

(4) Within 60 days after the end of any probationary period, CMS will make a final determination as to whether or not an accreditation program continues to meet the criteria described at paragraph (a)(1) of this section and will issue an appropriate notice (including reasons for the determination) to the accreditation organization and affected providers or suppliers. This determination will be based on any of the following—

(i) The evaluation of the most current validation survey and review findings. The evaluation must indicate an acceptable rate of disparity of less than 20 percent between the certifications of the accreditation organization and the certifications of the State agency as

described at paragraph (d)(2)(i) of this section in order for the accreditation organization to retain its approval;

(ii) The evaluation of facility-specific data, as necessary, as well as other related information;

(iii) The evaluation of an accreditation organization's surveyors in terms of qualifications, ongoing training composition of survey team, etc.;

(iv) The evaluation of survey procedures; or

(v) The accreditation requirements.

(5) If the accreditation program has not made improvements acceptable to CMS during the probationary period, CMS may remove recognition of deemed authority effective 30 days from the date that it provides written notice to the organization that its deeming authority will be removed.

(6) The existence of any validation review, deeming authority review, probationary period, or any other action by CMS, does not affect or limit the conducting of any validation survey.

(7) CMS will publish a notice in the FEDERAL REGISTER containing a justification of the basis for removing the deeming authority from an accreditation organization. The notice will provide the reasons the accreditation organization's accreditation program no longer meets Medicare requirements.

(8) After CMS removes approval of an accreditation organization's deeming authority, an affected provider's or supplier's deemed status continues in effect 60 days after the removal of approval. CMS may extend the period for an additional 60 days for a provider or supplier if it determines that the provider or supplier submitted an application within the initial 60 day timeframe to another approved accreditation organization or to CMS so that a certification of compliance with Medicare conditions can be determined.

(9) Failure to comply with the timeframe requirements specified in paragraph (f)(8) of this section will jeopardize a provider's or supplier's participation in the Medicare program and where applicable in the Medicaid program.

(g) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority of that accreditation organization.

(h) Any accreditation organization dissatisfied with a determination to remove its deeming authority may request a reconsideration of that determination in accordance with subpart D of this part.

[58 FR 61841, Nov. 23, 1993]

§ 488.9 Onsite observation of accreditation organization operations.

As part of the application review process, the validation review process, or the continuing oversight of an accreditation organization's performance, CMS may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

[58 FR 61842, Nov. 23, 1993]

§ 488.10 State survey agency review: Statutory provisions.

(a) Section 1864(a) of the Act requires the Secretary to enter into an agreement with any State that is able and willing to do so, under which appropriate State or local survey agencies will determine whether:

(1) Providers or prospective providers meet the Medicare conditions of participation or requirements (for SNFs and NFs);

(2) Suppliers meet the conditions for coverage; and

(3) Rural health clinics meet the conditions of certification.

(b) Section 1865(a) of the Act provides that if an institution is accredited as a hospital by the JCAHO, it will be deemed to meet the conditions of participation:

(1) Except those specified in § 488.5;

(2) Provided that such hospital, if it is included within a validation survey, authorizes the JCAHO to release to CMS (on a confidential basis) upon request a copy of the most current JCAHO accreditation survey.

(c) Section 1864(c) of the Act authorizes the Secretary to enter into agreements with State survey agencies for the purpose of conducting validation surveys in hospitals accredited by the JCAHO. Section 1865(b) provides that an accredited hospital which is found after a validation survey to have significant deficiencies related to the health and safety of patients will no longer be deemed to meet the conditions of participation.

(d) Section 1865(a) of the Act also provides that if CMS finds that accreditation of a hospital; psychiatric hospital; SNF; HHA; hospice; ASC; RHC; CORF; laboratory; screening mammography service; critical access hospital; or clinic, rehabilitation agency, or public health agency provider of outpatient physical therapy, occupational therapy, or speech pathology services by any national accreditation organization provides reasonable assurance that any or all Medicare conditions are met, CMS may treat the provider or supplier as meeting the conditions.

[53 FR 22859, June 17, 1988, as amended at 56 FR 48879, Sept. 26, 1991; 58 FR 61842, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997]

§ 488.11 State survey agency functions.

State and local agencies that have agreements under section 1864(a) of the Act perform the following functions:

(a) Survey and make recommendations regarding the issues listed in § 488.10.

(b) Conduct validation surveys of accredited facilities as provided in § 488.7.

(c) Perform other surveys and carry out other appropriate activities and certify their findings to CMS.

(d) Make recommendations regarding the effective dates of provider agreements and supplier approvals in accordance with § 489.13 of this chapter.

[62 FR 43936, Aug. 18, 1997]

§ 488.12 Effect of survey agency certification.

Certifications by the State survey agency represent recommendations to CMS.

(a) On the basis of these recommendations, CMS will determine whether:

(1) A provider or supplier is eligible to participate in or be covered under the Medicare program; or

(2) An accredited hospital is deemed to meet the Medicare conditions of participation or is subject to full review by the State survey agency.

(b) Notice of CMS's determination will be sent to the provider or supplier.

§ 488.14 Effect of QIO review.

When a QIO is conducting review activities under section 1154 of the Act and part 466 of this chapter, its activities are in lieu of the utilization review and evaluation activities required of health care institutions under sections 1861(e)(6), and 1861(k) of the Act.

[59 FR 56237, Nov. 10, 1994]

§ 488.18 Documentation of findings.

(a) The findings of the State agency with respect to each of the conditions of participation, requirements (for SNFs and NFs), or conditions for coverage must be adequately documented. When the State agency certifies to the Secretary that a provider or supplier is not in compliance with the conditions or requirements (for SNFs and NFs), and therefore not eligible to participate in the program, such documentation includes, in addition to the description of the specific deficiencies which resulted in the agency's recommendation, any provider or supplier response.

(b) If a provider or supplier is certified by the State agency as in compliance with the conditions or participation requirements (for SNFs and NFs) or as meeting the requirements for special certification (see § 488.54), with deficiencies not adversely affecting the health and safety of patients, the following information will be incorporated into the finding:

(1) A statement of the deficiencies that were found.

(2) A description of further action that is required to remove the deficiencies.

(3) A time-phased plan of correction developed by the provider and supplier and concurred with by the State agency.

(4) A scheduled time for a resurvey of the institution or agency to be conducted by the State agency within 90 days following the completion of the survey.

(c) If, on the basis of the State certification, the Secretary determines that the provider or supplier is eligible to participate, the information described in paragraph (b) of this section will be incorporated into a notice of eligibility to the provider or supplier.

(d) If the State agency receives information to the effect that a hospital or a critical access hospital (as defined in section 1861(mm)(1) of the Act) has violated § 489.24 of this chapter, the State agency is to report the information to CMS promptly.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and further redesignated at 42 FR 52826, Sept. 30, 1977. Redesignated at 53 FR 23100, June 17, 1988; 59 FR 32120, June 22, 1994; 59 FR 56237, Nov. 10, 1994; 62 FR 46037, Aug. 29, 1997]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, in § 488.18, paragraph (d) was added. The amendment contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 488.20 Periodic review of compliance and approval.

(a) Determinations by CMS to the effect that a provider or supplier is in compliance with the conditions of participation, or requirements (for SNFs and NFs), or the conditions for coverage are made as often as CMS deems necessary and may be more or less than a 12-month period, except for SNFs, NFs and HHAs. (See § 488.308 for special rules for SNFs and NFs.)

(b) The responsibilities of State survey agencies in the review and certification of compliance are as follows:

(1) Resurvey providers or suppliers as frequently as necessary to ascertain compliance and confirm the correction of deficiencies;

(2) Review reports prepared by a Professional Standards Review Organization (authorized under Part B Title XI of the Act) or a State inspection of care team (authorized under Title XIX of the Act) regarding the quality of a facility's care;

(3) Evaluate reports that may pertain to the health and safety of patients; and

(4) Take appropriate actions that may be necessary to achieve compliance or certify noncompliance to CMS.

(c) A State survey agency certification to CMS that a provider or supplier is no longer in compliance with the conditions of participation or requirements (for SNFs and NFs) or conditions for coverage will supersede the State survey agency's previous certification.

(Secs. 1102, 1814, 1861, 1863 through 1866, 1871, and 1881; 42 U.S.C. 1302, 1395f, 1395x, 1395z through 1395cc, 1395hh, and 1395rr)

[45 FR 74833, Nov. 12, 1981. Redesignated and amended at 53 FR 23100, June 17, 1988, and further amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 59 FR 56237, Nov. 10, 1994]

§ 488.24 Certification of noncompliance.

(a) Special rules for certification of noncompliance for SNFs and NFs are set forth in § 488.330.

(b) The State agency will certify that a provider or supplier is not or is no longer in compliance with the conditions of participation or conditions for coverage where the deficiencies are of such character as to substantially limit the provider's or supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients; or

(c) If CMS determines that an institution or agency does not qualify for participation or coverage because it is not in compliance with the conditions of participation or conditions for coverage, or if a provider's agreement is terminated for that reason, the institution or agency has the right to request that the determination be reviewed. (Appeals procedures are set forth in Part 498 of this chapter.)

[59 FR 56237, Nov. 10, 1994]

§ 488.26 Determining compliance.

(a) Additional rules for certification of compliance for SNFs and NFs are set forth in § 488.330.

(b) The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's or supplier's performance against these standards enables the State survey agency to document the nature and extent of deficiencies, if any, with respect to a particular function, and to assess the need for improvement in relation to the prescribed conditions.

(c) The State survey agency must adhere to the following principles in determining compliance with participation requirements:

(1) The survey process is the means to assess compliance with Federal health, safety and quality standards;

(2) The survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;

(3) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;

(4) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;

(5) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

(d) The State survey agency must use the survey methods, procedures, and forms that are prescribed by CMS.

(e) The State survey agency must ensure that a facility's actual provision of care and services to residents and the effects of that care on residents are assessed in a systematic manner.

[59 FR 56237, Nov. 10, 1994]

§ 488.28 Providers or suppliers, other than SNFs and NFs, with deficiencies.

(a) If a provider or supplier is found to be deficient with respect to one or more of the standards in the conditions of participation or conditions for coverage, it may participate in or be covered under the Health Insurance for the Aged and Disabled Program only if the facility has submitted an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary.

(b) The existing deficiencies noted either individually or in combination neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care.

(c)(1) If it is determined during a survey that a provider or supplier is not in compliance with one or more of the standards, it is granted a reasonable time to achieve compliance.

(2) The amount of time depends upon the—

(i) Nature of the deficiency; and

(ii) State survey agency's judgment as to the capabilities of the facility to provide adequate and safe care.

(d) Ordinarily a provider or supplier is expected to take the steps needed to achieve compliance within 60 days of being notified of the deficiencies but the State survey agency may recommend that additional time be granted by the Secretary in individual situations, if in its judgment, it is not reasonable to expect compliance within 60 days, for example, a facility must obtain the approval of its governing body, or engage in competitive bidding.

[59 FR 56237, Nov. 10, 1994]

Subpart B—Special Requirements

§ 488.52 [Reserved]

§ 488.54 Temporary waivers applicable to hospitals.

(a) *General provisions.* If a hospital is found to be out of compliance with one or more conditions of participation for hospitals, as specified in part 482 of this chapter, a temporary waiver may be granted by CMS. CMS may extend a temporary waiver only if such a waiver

would not jeopardize or adversely affect the health and safety of patients. The waiver may be issued for any one year period or less under certain circumstances. The waiver may be withdrawn earlier if CMS determines this action is necessary to protect the health and safety of patients. A waiver may be granted only if:

(1) The hospital is located in a rural area. This includes all areas not delineated as ''urban'' by the Bureau of the Census, based on the most recent census;

(2) The hospital has 50 or fewer inpatient hospital beds;

(3) The character and seriousness of the deficiencies do not adversely affect the health and safety of patients; and

(4) The hospital has made and continues to make a good faith effort to comply with personnel requirements consistent with any waiver.

(b) *Minimum compliance requirements.* Each case will have to be decided on its individual merits, and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(e)(1)–(8), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(e)(9). (For further information relating to the exception in section 1861(e)(5) of the Act, see paragraph (c) of this section.)

(c) *Temporary waiver of 24-hour nursing requirement of 24-hour registered nurse requirement.* CMS may waive the requirement contained in section 1861(e)(5) that a hospital must provide 24-hour nursing service furnished or supervised by a registered nurse. Such a waiver may be granted when the following criteria are met:

(1) The hospital's failure to comply fully with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located.

(2) A registered nurse is present on the premises to furnish or supervise the nursing services during at least the daytime shift, 7 days a week.

(3) The hospital has in charge, on all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse.

(4) The hospital complies with all requirements specified in paragraph (a) of this section.

(d) *Temporary waiver for technical personnel.* CMS may waive technical personnel requirements, issued under section 1861(e)(9) of the Act, contained in the Conditions of Participation; Hospitals (part 482 of this chapter). Such a waiver must take into account the availability of technical personnel and the educational opportunities for technical personnel in the area in which the hospital is located. CMS may also limit the scope of services furnished by a hospital in conjunction with the waiver in order not to adversely affect the health and safety of the patients. In addition, the hospital must also comply with all requirements specified in paragraph (a) of this section.

[39 FR 2251, Jan. 17, 1974. Redesignated at 39 FR 11419, Mar. 28, 1974, and amended at 41 FR 27962, July 8, 1976. Further redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 47 FR 31531, July 20, 1982; 51 FR 22041, June 17, 1986. Redesignated at 53 FR 23100, June 17, 1988]

§ 488.56 Temporary waivers applicable to skilled nursing facilities.

(a) *Waiver of 7-day registered nurse requirement.* To the extent that § 483.30 of this chapter requires any skilled nursing facility to engage the services of a registered nurse more than 40 hours a week, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individual patients therein,

(2) Such facility has at least one fulltime registered nurse who is regularly on duty at such facility 40 hours a week, and

(3) Such facility (i) has only patients whose attending physicians have indicated (through physicians' orders or admission notes) that each such patient does not require the services of a registered nurse for a 48-hour period, or (ii) has made arrangements for a registered nurse or a physician to spend

such time at the facility as is determined necessary by the patient's attending physician to provide necessary services on days when the regular fulltime registered nurse is not on duty.

(4) Such facility has made and continues to make a good faith effort to comply with the more than 40-hour registered nurse requirement, but such compliance is impeded by the unavailability of registered nurses in the area.

(b) *Waiver of medical director requirement.* To the extent that §488.75(i) of this chapter requires any skilled nursing facility to engage the services of a medical director either part-time or full-time, the Secretary may waive such requirement for such periods as he deems appropriate if, based upon documented findings of the State agency, he determines that:

(1) Such facility is located in an area where the supply of physicians is not sufficient to permit compliance with this requirement without seriously reducing the availability of physician services within the area, and

(2) Such facility has made and continues to make a good faith effort to comply with §488.75(i) of this chapter, but such compliance is impeded by the unavailability of physicians in the area.

[39 FR 35777, Oct. 3, 1974. Redesignated and amended at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 53 FR 23100, June 17, 1988, and further amended at 56 FR 48879, Sept. 26, 1991; 57 FR 43925, Sept. 23, 1992]

§488.60 Special procedures for approving end stage renal disease facilities.

(a) *Considerations for approval.* An ESRD facility which wishes to be approved for coverage, or which wishes any expansion of dialysis services to be approved for coverage in accordance with subpart U of part 405, must secure the Secretary's determination thereunder. In addition to the certification by the State agency referred to in §488.12 of this part, data furnished by network organizations and recommendations of the Public Health Service, concerning the contribution of a facility to the furnishing of end-stage renal disease services in its network and concerning the facility's compliance with professional norms and standards (see subpart U of part 405), shall be considered by the Secretary in determining whether to approve a facility for coverage or for any expansion of services under the End-Stage Renal Disease Program. The facility will also be required to submit data pertaining to its qualifications for approval or for any expansion of services, for consideration in the Secretary's determination.

(b) *Determining compliance with minimal utilization rates: Time limitations*—(1) *Unconditional status.* A facility which meets minimal utilization requirements will be assigned this status as long as it continues to meet these requirements.

(2) *Conditional status.* A conditional status may be granted to a facility for not more than four consecutive calendar years and will not be renewable (see §405.2122(b) of this chapter). Its status may be examined each calendar year to ascertain its compliance with Subpart U.

(3) *Exception status.* Under unusual circumstances (see §405.2122 (b) of this chapter) the Secretary may grant a time-limited exception to a facility which is not in compliance with the minimal utilization rate(s) for either unconditional status or conditional status. This exception status may be granted, and may be renewed on an annual basis, under circumstances where rigid application of minimal utilization rate requirements would adversely affect the achievement of ESRD program objectives.

(c) *New applicant.* A facility which has not previously participated in the ESRD program must submit a plan detailing how it expects to meet the conditional minimal utilization rate status by the end of the second calendar year of its operation under the program and meet the unconditional minimal utilization rate status by the end of the fourth calendar year of its operation under the program.

(d) *Notification.* The Secretary will notify each facility and its network coordinating council of its initial and its subsequent minimal utilization rate classification.

(e) *Failure to meet minimal utilization rate.* A facility failing to meet standards for unconditional status or conditional status, or if applicable, for exception status, will be so notified at the time of such classification.

(f) *Interim regulations participant.* A facility previously participating under the interim regulations will not be approved under the program established by subpart U until it has demonstrated that it meets all the applicable requirements of this subpart, including the appropriate minimal utilization rate. It may continue under the interim program only for a period not to exceed 1 year from the effective date of these amendments (see § 405.2100(c) of this chapter). During this period it may demonstrate its ability to meet the appropriate minimal utilization rate. Failure to qualify under this subpart will automatically terminate coverage of such facility's services under the ESRD program at the end of such year.

[41 FR 22510, June 3, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and further amended at 45 FR 58124, Sept. 2, 1980. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.64 Remote facility variances for utilization review requirements.

(a) As used in this section:

(1) An ''available'' individual is one who:

(i) Possesses the necessary professional qualifications;

(ii) Is not precluded from participating by reason of financial interest in any such facility or direct responsibility for the care of the patients being reviewed or, in the case of a skilled nursing facility, employment by the facility; and

(iii) Is not precluded from effective participation by the distance between the facility and his residence, office, or other place of work. An individual whose residence, office, or other place of work is more than approximately one hour's travel time from the facility shall be considered precluded from effective participation.

(2) ''Adjacent facility'' means a health care facility located within a 50-mile radius of the facility which requests a variance.

(b) The Secretary may grant a requesting facility a variance from the time frames set forth in §§ 405.1137(d) of this chapter and 482.30 as applicable, within which reviews all of cases must be commenced and completed, upon a showing satisfactory to the Secretary that the requesting facility has been unable to meet one or more of the requirements of § 405.1137 of this chapter or § 482.30 of this chapter, as applicable, by reason of insufficient medical and other professional personnel available to conduct the utilization review required by § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(c) The request for variance shall document the requesting facility's inability to meet the requirements for which a variance is requested and the facility's good faith efforts to comply with the requirements contained in § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(d) The request shall include an assurance by the requesting facility that it will continue its good faith efforts to meet the requirements contained in § 405.1137 of this chapter or § 482.30 of this chapter, as applicable.

(e) A revised utilization review plan for the requesting facility shall be submitted concurrently with the request for a variance. The revised plan shall specify the methods and procedures which the requesting facility will use, if a variance is granted, to assure:

(1) That effective and timely control will be maintained over the utilization of services; and

(2) That reviews will be conducted so as to improve the quality of care provided to patients.

(f) The request for a variance shall include:

(1) The name, location, and type (e.g., hospital, skilled nursing facility) of the facility for which the variance is requested;

(2) The total number of patient admissions and average daily patient census at the facility within the previous six months;

(3) The total number of title XVIII and title XIX patient admissions and the average daily patient census of title XVIII and title XIX patients in the facility within the previous six months;

(4) As relevant to the request, the names of all physicians on the active staff of the facility and the names of all other professional personnel on the staff of the facility, or both;

(5) The name, location, and type of each adjacent facility (e.g., hospital, skilled nursing facility);

(6) The distance and average travel time between the facility and each adjacent facility;

(7) As relevant to the request, the location of practice of available physicians and the estimated number of other available professional personnel, or both (see paragraph (a)(1)(iii) of this section);

(8) Documentation by the facility of its attempt to obtain the services of available physicians or other professional personnel, or both; and

(9) A statement of whether a QIO exists in the area where the facility is located.

(g) The Secretary shall promptly notify the facility of the action taken on the request. Where a variance is in effect, the validation of utilization review pursuant to § 405.1137 of this chapter or § 482.30 shall be made with reference to the revised utilization review plan submitted with the request for variance.

(h) The Secretary, in granting a variance, will specify the period for which the variance has been granted; such period will not exceed one year. A request for a renewal shall be submitted not later than 30 days prior to the expiration of the variance and shall contain all information required by paragraphs (c), (d), and (f) of this section. Renewal of the variance will be contingent upon the facility's continuing to meet the provisions of this section.

[40 FR 30818, July 23, 1975. Redesignated at 42 FR 52826, Sept. 30, 1977; 51 FR 22041, June 17, 1986; 51 FR 27847, Aug. 4, 1986; 51 FR 43197, Dec. 1, 1986. Redesignated and amended at 53 FR 23100, June 17, 1988]

§ 488.68 State Agency responsibilities for OASIS collection and data base requirements.

As part of State agency survey responsibilities, the State agency or other entity designated by CMS has overall responsibility for fulfilling the following requirements for operating the OASIS system:

(a) *Establish and maintain an OASIS database.* The State agency or other entity designated by CMS must—

(1) Use a standard system developed or approved by CMS to collect, store, and analyze data;

(2) Conduct basic system management activities including hardware and software maintenance, system back-up, and monitoring the status of the database; and

(3) Obtain CMS approval before modifying any parts of the CMS standard system including, but not limited to, standard CMS-approved—

(i) OASIS data items;

(ii) Record formats and validation edits; and

(iii) Agency encoding and transmission methods.

(b) *Analyze and edit OASIS data.* The State agency or other entity designated by CMS must—

(1) Upon receipt of data from an HHA, edit the data as specified by CMS and ensure that the HHA resolves errors within the limits specified by CMS;

(2) At least monthly, make available for retrieval by CMS all edited OASIS records received during that period, according to formats specified by CMS, and correct and retransmit previously rejected data as needed; and

(3) Analyze data and generate reports as specified by CMS.

(c) *Ensure accuracy of OASIS data.* The State agency must audit the accuracy of the OASIS data through the survey process.

(d) *Restrict access to OASIS data.* The State agency or other entity designated by CMS must do the following:

(1) Ensure that access to data is restricted except for the transmission of data and reports to—

(i) CMS;

(ii) The State agency component that conducts surveys for purposes related to this function; and

(iii) Other entities if authorized by CMS.

(2) Ensure that patient identifiable OASIS data is released only to the extent that it is permitted under the Privacy Act of 1974.

(e) *Provide training and technical support for HHAs.* The State agency or other entity designated by CMS must—

(1) Instruct each HHA on the administration of the data set, privacy/confidentiality of the data set, and integration of the OASIS data set into the facility's own record keeping system;

(2) Instruct each HHA on the use of software to encode and transmit OASIS data to the State;

(3) Specify to a facility the method of transmission of data to the State, and instruct the facility on this method.

(4) Monitor each HHA's ability to transmit OASIS data.

(5) Provide ongoing technical assistance and general support to HHAs in implementing the OASIS reporting requirements specified in the conditions of participation for home health agencies; and

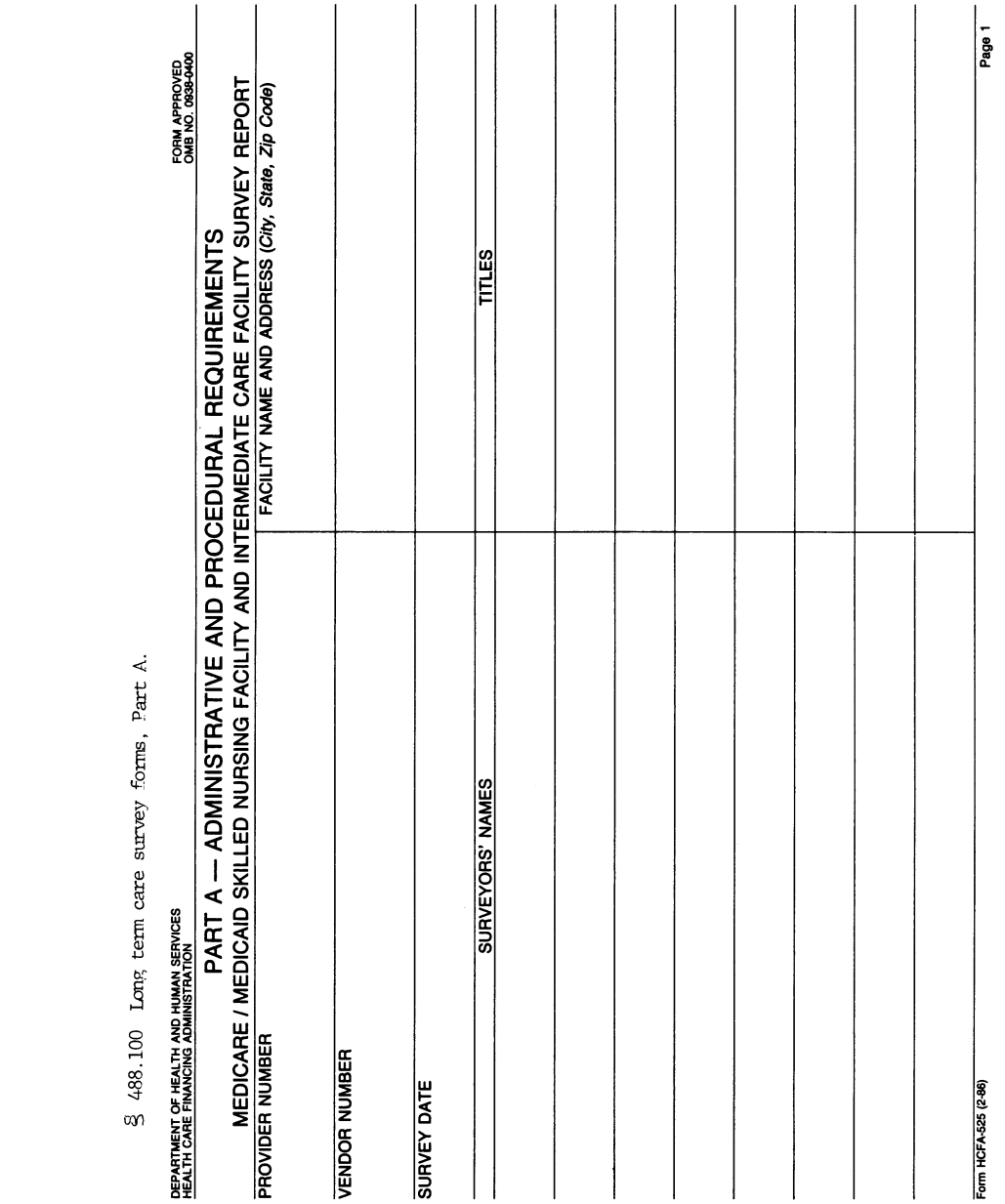
(6) Carry out any other functions as designated by CMS necessary to maintain OASIS data on the standard State system.

[64 FR 3763, Jan. 25, 1999]

SUBPART C—SURVEY FORMS AND PROCEDURES

§ 488.100 Long term care survey forms, Part A.

§ 488.100 Long term care survey forms, Part A.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

PART A — ADMINISTRATIVE AND PROCEDURAL REQUIREMENTS

MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT

PROVIDER NUMBER	FACILITY NAME AND ADDRESS (*City, State, Zip Code*)
VENDOR NUMBER	
SURVEY DATE	
SURVEYORS' NAMES	TITLES

Form HCFA-525 (2-86) Page 1

NAME OF FACILITY

CODE	COMPLIANCE WITH STATE AND LOCAL LAWS	YES	NO	N/A	EXPLANATORY STATEMENT
	Compliance with State and Local Laws *(Condition of Participation)*				
F500	SNF (405.1120) ☐ MET ☐ NOT MET				
	A. Licensure				
F501	**SNF (405.1120(a))** (Standard) ☐ MET ☐ NOT MET				
F502	ICF (442.251) (Standard) ☐ MET ☐ NOT MET				
F503	The facility has a current State License (Number _____)				
	B. Personnel Licensure				
F504	**SNF (405.1120(b))** (Standard) ☐ MET ☐ NOT MET				
F505	ICF (442.302) (Standard) ☐ MET ☐ NOT MET				
F506	Staff of the facility are licensed or registered in accordance with applicable State laws.				
	C. Compliance with Other Laws				
F507	**SNF (405.1120(c))** (Standard) ☐ MET ☐ NOT MET				
F508	ICF (442.252) (Standard) ☐ MET ☐ NOT MET				
F509	ICF (442.315) (Standard) ☐ MET ☐ NOT MET				
F510	The facility is in compliance with applicable Federal, State and local laws and regulations relating to fire and safety, sanitation, communicable and reportable diseases, postmortem procedures and other relevant health and safety requirements.				

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NAME OF FACILITY

CODE	COMPLIANCE WITH STATE AND LOCAL LAWS/ GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	The facility is in compliance with applicable regulations pertaining to:				
F511	Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances. **Exception: Not applicable to SNFs.**				
F512	Construction, maintenance and equipment. **Exception: Not applicable to SNFs.**				
F513	Current reports from all responsible governmental agencies are retained at the facility.				
	Governing Body and Management ***(Condition of Participation)***				
F514	SNF (405.1121) ☐ MET ☐ NOT MET The facility has a governing body with full legal authority and responsibility for operation of the facility.				
	A. **Disclosure**				
F515	SNF (405.1121(a)) (Standard) ☐ MET ☐ NOT MET Full disclosure of ownership has been made in accordance with requirements at 42 CFR 420.206.				
	B. **Administration**				
F516	SNF (405.1121(c)) (Standard) ☐ MET ☐ NOT MET				
F517	1. Written bylaws address the operation of the facility.				
F518	2. Written bylaws and policies address effective resident care.				
F519	3. Bylaws are reviewed and revised as necessary.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F520	ICF (442.301) (Standard) ☐ MET ☐ NOT MET				
	C. Independent Medical Review				
F521	SNF (405.1121(d)) (Standard) ☐ MET ☐ NOT MET The facility has policies which ensure that the facility cooperates in an effective program for regular independent medical evaluation and audit of residents in the facility to the extent required by the programs in which the facility participates.				
	D. Administrator				
F522	SNF (405.1121(e)) (Standard) ☐ MET ☐ NOT MET				
F523	ICF (442.303) (Standard) ☐ MET ☐ NOT MET				
F524	The facility has a licensed administrator who has authority for the overall operation of the facility. (Administrator's license or registration number _____).				
	E. Resident Care Director				
F525	ICF (442.304) (Standard) ☐ MET ☐ NOT MET				
F526	1. The administrator or another professional staff member is the resident care director (RSD).				
F527	2. The RSD coordinates and monitors each resident's care.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	F. **Institutional Planning**				
F528	SNF (405.1121(f)) (Standard) ☐ MET ☐ NOT MET				
F529	1. The facility has an overall plan and budget prepared by a committee of representatives from the governing body, administrative staff, and the organized medical staff (if any).				
F530	2. The overall plan and budget is reviewed and updated at least annually.				
F531	3. The plan includes a capital expenditures plan, if necessary.				
	G. **Personnel Policies and Procedures**				
F532	SNF (405.1121(g)) (Standard) ☐ MET ☐ NOT MET				
	1. The facility has written policies and procedures that support sound resident care and personnel practices and address, at least:				
F533	a. Control of communicable disease;				
F534	b. The review of employee incidents and accidents to identify health and safety hazards; and				
F535	c. The existence of a safe and sanitary environment.				
F536	2. Personnel records are current, available to each employee, and contain sufficient information to support placement in the position to which assigned.				
F537	3. Referral or provision for periodic health examinations to ensure freedom from communicable disease.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	H. **Outside Resources/Consultant Agreements**				
F538	SNF (405.1121(i)) (Standard) ☐ MET ☐ NOT MET				
F539	ICF (442.317) (Standard) ☐ MET ☐ NOT MET				
F540	The facility has written agreements with qualified persons to render a service (if it does not employ a qualified professional person to do so). The agreements:				
F541	1. Address the responsibilities, functions, objectives, and terms (including financial arrangements and charges);				
F542	2. Are signed by an authorized representative of the facility and the outside resource; and				
F543	3. Specify that the facility retains ultimate responsibility for the services rendered.				
	I. **Notification of Change in Resident Status**				
F544	SNF (405.1121(j)) (Standard) ☐ MET ☐ NOT MET				
F545	The facility has policies and procedures to notify physicians and other responsible persons in the event of an accident involving the resident, or resident's physical, mental or emotional status, or resident charges, billings or related administrative matter.				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	J. Resident Rights				
F546	SNF (405.1121(k)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 12 apply to SNFs.**				
F547	ICF (442.311) (Standard) ☐ MET ☐ NOT MET				
	1. Information				
F548	a. The facility informs each resident, before or at the time of admission, of his rights and responsibilities.				
F549	b. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.				
F550	c. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.				
F551	d. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.				
F552	e. The resident must be informed in writing of all services and charges for services.				
F553	f. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.				
F554	g. The resident must be informed of services not covered by Medicare or Medicaid in the basic rate.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	2. Medical Condition and Treatment				
F555	a. Each resident is informed by a physician of his health and medical condition unless the physician decides that informing the resident is medically contraindicated.				
F556	b. Each resident is given an opportunity to participate in planning his total care and medical treatment.				
F557	c. Each resident is given an opportunity to refuse treatment.				
F558	d. Each resident gives informed, written consent before participating in experimental research.				
F559	e. If the physician decides that informing the resident of his health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.				
	3. Transfer and Discharge				
F560	Each resident is transferred or discharged only for: a. Medical reasons.				
F561	b. His/her welfare or that of other residents.				
F562	c. Nonpayment except as prohibited by the Medicare or Medicaid program.				
	4. Exercising Rights				
F563	a. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.				
F564	b. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.				
F565	c. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	5. **Financial Affairs**				
F566	a. Residents are allowed to manage their own personal financial affairs.				
F567	b. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to residents in skilled nursing facilities at least on a quarterly basis.				
F568	c. The facility does not commingle resident funds with any other funds other than resident funds.				
F569	d. If a resident requests assistance from the facility in managing his personal financial affairs, resident's delegation is in writing.				
	e. The facility system of accounting includes written receipts for:				
F570	1. All personal possessions and funds received by or deposited with the facility.				
F571	2. All disbursement made to or for the resident.				
F572	f. The financial record must be available to the resident and his/her family.				
	6. **Freedom from Abuse and Restraints**				
F573	a. Each resident is free from mental and physical abuse.				
F574	b. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.				
F575	c. If used in emergencies, they are necessary to protect the resident from injury to himself or others.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F576	d. The use is authorized by a professional staff member identified in the written policies and procedures of the facility.				
F577	e. The use is reported promptly to the resident's physician by the staff member.				
	7. **Privacy**				
F578	a. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.				
F579	b. Each resident is given privacy during treatment and care of personal needs.				
F580	c. Each resident's records, including information in an automated data bank, are treated confidentially.				
F581	d. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.				
F582	e. Married residents are given privacy during visits by their spouses.				
F583	f. Married residents are permitted to share a room.				
	8. **Work**				
F584	No resident may be required to perform services for the facility.				
	9. **Freedom of Association and Correspondence**				
F585	a. Each resident is allowed to communicate, associate and meet privately with individuals of his choice unless this infringes upon the rights of another resident.				
F586	b. Each resident is allowed to send and receive personal mail unopened.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	10. **Activities**				
F587	Each resident is allowed to participate in social, religious, and community group activities.				
	11. **Personal Possessions**				
F588	Each resident is allowed to retain and use his personal possessions and clothing as space permits.				
	12. **Written Policies and Procedures: Delegation of Rights and Responsibilities**				
F589	ICF (442.312) (Standard) ☐ MET ☐ NOT MET				
F590	a. The facility has written policies and procedures that provide that all the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his physician to be incapable of understanding his rights and responsibilities.				
F591	b. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.				
	K. **Resident Care Policies**				
F592	SNF (405.1121(l)) (Standard) ☐ MET ☐ NOT MET				
F593	1. The facility has written policies to govern the continuing skilled nursing care and related medical or other services provided.				
F594	2. These policies reflect awareness of and provision for meeting the total medical and psychosocial needs of residents including admission, transfer, discharge planning, and the range of services available to residents; and				

NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F595	3. The protection of residents' personal and property rights.				
F596	4. The policies are developed by a group of professional personnel, including the Medical Director or the organized medical staff, and are periodically reviewed and revised (if necessary).				
F597	5. These policies are available to admitting physicians, sponsoring agencies, residents, and the public.				
F598	6. The Medical Director or a registered nurse is designated as responsible for the execution of the policies.				
	L. Public Availability				
F599	ICF (442.305) (Standard) ☐ MET ☐ NOT MET				
F600	1. The facility has written policies and procedures governing all the services it provides.				
F601	2. The policies and procedures are available to the staff and residents, members of the family, the public, and legal representatives of residents.				
	M. Admissions				
F602	ICF (442.306) (Standard) ☐ MET ☐ NOT MET				
	The facility has written policies and procedures that ensure that it admits as residents only those residents whose needs can be met by:				
F603	1. the facility itself.				
F604	2. the facility in cooperation with community resources.				
F605	3. the facility in cooperation with other providers of care affiliated with or under contract to the facility.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	N. Transfers				
F606	ICF (442.307) (Standard) ☐ MET ☐ NOT MET				
F607	1. The facility has written policies and procedures to ensure that residents are transferred promptly to a hospital, SNF or other appropriate facility when a change is necessary.				
F608	2. Except in emergencies, the facility consults the resident, his next of kin, the attending physician, and the responsible agency, if any, at least five days before discharge.				
F609	3. The facility uses casework services and other means to ensure that adequate arrangements are made to meet resident's needs through other resources.				
	O. Restraints				
F610	ICF (442.308) (Standard) ☐ MET ☐ NOT MET				
	The facilty has written policies and procedures that:				
F611	1. Define the uses of chemical and physical restraints.				
F612	2. Identify the professional personnel who may authorize the use of restraints in emergencies under 442.311(f).				
F613	3. Describe procedures for monitoring and controlling the use of these restraints.				
	P. Complaints				
F614	ICF (442.309) (Standard) ☐ MET ☐ NOT MET				
	The facility has written policies and procedures that:				
F615	1. Describe the procedures the facility uses to receive complaints and recommendations from residents.				
F616	2. Ensure that the facility responds to complaints and recommendations.				

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NAME OF FACILITY

CODE	GOVERNING BODY AND MANAGEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	Q. Staff Development				
F617	SNF (405.1121(h)) (Standard) ☐ MET ☐ NOT MET				
F618	ICF (442.314) (Standard) ☐ MET ☐ NOT MET				
F619	1. The facility conducts an orientation program for all new employees that includes a review of all its policies.				
F620	2. The facility plans and conducts an inservice staff development program for all personnel to assist them in developing and improving their skills.				
F621	3. The facility maintains a record of the orientation and staff development programs it conducts.				
F622	4. The record includes the content of the program and the names of participants.				
F623	5. Inservice training includes at least prevention and control of infections, fire prevention and safety, confidentiality of resident information, and preservation of resident dignity including protection of resident's privacy and personal and property rights.				

NAME OF FACILITY

CODE	MEDICAL DIRECTION	YES	NO	N/A	EXPLANATORY STATEMENT
	Medical Direction *(Condition of Participation)*				
F624	SNF (405.1122) ☐ MET ☐ NOT MET The facility has a written agreement with a licensed physician to serve as Medical Director on a part-time or full-time basis as is appropriate to the needs of the residents and the facility. (See 405.1911(b) regarding waiver of this requirement.)				
	A. **Coordination of Medical Care**				
F625	SNF (405.1122(a)) (Standard) ☐ MET ☐ NOT MET				
F626	1. Medical direction and coordination of medical care in the facility are provided by a Medical Director.				
F627	2. The Medical Director is responsible for development of policies approved by the governing body.				
F628	3. Coordination of medical care includes liaison with attending physicians to ensure their writing orders promptly upon admission of a resident, and periodic evaluation of the adequacy and appropriateness of health professional and supportive staff and services.				
	B. **Responsibilities to the Facility**				
F629	SNF (405.1122(b)) (Standard) ☐ MET ☐ NOT MET				
F630	1. The Medical Director is responsible for surveillance of the health status of the facility's employees.				
F631	2. Incidents and accidents that occur on the premises are reviewed by the Medical Director to identify hazards to health and safety.				

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NAME OF FACILITY

CODE	PHYSICIAN SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Physician Services *(Condition of Participation)*				
F632	SNF (405.1123) ☐ MET ☐ NOT MET Residents in need of skilled or rehabilitative care are admitted to the facility only upon the recommendation of, and remain under the care of, a physician. To the extent feasible, each resident designates a personal physician.				
	A. Physician Supervision				
F633	SNF (405.1123(b)) (Standard) ☐ MET ☐ NOT MET				
F634	ICF (442.346) (Standard) ☐ MET ☐ NOT MET				
F635	1. The facility has a policy that the health care of every resident must be under the supervision of a physician.				
F636	2. All attending physicians must make arrangements for the medical care of their residents in their absence.				
	B. Emergency Services				
F637	SNF (405.1123(c)) (Standard) ☐ MET ☐ NOT MET The facility has written procedures available at each nurses' station, that provide for having a physician available to furnish necessary medical care in case of emergency.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Nursing Services *(Condition of Participation)*				
F638	SNF (405.1124) ☐ MET ☐ NOT MET The facility provides 24-hour service by licensed nurses, including the services of a registered nurse at least during the day tour of duty, 7 days a week. There is an organized nursing service with a sufficient number of qualified nursing personnel to meet the total nursing needs of all residents (See 405.1911(a) regarding waiver of the 7-day registered nurse requirement).				
F639	ICF (442.342) (Standard) ☐ MET ☐ NOT MET The facility provides nursing care as needed including restorative nursing care.				
	A. **Director of Nursing Services**				
F640	SNF (405.1124(a)) (Standard) ☐ MET ☐ NOT MET				
F641	1. The director of nursing services is a qualified registered nurse employed full-time.				
F642	2. The director of nursing services has, in writing, administrative authority, responsibility, and accountability for the functions, activities, and training of the nursing services staff, and serves only one facility in this capacity.				
F643	3. If the director of nursing services has other institutional responsibilities, a qualified registered nurse serves as assistant so that there is the equivalent of a full-time director of nursing services on duty.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. **Health Services Supervision**				
F644	ICF (442.339) (Standard) ☐ MET ☐ NOT MET				
F645	1. The facility has a full-time registered nurse, or a licensed practical or vocational nurse to supervise the health services 7 days a week on the day shift.				
F646	2. The nurse has a current State license.				
F647	3. If the supervisor of health services is a licensed practical or vocational nurse, the facilty has a formal contract with a registered nurse to serve as a consultant no less than 4 hours a week.				
F648	4. To qualify to serve as a health services supervisor, a licensed practical or vocational nurse must: a. Have graduated from a State-approved school of practical nursing, or				
F649	b. Have education or other training that the State authority responsible for licensing practical nurses considered equal to graduation from a State-approved school of practical nursing, or				
F650	c. Have passed the Public Health Service examination for waivered licensed practical or vocational nurses.				
F651	5. If the nurse in charge is licensed by the State in a category other than registered nurse or licensed practical or vocational nurse: a. The individual has completed a training program to get the license that includes at least the same number of classroom and practice hours in all nursing subjects as in the program of a State-approved school of practical or vocational nursing, and				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F652	b. The State agency responsible for licensing the individual submits a report to the Medicaid agency comparing State-licensed practical nurse or vocational nurse course requirements with those for the program completed by the individual.				
	C. **Twenty-four Hour Nursing Service**				
F653	SNF (405.1124(c)) (Standard) ☐ MET ☐ NOT MET				
F654	ICF (442.338) (Standard) ☐ MET ☐ NOT MET				
F655	1. 24-Hour Nursing Nursing policies and procedures address the total nursing needs of the residents.				
F656	The policies are designed to ensure that each resident receives: Treatment.				
F657	Medications as prescribed.				
F658	Diet as prescribed.				
F659	Rehabilitative nursing care as needed.				
F660	Proper care to prevent decubitus ulcers and deformities.				
F661	Proper care to ensure that residents are clean, well-groomed and comfortable.				
F662	Protection from accident and injury.				
F663	Protection from infection.				
F664	Encouragement, assistance, and training in self-care and group activities.				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F665	2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty.				
	D. **Rehabilitative Nursing Care**				
F666	SNF (405.1124(e)) (Standard) ☐ MET ☐ NOT MET				
F667	Nursing personnel are trained in rehabilitative nursing.				
	E. **Supervision of Resident Nutrition**				
F668	SNF (405.1124(f)) (Standard) ☐ MET ☐ NOT MET				
F669	A procedure is established to inform dietetic service of physicians' diet orders and of residents' dietetic problems.				
	F. **Administration of Drugs**				
F670	SNF (405.1124(g)) (Standard) ☐ MET ☐ NOT MET				
F671	Procedures are established by the Pharmaceutical Services Committee (see 405.1127(d)) to ensure that drugs are checked against physicians' orders.				
	G. **Conformance with Physicians' Drug Orders**				
F672	SNF (405.1124(h)) (Standard) ☐ MET ☐ NOT MET **Indicators 1 thru 4 apply to SNFs.**				
F673	ICF (442.335) (Standard) ☐ MET ☐ NOT MET				
F674	1. Drugs not specifically limited as to time or number of doses when ordered are controlled by automatic stop orders or other methods in accordance with written policies.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F675	2. The attending physician is notified of an automatic stop order prior to the last dose so that the physician may decide if the administration of the drug or biological is to be continued or altered.				
F676	ICF (442.334) (Standard) ☐ MET ☐ NOT MET				
F677	3. Physicians' verbal orders for drugs are given only to a licensed nurse, pharmacist, or physician and are immediately recorded and signed by the person receiving the order. (Verbal orders for Schedule II drugs are permitted only in the case of a bona fide emergency situation.)				
F678	4. Such orders are countersigned by the attending physician within a reasonable time.				
	H. **Storage of Drugs and Biologicals**				
F679	SNF (405.1124(i)) (Standard) ☐ MET ☐ NOT MET				
F680	1. Procedures for storing and disposing of drugs and biologicals are established by the pharmaceutical services committee.				
F681	2. In accordance with State and Federal laws, all drugs and biologicals are stored in locked compartments under proper temperature controls.				
F682	3. Only authorized personnel have access to the keys.				
F683	4. Separately locked, permanently affixed compartments are provided for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit dosage distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.				
F684	5. An emergency medication kit approved by the pharmaceutical services committee is kept readily available.				

NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	Dietetic Services *(Condition of Participation)*				
F685	SNF (405.1125) ☐ MET ☐ NOT MET The facility provides a hygienic dietetic service that meets the daily nutritional needs of patients, ensures that special dietary needs are met, and provides palatable and attractive meals. A facility that has a contract with an outside food management company may be found to be in compliance with this condition provided the facility and/or company meets the standards listed herein.				
	A. **Staffing**				
F686	SNF (405.1125(a)) (Standard) ☐ MET ☐ NOT MET				
F687	1. Overall supervisory responsibility for the dietetic service is assigned to a full-time qualified dietetic service supervisor.				
F688	2. If the dietetic service supervisor is not a qualified dietitian, the dietetic service supervisor functions with frequent, regularly scheduled consultation from a person so qualified. (§405.1101(e).)				
F689	3. In addition, the facility employs sufficient supportive personnel competent to carry out the functions of the dietetic service.				
F690	4. If consultant dietetic services are used, the consultant's visits are at appropriate times, and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, resident counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus, and participation in the development or revisions of dietetic policies and procedures. (See §405.1121(j).)				

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NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Staffing				
F691	ICF (442.332) (Standard) ☐ MET ☐ NOT MET				
F692	1. The facility has a staff member trained or experienced in food management or nutrition who is responsible for: a. Planning meals that meet the nutritional needs of each resident.				
F693	b. Following the orders of the resident's physician.				
F694	c. To the extent medically possible, following the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances, 8th Ed., 1974).				
F695	d. Supervising the meal preparation and service to ensure that the menu plan is followed.				
F696	2. For residents who required medically prescribed special diets, the facility: a. Has menus for those residents planned by a professionally qualified dietitian or reviewed and approved by the attending physician; and				
F697	b. Supervises the preparation and serving of meals to ensure that the resident accepts the special diet.				
F698	3. The facility keeps for 30 days a record of each menu as served.				

NAME OF FACILITY

CODE	DIETETIC SERVICES/ SPECIALIZED REHABILITATION SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Hygiene of Staff**				
F699	SNF (405.1125(f)) (Standard) ☐ MET ☐ NOT MET				
F700	In the event food service employees are assigned duties outside the dietetic service, these duties do not interfere with the sanitation, safety, or the time required for dietetic work assignments. (See §405.1121(g).)				
	D. **Sanitary Conditions**				
F701	SNF (405.1125(g)) (Standard) ☐ MET ☐ NOT MET				
F702	Written reports of inspections by State and local health authorities are on file at the facility, with notation made of action taken by the facility to comply with any recommendations.				
	Specialized Rehabilitation Services *(Condition of Participation)*				
F703	SNF (405.1126) ☐ MET ☐ NOT MET The facility provides, or arranges for, under written agreement, specialized rehabilitative services by qualified personnel (i.e., physical therapy, speech pathology and audiology, and occupational therapy) as needed by residents to improve and maintain functioning. Safe and adequate space and equipment are available, commensurate with the services offered. If the facility does not offer such services directly, it does not admit nor retain residents in need of this care unless provision is made for such services under arrangement with qualified outside resources under which the facility assumes professional responsibility for the services rendered. (See §405.1121(i).)				

NAME OF FACILITY

CODE	SPECIALIZED REHABILITATION SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing and Organization				
F704	SNF (405.1126(a)) (Standard) ☐ MET ☐ NOT MET				
	Indicators 1 thru 3 apply to SNFs				
F705	ICF (442.343) (Standard) ☐ MET ☐ NOT MET				
F706	1. Specialized rehabilitative services are provided, in accordance with accepted professional practices, by qualified therapists or by qualified assistants or other supportive personnel under the supervision of qualified therapists.				
F707	2. Other rehabilitative services also may be provided, but must be in a facility where all rehabilitative services are provided through an organized rehabilitative service under the supervision of a physician qualified in physical medicine who determines the goals and limitations of these services and assigns duties appropriate to the training and experience of those providing such services. **Exception: Does not apply to ICFs.**				
F708	3. Written administrative and resident care policies and procedures are developed for rehabilitative services by appropriate therapists and representatives of the medical, administrative, and nursing staffs. **Exception: Does not apply to ICF's See General Requirements 442.305**				

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NAME OF FACILITY

CODE	SPECIALIZED REHABILITATION SERVICES/ PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. **Documentation of Services**				
F709	SNF (405.1126(c)) (Standard) ☐ MET ☐ NOT MET The physician's order, the plan of rehabilitative care, services rendered, evaluations of progress, and other pertinent information are recorded in the patient's medical record, and are dated and signed by the physician ordering the service and the person who provided the service.				
	C. **Qualifying to Provide Outpatient Physical Therapy Services**				
F710	SNF (405.1126(d)) (Standard) ☐ MET ☐ NOT MET If the facility provides outpatient physical therapy services, it meets the applicable health and safety regulations pertaining to such services as are included in Subpart Q of this part. (See §405.1719, 405.1720, 405.1722(a) and (b)(1)(2)(3)(i), (4), (5), (6), (7), and (8); and 405.1725.)				
	Pharmaceutical Services *(Condition of Participation)*				
F711	SNF (405.1127) ☐ MET ☐ NOT MET The facility has appropriate methods and procedures for the dispensing and administering of drugs and biologicals. The facility is responsible for providing such drugs and biologicals for its residents, insofar as they are covered under the programs, and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles.				

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Supervision of Services				
F712	SNF (405.1127(a)) (Standard) ☐ MET ☐ NOT MET				
F713	1. The pharmaceutical services are under the general supervision of a qualified pharmacist.				
F714	2. The pharmacist is responsible to the administrative staff for developing coordinating, and supervising all pharmaceutical services.				
F715	3. The pharmacist (if not a full-time employee) devotes a sufficient number of hours, based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities.				
F716	ICF (442.333) (Standard) ☐ MET ☐ NOT MET				
F717	1. The facility employs a licensed pharmacist, or				
F718	2. The facility has formal arrangements with a licensed pharmacist to advise the facility on ordering, storage, administration, disposal and recordkeeping of drugs and biologicals.				
	B. Control and Accountability				
F719	SNF (405.1127(b)) (Standard) ☐ MET ☐ NOT MET				
F720	1. The pharmaceutical service has procedures for control and accountability of all drugs and biologicals throughout the facility.				
F721	2. Only approved drugs and biologicals are used in the facility.				
F722	3. Records of receipt and disposition of all controlled drugs are maintained in sufficient detail to enable an accurate reconciliation.				

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NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES/ LABORATORY AND RADIOLOGIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Pharmaceutical Services Committee**				
F723	SNF (405.1127(d)) (Standard) ☐ MET ☐ NOT MET				
F724	1. A pharmaceutical services committee or its equivalent develops written policies and procedures for safe and effective drug therapy, distribution, control and use.				
F725	2. The committee is comprised of at least the pharmacist, the director of nursing services, the administrator, and one physician.				
F726	3. The committee oversees pharmaceutical services in the facility, makes recommendations for improvement, and monitors the service to ensure its accuracy and adequacy.				
	Laboratory and Radiologic Services *(Condition of Participation)*				
F727	SNF (405.1128) ☐ MET ☐ NOT MET The facility has provision for promptly obtaining required laboratory, X-ray, and other diagnostic services.				
	A. **Provision for Services**				
F728	SNF (405.1128(a)) (Standard) ☐ MET ☐ NOT MET				
F729	1. If the facility provides its own laboratory and X-ray services, these meet the applicable conditions established for certification of hospitals that are contained in 405.1028 and 405.1029, respectively.				

NAME OF FACILITY

CODE	LABORATORY AND RADIOLOGIC SERVICES/ DENTAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F730	2. If the facility itself does not provide such services, arrangements are made for obtaining these services from a physician's office, a participating hospital or skilled nursing facility, or a portable X-ray supplier or independent laboratory which is approved to provide these services under the program.				
F731	3. The facility assists the resident, if necessary, in arranging for transportation to and from the source of service.				
	B. Blood and Blood Products				
F732	SNF (405.1128(b)) (Standard) ☐ MET ☐ NOT MET				
F733	1. Blood handling and storage facilities are safe, adequate, and properly supervised.				
F734	2. If the facility provides for maintaining and transfusing blood and blood products, it meets the conditions established for certification of hospitals that are contained in §405.1028(j).				
F735	3. If the facility does not provide its own facility but does provide transfusion services alone, it meets at least the requirements of §405.1028(j)(1), (3), (4), (6), and (9).				
	Dental Services (Condition of Participation)				
F736	SNF (405.1129) ☐ MET ☐ NOT MET The facility has satisfactory arrangements to assist residents to obtain routine and emergency dental care (See §405.1121(i). (The basic Hospital Insurance Program does not cover the services of a dentist in a skilled nursing facility in connection with the care, treatment, filling, removal, or replacement of teeth or structures supporting the teeth; and only certain oral surgery is included in the Supplemental Medical Insurance Program.)				

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NAME OF FACILITY

CODE	DENTAL SERVICES/SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Advisory Dentist				
F737	SNF (405.1129(a)) (Standard) ☐ MET ☐ NOT MET				
F738	A dentist recommends oral hygiene policies and practices for the care of residents. (§405.1121(h).				
	B. Arrangements of Outside Services				
F739	SNF (405.1129(b)) (Standard) ☐ MET ☐ NOT MET				
F740	1. The facility has a cooperative agreement with a dentist, and				
F741	2. Maintains a list of dentists in the community for residents who do not have a private dentist.				
F742	3. The facility assists the resident, if necessary, in arranging for transportation to and from the dentist's office.				
	Social Services *(Condition of Participation)*				
F743	SNF (405.1130) ☐ MET ☐ NOT MET The facility has satisfactory arrangements for identifying the medically related social and emotional needs of the resident. It is not mandatory that the skilled nursing facility itself provide social services in order to participate in the program. If the facility does not provide social services, it has written procedures for referring residents in need of social services to appropriate social agencies. If social services are offered by the facility, they are provided under a clearly defined plan, by qualified persons, to assist each resident to adjust to the social and emotional aspects of the resident's illness, treatment, and stay in the facility.				

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NAME OF FACILITY

CODE	SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Social Service Functions				
F744	SNF (405.1130(a)) (Standard) ☐ MET ☐ NOT MET				
F745	Services are provided to meet the social and emotional needs of residents by qualified staff of the facility, or by referral, based on established procedures, to appropriate social agencies.				
F746	ICF (442.344(b)) ☐ MET ☐ NOT MET The facility either provides these services itself or arranges for them with qualified outside resources.				
	B. Staffing				
F747	SNF (405.1130(b)) (Standard) ☐ MET ☐ NOT MET				
F748	1. If the facility offers social services, a member of the staff of the facility is designated as responsible for social services.				
F749	2. If the designated person is not a qualified social worker, the facility has a written agreement with a qualified social worker or recognized social agency for consultation and assistance on a regularly scheduled basis. (See §405.1101(s).)				
F750	3. The social service also has sufficient supportive personnel to meet resident needs.				
F751	4. Facilities are adequate for social service personnel, easily accessible to residents and medical and other staff, and ensure privacy for interviews.				

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NAME OF FACILITY

CODE	SOCIAL SERVICES/ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
F752	ICF (442.344(c)) ☐ MET ☐ NOT MET				
F753	The facility designates one staff member, qualified by training or experience, to be responsible for: a. Arranging for social services; and				
F754	b. Integrating social services with other elements of the plan of care.				
	C. Records and Confidentiality				
F755	SNF (405.1130(c)) (Standard) ☐ MET ☐ NOT MET				
F756	Records of pertinent social data about personal and family problems medically related to the resident's illness and care, and of action taken to meet the resident's needs, are maintained in the resident's medical records.				
F757	If social services are provided by an outside resource, a record is maintained of each referral to such resource.				
	Activities (Condition of Participation)				
F758	SNF (405.1131) ☐ MET ☐ NOT MET The facility provides for an activities program, appropriate to the needs and interests of each resident, to encourage self care, resumption of normal activities, and maintenance of an optimal level of psychosocial functioning.				

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NAME OF FACILITY

CODE	ACTIVITIES/MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing				
F759	SNF (405.1131(a)) (Standard) ☐ MET ☐ NOT MET				
F760	A member of the facility's staff is designated as responsible for the activities program.				
F761	If not a qualified activities coordinator, this staff member functions with frequent, regularly scheduled consultation from a person so qualified. (See §405.1101(o).)				
F762	ICF (442.345(b)) ☐ MET ☐ NOT MET The facility designates one staff member, qualified by training or experience in directing group activity, to be responsible for activity service.				
	Medical Records *(Condition of Participation)*				
F763	SNF (405.1132) ☐ MET ☐ NOT MET The facility maintains clinical (medical) records on all residents in accordance with accepted professional standards and practices. The medical record service has sufficient staff, facilities, and equipment to provide medical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.				
F764	ICF (442.318(a)) ☐ MET ☐ NOT MET The facility maintains an organized resident record system that contains a record for each resident.				

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NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Staffing				
F765	SNF (405.1132(a)) (Standard) ☐ MET ☐ NOT MET				
F766	1. Overall supervisory responsibility for the medical record service is assigned to a full-time employee of the facility.				
F767	2. The facility also employs sufficient supportive personnel competent to carry out the functions of the medical record service.				
F768	3. If the medical record supervisor is not a qualified medical record practitioner, this person functions with consultation from a person qualified. (See §405.1101(i).)				
	B. Protection of Medical Record Information				
F769	SNF (405.1132(b)) (Standard) ☐ MET ☐ NOT MET				
F770	ICF (442.318(d)) ☐ MET ☐ NOT MET				
F771	The facility safeguards medical record information against loss, destruction, or unauthorized use.				
	C. Physician Documentation				
F772	SNF (405.1132(d)) (Standard) ☐ MET ☐ NOT MET				
F773	1. Only physicians enter or authenticate in medical records opinions that require medical judgment (in accordance with medical staff bylaws, rules, and regulations, if applicable).				
F774	2. All physicians sign their entries into the medical record.				

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NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	D. Completion of Records and Centralization of Reports				
F775	SNF (405.1132(e)) (Standard) ☐ MET ☐ NOT MET				
F776	1. Current medical records and those of discharged residents are completed promptly.				
F777	2. All clinical information pertaining to a resident's stay is centralized in the resident's medical record.				
	E. Retention and Preservation				
F778	SNF (405.1132(f)) (Standard) ☐ MET ☐ NOT MET Medical records are retained for a period of time not less than that determined by the respective State statute, the statue of limitations in the State, or 5 years from the date of discharge in the absence of a State statute, or, in the case of a minor, 3 years after the resident becomes of age under State law.				
F779	ICF (442.318(e)) ☐ MET ☐ NOT MET The facility must keep a resident's record for at least 3 years after the resident is discharged.				
	F. Location and Facilities				
F780	SNF (405.1132(h)) (Standard) ☐ MET ☐ NOT MET The facility maintains adequate facilities and equipment, conveniently located to provide efficient processing of medical records (reviewing, indexing, filing, and prompt retrieval).				

NAME OF FACILITY

CODE	TRANSFER AGREEMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	Transfer Agreement *(Condition of Participation)*				
F781	SNF (405.1133) ☐ MET ☐ NOT MET				
F782	ICF (442.316) (Standard) ☐ MET ☐ NOT MET				
F783	The facility has in effect a transfer agreement with one or more hospitals approved for participation under the programs, which provides the basis for effective working arrangements under which inpatient hospital care or other hospital services are available promptly to the facility's residents when needed. (A facility that has been unable to establish a transfer agreement with the hospital(s) in the community or service area after documented attempts to do so is considered to have such an agreement in effect.) Exception: A facility that has been unable to establish a written agreement after documented attempts to do so, is considered to have such an agreement.				
	Resident Transfer				
F784	SNF (405.1133(a)) (Standard) ☐ MET ☐ NOT MET				
F785	A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case of two institutions are under common control) by resaon of a written undertaking by the person or body which controls them, there is reasonable assurance that: 1. Transfer of patients will be effected between the hospital and the skilled nursing facility, ensuring timely admission, whenever such transfer is medically appropriate as determined by the attending physician.				

NAME OF FACILITY

CODE	TRANSFER AGREEMENT/PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F786	2. There will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.				
F787	3. Security and accountability for residents' personal effects are provided on transfer.				
	Physical Environment *(Condition of Participation)*				
F788	SNF (405.1134) ☐ MET ☐ NOT MET The facility is constructed, equipped, and maintained to protect the health and safety or residents, personnel, and the public.				
	A. **Life Safety from Fire**				
	SNF (405.1134(a)) (Standard) ☐ MET ☐ NOT MET				
	ICF (442.321) (Standard) ☐ MET ☐ NOT MET				
	(See appropriate HCFA Fire Safety survey form.)				
	B. **Maintenance of Equipment, Building, and Grounds**				
F789	SNF (405.1134(i)) (Standard) ☐ MET ☐ NOT MET				
F790	The facility establishes a written preventative maintenance program to ensure that all equipment is operative.				

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NAME OF FACILITY

CODE	INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	Infection Control *(Condition of Participation)*				
F791	SNF (405.1135) ☐ MET ☐ NOT MET The facility establishes an infection control committee of representative professional staff with responsibility for overall infection control in the facility. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.				
	A. **Infection Control Committee**				
F792	SNF (405.1135(a)) (Standard) ☐ MET ☐ NOT MET				
F793	1. The infection control committee is composed of members of the medical and nursing staffs, administration, and the dietetic, pharmacy, housekeeping, maintenance, and other services.				
F794	2. The committee establishes policies and procedures for investigating, controlling, and preventing infection in the facility.				
F795	3. The committee monitors staff performance to ensure that the policies and procedures are executed.				
	B. **Aseptic and Isolation Techniques**				
F796	SNF (405.1135(b)) (Standard) ☐ MET ☐ NOT MET				
F797	1. The facility has written procedures for aseptic and isolation techniques.				
F798	2. These procedures are reviewed and revised for effectiveness and improvement as necessary.				

NAME OF FACILITY

CODE	INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	C. **Housekeeping**				
F799	SNF (405.1135(c)) (Standard) ☐ MET ☐ NOT MET				
F800	1. The facility employs sufficient housekeeping personnel.				
F801	2. Provides all necessary equipment to maintain a safe, clean and orderly interior.				
F802	3. A full-time employee is designated responsible for the services and for supervision and training of personnel.				
F803	4. If a facility has a contract with an outside resource for housekeeping services, the facility and/or outside resource meets the requirements of the standards.				
	D. **Pest Control**				
F804	SNF (405.1135(e)) (Standard) ☐ MET ☐ NOT MET The facility has an ongoing pest control program.				

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NAME OF FACILITY

CODE	DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
	Disaster Preparedness *(Condition of Participation)*				
F805	SNF (405.1136) ☐ MET ☐ NOT MET The facility has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (residents and personnel) arising from such disasters.				
	A. Plan				
F806	ICF (442.313) (Standard) ☐ MET ☐ NOT MET				
F807	1. The facility has a written plan for staff and residents to follow in case of emergencies such as fire or explosion.				
F808	2. The facility rehearses the plan regularly.				
F809	3. The facility has written procedures for the staff to follow in case of an emergency involving an individual resident.				
F810	4. These procedures include: a. Caring for the resident.				
F811	b. Notifying the attending physician and other individuals responsible for the resident.				
F812	c. Arranging for transportation, hospitalization, and other appropriate services.				
F813	SNF (405.1136(a)) (Standard) ☐ MET ☐ NOT MET				
F814	1. The facility has an acceptable written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster.				
F815	2. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts.				

NAME OF FACILITY

CODE	DISASTER PREPAREDNESS/UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F816	3. Includes procedures for prompt transfer of casualties and records.				
F817	4. Instructions regarding the location and use of alarm systems and signals and of fire-fighting equipment.				
F818	5. Information regarding methods of containing fire.				
F819	6. Procedures for notification of appropriate persons.				
F820	7. Specifications of evacuation routes and procedures. (See §405.1134(a).)				
	B. **Orientation and training**				
F821	SNF (405.1136(b)) (Standard) ☐ MET ☐ NOT MET				
F822	The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster (See §405.1121(h).)				
	Utilization Review *(Condition of Participation)*				
F823	SNF (405.1137) ☐ MET ☐ NOT MET The facility carries out utilization review of the services provided in the facility to residents who are entitled to benefits under the program(s). Utilization review assures the maintenance of high quality care and appropriate and efficient utilization of facility services. There are two elements to utilization review: medical care evaluation studies and review of extended duration cases.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
	A. Plan				
F824	SNF (405.1137(a)) (Standard) ☐ MET ☐ NOT MET				
F825	1. The facility has a currently applicable written description of its utilization review plan.				
F826	2. Such description includes:				
	a. The organization and composition of the committee or group which will be responsible for the utilization review function.				
F827	b. Methods of criteria (including norms where available) to be used to define periods of continuous extended duration and to assign or select subsequent dates for continued stay review.				
F828	c. Methods for selection and conduct of medical care evaluation studies.				
	B. Organization and Composition of Utilization Review Committees				
F829	SNF (405.1137(b)) (Standard) ☐ MET ☐ NOT MET				
F830	1. The utilization review (UR) function is conducted by:				
	a. A staff committee of the skilled nursing facility which is composed of two or more physicians, with participation of other professional personnel; or,				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F831	b. A group outside the facility which is similarly composed and which is established by the local medical or osteopathic society and some or all of the hospitals and skilled nursing facilities in the locality; or (indicate name of the outside group and briefly describe the organization.)				
F832	c. A group established and organized in a manner approved by the Secretary that is capable of performing such function.				
F833	2. The medical care evaluation studies, educational duties of the review program, and the review of admissions and long-stay cases are performed by: a. the same committee or group;				
F834	b. or more committees or groups. Briefly explain who performs these functions.				
	C. Medical Care Evaluation Studies				
F835	SNF (405.1137(c)) (Standard) ☐ MET ☐ NOT MET				
F836	1. Medical care evaluation studies are performed to promote the most effective and efficient use of available health facilities and services consistent with resident needs and professionally recognized standards of health care.				
F837	2. Studies emphasize identification and analysis of patterns of resident care and suggest, where appropriate, possible changes for maintaining consistently high quality care and effective and efficient use of services.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F838	3. Each medical care evaluation study identifies and analyzes factors related to the care rendered in the facility and where indicated, results in recommendations for change beneficial to residents, staff, the facility, and the community.				
F839	4. Studies, on a sample or other basis, include, but need not be limited to, admissions, durations of stay, ancillary services furnished (including drugs and biologicals), and professional services performed on premises.				
F840	At least one study was completed during the last year. Type of study last completed: _____				
	D. **Extended Stay Review**				
F841	SNF (405.1137(d)) (Standard) ☐ MET ☐ NOT MET				
F842	1. Periodic review is made of each current inpatient skilled nursing facility beneficiary case of continuous extended duration, and the length of which is defined in the utilization review plan to determine whether further inpatient stay is necessary.				
F843	2. The review is based on the attending physician's reasons for and plan for continued stay and any other documentation the committee or group deems appropriate.				
F844	3. Cases are screened by: a. A qualified non-physician representative of the committee.				
F845	b. The group.				
F846	c. The reviewer uses criteria established by the physician members of the committee.				

NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F847	4. In instances when non-physician members are utilized, those cases are referred to a physician member for further review when it appears that the resident no longer requires further inpatient care.				
F848	5. Non-physician representatives used to screen extended stay review cases, have experience in such screening or appropriate training in the application of the screening criteria used, or both.				
F849	6. Before the expiration of each new period, the case must be reviewed again in like manner with such reviews being repeated as long as the stay continues beyond the scheduled review dates and notice has not been given pursuant to paragraph (e) of this section.				
	E. Further Stay Not Medically Necessary				
F850	SNF (405.1137(e)) (Standard) ☐ MET ☐ NOT MET				
F851	1. A final determination of the committee or group that continued stay is not medically necessary is made by at least two physician members of the committee or group, except that the final determination may be made by one physician where the attending physician, when given an opportunity to express his views, does not do so, or does not contest the finding that the continued stay is not medically necessary.				
F852	2. If the committee or group, or its nonphysician representative where a physician member concurs, has reason to believe from the review of an extended duration case or a case reviewed as part of a medical care evaluation study that further stay is no longer medically necessary, the committee or group shall notify the individual's attending physician and afford him an opportunity to present his views before it makes a final determination.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F853	3. If the final determination of the committee or group is that further stay is no longer medically necessary, written notification of the finding is given to the facility, the attending physician, and the individual (or where appropriate, his next of kin) no later than 2 days after such final determination is made and, in no event in the case of an extended duration case, later than 3 working days after the end of the extended duration period specified pursuant to paragraph (d) of this section.				
	F. Administrative Responsibilities				
F854	SNF (405.1137(f)) (Standard) ☐ MET ☐ NOT MET				
F855	The administrative staff of the facility is kept directly and fully informed of committee activities to facilitate support and assistance. (Explain)				
	G. Utilization Review Records				
F856	SNF (405.1137(g)) (Standard) ☐ MET ☐ NOT MET				
F857	1. Written records of committee activities are maintained.				
F858	2. Appropriate reports, signed by the committee chairman, are made regularly to the medical staff, administrative staff, governing body, and sponsors (if any).				
F859	3. Minutes of each committee meeting is maintained and include at least: a. Name of committee.				
F860	b. Date and duration of meeting.				
F861	c. Names of committee members present and absent.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F862	4. Description of activities presently in progress to satisfy the requirements for medical care evaluation studies, including the subject, reason for study, dates of commencement and expected completion, summary of studies completed since the last meeting, conclusions and follow-up on implementation of recommendations made from previous studies.				
F863	5. Summary of extended duration cases reviewed including the number of cases, identification number, admission and review dates, and decision reached, including the basis for each determination and action taken for each case not approved for extended care.				
	H. **Discharge Planning**				
F864	SNF (405.1137(h)) (Standard) ☐ MET ☐ NOT MET The facility maintains a centralized, coordinated program to ensure that each resident has a planned program of continuing care which meets his postdischarge needs.				
F865	1. The facility has in operation an organized discharge planning program.				
F866	The utilization review committee, in its evaluation of the current status of each extended duration case, has available to it the results of such discharge planning and information on alternative available community resources to which the resident may be referred.				
F867	2. The facility maintains written discharge planning procedures which describe: a. How the discharge coordinator will function, and his authority and relationships with the facility's staff.				
F868	b. The maximum time period after which reevaluation of each resident's discharge plan is made.				

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NAME OF FACILITY

CODE	UTILIZATION REVIEW	YES	NO	N/A	EXPLANATORY STATEMENT
F869	c. Local resources available to the facility, the resident, and the attending physician to assist in developing and implementing individual discharge plans; and				
F870	d. Provisions for periodic review and reevaluation of the facility's discharge planning program.				
F871	3. At the time of discharge, the facility provides those responsible for the resident's post discharge care with appropriate summary of information about the discharged resident to ensure the optimal continuity of care.				
	The discharge summary includes at least the following:				
F872	a. Current information relative to diagnoses.				
F873	b. Rehabilitation potential.				
F874	c. A summary of the course of prior treatment.				
F875	d. Physician orders for the immediate care of the resident.				
F876	e. Pertinent social information.				

U.S. GOVERNMENT PRINTING OFFICE 1988 - 201-817 - 81477/3616

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

PART B
MEDICARE / MEDICAID SKILLED NURSING FACILITY AND INTERMEDIATE CARE FACILITY SURVEY REPORT

PROVIDER NUMBER	FACILITY NAME AND ADDRESS (*City, State, Zip*)
VENDOR NUMBER	
SURVEY DATE	

SURVEYORS' NAMES	TITLES

SURVEY TEAM COMPOSITION

F1 Indicate the Number of Surveyors According to Discipline:

A.	Administrator	H.	Life Safety Code Specialist
B.	Nurse	I.	Laboratorian
C.	Dietitian	J.	Sanitarian
D.	Pharmacist	K.	Therapist
E.	Records Administrator	L.	Physician
F.	Social Worker	M.	National Institute of Mental Health
G.	Qualified Mental Retardation Professional	N.	Other

Note: More than one discipline may be marked for surveyors qualified in multiple disciplines.

F2 Indicate the Total Number of Surveyors Onsite: _____

Form HCFA-519 (2-86) *(CONTINUED ON REVERSE)* Page 1

LONG TERM CARE SURVEY

RESIDENT CENSUS AND CONDITIONS OF RESIDENTS

PROVIDER NO. _____ | F3 ☐ MEDICARE _____ | F4 ☐ MEDICAID _____ | F5 ☐ OTHER _____ | F6 TOTAL RESIDENTS _____

CODE		
	BATHING	
F7	___	Number of residents requiring assistance in bathing more than one part of body—or does not bathe self.
F8	___	Number of residents requiring assistance in bathing only a single part (as back or disabled extremity) or bathes self completely.
F9	___	**TOTAL***
	DRESSING	
F10	___	Number of residents totally dressed by another person.
F11	___	Number of residents needing assistance to dress self or remain partly dressed. (Exclude those residents totally dressed.)
F12	___	Number of residents able to get clothes from closets and drawers-puts on clothes, outer garments, braces-manages fasteners. Act of tying shoes is excluded.
F13	___	**TOTAL***
	TOILETING	
F14	___	Number of residents not toileted. (Use protective padding, catheter.)
F15	___	Number of residents who must use a bedpan or commode and/or receive assistance in getting to and using a toilet.
F16	___	Number of residents able to get to toilet—gets on and off toilet—cleans self—arranges clothes.
F17	___	**TOTAL***
	TRANSFERRING	
F18	___	Number of residents needing assistance in all transfers (moving in or out of bed and/or chair, toilet, tub transfers).
F19	___	Number of residents needing assistance in transferring to toilet and tub only.
F20	___	Number of residents able to complete all transfers independently (may or may not be using mechanical supports).
F21	___	Total*

CODE		
	CONTINENCE	
F22	___	Number of residents with indwelling or external catheters.
F23	___	Number of residents with partial or total incontinence in urination or defecation—partial or total control by suppositories or enemas, regulated use of urinals and/or bedpans.
F24	___	Number of residents with urination and defecation entirely self-controlled.
F25	___	**TOTAL***
	FEEDING	
F26	___	Number of residents who receive enteral/parenteral feedings.
F27	___	Number of residents who receive NG tube feedings.
F28	___	Number of residents who require assistance in act of eating.
F29	___	Number of residents who get food from plate or its equivalent into mouth—(pre-cutting of meat and preparation of food, buttering bread, opening cartons, removing plate covers, etc., are *excluded* from evaluation).
F30	___	**TOTAL***
F31	___	Number of completely bedfast residents.
F32	___	Number of chairbound residents.
F33	___	Number of ambulatory residents (may use cane, walker, or crutches).
F34	___	Number of physically restrained residents (belt, vest, cuffs).
F35	___	Number of residents receiving psychotropic drugs.
F36	___	Number of confused or disoriented residents.
F37	___	Number of residents with decubiti.
F38	___	Number of residents on individually written bowel and bladder retraining program.
F39	___	Number of residents receiving special skin care.
F40	___	Number of residents receiving intravenous therapy and/or blood transfusion.
F41	___	Number of residents requiring no assistance in ADLs.
F42	___	Number of residents on self-administration of drugs.
F43	___	Number of residents with contractures.
F44	___	Number of residents receiving respiratory care.
F45	___	Number of residents receiving tracheostomy care.
F46	___	Number of residents receiving suctioning.
F47	___	Number of residents receiving rehabilitative services (physical therapy, speech pathology and audiology, occupational therapy)
F48	___	Number of residents receiving injections.
F49	___	Number of residents receiving colostomy care.

Form HCFA-519 (2-86) *MUST EQUAL TOTAL NUMBER OF RESIDENTS IN FACILITY Page 2

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	GOVERNING BODY *(CONDITION OF PARTICIPATION)*				
F50	SNF (405.1121) ☐ MET ☐ NOT MET				
	RESIDENT RIGHTS				
F51	SNF (405.1121(k)) (Standard) ☐ MET ☐ NOT MET Indicators A thru K apply to this standard for SNFs.				
F52	ICF (442.311) (Standard) ☐ MET ☐ NOT MET Indicators A thru K apply to this standard for ICFs.				
	A. Information				
F53	1. The facility informs each resident, before or at the time of admission, of his/her rights and responsibilities.				
F54	2. The facility informs each resident, before or at the time of admission, of all rules governing resident conduct.				
F55	3. The facility informs each resident of amendments to their policies on residents' rights and responsibilities and rules governing conduct.				
F56	4. Each resident acknowledges in writing receipt of residents' rights information and any amendment to it.				
F57	5. The resident must be informed in writing of all services and charges for services.				
F58	6. The resident must be informed in writing of all changes in services and charges before or at the time of admission and on a continuing basis.				
F59	7. The resident must be informed of services not covered by Medicare or Medicaid and not covered in the basic rate.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Medical Condition and Treatment				
F60	1. Each resident is informed by a physician of his/her health and medical condition unless the physician decides that informing the resident is medically contraindicated.				
F61	2. Each resident is given an opportunity to participate in planning his/her total care and medical treatment.				
F62	3. Each resident is given an opportunity to refuse treatment.				
F63	4. Each resident gives informed, written consent before participating in experimental research.				
F64	5. If the physician decides that informing the resident of his/her health and medical condition is medically contraindicated, the physician has documented this decision in the resident's medical record.				
	C. Transfer and Discharge				
	Each resident is transferred or discharged only for:				
F65	1. Medical reasons.				
F66	2. His/her welfare or that of other residents.				
F67	3. Nonpayment except as prohibited by the Medicare or Medicaid program.				
F68	4. Each resident is given reasonable advance notice to ensure orderly transfer or discharge. EXCEPTION: Not required for ICF residents.				
	D. Exercising Rights				
F69	1. Each resident is encouraged and assisted to exercise his/her rights as a resident of the facility and as a citizen.				
F70	2. Each resident is allowed to submit complaints and recommendations concerning the policies and services of the facility to staff or to outside representatives of the resident's choice or both.				

NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F71	3. Such complaints are submitted free from restraint, coercion, discrimination, or reprisal.				
	E. Financial Affairs				
F72	1. Residents are allowed to manage their own personal financial affairs.				
F73	2. The facility establishes and maintains a system that assures full and complete accounting of residents' personal funds. An accounting report is made to each resident in a skilled nursing facility at least on a quarterly basis.				
F74	3. The facility does not commingle resident funds with any other funds.				
F75	4. If a resident requests assistance from the facility in managing his/her personal financial affairs, resident's delegation is in writing.				
F76	5. The facility system of accounting includes written receipts for: All personal possessions and funds received by or deposited with the facility.				
F77	All disbursements made to or for the resident.				
F78	6. The financial record must be available to the resident and his/her family.				
	F. Freedom from Abuse and Restraints				
F79	1. Each resident is free from mental and physical abuse.				
F80	2. Chemical and physical restraints are only used when authorized by a physician in writing for a specified period of time or in emergencies.				

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NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F81	3. If used in emergencies, they are necessary to protect the resident from injury to himself/herself or others.				
F82	4. The emergency use is authorized by a professional staff member identified in the written policies and procedures of the facility.				
F83	5. The emergency use is reported promptly to the resident's physician by the staff member.				
	G. Privacy				
F84	1. Each resident is treated with respect, consideration and full recognition of his/her dignity and individuality.				
F85	2. Each resident is given privacy during treatment and care of personal needs.				
F86	3. Each resident's records, including information in an automated data bank, are treated confidentially.				
F87	4. Each resident must give written consent before the facility releases information from his/her record to someone not otherwise authorized to receive it.				
F88	5. Married residents are given privacy during visits by their spouses.				
F89	6. Married residents are permitted to share a room.				
	H. Work				
F90	No resident may be required to perform services for the facility.				

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NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
	I. Freedom of Association and Correspondence				
F91	1. Each resident is allowed to communicate, associate and meet privately with individuals of his/her choice unless this infringes upon the rights of another resident.				
F92	2. Each resident is allowed to send and receive personal mail unopened.				
	J. Activities				
F93	Each resident is allowed to participate in social, religious, and community group activities.				
	K. Personal Possessions				
F94	Each resident is allowed to retain and use his/her personal possessions and clothing as space permits.				
	L. Delegation of Rights and Responsibilities				
F95	ICF (442.312) (Standard) ☐ MET ☐ NOT MET				
F96	1. All the rights and responsibilities of a resident pass to the resident's guardian, next of kin or sponsoring agency or agencies if the resident is adjudicated incompetent under State law or is determined by his/her physician to be incapable of understanding his/her rights and responsibilities.				
F97	2. Physician determinations of incapability and the specific reasons thereof are recorded by the physician in the resident's record.				

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NAME OF FACILITY

CODE	GOVERNING BODY	YES	NO	N/A	EXPLANATORY STATEMENT
F98	STAFF DEVELOPMENT SNF (405.1121(h)) (Standard) ☐ MET ☐ NOT MET				
F99	ICF (442.314) (Standard) ☐ MET ☐ NOT MET				
F100	1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.				
F101	2. Facility staff practices proper techniques in providing care to the aged, ill, and disabled.				
F102	3. Facility staff practice proper technique for prevention and control of infection, fire prevention and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity, including protection of privacy and personal and property rights.				
	STATUS CHANGE NOTIFICATIONS				
F103	SNF (405.1121(j)) (Standard) ☐ MET ☐ NOT MET				
F104	ICF (442.307) (Standard) ☐ Met ☐ Not Met				
F105	1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or resident charges, billings, and related administrative matters.				
F106	2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor.				

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NAME OF FACILITY

CODE	PHYSICIANS' SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	PHYSICIANS' SERVICES *(CONDITION OF PARTICIPATION)*				
F107	SNF (405.1123) ☐ MET ☐ NOT MET				
	A. Medical Findings and Orders at Time of Admission				
F108	SNF (405.1123(a)) (Standard) ☐ MET ☐ NOT MET				
F109	1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings, diagnoses, and orders from a physician for immediate care of the resident.				
F110	2. Information about the rehabilitation potential of the resident and a summary of prior treatment are made available to the facility at the time of admission or within 48 hours thereafter.				

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NAME OF FACILITY

CODE	PHYSICIANS' SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Resident Supervision by Physician				
F111	SNF (405.1123(b)) (Standard) ☐ MET ☐ NOT MET				
F112	ICF (442.346) (Standard) ☐ MET ☐ NOT MET **Indicators B and C apply to** this standard for ICFS.				
F113	1. Every resident must be under the supervision of a physician.				
F114	2. A physician prescribes a planned regimen of care based on a medical evaluation of each resident's immediate and long-term care needs. **Exception: Not required for ICF residents**				
F115	3. A physician is available to provide care in the absence of any resident's attending physician.				
F116	4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admission. **Exception: Not required for ICF residents.**				
F117	5. Each resident is seen by their attending physician at least once every 30 days for the first 90 days after admission. **Exception: ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician.**				
F118	6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and revised as necessary. **Exception: Only medications must be reviewed quarterly for ICF residents.**				

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NAME OF FACILITY

CODE	PHYSICIANS' SERVICES/NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F119	7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.				
F120	8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in the medical record. These visits cannot exceed 60 days or apply to residents who require specialized rehabilitation schedules. EXCEPTION: Not required for ICF residents.				
	C. **Emergency Services**				
F121	SNF (405.1123(c)) (Standard) ☐ MET ☐ NOT MET				
F122	Emergency services from a physician are available and provided to each resident who requires emergency care.				
	NURSING SERVICES *(CONDITION OF PARTICIPATION)*				
F123	SNF (405.1124) ☐ MET ☐ NOT MET				
F124	SNF (405.1124(c)) (Standard) ☐ Met ☐ Not Met Indicators A and B apply to this standard for SNFs.				
F125	ICF (442.338) ☐ Met ☐ Not Met Indicators A thru E apply to this standard for ICFs except where noted.				
F126	A. The facility provides nursing services which are sufficient to meet nursing needs of all residents all hours of each day. 1. Each resident receives all treatments, medications and diet as prescribed. Deviations are reported and appropriate action is taken.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F127	2. Each resident receives daily personal hygiene as needed to assure cleanliness, good skin care, good grooming, and oral hygiene taking into account individual preferences. Residents are encouraged to engage in self care activity.				
F128	3. Each resident receives care necessary to prevent skin breakdown.				
F129	4. Each resident with a decubitus receives care necessary to promote the healing of the decubitus including proper dressing.				
F130	5. When residents require restraints the application is ordered by the physician, applied properly, and released at least every 2 hours.				
F131	6. Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.				
F132	7. Each resident with a urinary catheter receives proper routine care including periodic evaluation.				
F133	8. Each resident receives proper care for the following needs: Injections Parenteral Fluids Colostomy/Ileostomy Respiratory Care Tracheostomy Care Suctioning Tube Feeding				
F134	9. Infection Control Techniques are properly carried out in the provision of care to each resident.				

Form HCFA-519 (2-98) Page 11

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F135	10. Proper nursing and sanitary procedures and techniques are used when medications are given to residents.				
F136	11. Adequate resident care supplies are available for providing treatments.				
	B. **Twenty-Four Hour Nursing Service**				
F137	1. Nursing personnel,including registered nurses, licensed practical (vocational) nurses, nurse aides, orderlies, and ward clerks, are assigned duties consistent with their education and experience, and based on the characteristics of the resident load. EXCEPTION: Not required for ICFs.				
F138	2. Weekly time schedules are maintained and indicate the number and classifications of nursing personnel including relief personnel, who worked on each unit for each tour of duty. (If a distinct part certification, show the staffing for the DP and, if appropriate, any nonparticipating remainder and explain any sharing of nursing personnel.) **Exception: Not required for Freestanding ICFs.**				
F139	3. There is a sufficient number of nursing staff available to meet the total needs of all residents.				
F140	4. There is a registered nurse on the day tour of duty 7 days a week. **Exception: Not required for ICF residents.**				

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. Charge Nurse				
F141	SNF (405.1124(b)) (Standard) ☐ MET ☐ NOT MET				
F142	1. A registered nurse or a qualified licensed practical (or vocational) nurse is designated as charge nurse by the director of nursing for each tour of duty. **Exception: Not required for ICFs.**				
F143	2. The director of nursing services does not serve as charge nurse in a facility with an average daily total occupancy of 60 or more residents. **Exception: Not required for ICFs.**				
F144	3. The ICF must have a registered nurse, or a licensed practical or vocational nurse full-time, 7 days a week, on the day shift. **Exception: Not required for SNFs.**				

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NAME OF FACILITY

List the number of full-time equivalents of RN's, LPN's, Aides/Orderlies assigned to nursing duty from the last 3 complete weeks. (Note only actual staff on duty.)

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP	F145																					
	Entire Facility	F146																					
EVENING	DP	F147																					
	Entire Facility	F148																					
NIGHT	DP	F149																					
	Entire Facility	F150																					

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP																						
	Entire Facility																						
EVENING	DP																						
	Entire Facility																						
NIGHT	DP																						
	Entire Facility																						

NAME OF FACILITY

Shift		CODE	Day 1			Day 2			Day 3			Day 4			Day 5			Day 6			Day 7		
			RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	DP	F151																					
	Entire Facility	F152																					
EVENING	DP	F153																					
	Entire Facility	F154																					
NIGHT	DP	F155																					
	Entire Facility	F156																					

STAFFING PATTERN WORKSHEETS DAY OF SURVEY (OPTIONAL)

ENTIRE FACILITY STAFFING PATTERN (DAY OF SURVEY)

	CODE		RN	PN	A
DAY	F157	REPORT			
	F158	ACTUAL			
EVENING	F159	REPORT			
	F160	ACTUAL			
NIGHT	F161	REPORT			
	F162	ACTUAL			

UNIT STAFFING PATTERN WORKSHEET (DAY OF SURVEY)

	CODE	Unit			Unit			Unit			Unit			Unit			Unit			Unit		
		RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A	RN	PN	A
DAY	F163																					
EVENING	F164																					
NIGHT	F165																					
CENSUS	F166																					

NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	D PATIENT CARE MANAGEMENT				
F167	SNF (405.1124(d)) (Standard) ☐ MET ☐ NOT MET				
F168	ICF (442.341) (Standard) ☐ MET ☐ NOT MET				
F169	1. Each resident's needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician's plan of medical care, and implemented shortly after admission.				
F170	2. Each professional service identifies needs, goals, plans, and evaluates the effectiveness of interventions, plus institutes changes in the plan of care in a timely manner.				
	E. Rehabilitative Nursing Services are performed daily, and recorded for those residents who require such service.				
F171	SNF (405.1124(e)) (Standard) ☐ MET ☐ NOT MET				
F172	ICF (442.342) (Standard) ☐ Met ☐ Not Met				
F173	1. Each resident receives rehabilitative nursing care to promote maximum physical functioning to prevent immobility, deformities, and contractures.				
F174	2. There is an ongoing evaluation of each resident's rehabilitative nursing needs. This may include;				
F175	(a) Range of motion, ambulation, turning and positioning and other activities;				
F176	(b) Assistance and instruction in the activities of daily living such as feeding, dressing, grooming, oral hygiene and toilet activities;				
F177	(c) Remotivation therapy and/or reality orientation when appropriate.				
F178	3. These activities are coordinated with other resident care services.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	F. The facility has an awareness of nutritional needs and fluid intake of residents and provides prompt assistance where necessary in feeding residents.				
F179	SNF (405.1124(f)) (Standard) ☐ MET ☐ NOT MET				
F180	1. Each resident is provided with the amount of food and fluid on a daily basis necessary to maintain their appropriate minimum average weight. Between meal feedings are offered and the amount consumed is observed. Daily food and fluid intake is observed and encouraged.				
F181	2. Each resident needing assistance in eating or drinking is provided prompt assistance. Specific self-help devices are available when necessary.				
F182	3. Deviations from normal food and fluid intake are recorded and reported to the charge nurse and the attending physician.				

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NAME OF FACILITY

CODE	NURSING SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	G. **Administration of Drugs**				
F183	SNF (405.1124(g)) (Standard) ☐ MET ☐ NOT MET				
F184	ICF (442.337) (Standard) ☐ MET ☐ NOT MET				
F185	1. The resident is identified prior to administration of a drug.				
F186	2. Drugs and biologicals are administered as soon as possible after doses are prepared.				
F187	3. Administered by same person who prepared the doses for administration except under single unit dose package distribution systems.				
F188	**Exception: ICF residents may self administer medication only with their physician's permission.**				
	H. **Conformance with Physician Drug Orders**				
F189	SNF (405.1124(h)) (Standard) ☐ MET ☐ NOT MET				
F190	ICF (442.334) (Standard) ☐ MET ☐ NOT MET				
F191	Drugs are administered in accordance with written orders of the attending physician.				
F192	Drug Error Rate _____% (See Form HCFA-522)				

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NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	DIETETIC SERVICES *(CONDITION OF PARTICIPATION)*				
F193	SNF (405.1125) ☐ MET ☐ NOT MET				
F194	ICF (442.332) (Standard) ☐ MET ☐ NOT MET Indicators A and B apply to this standard for ICFS.				
	A. Menus and Nutritional Adequacy				
F195	SNF (405.1125(b)) (Standard) ☐ MET ☐ NOT MET				
F196	Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.				
	B. Therapeutic Diets				
F197	SNF (405.1125(c)) (Standard) ☐ MET ☐ NOT MET				
F198	1. Therapeutic diets are prescribed by the attending physician.				
F199	2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietitian and advice from the physician whenever necessary.				
F200	Number of Regular Diets_____				
F201	Number of Therapeutic Diets_____				
F202	Number of Mechanically Altered Diets _____				
F203	Number of Tube Feedings_____				

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NAME OF FACILITY

CODE	DIETETIC SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	C. Preparation				
F204	SNF (405.1125(e)) (Standard) ☐ MET ☐ NOT MET				
F205	1. Food is prepared by methods that conserve its nutritive value and flavor.				
F206	2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs.				
F207	3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered.				
	D. Frequency				
F208	SNF (405.1125(d)) (Standard) ☐ MET ☐ NOT MET				
F209	ICF (442.331) (Standard) ☐ MET ☐ NOT MET				
F210	1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast.				
F211	2. To the extent medically possible, bedtime nourishments are offered to all residents. **Exception: Not required for ICF Residents.**				
	E. Staffing				
F212	SNF (405.1125.(a)) (Standard) ☐ MET ☐ NOT MET				
F213	1. Food service personnel are on duty daily over a period of 12 or more hours.				

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NAME OF FACILITY

CODE	SPECIALIZED REHABILITATIVE SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	SPECIALIZED REHABILITATIVE SERVICES *(CONDITION OF PARTICIPATION)*				
F214	SNF (405.1126) ☐ MET ☐ NOT MET				
F215	SNF (405.1128(b)) (Standard) ☐ MET ☐ NOT MET				
F216	ICF (442.343) (Standard) ☐ MET ☐ NOT MET				
	A. Plan of Care				
F217	Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapists(s) and the nursing service.				
	B. Therapy				
F218	Therapy is provided according to orders of the attending physician in accordance with accepted professional practices by qualified therapists or qualified assistants.				
	C. Progress				
F219	1. A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. **Exception: ICF resident's progress must be reviewed regularly.**				

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NAME OF FACILITY

CODE	SPECIALIZED REHABILITATIVE SERVICES/PHARMACEUTICAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
F220	2. The resident's progress is thereafter reviewed regularly, and the plan of rehabilitative care is reevaluated as necessary, but at least every 30 days, by the physician and the therapist. **Exceptions: ICF residents' plans must be revised as necessary.**				
	PHARMACEUTICAL SERVICES *(CONDITION OF PARTICIPATION)*				
F221	SNF (405.1127) ☐ MET ☐ NOT MET				
	A. **Supervision**				
F222	SNF (405.1127(a)) (Standard) ☐ MET ☐ NOT MET				
F223	ICF (442.336) (Standard) ☐ MET ☐ NOT MET				
F224	The pharmacist reviews the drug regimen of each resident at least monthly and reports any irregularities to the medical director and administrator.				

NAME OF FACILITY

CODE	PHARMACEUTICAL SERVICES LABORATORY AND RADIOLOGIC SERVICES/SOCIAL SERVICES	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Labeling of Drugs and Biologicals				
F225	SNF (405.1127(c)) (Standard) ☐ MET ☐ NOT MET				
F226	ICF (442.333) (Standard) ☐ MET ☐ NOT MET				
F227	The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessary and cautionary instructions as well as an expiration date when applicable.				
	LABORATORY AND RADIOLOGIC SERVICES *(CONDITION OF PARTICIPATION)*				
F228	SNF (405.1128) ☐ MET ☐ NOT MET				
F229	SNF (405.1128(a)) (Standard) ☐ MET ☐ NOT MET				
	Provision of Services				
F230	1. All services are provided only on the orders of a physician.				
F231	2. The attending physician is notified promptly of diagnostic findings.				
F232	3. Signed and dated reports of a clinical laboratory, X-ray and other diagnostic services are filed with the resident's medical record.				

Form HCFA-519 (2-86) Page 22

NAME OF FACILITY

CODE	SOCIAL SERVICES/ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
	SOCIAL SERVICES *(CONDITION OF PARTICIPATION)*				
F233	SNF (405.1130) ☐ MET ☐ NOT MET				
F234	SNF (405.1130(a)) (Standard) ☐ MET ☐ NOT MET				
F235	ICF (442.344) (Standard) ☐ MET ☐ NOT MET				
	A. Plan				
F236	The medically related social and emotional needs of the resident are identified.				
	B. Provision of Services				
F237	1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.				
F238	2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.				
	ACTIVITIES *(CONDITION OF PARTICIPATION)*				
F239	SNF(405.1131) ☐ MET ☐ NOT MET				
	Provision of Services				
F240	SNF (405.1131(b)) (Standard) ☐ MET ☐ NOT MET				

Form HCFA-519 (2-86) Page 23

NAME OF FACILITY

CODE	ACTIVITIES	YES	NO	N/A	EXPLANATORY STATEMENT
F241	ICF (442.345) (Standard) ☐ MET ☐ NOT MET				
F242	1. An ongoing program of meaningful activities is provided based on identified needs and interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any.				
F243	2. Unless contraindicated by the attending physicians each resident is encouraged to participate in the activities program.				
F244	3. The activities promote the physical, social and mental well-being of the resident.				
F245	4. Equipment is maintained in good working order.				
F246	5. Supplies and equipment are available.				

NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	MEDICAL RECORDS *(CONDITION OF PARTICIPATION)*				
F247	SNF (405.1132) ☐ MET ☐ NOT MET				
	Content				
F248	SNF (405.1132(c)) (Standard) ☐ MET ☐ NOT MET				
F249	ICF (442.318) (Standard) ☐ MET ☐ NOT MET				
F250	1. The medical record contains sufficient information to identify the resident clearly, to justify diagnoses and treatment, and to document results accurately.				

Form HCFA-519 (2-98) Page 25

NAME OF FACILITY

CODE	MEDICAL RECORDS	YES	NO	N/A	EXPLANATORY STATEMENT
	2. The medical record contains the following information:				
F251	a. Identification information				
F252	b. Admission data including past medical and social history				
F253	c. Transfer form, discharge summary from any transferring facility				
F254	d. Report of resident's attending physician				
F255	e. Report of physical examinations				
F256	f. Reports of physicians' periodic evaluations and progress notes				
F257	g. Diagnostic reports and therapeutic orders				
F258	h. Reports of treatments				
F259	i. Medications administered				
F260	j. An overall plan of care setting forth goals to be accomplished through each service's designed activities, therapies and treatments.				
F261	k. Assessments and goals of each service's plan of care				
F262	l. Treatments and services rendered				
F263	m. Progress notes				
F264	n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.				

Form HCFA-519 (2-86) Page 26

NAME OF FACILITY

CODE		YES	NO	N/A	EXPLANATORY STATEMENT
	TRANSFER AGREEMENT *(CONDITION OF PARTICIPATION)*				
F265	SNF (405.1133) ☐ MET ☐ NOT MET				
F266	SNF (405.1133(a)) (Standard) ☐ MET ☐ NOT MET				
F267	ICF (442.316) (Standard) ☐ MET ☐ NOT MET				
F268	A. Whenever the attending physician determines that a transfer is medically appropriate between a hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.				
F269	B. Information necessary for providing care and treatment to transferred individuals is provided.				

Form HCFA-519 (2-86)

Page 27

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	PHYSICAL ENVIRONMENT *(CONDITION OF PARTICIPATION)*				
F270	SNF (405.1134) ☐ MET ☐ NOT MET				
	A. Nursing Unit				
F271	SNF (405.1134(d)) (Standard) ☐ MET ☐ NOT MET				
F272	1. The unit is properly equipped for preparation and storage of drugs and biologicals.				
F273	2. Utility and storage rooms are adequate in size.				
F274	3. The unit is equipped to register resident calls with a functioning communication system from resident areas including resident rooms and toilet and bathing facilities.				
	B. Dining and Activities Area				
F275	SNF (405.1134(g) (Standard) ☐ MET ☐ NOT MET				
F276	ICF (442.329) (Standard) ☐ MET ☐ NOT MET				
F277	1. The facility provides one or more clean, orderly and appropriately furnished rooms of adequate size, designated for resident dining and resident activities.				
F278	2. Dining and activity rooms are well lighted and ventilated.				
F279	3. Any multipurpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.				

Form HCFA-519 (2-96) Page 28

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F280	SNF (405.1134(e)) (Standard) ☐ MET ☐ NOT MET INDICATORS C AND D APPLY TO THIS STANDARD FOR SNF				
	C. Resident Rooms				
F281	ICF (442.325) (Standard) ☐ MET ☐ NOT MET				
F282	1. Single resident rooms have at least 100 square feet.				
F283	2. Multiple resident rooms have no more than four residents and at least 80 square feet per resident.				
F284	3. Each room is equipped with or conveniently located near toilet and bathing facilities.				
F285	4. There is capability of maintaining privacy in each.				
F286	5. There is adequate storage space for each resident.				
F287	6. There is a comfortable and functioning bed and chair plus a functional cabinet and light.				
F288	7. The resident call system functions in resident rooms.				
F289	8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of the residents.				
F290	9. Each room is at or above grade level.				
F291	10. Each room has direct access to a corridor and outside exposure. **Exception: Not required for ICF residents.**				

Form HCFA-519 (2-86)

Page 29

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	D. Toilet and Bath Facilities				
F292	ICF (442.326) (Standard) ☐ MET ☐ NOT MET				
F293	1. Facilities are clean, sanitary and free of odors.				
F294	2. Facilities have safe and comfortable hot water temperatures.				
F295	3. Facilities maintain privacy.				
F296	4. Facilities have grab bars and other safeguards against slipping.				
F297	5. Facilities have fixtures in good condition.				
F298	6. The resident call system functions in toilet and bath facilities.				
	E. Social Service Area				
F299	SNF (405.1130(b)) (Standard) ☐ MET ☐ NOT MET				
F300	1. Ensures privacy for social service interviewing.				
F301	2. Adequate space for clerical and interviewing functions is provided.				
F302	3. Facilities are easily acessible to residents and staff.				

Form HCFA-519 (2-86)

Page 30

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
	F. Therapy Areas				
F303	SNF (405.1126(a)) (Standard) ☐ MET ☐ NOT MET				
F304	ICF (442.328(a)) ☐ MET ☐ NOT MET				
F305	1. Space is adequate for proper use of equipment by all residents receiving treatments.				
F306	2. Equipment is safe and in proper working condition.				
	G. Facilities for Special Care				
F307	SNF (405.1134(f)) (Standard) ☐ MET ☐ NOT MET				
F308	ICF (442.328(b)) ☐ MET ☐ NOT MET				
F309	1. Single rooms with private toilet and handwashing facilities are available for isolating residents.				
F310	2. Precautionary signs are used to identify these rooms when in use.				
	H. Common Resident Areas				
F311	SNF (405.1134(j)) (Standard) ☐ MET ☐ NOT MET				
F312	ICF (442.324) (Standard) ☐ MET ☐ NOT MET				
F313	1. All common resident areas are clean, sanitary and free of odors.				
F314	2. Provision is made for adequate and comfortable lighting levels in all areas.				
F315	3. There is limitation of sounds at comfort levels.				

Form HCFA-519 (2-86) Page 31

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT	YES	NO	N/A	EXPLANATORY STATEMENT
F316	4. A comfortable room temperature is maintained.				
F317	5. There is adequate ventilation through windows or mechanical means or a combination of both.				
F318	6. Corridors are equipped with firmly secured handrails on each side.				
F319	7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.				
	I. **Maintenance of Building and Equipment**				
F320	SNF (405.1134(i)) (Standard) ☐ MET ☐ NOT MET				
F321	1. The interior and exterior of the building are clean and orderly.				
F322	2. All essential mechanical and electrical equipment is maintained in safe operating condition.				
F323	3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.				
F324	4. Resident care equipment is clean and maintained in safe operating condition.				
F325	ICF (442.331(b)) ☐ MET ☐ NOT MET Indicators J thru L apply to ICFs.				
	J. **Dietetic Service Area**				
F326	SNF (405.1134(h)) (Standard) ☐ MET ☐ NOT MET				
F327	1. Kitchen and dietetic service areas are adequate to insure proper, timely food services for all residents				
F328	2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.				

Form HCFA-519 (2-86) Page 32

NAME OF FACILITY

CODE	PHYSICAL ENVIRONMENT/INFECTION CONTROL	YES	NO	N/A	EXPLANATORY STATEMENT
	K. HYGIENE OF DIETARY STAFF				
F329	SNF (405.1125(f)) (Standard) ☐ Met ☐ Not Met				
F330	Dietetic service personnel practice hygienic food handling techniques.				
	L. DIETARY SANITARY CONDITIONS				
F331	SNF (405.1125(g)) (Standard) ☐ Met ☐ Not Met				
F332	1. Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions.				
F333	2. Waste is disposed of properly.				
	M. **Emergency Power**				
F334	SNF (405.1134(b)) (Standard) ☐ MET ☐ NOT MET				
F335	1. An emergency source of electrical power necessary to protect the health and safety of residents is available in the event the normal electrical supply is interrupted.				
F336	2. Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life safety support systems.				
F337	3. Emergency power is provided by an emergency electrical generator located on the premises where life support systems are used.				
	INFECTION CONTROL *(CONDITION OF PARTICIPATION)*				
F338	SNF (405.1135) ☐ MET ☐ NOT MET				
	A. **Infection Control**				
F339	SNF (405.1135(b)) (Standard) ☐ MET ☐ NOT MET				
F340	Aseptic and isolation techniques are followed by all personnel.				

Form HCFA-519 (2-86) Page 33

NAME OF FACILITY

CODE	INFECTION CONTROL/DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
	B. Sanitation				
F341	SNF (405.1135(c)) (Standard) ☐ MET ☐ NOT MET				
F342	The facility maintains a safe, clean, and orderly interior.				
	C. Linen				
F343	SNF (405.1135(d) (Standard) ☐ MET ☐ NOT MET				
F344	ICF (442.327) (Standard) ☐ MET ☐ NOT MET				
F345	1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.				
F346	2. Linens are handled; stored, processed, and transported in such a manner as to prevent the spread of infection.				
	D. PEST CONTROL				
F347	SNF (405.1135(e)) (Standard) ☐ Met ☐ Not Met				
F348	ICF (442.315(c)) (Standard) ☐ Met ☐ Not Met				
F349	The facility is maintained free from insects and rodents.				
	DISASTER PREPAREDNESS (CONDITION OF PARTICIPATION)				
F350	SNF (405.1136) ☐ MET ☐ NOT MET				
F351	SNF (405.1136(a)) (Standard) ☐ MET ☐ NOT MET				
F352	ICF (442.313) (Standard) ☐ MET ☐ NOT MET Indicators A and B apply to this standard for ICFS.				
	A. Disaster Plan				
F353	1. Facility staff are aware of plans, procedures to be followed for fire, explosion or other disaster.				

Form HCFA-519 (2-86) Page 34

NAME OF FACILITY

CODE	DISASTER PREPAREDNESS	YES	NO	N/A	EXPLANATORY STATEMENT
F354	2. Facility staff are knowledgeable about evacuation routes.				
F355	3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.				
F356	4. Facility staff are aware of methods of containing fire.				
	B. Drills				
F357	SNF (405.1136(b)) (Standard) ☐ MET ☐ NOT MET				
F358	1. All employees are trained, as part of their employment orientation in all aspects of preparedness for any disaster.				
F359	2. Facility staff participate in ongoing training and drills in all procedures so that each employee promptly and correctly carries out a specific role in case of a disaster.				

Form HCFA-619 (2-86) Page 35

SKILLED NURSING FACILITY & INTERMEDIATE CARE FACILITY

SURVEY REPORT — PART B
CRUCIAL DATA EXTRACT
(To be used with 2-86 Revision of Form HCFA-519)

PROVIDER NO.	FACILITY NAME	SURVEY DATE

SURVEY TEAM COMPOSITION

*F1: INDICATE THE NUMBER OF SURVEYORS ACCORDING TO DISCIPLINE:

A.	_____	ADMINISTRATOR	H.	_____	LIFE SAFETY CODE SPECIALIST
B.	_____	NURSE	I.	_____	LABORATORIAN
C.	_____	DIETITIAN	J.	_____	SANITARIAN
D.	_____	PHARMACIST	K.	_____	THERAPIST
E.	_____	RECORDS ADMINISTRATOR	L.	_____	PHYSICIAN
F.	_____	SOCIAL WORKER	M.	_____	NATIONAL INSTITUTE OF MENTAL HEALTH
G.	_____	QUALIFIED MENTAL RETARDATION PROFESSIONAL	N.	_____	OTHER

NOTE: MORE THAN ONE DISCIPLINE MAY BE MARKED FOR SURVEYORS QUALIFIED IN MULTIPLE DISCIPLINES.

*F2: INDICATE THE TOTAL NUMBER OF SURVEYORS ONSITE: ____

*F193 DRUG ERROR RATE: _____% (Round % to nearest whole number.)

*SF5 Survey Form Indicator (Check one)

Traditional Survey (1) ☐ New LTC Survey (2) ☐

NOTE: PLEASE ATTACH COPY OF PAGES 2, 14 AND 15.

*Mandatory

Form HCFA-519E (2-86)

☆U.S. GOVERNMENT PRINTING OFFICE : 1986 O - 153-203 : QL 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

RESIDENTS SELECTED FOR INDEPTH REVIEW

PROVIDER NUMBER | SURVEY DATE

	RESIDENT NAME (TARGETED)*	ROOM NUMBER	REASON FOR SELECTION
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			

FORM HCFA-520 (2-86) * NOTE IF ICF OR SNF RESIDENT

* U.S.GPO 1986-0-181-264/53839

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

TOUR NOTES WORKSHEET

PROVIDER NUMBER	SURVEY DATE

INSTRUCTIONS

1. *Note care and problems in care on all units.*
2. *Report deficiencies directly to survey report form or evaluate further during indepth sample review.*
3. *Select residents for indepth review.*
4. *Select a proportionate number from each section.*

INDEPTH SAMPLE

Facility Census	0-60	61-120	121-200	200+
				10%
Sample Size	25% (Min10)	20% (Min15)	15% (Min24)	(Min30) (Max50)

OBSERVE RESIDENTS FOR THE FOLLOWING CARE PROBLEMS

GROOMING/PERSONAL HYGIENE

POSITIONING

ASSISTIVE DEVICES

AMBULATION

RESTRAINTS

HYDRATION

INFECTION CONTROL

PATIENT RIGHTS

OTHER

FORM HCFA-521 (2-86)

* U S GPO 1986 O-181-284/53827

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

OBSERVATION / INTERVIEW RECORD REVIEW WORKSHEET

PROVIDER NUMBER	SURVEY DATE	OBSERVATION/INTERVIEW OF: (RESIDENT IDENTIFIER)

INSTRUCTIONS

1. **Observe each resident in sample to identify ADL needs and potential problems. Check appropriate blocks.**
2. **Interview only residents in sample who are capable and willing.**
3. **Review each resident's record to ensure assessments, plans, interventions and evaluations are appropriate and current.**
4. **Note deficiencies on survey report form after reviewing all residents in sample.**

RESIDENT NEEDS

ADL's
- ☐ Bathing
- ☐ Dressing
- ☐ Toileting
- ☐ Transferring
- ☐ Continence
- ☐ Feeding

SKIN
- ☐ Tears/Wounds
- ☐ Ulcers
- ☐ Rashes
- ☐ Flaking
- ☐ Scaling
- ☐ Red Area

DECUBITUS
- ☐ Grade
- ☐ Foul Odor
- ☐ Draining
- ☐ Dressing
- ☐ Unclean
- ☐ Not Dry
- ☐ Not Intact
- ☐ Poor Technique

GROOMING/HYGIENE
- ☐ Eyes/Ears/Mouth
- ☐ Oral/Dental Hygiene
- ☐ Foot Care
- ☐ Facial Hair
- ☐ Hair/Scalp
- ☐ Nails
- ☐ Clothing
- ☐ Shoes/Slippers
- ☐ Odors

POSITIONING
- ☐ Need Present
- ☐ Contracted Extremities
- ☐ Improper Position
- ☐ No Protective Device
- ☐ ROM Improper
- ☐ Lack of Turning as Needed
- ☐ Schedule Not Present
- ☐ Improper Techniques
- ☐ Aseptic/Other

DRESSINGS
- ☐ Present
- ☐ Unclean
- ☐ Not Dry
- ☐ Not Intact
- ☐ Foul Odor
- ☐ Poor Technique

RESTRAINTS
- ☐ Type
- ☐ Inappropriate Application
- ☐ Improper Body Alignment/Support
- ☐ Not Released/Exercised Every 2 Hours
- ☐ Chemically Restrained

BOWEL/BLADDER
- ☐ Incontinent
- ☐ Not Routinely Toileted
- ☐ Commode Not Available
- ☐ Schedule Not Available

CATHETER
- ☐ Present
- ☐ Inappropriate
- ☐ Poor Drainage
- ☐ Drainage System Open
- ☐ No Urine in Bag
- ☐ Urine Leaking
- ☐ Abdomen Distended
- ☐ Tubing Not Clean
- ☐ No I/O Recording
- ☐ Supply Storage Unclean

INJECTIONS
- ☐ Receives Injections
- ☐ Site Red/Swollen
- ☐ Improper Technique
- ☐ Resident Reacts

COLOSTOMY/ILEOSTOMY
- ☐ Present
- ☐ Not Well Regulated
- ☐ Odors
- ☐ Diarrhea/Constipation
- ☐ Site Red/Irritated

PARENTERAL FLUID/IV'S
- ☐ Present
- ☐ Rate Incorrect/Stopped
- ☐ Site Red/Swollen
- ☐ Dressing Unclean
- ☐ Unsafe Splint
- ☐ Improper Label
- ☐ Outdated Solution
- ☐ No I/O Recording

TRACHEOSOTOMY
- ☐ Present
- ☐ Site Red/Swollen
- ☐ Obstructed
- ☐ Unclean
- ☐ Improper Suctioning
- ☐ Equipment Not Available

SUCTIONING
- ☐ Need Present
- ☐ Audible Rales
- ☐ Labored Breathing
- ☐ Drainage
- ☐ Equipment Not Available

RESPIRATORY
- ☐ Congested/Short Breath
- ☐ IPPB Not Available
- ☐ Oxygen Not Available
- ☐ Improper Equipment Use

DIETARY NEEDS
- ☐ Over/Underweight
- ☐ Dehydrated
- ☐ Edema
- ☐ Emaciated
- ☐ Dull/Dry Hair
- ☐ Swollen/Red Tongue
- ☐ Bleeding Gums
- ☐ Cracked Lips
- ☐ Inability to Chew
- ☐ Swallowing Prob.
- ☐ Pallor

TUBE FEEDING
- ☐ Present
- ☐ Nutrition Inadequate
- ☐ Poorly Tolerated
- ☐ Vomits
- ☐ Dehydrated
- ☐ Over/Underweight
- ☐ Diarrhea/Constipation
- ☐ Poor Skin Condition
- ☐ Poor Mouth Condition
- ☐ Improper Technique

REHABILITATION NEEDS
- ☐ Cannot Communicate
- ☐ Ineffective Use of Assistive Device
- ☐ Improper Equipment Use
- ☐ Improper Technique
- ☐ Equipment Inadequate

SOCIAL SERVICE NEEDS
- ☐ Not Oriented
- ☐ Not Able to Converse
- ☐ Uncooperative/Disrupts
- ☐ Withdrawn
- ☐ Anxious
- ☐ Confused
- ☐ Lonely
- ☐ Vision/Hearing Needs
- ☐ Mentally Retarded

OTHER
- ☐
- ☐
- ☐
- ☐
- ☐

ACTIVITY NEEDS
- ☐ Not Participating
- ☐ Vision/Hearing
- ☐ Chair/Bedfast
- ☐ Dependence ≥ 4 ADL's

PATIENT RIGHTS
- ☐ Privacy Not Maintained
- ☐ Staff Not Courteous
- ☐ Not Informed of Rights
- ☐ Mental/Physical Abuse
- ☐ Cannot Exercise Rights
- ☐ Cannot Manage Affairs

NOTES:

Form HCFA 524 (2-86)

SEE REVERSE

RECORD REVIEW

☐ Drug Regimen Review (See SOM Appendix N Part 1): ☐ Satisfactory ☐ Unsatisfactory

ROUTINE REPORTS: ☐ Weights ☐ Lab ☐ X-ray ☐ Other

ASSESSMENT	PLAN	INTERVENTION	EVALUATION

PHYSICIAN SERVICES

☐ Admission Information
☐ Rehabilitation Information
☐ Physical Exam
☐ Written Care Plan
☐ Signs Orders/Notes
☐ Required Visits
☐ Emergency Availability
☐ Review of Care

★U.S.GPO:1986-0-181-264/53835

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

DRUG PASS WORKSHEET

PROVIDER NUMBER | SURVEY DATE | ERROR RATE

INSTRUCTIONS

1. *Perform Drug Pass Observations on 20 Residents.*
2. *Record Observation of each Opportunity.*
3. *Compare Observation Notes with Physician Orders.*
4. *Calculate and Note Error Rate.*
5. *Note Deficiencies on Survey Report Form.*

DEFICIENCY FORMULA

1. *One or more Significant Errors = Deficiency*
2. *Significant + Non-significant / Doses Given + Doses Ordered But Not Given X 100 ≥ 5% = Deficiency*

IDENTIFIER	POUR	PASS	RECORD
RESIDENT'S FULL NAME, ROOM NUMBER, TIME	DRUG PRESCRIPTION NAME, DOSE AND FORM	OBSERVATION OF ADMINISTRATION	DRUG ORDER WRITTEN AS *(IF DIFFERS FROM ADMINS ONLY)*

FORM HCFA-522 (2-86)

SEE REVERSE

DRUG ERROR CALCULATION
(SEE SOM Appendix N Part 2)

How to Calculate a Medication Error Rate—In calculating the percentage of errors, the numerator in the ratio is the total number of errors that you observe, both significant and non-significant. The denominator is all the doses observed being administered **plus** the doses ordered but not administered. The equation for calculating a medication error rate is as follows:

$$\text{Medication Error Rate} = \frac{\text{Number of errors observed}}{\text{Opportunities for errors}} \times 100$$

Where: Opportunities for errors equals the number of doses administered **plus** the number of doses ordered but not administered.

Comments

For example, you observed the administration of drugs to 20 patients. There were a total of 47 drugs administered (47 opportunities for errors). At the completion of the reconciliation of your Observations with the physicians' orders, you find that three medication errors were made in administration and one medication was omitted (ordered but not administered). The omitted dose is included in both the numerator and the denominator. Therefore, following the above formula, your equation would be as follows:

$$\frac{3 + 1}{47 + 1} \times 100 = 8.3\%$$

★U.S.GPO:1986-0-181-264/53836

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

DINING AREA & EATING ASSISTANCE WORKSHEET

PROVIDER NUMBER	SURVEY DATE

INSTRUCTIONS

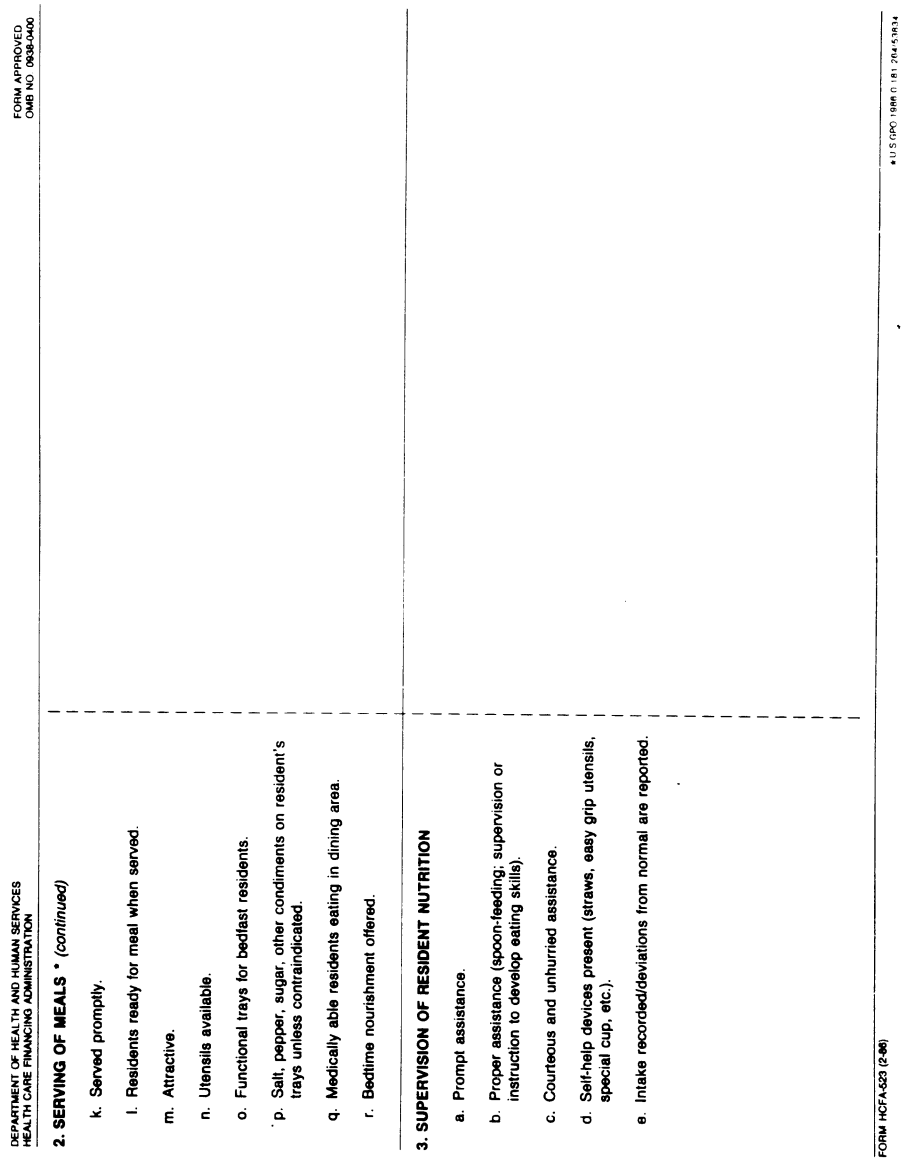
TASKS 1. Observe Dining Area.
2. Note Meals Served/Review Physicians Orders.
3. Note Assistance Provided.
4. Note Deficiencies on Survey Summary Form.

➡ *SAMPLE A MINIMUM OF FIVE (5) RESIDENTS ⬅

1. DINING AREA AND MEALS	
a. Size does not restrict movement.	
b. Accommodates all residents.	
c. Cleanliness.	
d. Adequate/comfortable lighting.	
e. Adequate/comfortable ventilation.	
2. SERVING OF MEALS *	
a. Number of meals/time span between meal.	
b. Conformance to physicians order.	
c. Nutritional adequacy.	
d. Adequacy of portions.	
e. Residents eat approximately 75% of meals.	
f. Puree dishes served individually.	
g. Food cut, chopped or ground for individual resident needs.	
h. Acceptable taste.	
i. Proper temperature.	
j. Plates covered.	

FORM HCFA-523 (2-86)

SEE REVERSE



DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0400

2. SERVING OF MEALS * *(continued)*

k. Served promptly.

l. Residents ready for meal when served.

m. Attractive.

n. Utensils available.

o. Functional trays for bedfast residents.

p. Salt, pepper, sugar, other condiments on resident's trays unless contraindicated.

q. Medically able residents eating in dining area.

r. Bedtime nourishment offered.

3. SUPERVISION OF RESIDENT NUTRITION

a. Prompt assistance.

b. Proper assistance (spoon-feeding; supervision or instruction to develop eating skills).

c. Courteous and unhurried assistance.

d. Self-help devices present (straws, easy grip utensils, special cup, etc.).

e. Intake recorded/deviations from normal are reported.

FORM HCFA-523 (2-86)

* U.S. GPO 1986 0-181-264/53834

§488.110 Procedural guidelines.

SNF/ICF Survey Process. The purpose for implementing a new SNF/ICF survey process is to assess whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes. Although the onsite review procedures have been changed, facilities must continue to meet all applicable Conditions/Standards, in order to participate in Medicare/Medicaid programs. That is, the methods used to

compile information about compliance with law and regulations are changed; the law and regulations themselves are not changed. The new process differs from the traditional process, principally in terms of its emphasis on resident outcomes. In ascertaining whether residents grooming and personal hygiene needs are met, for example, surveyors will no longer routinely evaluate a facility's written policies and procedures. Instead, surveyors will observe residents in order to make that determination. In addition, surveyors will confirm, through interviews with residents and staff, that such needs are indeed met on a regular basis. In most reviews, then, surveyors will ascertain whether the facility is actually providing the required and needed care and services, rather than whether the facility is capable of providing the care and services.

THE OUTCOME-ORIENTED SURVEY PROCESS—SKILLED NURSING FACILITIES (SNFS) AND INTERMEDIATE CARE FACILITIES (ICFS)

(a) General.
(b) The Survey Tasks.
(c) Task 1—Entrance Conference.
(d) Task 2—Resident Sample—Selection Methodology.
(e) Task 3—Tour of the Facility.
(f) Task 4—Observation/Interview/Medical Record Review (including drug regimen review).
(g) Task 5—Drug Pass Observation.
(h) Task 6—Dining Area and Eating Assistance Observation.
(i) Task 7—Forming the Deficiency Statement.
(j) Task 8—Exit Conference.
(k) Plan of Correction.
(l) Followup Surveys.
(m) Role of Surveyor.
(n) Confidentiality and Respect for Resident Privacy.
(o) Team Composition.
(p) Type of Facility-Application of SNF or ICF Regulations.
(q) Use of Part A and Part B of the Survey Report.

(a) *General.* A complete SNF/ICF facility survey consists of three components:

• Life Safety Code requirements;

• Administrative and structural requirements (Part A of the Survey Report, Form CMS–525); and

• Direct resident care requirements (Part B of the Survey Report, Form CMS–519), along with the related worksheets (CMS–520 through 524).

Use this survey process for all surveys of SNFs and ICFs—whether freestanding, distinct parts, or dually certified. Do not use this process for surveys of Intermediate Care Facilities for Mentally Retarded (ICFs/MR), swingbed hospitals or skilled nursing sections of hospitals that are not separately certified as SNF distinct parts. Do not announce SNF/ICF surveys ahead of time.

(b) *The Survey Tasks.* Listed below are the survey tasks for easy reference:

• Task 1. Entrance Conference.

• Task 2. Resident Sample—Selection Methodology.

• Task 3. Tour of the Facility. Resident Needs. Physical Environment. Meeting with Resident Council Representatives. Tour Summation and Focus of Remaining Survey Activity.

• Task 4. Observation/Interview/Medical Record. Review of Each Individual in the Resident Sample (including drug regimen review).

• Task 5. Drug Pass Observation.

• Task 6. Dining Area and Eating Assistance Observation.

• Task 7. Forming the Deficiency Statement (if necessary).

• Task 8. Exit Conference.

(c) *Task 1—Entrance Conference.* Perform these activities during the entrance conference in every certification and recertification survey:

• Introduce all members of the team to the facility staff, if possible, even though the whole team may not be present for the entire entrance conference. (All surveyors wear identification tags.)

• Explain the SNF/ICF survey process as resident centered in focus, and outline the basic steps.

• Ask the facility for a list showing names of residents by room number with each of the following care needs/treatments identified for each resident to whom they apply:

—Decubitus care
—Restraints
—Catheters
—Injections
—Parenteral fluids
—Rehabilitation service
—Colostomy/ileostomy care
—Respiratory care

—Tracheostomy care
—Suctioning
—Tube feeding

Use this list for selecting the resident sample.

• Ask the facility to complete page 2 of Form CMS–519 (Resident Census) as soon as possible, so that the information can further orient you to the facility's population. In a survey of a SNF with a distinct part ICF, you may collect two sets of census data. However, consolidate the information when submitting it to the regional office. You may modify the Resident Census Form to include the numbers of licensed and certified beds, if necessary.

• Ask the facility to post signs on readily viewed areas (at least one on each floor) announcing that State surveyors are in the facility performing an ''inspection,'' and are available to meet with residents in private. Also indicate the name and telephone number of the State agency. Hand-printed signs with legible, large letters are acceptable.

• If the facility has a Resident Council, make mutually agreeable arrangements to meet privately with the president and officers and other individuals they might invite.

• Inform the facility that interviews with residents and Resident Councils are conducted privately, unless they independently request otherwise, in order to enhance the development of rapport as well as to allay any resident anxiety. Tell the facility that information is gathered from interviews, the tour, observations, discussions, record review, and facility officials. Point out that the facility will be given an opportunity to respond to all findings.

(d) *Task 2—Resident Sample—Selection Methodology*. This methodology is aimed at formulating a sample that reflects the actual distribution of care needs/treatments in the facility population.

Primarily performed on a random basis, it also ensures representation in the sample of certain care needs and treatments that are assessed during the survey.

(1) *Sample Size*. Calculate the size of the sample according to the following guide:

Number of residents in facility	Number of residents in sample[1]
0–60 residents.	25% of residents (minimum—10).
61–120 residents.	20% of residents (minimum—15).
121–200 residents.	15% of residents (minimum—24).
201+ residents.	10% of residents (minimum—30).

[1] Maximum—50.

Note that the calculation is based on the resident census, not beds. After determining the appropriate sample size, select residents for the sample in a random manner. You may, for example, select every fifth resident from the resident census, beginning at a random position on the list. For surveys of dually certified facilities or distinct part SNFs/ICFs, first use the combined SNF/ICF population to calculate the size of the sample, and then select a sample that reflects the proportions of SNF and ICF residents in the facility's overall population.

(2) *Special Care Needs/Treatments*. The survey form specifies several care needs/treatments that must always be reviewed when they apply to any facility residents. These include:

- Decubitus Care
- Restraints
- Catheters
- Injections, Parenteral Fluids, Colostomy/Ileostomy, Respiratory Care, Tracheostomy Care, Suctioning, Tube Feeding
- Rehabilitative Services (physical therapy, speech pathology and audiology services, occupational therapy)

Due to the relatively low prevalence of these care needs/treatments, appropriate residents may be either underrepresented or entirely omitted from the sample. Therefore, determine during the tour how many residents in the random selection fall into each of these care categories. Then, compare the number of such residents in the random selection with the total number of residents in the facility with each specified care need/treatment (based on either the resident census or other information provided by the facility).

Review no less than 25 percent of the residents in each of these special care needs/treatments categories. For example, if the facility has 10 residents with

decubitus ulcers, but only one of these residents is selected randomly, review two more residents with decubitis ulcers (25% of 10 equals 2.5, so review a total of 3). Or, if the facility has two residents who require tube feeding, neither of whom is in the random selection, review the care of at least one of the these residents. This can be accomplished in the following manner:

Conduct in-depth reviews of the randomly selected residents and then perform limited reviews of additional residents as needed to cover the specified care categories. Such reviews are limited to the care and services related to the pertinent care areas only, e.g., catheters, restraints, or colostomy. Utilize those worksheets or portions of worksheets which are appropriate to the limited review. Refer to the Care Guidelines, as a resource document, when appropriate.

Always keep in mind that neither the random selection approach nor the review of residents within the specified care categories precludes investigation of other resident care situations that you believe might pose a serious threat to a resident's health or safety. Add to the sample, as appropriate.

(e) *Task 3—Tour of the Facility*—(1) *Purpose.* Conduct the tour in order to:

• Develop an overall picture of the types and patterns of care delivery present within the facility;

• View the physical environment; and

• Ascertain whether randomly selected residents are communicative and willing to be interviewed.

(2) *Protocol.* You may tour the entire facility as a team or separately, as long as all areas of the facility are examined by at least one team member. Success of the latter approach, however, is largely dependent on open intra-team communication and the ability of each team member to identify situations for further review by the team member of the appropriate discipline. You may conduct the tour with or without facility staff accompanying you, as you prefer. Facilities, however, vary in staff member availability. Record your notes on the Tour Notes Worksheet, Form CMS–521.

Allow approximately three hours for the tour. Converse with residents, family members/significant others (if present), and staff, asking open-ended questions in order to confirm observations, obtain additional information, or corroborate information, (e.g., accidents, odors, apparent inappropriate dress, adequacy and appropriateness of activities). Converse sufficiently with residents selected for in-depth review to ascertain whether they are willing to be interviewed and are communicative. Observe staff interactions with other staff members as well as with residents for insight into matters such as resident rights and assignments of staff responsibilities.

Always knock and/or get permission before entering a room or interrupting privacy. If you wish to inspect a resident's skin, observe a treatment procedure, or observe a resident who is exposed, courteously ask permission from the resident if she/he comprehends, or ask permission from the staff nurse if the resident cannot communicate. Do not do ''hands-on'' monitoring such as removal of dressings; ask staff to remove a dressing or handle a resident.

(3) *Resident Needs.* While touring, focus on the residents' needs—physical, emotional, psychosocial, or spiritual—and whether those needs are being met. Refer to the following list as needed:

—Personal hygiene, grooming, and appropriate dress
—Position
—Assistive and other restorative devices
—Rehabilitation issues
—Functional limitations in ADL
—Functional limitations in gait, balance and coordination
—Hydration and nutritional status
—Resident rights
—Activity for time of day (appropriate or inappropriate)
—Emotional status
—Level of orientation
—Awareness of surroundings
—Behaviors
—Cleanliness of immediate environment (wheelchair, bed, bedside table, etc.)
—Odors
—Adequate clothing and care supplies as well as maintenance and cleanliness of same

(4) *Review of the Physical Environment.* As you tour each resident's room and

auxiliary rooms, also examine them in connection with the physical environment requirements. You need not document physical environment on the Tour Notes Worksheet. Instead, you may note any negative findings directly on the Survey Report Form in the remarks section.

(5) *Meeting With Resident Council Representatives.* If a facility has a Resident Council, one or more surveyors meet with the respresentatives in a private area. Facility staff members do not attend unless specifically requested by the Council. Explain the purpose of the survey and briefly outline the steps in the survey process, i.e., entrance conference * * * exit conference. Indicate your interest in learning about the strengths of the facility in addition to any complaints or shortcomings. State that this meeting is one part of the information gathering; the findings have not yet been completed nor the conclusions formulated. Explain further, however, that the official survey findings are usually available within three months after the completion of the survey, and give the telephone number of the State agency office.

Use this meeting to ascertain strengths and/or problems, if any, from the consumer's perspective, as well as to develop additional information about aspects of care and services gleaned during the tour that were possibly substandard.

Conduct the meeting in a manner that allows for comments about any aspect of the facility. (See the section on Interview Procedures.) Use open-ended questions such as:

- ''What is best about this home?''
- ''What is worst?''
- ''What would you like to change?''

In order to get more detail, use questions such as:

- ''Can you be more specific?''
- ''Can you give me an example?''
- ''What can anyone else tell me about this?''

If you wish to obtain information about a topic not raised by the residents, use an approach like the following:

- ''Tell me what you think about the food/staff/cleanliness here.''
- ''What would make it better?''
- ''What don't you like? What do you like?''

(6) *Tour Summation and Focus of Remaining Survey Activity.* When the tour is completed, review the resident census data provided by the facility. Determine if the care categories specified in the section on Resident Sample are sufficiently represented in the random selection, make adjustments as needed, and complete the listing of residents on the worksheet labeled ''Residents Selected for In-depth Review'', Form CMS–520.

Transcribe notes of a negative nature onto the SRF in the ''Remarks'' column under the appropriate rule. Findings from a later segment in the survey or gathered by another surveyor may combine to substantiate a deficiency. You need not check ''met'' or ''not met'' at this point in the survey. Discuss significant impressions/conclusions at the completion of each subsequent survey task, and transfer any negative findings onto the Survey Report Form in the Remarks section.

(f) *Task 4—Observation/Interview/Medical Record Review (including drug regimen review).* Perform the in-depth review of each individual in the resident sample in order to ascertain whether the facility is meeting resident needs. Evaluate specific indicators for each resident, utilizing the front and back of the ''Observation/Interview/Record Review (OIRR)'' worksheet, Form CMS–524. You may prefer to perform the record review first, complete resident/staff/family observations and interviews, and finally, return to the record for any final unresolved issues. On the other hand, you may prefer to do the interviews first. Either method is acceptable. Whenever possible, however, complete one resident's observation/interview/medical record review and document the OIRR before moving onto another resident. If because of the facility layout, it is more efficient to do more than one record review at a time, limit such record review to two or three residents so your familiarity with the particular resident and continuity of the OIRR are not compromised.

(1) *Observation.* Conduct observations concurrently with interviews of residents, family/significant others, and

discussions with direct care staff [of the various disciplines involved. In multi-facility operations, whenever possible, observe staff that is regularly assigned to the facility in order to gain an understanding of the care and services usually provided.] Maintain respect for resident privacy. Minimize disruption of the operations of the facility or impositions upon any resident as much as possible. Based upon your observations of the residents' needs, gather information about any of the following areas, as appropriate:

Bowel and bladder training
Catheter care
Restraints
Injections
Parenteral fluids
Tube feeding/gastrostomy
Colostomy/ileostomy
Respiratory therapy
Tracheostomy care
Suctioning

(2) *Interviews.* Interview each resident in private unless he/she independently requests that a facility staff member or other individual be present. Conduct the in-depth interview in a nonthreatening and noninvasive fashion so as to decrease anxiety and defensiveness. The open-ended approach described in the section on the Resident Council is also appropriate for the in-depth interview. While prolonged time expenditure is not usually a worthwhile use of resources or the resident's time, do allow time initially to establish rapport.

At each interview:

- Introduce yourself.
- Address the resident by name.
- Explain in simple terms the reason for your visit (e.g., to assure that the care and services are adequate and appropriate for each resident).
- Briefly outline the process—entrance conference, tour, interviews, observations, review of medical records, resident interviews, and exit conference.
- Mention that the selection of a particular resident for an interview is not meant to imply that his/her care is substandard or that the facility provides substandard care. Also mention that most of those interviewed are selected randomly.
- Assure that you will strive for anonymity for the resident and that the interview is used in addition to medical records, observations, discussions, etc., to capture an accurate picture of the treatment and care provided by the facility. Explain that the official findings of the survey are usually available to the public about three months after completion of the survey, but resident names are not given to the public.
- When residents experience difficulty expressing themselves:

—Avoid pressuring residents to verbalize
—Accept and respond to all communication
—Ignore mistakes in word choice
—Allow time for recollection of words
—Encourage self-expression through any means available

- When interviewing residents with decreased receptive capacity:

—Speak slowly and distinctly
—Speak at conversational voice level
—Sit within the resident's line of vision

- Listen to all resident information/allegations without judgment. Information gathered subsequently may substantiate or repudiate an allegation.

The length of the interview varies, depending on the condition and wishes of the resident and the amount of information supplied. Expect the average interview, however, to last approximately 15 minutes. Courteously terminate an interview whenever the resident is unable or unwilling to continue, or is too confused or disoriented to continue. Do, however, perform the other activities of this task (observation and record review). If, in spite of your conversing during the tour, you find that less than 40 percent of the residents in your sample are sufficiently alert and willing to be interviewed, try to select replacements so that a complete OIRR is performed for a group this size, if possible. There may be situations, however, where the resident population has a high percentage of confused individuals and this percentage is not achievable. Expect that the information from confused individuals can be, but is not necessarily, less

reliable than that from more alert individuals.

Include the following areas in the interview of each resident in the sample:

Activities of daily living
Grooming/hygiene
Nutrition/dietary
Restorative/rehabilitation care and services
Activities
Social services
Resident rights

Refer to the Care Guidelines ''evaluation factors'' as a resource for possible elements to consider when focusing on particular aspects of care and resident needs.

Document information obtained from the interviews/observations on the OIRR Worksheet. Record in the ''Notes'' section any additional information you may need in connection with substandard care or services. Unless the resident specifically requests that he/she be identified, do not reveal the source of the information gleaned from the interview.

(3) *Medical Record Review.* The medical record review is a three-part process, which involves first reconciling the observation/interview findings with the record, then reconciling the record against itself, and lastly performing the drug regimen review.

Document your findings on the OIRR Worksheet, as appropriate, and summarize on the Survey Report Form the findings that are indicative of problematic or substandard care. Be alert for repeated similar instances of substandard care developing as the number of completed OIRR Worksheets increases.

NOTE: The problems related to a particular standard or condition could range from identical (e.g., meals not in accordance with dietary plan) to different but related (e.g., nursing services—lapse in care provided to residents with catheters, to residents with contractures, to residents needing assistance for personal hygiene and residents with improperly applied restraints).

(i) *Reconciling the observation/interview findings with the record.* Determine if:

- An assessment has been performed.
- A plan with goals has been developed.
- The interventions have been carried out.
- The resident has been evaluated to determine the effectiveness of the interventions.

For example, if a resident has developed a decubitus ulcer while in the facility, record review can validate staff and resident interviews regarding the facility's attempts at prevention. Use your own judgment; review as much of the record(s) as necessary to evaluate the care planning. Note that facilities need not establish specific areas in the record stating ''Assessment,'' ''Plan,'' ''Intervention,'' or ''Evaluation'' in order for the documentation to be considered adequate.

(ii) *Reconciling the record with itself.* Determine:

- If the resident has been properly assessed for all his/her needs.
- That normal and routine nursing practices such as periodic weights, temperatures, blood pressures, etc., are performed as required by the resident's conditions.

(iii) *Performing the drug regimen review.* The purpose of the drug regimen review is to determine if the pharmacist has reviewed the drug regimen on a monthly basis. Follow the procedures in Part One of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities. Fill in the appropriate boxes on the top left hand corner of the reverse side of the OIRR Worksheet, Form CMS–524. Appendix N lists many irregularities that can occur. Review at least six different indicators on each survey. However, the same six indicators need not be reviewed on every survey.

NOTE: If you detect irregularities and the documentation demonstrates that the pharmacist has notified the attending physician, do not cite a deficiency. Do, however, bring the irregularity to the attention of the medical director or other facility official, and note the official's name and date of notification on the Survey Report Form.

(g) *Task 5—Drug Pass Observation.* The purpose of the drug pass observation is to observe the actual preparation and administration of medications to residents. With this approach, there is no doubt that the errors detected, if any, are errors in drug administration, not

documentation. Follow the procedure in Part Two of Appendix N, Surveyor Procedures for Pharmaceutical Service Requirements in Long-Term Care Facilities, and complete the Drug Pass Worksheet, Form CMS–522. Be as neutral and unobtrusive as possible during the drug pass observation. Whenever possible, select one surveyor, who is a Registered Nurse or a pharmacist, to observe the drug pass of approximately 20 residents. In facilities where fewer than 20 residents are receiving medications, review as many residents receiving medications as possible. Residents selected for the in-depth review need not be included in the group chosen for the drug pass; however, their whole or partial inclusion is acceptable. In order to get a balanced view of a facility's practices, observe more than one person administering a drug pass, if feasible. This might involve observing the morning pass one day in Wing A, for example, and the morning pass the next day in Wing B.

Transfer findings noted on the ''Drug Pass'' worksheet to the SRF under the appropriate rule. If your team concludes that the facility's medication error rate is 5 percent or more, cite the deficiency under Nursing Services/Administration of Drugs. Report the error rate under F209. If the deficiency is at the standard level, cite it in Nursing Services, rather than Pharmacy.

(h) *Task 6—Dining Area and Eating Assistance Observation.* The purpose of this task is to ascertain the extent to which the facility meets dietary needs, particularly for those who require eating assistance. This task also yields information about staff interaction with residents, promptness and appropriateness of assistance, adaptive equipment usage and availability, as well as appropriateness of dress and hygiene for meals.

For this task, use the worksheet entitled ''Dining Area and Eating Assistance Observation'' (Form CMS–523). Observe two meals; for a balanced view, try to observe meals at different times of the day. For example, try to observe a breakfast and a dinner rather than two breakfasts. Give particular care to performing observations as unobtrusively as possible. Chatting with residents and sitting down nearby may help alleviate resident anxiety over the observation process.

Select a minimum of five residents for each meal observation and include residents who have their meals in their rooms. Residents selected for the in-depth review need not be included in the dining and eating assistance observation; however, their whole or partial inclusion is acceptable. Ascertain the extent to which the facility assesses, plans, and evaluates the nutritional care of residents and eating assistance needs by reviewing the sample of 10 or more residents. If you are unable to determine whether the facility meets the standards from the sample reviewed, expand the sample and focus on the specific area(s) in question, until you can formulate a conclusion about the extent of compliance. As with the other survey tasks, transfer the findings noted on the ''Dining & Eating Assistance Observation'' worksheet to the Survey Report Form.

(i) *Task 7—Forming the Deficiency Statement*—(1) *General.* The Survey Report Form contains information about all of the negative findings of the survey. Be sure to transfer to the Survey Report Form data from the tour, drug pass observation, dining area and eating assistance observation, as well as in-depth review of the sample of residents. Transfer only those findings which could possibly contribute to a determination that the facility is deficient in a certain area.

Meet as a group in a pre-exit conference to discuss the findings and make conclusions about the deficiencies, subject to information provided by facility officials that may further explain the situation. Review the summaries/conclusions from each task and decide whether any further information and/or documentation is necessary to substantiate a deficiency. As the facility for additional information for clarification about particular findings, if necessary. Always consider information provided by the facility. If the facility considers as acceptable, practices which you believe are not acceptable, ask the facility to backup its contention with suitable reference material or sources and submit them for your consideration.

(2) *Analysis.* Analyze the findings on the Survey Report Form for the degree of severity, frequency of occurrence and impact on delivery of care or quality of life. The threshold at which the frequency of occurrences amounts to a deficiency varies from situation to situation. One occurrence directly related to a life-threatening or fatal outcome can be cited as a deficiency. On the other hand, a few sporadic occurrences may have so slight an impact on delivery of care or quality of life that they do not warrant a deficiency citation. Review carefully all the information gathered. What may appear during observation as a pattern, may or may not be corroborated by records, staff, and residents. For example, six of the 32 residents in the sample are dressed in mismatched, poorly buttoned clothes. A few of the six are wearing slippers without socks. A few others are wearing worn clothes. Six occurrences might well be indicative of a pattern of susbstandard care. Close scrutiny of records, discussions with staff, and interviews reveal, however, that the six residents are participating in dressing retraining programs. Those residents who are without socks, chose to do so. The worn clothing items were also chosen—they are favorites.

Combinations of substandard care such as poor grooming of a number of residents, lack of ambulation of a number of residents, lack of attention to positioning, poor skin care, etc., can yield a deficiency in nursing services just as 10 out of 10 residents receiving substandard care for decubiti yields a deficiency.

(3) *Deficiencies Alleged by Staff or Residents.* If staff or residents allege deficiencies, but records, interviews, and observation fail to confirm the situation, it is unlikely that a deficiency exists. Care and services that are indeed confirmed by the survey to be in compliance with the regulatory requirements, but considered deficient by residents or staff, cannot be cited as deficient for certification purposes. On the other hand, if an allegation is of a very serious nature (e.g., resident abuse) and the tools of record review and observation are not effective because the problem is concealed, obtain as much information as possible or necessary to ascertain compliance, and cite accordingly. Residents, family, or former employees may be helpful for information gathering.

(4) *Composing the Deficiency Statement.* Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Do not delve into the facility's policies and procedures to determine or speculate on the root cause of a deficiency, or sift through various alternatives in an effort to prescribe an acceptable remedy. Indicate the data prefix tag and regulatory citation, followed by a summary of the deficiency and supporting findings using resident identifiers, not resident names, as in the following example.

F102 SNF 405.1123(b).—Each resident has not had a physician's visit at least once every 30 days for the first 90 days after admission. Resident #1602 has not been seen by a physician since she was admitted 50 days ago. Her condition has deteriorated since that time (formulation of decubiti, infections).

When the data prefix tag does not repeat the regulations, also include a short phrase that describes the prefix tag (e.g., F117 decubitus ulcer care). List the data tags in numerical order, whenever possible.

(j) *Task 8—Exit Conference.* The purpose of the exit conference is to inform the facility of survey findings and to arrange for a plan of correction, if needed. Keep the tone of the exit conference consistent with the character of the survey process—inspection and enforcement. Tactful, business-like, professional presentation of the findings is of paramount importance. Recognize that the facility may wish to respond to various findings. Although deficiency statements continue to depend, in part, on surveyor professional judgment, support your conclusions with resident-specific examples (identifiers other than names) whenever you can do so without compromising confidentiality. Before formally citing deficiencies, discuss any allegations or findings that could not be substantiated during earlier tasks in the process. For example, if information is gathered that suggests a newly hired

R.N. is not currently licensed, ask the facility officials to present current licensure information for the nurse in question. Identify residents when the substandard care is readily observed or discerned through record review. Ensure that the facility improves the care provided to all affected residents, not only the identified residents. Make clear to the facility that during a follow-up visit the surveyors may review residents other than those with significant problems from the original sample, in order to see that the facility has corrected the problems overall. Do not disclose the source of information provided during interviews, unless the resident has specifically requested you to inform the facility of his/her comments or complaints. In accordance with your Agency's policy, present the Statement of Deficiencies, form CMS–2567, on site or after supervisory review, no later than 10 calendar days following the survey.

(k) *Plan of Correction.* Explain to the facility that your role is to identify care and services which are not consistent with the regulatory requirements, rather than to ascertain the root causes of deficiencies. Each facility is expected to review its own care delivery. Subsequent to the exit conference, each facility is required to submit a plan of correction that identifies necessary changes in operation that will assure correction of the cited deficiencies. In reviewing and accepting a proposed plan of correction, apply these criteria:

• Does the facility have a reasonable approach for correcting the deficiencies?

• Is there a high probability that the planned action will result in compliance?

• Is compliance expected timely?

Plans of correction specific to residents identified on the deficiency statement are acceptable only where the deficiency is determined to be unique to that resident and not indicative of a possible systemic problem. For example, as a result of an aide being absent, two residents are not ambulated three times that day as called for in their care plans. A plan of correction that says ''Ambulate John Jones and Mary Smith three times per day,'' is not acceptable. An acceptable plan of correction would explain changes made to the facility's staffing and scheduling in order to gurantee that staff is available to provide all necessary services for all residents.

Acceptance of the plan of correction does not absolve the facility of the responsibility for compliance should the implementation not result in correction and compliance. Acceptance indicates the State agency's acknowledgement that the facility indicated a willingness and ability to make corrections adequately and timely.

Allow the facility up to 10 days to prepare and submit the plan of correction to the State agency, however, follow your SA policy if the timeframe is shorter. Retain the various survey worksheets as well as the Survey Report Form at the State agency. Forward the deficiency statement to the CMS regional office.

(l) *Follow-up Surveys.* The purpose of the follow-up survey is to re-evaluate the specific types of care or care delivery patterns that were cited as deficient during the original survey. Ascertain the corrective status of all deficiencies cited on the CMS–2567. Because this survey process focuses on the actual provision of care and services, revisits are almost always necessary to ascertain whether the deficienicies have indeed been corrected. The nature of the deficiencies dictates the scope of the follow-up visit. Use as many tasks or portions of the Survey Report Form(s) as needed to ascertain compliance status. For example, you need not perform another drug pass if no drug related deficiencies were cited on the initial survey. Similarly, you need not repeat the dining area and eating assistance observations if no related problems were identified. All or some of the aspects of the observation/interview/medical record review, however, are likely to be appropriate for the follow-up survey.

When selecting the resident sample for the follow-up, determine the sample size using the same formula as used earlier in the survey, with the following exceptions:

• The maximum sample size is 30 residents, rather than 50.

• The minimum sample size of 10 residents does not apply if only one care category was cited as deficient and the total number of residents in the facility in that category was less than 10 (e.g., deficiency cited under catheter care and only five residents have catheters).

Include in the sample those residents who, in your judgment, are appropriate for reviewing vis-a-vis the cited substandard care. If possible, include some residents identified as receiving substandard care during the initial survey. If after completing the follow-up activities you determine that the cited deficiencies were not corrected, initiate adverse action procedures, as appropriate.

(m) *Role of Surveyor.* The survey and certification process is intended to determine whether providers and suppliers meet program participation requirements. The primary role of the surveyor, then, is to assess the quality of care and services and to relate those findings to statutory and regulatory requirements for program participation.

When you find substandard care or services in the course of a survey, carefully document your findings. Explain the deficiency in sufficient detail so that the facility officials understand your rationale. If the cause of the deficiency is obvious, share the information with the provider. For example, if you cite a deficiency for restraints (F118), indicate that restraints were applied backwards on residents 1621, 1634, 1646, etc.

In those instances where the cause is not obvious, do not delve into the facility's policies and procedures to determine the root cause of any deficiency. Do not recommend or prescribe an acceptable remedy. The provider is responsible for deciding on and implementing the action(s) necessary for achieving compliance. For the restraint situation in the example above, you would not ascertain whether the improper application was due to improper training or lack of training, nor would you attempt to identify the staff member who applied the restraints. It is the provider's responsibility to make the necessary changes or corrections to ensure that the restriants are applied properly.

A secondary role for the surveyor is to provide general consultation to the provider/consumer community. This includes meeting with provider/consumer associations and other groups as well as participating in seminars. It also includes informational activities, whereby you respond to oral or written inquiries about required outcomes in care and services.

(n) *Confidentiality and Respect for Resident Privacy.* Conduct the survey in a manner that allows for the greatest degree of confidentiality for residents, particularly regarding the information gathered during the in-depth interviews. When recording observations about care and resident conditions, protect the privacy of all residents. Use a code such as resident identifier number rather than names on worksheets whenever possible. Never use a resident's name on the Deficiency Statement, Form CMS–2567. Block out resident names, if any, from any document that is disclosed to the facility, individual or organization.

When communicating to the facility about substandard care, fully identify the resident(s) by name if the situation was identified through observation or record review. Improperly applied restraints, expired medication, cold food, gloves not worn for a sterile procedure, and diet inconsistent with order, are examples of problems which can be identified to the facility by resident name. Information about injuries due to broken equipment, prolonged use of restraints, and opened mail is less likely to be obtained through observation or record review. Do not reveal the source of information unless actually observed, discovered in the record review, or requested by the resident or family.

(o) *Team Composition.* Whenever possible, use the following survey team model:

SNF/ICF SURVEY TEAM MODEL

In facilities with 200 beds or less, the team size may range from 2 to 4 members. If the team size is:

• *2 members:* The team has at least one RN plus another RN or a dietitian or a pharmacist.

• *3–4 member:* In addition to the composition described above, the team has one or two members of any discipline such as a social worker, sanitarian, etc.

If the facility has over 200 beds *and* the survey will last more than 2 days, the team size may be greater than 4 members. Select additional disciplines as appropriate to the facility's compliance history.

Average onsite time per survey: 60 person hours (Number of surveyors multiplied by the number of hours on site)

Preferably, team members have gerontological training and experience. Any member may serve as the team leader, consistent with State agency procedures. In followup surveys, select disciplines based on major areas of correction. Include a social worker, for example, if the survey revealed major psychosocial problems. This model does not consider integrated survey and Inspection of Care review teams, which typically would be larger.

(p) *Type of Facility—Application of SNF or ICF Regulations.* Apply the regulations to the various types of facilities in the following manner:

• Freestanding Skilled Nursing Facility (SNF)	Apply SNF regulations.
• Freestanding Intermediate Care Facility (ICF)	Apply ICF regulations.
• SNF Distinct Part of a Hospital	Apply SNF regulations.
• ICF Distinct Part of a Hospital	Apply ICF regulations.
• Dually Certified SNF/ICF	Apply SNF regulations and 442.346(b).
• Freestanding SNF with ICF Distinct Part (Regardless of the proportion of SNF and ICF beds, the facility type is determined by the higher level of care. Therefore, LTC facilities with distinct parts are defined as SNFs with ICF distinct parts.)	Apply SNF regulations for SNF unit. Apply ICF regulations for ICF distinct part. Apply both SNF and ICF regulations for shared services (e.g., dietary). If the same deficiency occurs in both the SNF and ICF components of the facility, cite both SNF and ICF regulations. If the deficiency occurs in the SNF part only, cite only the SNF regulation. If the deficiency occurs in the ICF part only, cite only the ICF regulation.

(q) *Use of Part A and Part B of the Survey Report*—(1) *Use of Part A (CMS–525).* Use Part A for initial certification surveys only, except under the following circumstances:

• When a terminated facility requests program participation 60 days or more after termination. Treat this situation as a request for initial certification and complete Part A of the survey report in addition to Part B.

• If an ICF with a favorable compliance history requests to covert a number of beds to SNF level, complete both Part A and Part B for compliance with the SNF requirements. If distinct part status is at issue, also examine whether it meets the criteria for certification as a distinct part.

(i) *Addendum for Outpatient Physical Therapy (OPT) or Speech Pathology Services.* Use the Outpatient Physical Therapy—Speech Pathology SRF (CMS–1893) as an addendum to Part A.

(ii) *Resurvey of Participating Facilities.* Do not use Part A for resurveys of participating SNFs and ICFs. A determination of compliance, based on documented examination of the written policies and procedures and other pertinent documents during the initial survey, establishes the facility's compliance status with Part A requirements. This does not preclude citing deficiencies if they pertain to administrative or structural requirements from Part A that are uncovered incidental to a Part B survey. As an assurance measure, however, each facility at the time of recertification must complete an affidavit (on the CMS–1516) attesting that no substantive changes have occurred that would affect compliance. Each facility must also agree to notify the State agency immediately of any upcoming changes in its organization or management which may affect its compliance status. If a new administrator is unable to complete the affidavit, proceed with the survey using the Part B form and worksheets; do not use the Part A form. The survey cannot be considered complete, however, until the affidavit is signed. If the facility fails to complete the affidavit, it cannot participate in the program.

(iii) *Substantial Changes in a Facility's Organization and Management.* If you receive such information, review the changes to ensure compliance with the regulations. Request copies of the appropriate documents (e.g., written policies and procedures, personnel qualifications, or agreements) if they were

not submitted. If the changes have made continued compliance seem doubtful, determine through a Part B survey whether deficiencies have resulted. Cite any deficiencies on the CMS–2567 and follow the usual procedures.

(2) *Use of Part B (CMS–519).* Use Part B and the worksheets for all types of SNF and ICF surveys—initials, recertifications, followup, complaints, etc.

The worksheets are:

- CMS–520—Residents Selected for In-depth Review
- CMS–521—Tour Notes Worksheet
- CMS–522—Drug Pass Worksheet
- CMS–523—Dining Area and Eating Assistance Worksheet
- CMS–5245—Observation/Interview/Record Review Worksheet

For complaint investigations, perform a full or partial Part B survey based on the extent of the allegations. If the complaint alleges substandard care in a general fashion or in a variety of services and care areas, perform several tasks or a full Part B survey, as needed. If the complaint is of a more specific nature, such as an allegation of improper medications, perform an appropriate partial Part B survey, such as a drug pass review and a review of selected medical records.

§ 488.115 Care guidelines.

§ 488.115 Care guidelines.

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Resident Rights					
F53 SNF 405.1121(k)(1) ICF 442.311(a)		Ask Resident: - Did you receive a copy of the Resident's Bill of Rights? Was it explained to you?	Looked for signed acknowledgement of receipt of resident rights information. Residents unable to sign name may have their "mark" witnessed.	Because of the confusion surrounding admission to a new facility and the large amount of information given to a resident or resident's family on admission, information given at this time is often forgotten. Therefore, surveyor should verify resident's recollection with staff interviews and record checks. Written information on services and costs must be given to the resident, as well as copies of residents rights and responsibilities. Copies of residents' rights should also be available to patients and visitors, e.g., in resident lounges, lobbies, or other area where residents and visitors could easily see and read them.	Notification of Change in Status 405.1121(j) 442.307
F54 SNF 405.1121(h)(1) ICF 442.311(a)(1)			Look for written statement of charges services.		Patient Care Policies 405.1121(e)
A. Information*					
F55 SNF 405.1121(h)(1) ICF 442.311(a)(2) 1. Rights and Responsibilities	Where is information concerning resident rights and responsibilities available in the facility?	- Were you told of any responsibilities you have in living here?	Social Work records may idicate patient rights information discussed with resident.		442.308 442.309 442.310 442.305 Medical Direction 405.1122(a)
F56 SNF 405.1121(k)(1) ICF 442.311(a)(3) 2. Rules of Resident Conduct		- Were you given a chance to ask questions?			Medical Records 405.1132(b)(d) 442.310
F57 SNF 405.1121(h)(2) ICF 442.311(a)(4) 3. Resident Acknowledgement		- Did he/she receive a written copy of services provided by the facility and any additional costs for these services?			

INTENT
To assure that the resident maintains, in so far as possible, those personal rights that are a part of normal, adult life, and including the right to personal dignity.

*Information concerning incompetent residents is given in L. Delegation of Rights and Responsibilities.

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F58 SNF 405.1121(k)(2) ICF 442.311(a)(4) 4. Resident informed in writing of changes in services and charges for services.		Ask Resident: - If there are changes in services or costs does someone explain these? Ask Administrative Staff: - How do residents learn what is expected of them? - How do they learn about any changes in the facility's procedures and/or costs?			
F59 SNF 405.1121(k)(2) ICF 442.311(a)(4) 5. Information to resident of services not covered by Medicare or Medicaid and not covered in the basic rate.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
B. Medical Condition & Treatment F60–64 SNF 405.1121(k)(2) ICF 442.311(b)		Ask Resident: – Has your doctor discussed your health with you, how is it, what's wrong, and what you can expect in the future? – Have you had the opportunity to help plan what you need and how you are taken care of? – Do you know that you can refuse treatment or medication? – Have you ever refused medication or treatment? – What happened when you did? Ask Staff: – Is the facility participating in any experimental research? If yes, ask what residents are involved. Interview a sample of these residents. Ask Resident (or Guardian: – Are you participating in the _____ study? – Was this explained to you well enough so that you understand what the study is about and any risks that may be involved?	If the resident has not been informed of his/her medical condition, physician notes should document that the resident was not informed because it was medically contraindicated. Do care plans or other documentation reflect resident participation in care planning? If resident states he/she has refused treatment or medication does documentation indicate adherence to/violation of resident rights. Review records of residents identified as participating in a clinical research study. Are informed consent forms signed? Do these signed forms list all known risks for the resident? All needed informed consent statements are present and properly signed.	Unless there is documentation that the residents medical condition should not be discussed with him/her resident interviews/record reviews should indicate that the resident and physician have discussed his/her medical condition.* If you cannot confirm that this has occurred, interview staff to get further clarification. Almost all residents who are able to participate to some extent in their care planning do so. You should find evidence of this for the majority of the residents (e.g., care planning interview, nurses notes, social worker progress notes). Residents do have the right to refuse medication or other treatment, but you would expect that the facility would discuss the implications of this refusal with the resident and possibly do some "gentle persuasion".*	Patient Care Management 405.1124(d) 442.319 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F60-64 (cont'd)				However, except in an emergency situation force should never be used to compel a resident to accept medication or treatment. Deceit is also a violation of resident rights, except in the case of therapeutically indicated placebos ordered by the physician. Any resident participating in research studies should fully understand the implication of the study. The facility is not in compliance with the resident rights regulation if the resident consents to participate in a clinical study without full knowledge of the study. (Record review only as other nonclinical studies may not require informed consent).	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Transfer and Discharge F65-68 SNF 405.1121(k)(4) ICF 442.311(c)	Look for residents that may be inappropriately placed physically - an alert resident rooming with a confused, noisy resident; very ill resident placed far from the nurses station; residents not compatible with each other, (e.g., different life-styles, habits, etc.).	Ask Resident: - How well do you get along with your roommate? - Have you ever been moved from one room to another? If yes, why? - How were you involved in the decision to move? - How much time was there between the time they told you you were to be moved, and when you were moved? - Have you asked for your room to be changed? Ask Direct Care and Other Staff: - What are some of the reasons residents rooms are changed? - What are some of the reasons for discharge of residents or transfer to a hospital or LTC facility? - How are residents involved in the decision to move? - If a resident requests a room change, how is this handled? - When a resident requests a room change are the following areas of consideration presented and discussed:	Nursing, physician, and/or social service progress notes should indicate reason for transfer and discussion with resident and/or family/guardian. If staff interviews give you cause to feel that transfers and discharges may be in violation of these regulations, review a sample of closed records for transfer information on how it was handled. If residents are transferred between facilities with common ownership and similar levels of care, transfers must be reviewed to determine reasons for transfer. Efforts to maintain the census is not an acceptable reason for transfer. Do discharge records review: - reason for discharge, medical non-payment or need for different level of care?	To be in compliance with transfer and discharge regulations the facility must be able to confirm that all discharges/transfers were for medical or resident welfare reasons, or non-payment. Welfare reasons include physical, emotional, social issues. Transfers and discharges made solely for the convenience of the facility are unacceptable. (Relocation to accommodate contagious or other disorders requiring isolation procedures are not for the convenience of the facility).	Status Change Notification 405.1121(j) Medical Records 405.1132(c)(e) 442.318(c)(4) Transfer Agreement 405.1133(a)(2) 442.307(b)(1)(2)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F65-68 (cont'd)		+ cost factors + resident welfare + resident's reason for requesting the move + facility's assessment of whether the move would be beneficial or not for the resident.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Exercising Rights F69 SNF 405.1121(k)(5) ICF 442.311(d)	Do residents appear comfortable when speaking to the surveyors as opposed to being afraid that someone may see them or overhear their conversation?	Ask Resident: - Do you belong to, or have representation on the resident council? - Are you informed of changes in the facility that will affect you? - Are you given a chance to express views on these changes prior to their implementation? - Does the facility assist in arranging for you to vote either at the polls or via absentee ballot? - Are you assisted in obtaining legal or Social Services if needed? - Do you feel comfortable in expressing yourself freely or are you concerned about retaliation? - Is staff/administration responsive to complaints? Do you know who to complain to? Ask Staff: - What arrangements are made for residents to vote? - How do you handle it if someone needs a lawyer or other service that you don't provide?	Review resident council documentation, as available, to determine level of activity. Review social work or progress notes for legal referrals. Is there documentation in progress notes or elsewhere, of resident complaints and disposition of complaints?	Compliance determinations will be made based primarily on resident/staff interviews and the correlation of interview information with documentation in the Medical record. If residents ask, they should be allowed to speak to the surveyor without facility personnel being present. However the resident has the right to have a third party of their choosing present during an interview.	Social Services 405.1130 442.344

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
E. Financial Affairs F72-78 SNF 405.1121(k)(6) 405.1121(m) ICF 442.311(e) 442.320		Ask Residents: - Are you able to take care of your own financial affairs? - Does the facility keep some money for you that you can have when you request it? - When you ask for this money, how quickly do you get it? - Do you know the amount of money you have available at this time? - If the facility pays bills for you do they periodically provide an itemized listing of the transactions they have made? - When did you receive the last itemized statement? - Are you comfortable that your funds are taken care of correctly? - If you deposit money or valuables with the facility, do you receive a receipt for this deposit? - Are you or your family able to review your financial records when you request to do so? - Have you ever had money or anything else stolen? If so, what was done about it?	A copy of the statement should be in the residents financial record and given to the resident at least quarterly. Receipts, account logs showing deposits/withdrawals, authorization/reasons for withdrawals, and interest earned should be reviewed. If resident indicates there may be a problem, an in-depth interview should be conducted. Resident records indicate separate financial records from facility records.	Residents should have reasonable access to their funds (may not be available at 2 A.M.) and should have at least a quarterly accounting of their funds. If questions arise they should be resolved. Personal possessions and funds received from the residents should be protected from theft and other loss. If losses do occur there should be: 1. a procedure which is implemented to investigate the loss, and 2. a plan to prevent recurrence. Resident funds must not be appropriated for facility furnishings; linen direct care supplies, etc	Social Services 405.1130(a)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F72–78 (cont'd)		– Does the home provide safe-keeping for valuables? – Have they ever lost anything of yours? Ask Staff: – What is the procedure when residents lose personal belongings? Valuables? – How are resident personal funds handled? – What is your procedure when a resident asks to get an accounting of their funds? * The special needs of residents with Alzheimer's disease who "lose" personal possessions should be noted. Individuals in stages 2 and 3 of Alzheimer's disease sometimes believe their personal possessions were stolen.			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F. Freedom From Abuse and Restraints F79-83 SNF 405.1121(k)(7) ICF 442.311(f)	- How many residents are physically restrained? - What type or restraints are used? - Are they applied correctly? - What is the apparent physical/mental condition of those residents restrained? - Do you observe the release of restraints every 2 hours and the provision of at least 10 minutes exercise for the resident? - Do staff respond to request for water, assistance to bathroom, etc.; from a resident who is restrained? What is the interval between request and response?	Ask Resident: - Why are you wearing this? - How often is this worn? - Do you know what would happen if it were removed? - How often is it removed? - What is done for you when the restraint is removed? - For nonrestrained resident-- + Have you ever been restrained? + For what reason? + What explanation was given for the restraint? - Do you ever feel that you receive medication when you don't need it?	Look for a physician's order for the restraint. Review nurses', physicians' progress notes re: reason for restraints and resident reaction to them. Also any alternative methods tried. What time of day are restraints most often applied? Review schedule of releasing restraints. Care plans: - When restraint is to be used. - for how long. - What are plans for alternative measures. - Is the resident periodically re-evaluated? If appropriate are the Social Service or activities departments involved in providing different directions for resident attention?	There must be a physician's order for all restraints, including "safety devices" which are defined in some State laws. Progress notes should show evidence that methods other than restraints were initially used to protect the resident from injury, and that restraints were used only when other methods were not adequate If used in an "emergency" the reason for use must be documented and show that: a. Its use was necessary to protect the resident from injury. b. Its use was necessary to protect others from injury. The resident must be observed by a staff member at least every 30 mins. while restrained. The restraints must be released and the resident exercised, toileted, etc. at least every 2 hours.	Nursing Services 405.1124(c)(5) Rehab Nursing 405.1124(e) Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F79–83 (cont'd)	- How often are restrained residents observed by staff? - Observe effect on residents. Do you see what may be signs of over-medication? - How often is this observed? - Residents should be free from mental and physical abuse. -Observe interaction of staff and residents for any sign of harassment, humiliation or threats. - Do residents appear comfortable with staff? - Look for numbers of residents with bruises or other injuries (skin of the elderly bruises easily, so do not automatically assume abuse or injury). - Observe resident to resident interactions and staff response to any physical or mental abuse of one resident to another.	Ask Staff: - What is the facility policy regarding re: restraints? - What is considered an "emergency" need for restraints? - What is the most common reason for use of restraints? - Do you try any alternative measures before using restraints? - What information do you give the physician to help him make the decision to order restraints? - What do you routinely do for the resident when you periodically release the restraints? - Does use of restraints increase on evenings or nights when there are fewer staff members? - Have you had any accidents or incidents in the last year while residents were restrained? - How do you define the difference between a "safety device" and a "restraint"? - How do your policies differ in regard to "safety devices" and restraints?	Who authorizes the use of restraints in an emergency? Do progress notes indicate that a professional staff member authorized the use of "emergency" restraints? There should be documentation that the use of "emergency" restraint has been promptly reported to the residents physician. Review incident and accident reports to identify any problematic trends. Does the drug regimen review indicate appropriate use of psychoactive drugs? Are there resident complaints documented? What is the resolution of these complaints?	The restraint must be applied correctly. If the use of restraints increased during evening and night hours review progress notes, nurses notes and staffing to make a determination as to whether the restraints are justified or if they are for staff convenience. Care plans should plan not only for care while the resident is restrained but should show effort to find alternative treatments to restraints, or there should be documentation in the medical record that no alternative is appropriate. An appropriate drug regimen reviews should be conducted on the resident. Your observations should show interaction between residents and staff to be, except in unusual situations, free from tension and hostility. Staff should step into situation where one resident may be abusing another.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCI
F79-83 (cont'd)	- Observe for evidence of resident neglect, residents left in urine/feces without cleaning.	Ask Resident: - Do you feel safe in the facility? - Do you ever feel intimidated, harassed, or otherwise abused? - How are confused residents treated? - Is anyone ever hit or treated roughly? - Do you feel as if you are treated with respect /dignity? - Is the staff/administration responsive to complaints? - Do you know who to complain to?		Resident should feel free to voice complaints. If no complaints are noted in records or on record review, why not? Residents should seem comfortable in relating how they are treated?	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
G. Privacy F84–89 SNF 405.1121(k)(8)(9)(14) ICF 442.311(g)	- Observe interactions between staff and residents for indications of respect, consideration, dignity and individuality. - How do staff members enter a residents room or go behind a privacy curtain? - Are privacy curtains used or doors shut when personal care needs and/or treatments are rendered? - Are there areas for residents to be alone or meet in private with visitors?	Ask Resident: - Do you feel that you are treated as a worthwhile, adult individual? – - When you are being cared for, are you comfortable? - What is the degree of privacy and respect you receive? - Do you feel comforatable that if the door to your room is closed staff will knock or otherwise make their presence known before entry? - Do you have a private place to make telephone calls? – - Can you see your record if/when you ask? - Has any information about your condition been given to someone outside of the facility without your permission?	Review progress notes for indications that staff see resident as an individual– i.e., resident eats breakfast in bed because he/she enjoys it. Signed consent for release of information. Do maintenance of and content of medical records indicate that confidentiality is practiced?	Observations and interviews will give you information to determine if residents are respected and treated as individuals. Is privacy available—e.g., access to a private place to meet or make phone calls, ability to shut door when having visitors, etc. Medical records should not be left where unauthorized personnel can read them and there should be identification codes needed to access computerized records. Married residents should be sharing rooms if they desire to do so unless there are appropriate contradictions.	Medical Records 405.1132(b) 442.318(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F84-89 (cont'd)	- Are medical records kept in their assigned spots not carelessly left for nonauthorized persons to view? - Are married residents sharing rooms? - Observe for negative attitudes toward aging-infantilization and patronizing of residents. - If residents undress in public area, how does staff handle this? - Listen to staff conversation in public places (elevator, lobby). Are resident issues being discussed?	For Married Residents: - When your husband/wife visits can you shut your door and be assured of privacy? - Can you ask that you not be disturbed and have that request respected? Ask Staff: - What is done to assure that each resident maintains his/her dignity and individuality? - How are medical records kept secure? Who has access? - Do you have married couples here? - Do they share rooms? - If not, why? - What arrangements do you make for spouses or significant others to visit? - Do you allow their door to be closed? - Can you adhere to a request that they not be disturbed? - How are residents' medical records and conditions kept confidential?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Work F90 SNF 405.1121(k)(10) ICF 442.331(h)	- Are residents doing any type of work such as picking up dirty trays, pushing laundry hampers, etc.? - What about clerical work?	Ask Resident: - Are you ever asked to help out in the facility such as pick up dirty trays or stamp mail? - If yes, do you do this? - Do you want to, or do you feel it is expected of you? - Do you feel you can say "no"? Ask Staff: - Are residents asked to help with facility staff if you are shorthanded? - What is their reaction? - What useful work is available for residents who want/need to be usefully "employed"?	If residents are performing services for the facility, is that included in their care plan with specific therapeutic goals defined? If appropriate does the family concur? Are results documented in progress notes? What service (activities, nursing, etc.) is responsible for planning reevaluating and adjusting work activity? Look for physician's orders for approval or disapproval of work activity or restrictions on this activity. Look for evidence that the resident is given opportunities to refuse to do the work. The resident, however, is not restricted from doing the amount and type of work they desire unless it is in conflict with the plan of care.	Services performed by a resident should be part of the resident's plan of care and should be done only if the resident is in full agreement. Service rewards are specifically identified and not obtained using the residents own funds.	405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
I. Freedom of Association and Correspondence F91-92 SNF 405.1121(k)(11)(12) ICF 442.311(i)	- Are there areas in the facility-e.g., small lounges, etc., where residents can and do meet privately? - Is mail delivered unopened or unopened? - Are facility personnel assisting residents, if needed, in opening and/or reading mail?	Ask Residents: - Can you have visits from anyone? - Can you find a private place to visit? - Do you receive your mail unopened unless you request otherwise? - Are there telephones you have access to? - Does the staff or volunteers assist you in reading or sending mail, if needed? - How timely is your mail delivered? - How do you receive incoming calls? Ask Staff: - Where do residents go when they want privacy? - What telephones are available to residents? - What is the facility visiting policy?	Physician orders and care plans for indications of restrictions on visitors and/or receiving and sending mail.	All residents may have access to and maintain contact with the community and members of that community have access to them. Subject to reasonable scheduling restrictions, residents may receive visits from anyone they wish. A particular visitor may be restricted by the facility for one of the following reasons: - The resident refuses to see the visitor. - The resident's physician documents specific reasons why such a visit would be harmful to the resident's health. - The visitor's behavior is unreasonably disruptive of the functioning of the facility (reasons are documented and kept on file). Decisions to restrict a visitor are reviewed and reevaluated each time the resident's plan of care and medical orders are reviewed by the physician and nursing staff or at the resident's request.	Resident Rights 405.1121(k)(8) 442.311(g)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F91–92 (cont'd)	Do the available telephones accomodate the physically handicapped (e.g., wheelchair bound, hearing impaired, etc.).			Space is provided for residents to receive visitors in reasonable comfort and privacy. Telephones, consistent with ANSI standards (45.1134(c)), are made available and accessible for residents to make and receive calls with privacy. Residents who need help are assisted in using the phone. The fact that telephone communication is possible, as well as any restrictions, is made known to residents. Arrangements are made to provide assistance to residents who require help in reading or sending mail.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
J. Activities F93 SNF 405.1121(k)(12) ICF 442.311(j)	- What planned activities are occurring? - What unplanned activities are occurring—individual, 2 or 3 persons or a larger group. - If there is a facility chapel, is it open? - Are activities posted at wheelchair level and kept up to date? - Are residents lined up in front of a T.V. in a common room for hours? - Are activities offered during the evening and on weekends.	Ask Residents: - What do you like to do? - What did you do yesterday? (compare answers) - Is participation in activities optional? - Are you encouraged to participate? - Is pressure exerted on you to attend specific activities? - Which ones? (Surveyors should be aware of special encouragement—"gentle persuasion", which might be important for the depressed or withdrawn resident.) - Are residents notified of community activities? - Are arrangements made for transportation, etc. so that residents can participate? - Can residents go to religious services if they wish? - What opportunities are you given to make choices in your life within the facility? (eg. are all residents "put to bed" at the same time?). Ask Staff: - Are arrangements ever made to take residents to community activities? - Do friends and relatives ever take them to community activities? - Do your residents attend religious service of their choice? - How are residents kept informed/notified of activities?	Care plans or other documentation should indicate resident preferences for both facility and non-facility planned activities. Progress notes of responses to activities.	Compliance with this element is determined by evidence that residents are given the opportunity to participate in available activities they choose unless medically contraindicated. Residents must not be forced to participate against their wishes.	Patient Activities 405.1133(b) 442.345(a)(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
K. Personal Possessions F94 SNF 405.1121(k)(13) ICF 442.311(k)	- Are residents wearing their own clothing or facility nightgowns, robes, etc.? - In resident rooms observe for personal belongings. - Ask residents if you can look in the closet is personal clothing in there? - Ask residents if belongings such as clothing are identified with name tags or other identifying methods? - Is there enough space to store clothing?	Ask Residents: - What clothing and personal belongings can you have? - Is there a place that you can secure any valuables that you may not want to keep in your room? Ask Staff: - What personal belongings may residents have? - What do you do to secure valuables and other personal property? - What provisions are made for the care of personal clothing?	Admission notes on personal property inventory (e.g., the record should indicate a list of any personal property secured by the facility). The record should indicate how personal clothing will be laundered.	Residents are permitted to keep reasonable amounts of personal clothing and possessions for their use while in the facility and such personal property is kept in a safe location which is convenient to the resident. The amount that is reasonable will be dependent on space available in the facility. Patients are advised, prior to or at admission, of the kinds and amounts of clothing and possessions permitted for personal use, and whether the facility will accept responsibility for maintaining these items (e.g., cleaning and laundry). Any personal clothing or possessions retained by the facility for the patient during his stay is identified. The facility is responsible for secure storage of such items, and they are returned to the patient promptly upon request or upon discharge from the facility.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
L. Delegation of Rights and Responsibilities F95-97 SNF 405.1121(k) ICF 442.312		Ask Administrative Staff: - When do you have relatives make decisions for residents-i.e., how do you decide when the resident isn't capable of making decisions himself? - Have any legal steps been taken? Ask Resident and/or Guardian: - Do you feel that you are given all pertinent information? - What opportunities do you have to make decisions regarding clothing, meals, bathing schedules, etc.? - For guardian: are you notified/informed in a timely manner as appropriate?	Review physician progress notes--incapability must be documented. Is there clear documentation as to whom rights and responsibilities have been assigned? Are pertinent consents/documents signed by appointed guardian?	The fact that a resident has been judged incompetent, is medically incapable of understanding, or exhibits a communication barrier, does not absolve the facility from advising the resident of their rights to the extent the patient is able to understand them. If the resident is incapable of understanding their rights, the facility advises the guardian or sponsor and acquires a statement indicating an understanding of resident's rights. The surveyor reviews records of residents selected for indepth review who are classified either incompetent, medically incapable of understanding their rights, or have a communication barrier to verify documented evidence (signed acknowledgment) that the guardian or other sponsor has been advised of these resident rights and understand their role in acting on behalf of the resident.	Resident Rights 405.1121(k)(1) 442.311(a)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
STAFF DEVELOPMENT F98 SNF 405.1121		Ask Residents - Does staff know how to take care of you? - What things do they do to help you accommodate your (poor vision, unsteady walking, arthritis, etc.)?	Care plans reflect staff's knowledge of the problems and needs of the residents and special adaptations that are needed. Progress notes indicate that the special needs are considered in implementing planned care.	Facility staff adjusts care to needs/problems of resident. Staff is knowledgeable concerning facility policies and procedures. Staff practices correct techniques, i.e., infection control rehabilitation nursing techniques, etc. Staff interacts and treats residents in a kind, caring way.	Residents Rights SNF 405.1121(k) ICF 442.311 Infection Control 405.1135(a)(b)(c) (d)(e) 442.327(b) Physical Environment 405.1134(a) 442.315(b)(c) 442.326(a)(c) Nursing Services 405.1124(a)(c)(e) 442.338(a)(2) Social Services 405.1130(a)
F99 ICF 442.314					
F100 1. Facility staff are knowledgeable about the problems and needs of the aged, ill, and disabled.	How do staff relate to residents? Does the facility reflect adaptations for the elderly, i.e., information given in large print, floors covered with materials that allow for ease of movement with walkers, wheel chairs, etc.?	Ask Staff - What, if any, training have you had here to learn about unique problems and needs of the aged? - What training have you had during the last 12 months? - How have you learned about facility policies and procedures? - Does the facility ask your needs when they develop a training program? - In what areas would you like to have training?			
F101 2. Facility staff practices proper techniques in providing care to the aged, ill and diseased.	Is resident care given using accepted professional standards? Is privacy maintained during bathing treatment, toileting?				
F102 3. Facility staff practice proper technique for prevention and control of infection, fire prevention	Are housekeeping staff courteous and responsive to resident needs?				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F102 (cont'd) and safety, accident prevention, confidentiality of resident information, and preservation of resident dignity including protection of privacy and personal and property rights. INTENT To assure that facility provides ongoing training to staff so that they will be knowledgeable in current practices, use proper techniques, and interact with residents in a kind, caring way.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Status Change Notifications F103-104 SNF 405.1121(j) ICF 442.307 F105 1. The facility notifies the resident's attending physician and other responsible persons in the event of an accident involving the resident, or other significant change in the resident's physical, mental, or emotional status, or patient charges, billings, and related administrative matters.	Note residents condition: - Clean - Well groomed - Well adjusted - Casts - Bruises - Decubitus Ulcer - Multiple sites of edema - Aberrant behavior, e.g., abusive, disruptive, not reasonable, etc.	Ask Resident: - Have you been injured since you have been in the facility? - If you are injured or become ill, is your physician called? - Are your relatives notified? - Do you know who is notified if administrative changes such as changes in charges, billings, etc. occur? Ask Staff: - Who do you notify if a resident is injured or has a change in condition? - When would they be notified? Does the facility have a policy regarding how soon a relative or responsible party would be notified? - Do you notify them of actual changes in resident condition and also if resident's condition is getting progressively worse?	- Progress note should document injury/change in condition plus notification of physician and appropriate family member/guardian. - Changes in charges should be documented. Ask facility where this is located. - Review accident and incident reports for indepth sample.	- All injuries and changes in condition must be documented. The resident's physician and family must be notified of significant changes. This should be documented, but this notification should be confirmed by the resident if possible.	Resident Supervision by Physician 405.1123(b)(3) Emergency Services 405.1123(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F106 2. Except in a medical emergency, a resident is not transferred or discharged, nor is treatment altered radically, without consultation with the resident or, if the resident is incompetent, without prior notification of next of kin or sponsor. INTENT To assure that: - the resident receives proper treatment in the event of an accident or change of condition. - resident and/or next of kin or responsible party is aware in advance of any changes. - resident is not discharged to gain a higher source payment for that bed or facility convenience.		Ask Resident: - Have you ever been or do you know if others have been transferred or discharged without discussing it with you first?	- Nursing, physician and social work progress notes should be reviewed for evidence of discussion of transfer/discharge with resident or other designated person.	- Except in an emergency, all transfers or discharges are first discussed with the resident or next of kin as evidenced by documentation in the medical record or confirmed by asking resident.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Physician's Services F107 SNF 405.1123 A. Medical findings and Orders at Time of Admission F108 SNF 405.1123(a) F109 1. There is made available to the facility prior to or at the time of admission, resident information which includes current medical findings diagnoses, and orders from a physician for immediate care of the resident. F110 2. Information about the rehabilitation potential of		Ask Staff: - Interview nursing staff to determine if they receive transfer information and admission orders on day of admission. - Ask Administrator and Director of Nursing to explain procedure if a resident arrives without sufficient medical information and/or orders.	Review records of residents selected for indepth review to ascertain that: - There is a referral form from the transferring facility that was received in advance of admission or on date of admission that includes current medical findings, diagnosis and orders from a physician for the immediate care of the residents. - If the medical orders were not obtained from the residents attending physician, there are temporary orders from the emergency care physician. - Information on the rehabilitation potential (prognosis) of the resident and a summary of the course of treatment followed in the transferring facility were transmitted within 48 hours of admission. - The summary of treatment should include discharge summaries from therapies or special services when appropriate. - For residents admitted directly from the	Examine medical records of the residents selected for indepth review to determine if date of orders, medical data and other required information is the date of admission or within 48 hours of admission. The facility should receive sufficient information and orders to provide continuity of care of all residents.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F110 (cont'd) the resident and a summary of prior treatments are made available to the facility at the time of admission, or within 48 hours thereafter.			community, the attending physician provided current medical findings, diagnosis, prognosis, and orders. - The order should cover: + Medications and treatments + Diet + Therapies (P.T., O.T., Speech) + Activities (bedrest, ambulatory, able to participate with any specific limitations on activity).		

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Resident Supervision by Physician F111 SNF 405.1123(b) F112 ICF 442.346 B. Resident Supervision by Physician F113 1. Every resident must be under the supervision of a physician F114 2. A physician prescribes a planned regimen of care based on a medical evaluation of each resident's immediate and long-term care needs.	Observe resident for any problem/conditions that should be addressed by physician, e.g., edema, loss of appetite, weight loss, etc.	Ask Resident: - How often physician visits. - If physician has discussed plan of care and medical treatment. - If resident feels treatment and/or plan of care meets his/her needs. - What kinds of questions do you ask the physician about your health problems? (Cite examples). Ask Licensed Nursing Staff - How often physician visits and is it often enough to meet resident's need? - Does physician participate in evaluation and reevaluation of resident's plan of care? - Does plan of care meet resident's needs? - Is physician available in an emergency? - Is physician available to discuss residents treatment and care? Ask Administrator - Facility's policy regarding a physician to provide care in the absence of the resident's own physician. - Facility's policy on physician visits.	Review medical records of selected for indepth review for: - A current plan of care that is based upon physician's orders and resident needs. - Evidence that the plan is reviewed and revised as needed. - Evidence through physician's progress notes, nurses notes, physician's orders, that the physician participates in the resident's overall plan of care. - Evidence that rehabilitation potential is addressed. - Long range plans include an estimate of the length of time for skilled nursing care and a discharge plan. - Physician's orders for medications and treatments on admission and during stay. - A medical evaluation completed within 48 hours of admission unless done within 5 days prior to admission that includes attention to needs such as diet, vision, hearing, speech	Medical records should provide evidence that the residents are under the supervision of a physician by the coordination of physician's orders and progress notes with the resident's plan of care and observations of residents needs. There is evidence that the physician reviews and revises the plan of care as needed. There is evidence that physician services are available to the residents when the residents need such services. An alternate schedule for physician visits may be established if the attending physician determines that the resident need not be seen every 30 days. Justification for the decision is placed in the resident's medical record and is reviewed by the U.R. Committee and State medical review team. Where there is a change in the resident's condition and the physician has failed to document his findings or evaluation of the condition, the physician has failed to provide	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F114 (cont'd)			level of activity, emotional adjustment. - Evidence in care plans and treatment records that physician's orders are being implemented. - Discrepancies in medication record, diet order, intake and output records. - Evidence that an alternate physician provided care if applicable. - Progress notes by physician at least every 30 days for first 90 days (ICF-at least every 60 days). - Review of medications and treatments every 30 days or 60 days if an alternate schedule of visits has been approved. - Documentation of physician observations, actions and plans for treatment. - Justification for alternate schedule of visits. A few closed records should be reviewed to determine if residents were appropriately discharged by an order written by the attending physician. Also review	evidence of his evaluation of resident needs and supervised care. A physician is available to respond within a reasonable time when a resident needs medical attention. Although medical evaluation can be noted as a revision of the previous H&P A statement such as "no change" when in conflict with the status of the	
F115 3. A physician is available to provide care in the absence of any resident's attending physician.					
F116 4. Medical evaluation is done within 48 hours of admission unless done within 5 days prior to admissions. NOT ICFs.					
F117 5. Each SNF resident is seen by their attending physician at least once every 30 days for the first 90 days after admission.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F117 (cont'd) Exception: ICF residents must be seen every 60 days unless otherwise justified and documented by the attending physician. F118 6. Each resident's total program of care including medications and treatments is reviewed during a visit by the attending physician at least once every 30 days for the first 90 days and revised as necessary.			discharge plans to assure that they were adequate and implemented. Verbal medication orders are countersigned by a physician. Physician is reviewing all medication orders every quarter.	resident on this admission to the facility, does not constitute a medical evaluation. Verbal medication orders must be countersigned with 48 hours.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Exception: Only medications must be reviewed quarterly for ICF residents.					
F119 7. Progress notes are written and signed by the physician at the time of each visit, and all orders are signed by the physician.					
F120 8. Alternate physician visit schedules that exceed a 30-day schedule adopted after the 90th day following admission are justified by the attending physician in					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F120 (cont'd) the medical record. These visits cannot exceed 60 days or apply to patients who require specialized rehabilitation schedules. Exception ICF residents must be seen every 60 days unless justified otherwise documented by the attending physician.					
C. Emergency Services F121 SNF 405.1123(c) F122 Emergency services from a physician are available and provided to each resident who requires emergency care		Ask Staff: - Are you aware of physician reporting procedures and medical protocols to be followed during a fire emergency? - Do you know where names and telephone numbers are of physicians to be called in case of emergency?	- If records document an accident or a medical emergency, was the patient seen by a physician or was the physician notified promptly of the emergency? - Review physician's orders to see if specific medications or treatments were ordered to treat emergency situation if applicable.	- Surveyor verifies that there are readily available written procedures for securing a physician in case of emergency. - Names and telephone numbers are posted or on rolodex. - An alternate physician is designated.	Status Change Notification 405.1121(j)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F122 (cont'd) INTENT: To assure that a physician has overall responsibility for the managment and supervision of the residents care.			- Review physicians progress notes to see if emergency situation was addressed.	- There is provision for: + Notification of attending physician/ emergency and other responsible person. + Arrangements for transportation. + Preparation of reports. + There is evidence in the medical records that proper procedures have been carried out. + Residents with sudden changes in condition have been evaluated by the physician.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Nursing Services F123 SNF 405.1124					
F124 SNF 405.1124(c) F125 F126 ICF 442.1124(c) A facility provides nursing services sufficient to meet nursing needs of all residents all hours of each day.	Basic care provided to residents: Surveyors should observe the basic care provided by staff to the residents. Listed below are suggested areas of attention which may provide evidence of the quality of personal care: - Eyes/Ears/Mouth Presence/absence of: + Secretions forming around eyelids, redness or irritation of eyes. + Eyeglasses worn when appropriate are clean, in good repair and fit properly. + Backs of ears scaly, obvious wax build-up, discharge, odor. + Hearing aid worn when appropriate, is in good repair and working. + Dried food particles or drool, etc. around mouth.	Ask Resident: - If the resident's clothing is inappropriate, ask: + Did you choose your clothing today? + Is this what you want to wear? + Do you have other clothing available? - If the resident is not clean, poorly groomed, or inappropriately groomed, ask the resident: + Have you had any help in caring for yourself today (e.g., washing your face, brushing your teeth, etc.)? + How often do you have a bath/shower? + How often is your hair washed? + How often do you brush your teeth/clean your dentures? + Were there extenuating circumstances (e.g.,	Nursing notes, flow sheets or bathing records should indicate that the care plan for grooming and personal hygiene is being followed. For example: - Bathing schedules are being followed (including the use of any soaps or special lotions). - Assistance instruction and/or supervision is being provided as identified for each activity. Nursing documentation should also indicate resident response or any changes in the resident's behavior, reaction to an activity, or the ability to carry out grooming and personal hygiene activities. Look for indications of progress toward a goal or further deterioration of resident functioning.	Refer to information on observation. A pattern of evidence of poor personal care indicates non-compliance unless the care plan specifically deals with this and appropriate planning and implementation is occurring. The regulations require that individual preferences are taken into account when providing for grooming and personal hygiene and that residents are encouraged in self-care activity. Do your patient interviews substantiate compliance with the regulations?	Resident Rights 405.1121(k)(8)(13) 442.311 (g)(k) Social Services 405.1130(a) 442.344 Activities 405.1131 442.345(a)(c) Patient Care Management 405.1124(d) 442.341 Training 405.1121(h) 442.314
F127 Grooming and Personal Hygiene SNF 405.1124(c)					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F127 (cont'd)	+ Dentures worn when appropriate and in good repair. + Oral hygiene. - Odors presence/absence of: + Body odors - Hair/Scalp + Clean and free of rashes + Hair combed - Nails are clean and appropriate length - Clothing is appropriate, clean, and in good repair. + Extremities elevated as necessary while in chair or wheelchair. + Appropriate techniques to prevent infection. + Use of whirlpool as a treatment modality as available and appropriate. - With resident's permission check: + heels, feet and toes + lateral hip + scapular area + sacrum + buttocks + bony prominences in contact with braces + condition of stump (especially diabetic	resident is participating in dressing retraining program)? - Special consideration might be given to the demented patient who frequently "borrows" clothes and for whom removal may elicit catastrophic reaction- whether clothing "matches" may not be the most important issue in the care of these patients. Ask Direct Care Staff: - How do you choose what clothing each of your residents wear each day? - Do you have a specific schedule for washing residents' hair? - How did you learn to bathe resident? - How did you learn to wash residents hair? - How did you learn to shave residents? - How do you handle situations when residents want to wear dirty clothes, or mismatched clothes? - How much care do you let the residents do on their own?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F127 (cont'd)	amputees with elastic bandage or sock removed).				
Skin Condition F128–129 SNF 405.1124(c)	Observe with residents' permission: - General condition of skin + Redness + Blanching + Soft/dry/rough etc. + Rashes/irritation + Bruises + Scabs + Free of above - Measures taken to prevent skin breakdown. - Pressure sores - Pressure sores Rx - Factors contributing to prevention of pressure sores + Overall cleanliness and maintenance of dry and aerated skin (uncompromised by urine/feces/perspiration) + Padding for pressure points and bony prominences including padding on bed/chair + Proper gentle massage to bony areas several times a day.	Ask Resident: - Are your feet usually swollen? - Do you know what causes the swelling? - What do you do to alleviate it? - Is this discoloration normal for you? - How did this wound/bruise develop? - Are the treatments done about the same time every day? - What staff person has looked at your skin recently?	Look at nursing notes and P.O.C. for evidence of: - Planned preventive measures - Treatments/Intervention including nutrition - Routine assessment/evaluation of skin condition - Documentation of specific skin problems with location number, severity, measurements as appropriate, and cause - Progress or lack of progress in healing - Assessment/Reevaluation of interventions with alterations in plan - Appropriate nutritional plan - Methods to control edema of lower extremities	Preventable pressure sores are not occurring. Ulcers present are treated on a routine basis according to P.O.C. Is skin clean? Is resident dry? Is turning schedule adhered to? Are linens clean and smooth? Do personnel know preventive measures and practice these? Has a nutritional assessment been done, and if appropriate, recommendations implemented?	Dietetic Services 405.1125(i)(c)(e) 442.332(a)(1)(b)(1) Activities 405.1131(b) 442.345(a) Patient Care Management 405.1124(d) 442.341 Training 405.1121(h) 442.314 Rehabilitative Nursing 405.1124(e) 442.342 Supervision of Patient Nutrition 405.1124(f) 442.332(b)(2)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F128-129 (cont'd)	+ Regular assistance for resident to turn or shift weight (bedrails, footboards, trapeze). + Bed linens, clothing, underpads smooth and free from wrinkles. + Elastic bandages or hose are smooth and wrinkle free. + Elastic bandages wrapped smooth with appropriate overlap. + Dietary/nutritional support for skin integrity. (See Guidelines for Dietary/Nutrition Prevention of shearing force when resident's position altered by staff. + Turning and repositioning as needed. - Care and Treatment: + Turning and repositioning every two hours or as needed (e.g., alternative approach that is justified by the facility.) + Positioning of the ulcer site or protection of affected areas. + Use of effective pressure relief devices.	Ask Direct Care Staff: - What can you tell me about Mr./Mrs. _____ swollen feet/wounds/ bruisses/etc.? - What do you do for them? Ask Charge Nurse: - How did _____ get cuts, bruises, etc.? - What is being done to prevent further occurance? - What treatment is he/she receiving?			Resident Supervision by Physician 405.1123(b)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Wounds/Wound Dressings F126 SNF 405.1124(c)	- Condition of dressing - i.e., clean, firmly secured unless contraindicated. - Observe, if possible, and with resident's permission, a dressing change + Pre-dressing Removal Equipment and supplies organized Hands washed Residents provided with privacy - Dressing Is: + Old dressing observed for drainage? + Wound examined + Appropriate technique used + Proper disposal of old dressing? + Post dressing + Does staff member wash hands? + Return resident to comfortable position or previous activity?	Ask Resident: - How often is the dressing changed? - By whom is the dressing changed? - Does it seem dressing changes are frequent enough? - Are there any odors from the dressing? - Is the dressing change always done in a similar way? - If not, what are the differences? - Do you feel confident that the wound is being well cared for? - Is the area/wound healing? - What caused the ulcer, wound, etc.? Is it healing? Does the staff keep you informed of its status? Ask Staff: - Specific treatment and schedule for each resident?	- Physician orders for wound care - Progress notes detailing condition of wound - i.e., size, drainage, surrounding tissue, odor - Treatment provided - Progress/change - Plan of Care (POC) + The plan of care should address: - Area in need of treatment, treatment to be performed, frequency, and responsible staff. - All necessary solutions, ointments, irrigations, types of dressings, and materials. - Any necessary precautions, drains, if present, sutures and tubing. - Specific goals of treatment as well as any problems or limitations imposed as a result of treatment.	Physician orders, your observations, progress notes and POC should reflect the same information. Treatment provided over a period of time with no improvement and no re-evaluation also would represent non-compliance, unless nursing/physician progress notes address the "no improvement" problem. Compliance is evidenced by: - treatment given according to doctor's orders and POC. - use of appropriate technique when caring for wound/changing dressing (e.g., follows facility's written procedures). - periodic evaluation of healing process and revision of care plan as needed.	Physician Services 405.1123 442.346 Infection Control 405.1135(b) Pt. Care Management 405.1124 442.341 Dietetic Services 405.1125(b)(c)(e) 442.332(a)(1)(b)(1) Medical Records 405.1132 442.318

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Restraints F130 When residents require restraints the application is ordered by the physician, applied properly, and released at least every two hours. (See also information under Resident rights-Freedom from abuse & restraints)	Direct to evidence of: - Proper application - Proper use - Maintenance of good body alignment - Resident observation, release and exercise Observe frequently throughout your visit to validate care. Specific observations should include the following items: - Type of restraint: belts, wrist or ankle cuffs, blanket restraints, vests, bed nets, locked, etc., (When locked restraints are used can you readily find the key and/or scissors?) as well as geriatric chair or geri-table/tray in place for prolonged periods. - Protective devices and/or safety devices that are used as restraints must be evaluated as restraints. - Appropriate application: skin protected from injury (restraint neither too loose nor too tight to prevent	Use of restraints may be precipitated by an "emergency" situation in which there is a threat to the resident's health or safety, or a threat to the health and safety of others due to the resident's behavior. Restrained residents may not be coherent or rational enough to respond to questions and caution in interviewing therefore, must be exercised. However, observation of a resident in a geri-chair with table in place or a resident in a wheelchair (with vest restraint) for several hours would warrant appropriate questions as to when the staff last assisted him or her to move about or whether the resident would like to get out of the chair. Staff interviews focus on the reason why the resident is restrained. Ask Direct Care Staff and Charge Nurse: - When, why, and how to release and apply restraints? - Why is the resident	- Physician orders for restraint: reason, length of time, type - Progress notes - Describe the resident's status/behavior which prompted the use of the restraint. - If a chemical restraint, the order should indicate a specific time period for its use as well as a stop date. - Plan of Care should + Identify other methods or therapies that are being used in conjunction with restraints. + What alternatives to restraints have been considered. + Identify staff responsible for observing the resident (every 30 minutes), and releasing and exercising the resident (every 2 hours for at least 10 minutes). Time intervals should be identified. + Indicate involvement and input of other disciplines necessary to overcome the problem. + Indicate a specific period of time for	- Is there a physician's order, including the circumstances in which they will be used, the length of use, and the type of restraint? - Is the restraint applied properly? - Is it released at least every two hours and the resident provided with exercise and toilet facilities if needed? - Does the staff observe the resident frequently while he/she is restrained? - Are chemical restraints administered in accordance with physician's orders? - Is the order for restraints renewed only after a reassessment of the patient?	Patient Rights 405.1121(k)(1)(7) 442.311(f)(2)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F130 (cont'd)	rubbing and blistering or impeded circulation) - Body alignment and support: use of pillows, footboards, and wheelchair footrests to maintain appropriate posture, circulation, and to prevent skin injury or breakdown. - Periodic release and exercise: exercise may include ambulation, range of motion, massage, or other opportunities for motion (at least 10 minutes every 2 hours during day and evening hours). - Chemical restraints: residents appear drowsy throughout the day (may indicate tranquilizers or other drgus are being used to limit or control behavior for staff convenience).	restrained? - Was the resident given an option of restraint? - When were you taught the use of restraints? By whom? - If chemically restrained (excessively sedated) + Why is this done? + Whether alternate means of restraint have been attempted; for how long this will continue, etc. This should elucidate from staff whether the chemical restraint is necessary, or whether it is done for staff convience by controlling resident behavior - Do you ask the resident for permission before using restraints? - How does the restrained resident summon assistance? - What is the usual timeframe for assistance to reach the restrained resident? Ask Resident: + Why are you restrained? + What would happen if the restraint were removed? + When do you use bad rails? + What purpose do they serve? + How do you gain assistance?	using the restraint. - Indication of assessment of factors which precipitate residents behavior which has warrented restraints and plans to intervene early enough to prevent occurence. - Type, duration and frequency of exercise should be documented. - An assessment of why restraints are continued should be documented.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Bowel and Bladder F131 SNF 405.1124(c) Each resident with incontinence is provided with care necessary to encourage continence including frequent toileting and opportunities for rehabilitative training.	- There should be a chart/record in the resident's room on which the program is documented accurately. - If the room is located a distance from the toileting room or for residents with problems ambulating, a commode may be present in the room. - Verify that a call light is available to the resident if non-ambulatory or restrained. - Are fluids available at bedside? - Is there roughage on meal tray? - Diet is appropriate to enhance elimination?	Both the resident and direct care staff should be interviewed and should exhibit a good understanding of the importance of maintaining a regular schedule of elimination. If neither are aware of the intake and toileting schedule, then determine whether they are appropriately panning the resident or carrying out a retraining program. - Verify that the resident is aware that he/she is on a retraining program and knows the content of the program. Ask Resident: Suggested questions are: - How do you deal with constipation/diarrhea? - Are you involved in a special bowel/bladder training program? - If so, how does your program work? - Any problems with it? - Any successes to date? - What does the staff do for you in this matter? - Are they consistent and timely? - How long do you have to wait to be taken to the toilet?	- Physician orders if required by facility policy - Nursing notes for + Assessment + Documentation of techniques and progress, reevaluation - Plan of care The plan of care should clearly address: + Goals that resident will aim for. + Methods to accomplish the goals. + Schedule for fluid intake. + Schedule for toileting. + Responsible staff + Any limitations the resident may encounter as a result of either incontinence or the training program. - Progress notes/physician orders for cause of incontinence. - Laboratory tests of kidney function when available - Treatment for diarrhea/constipation - Residents preference for treatment of constipation. - Recently admitted and newly incontinent residents should be thoroughly assessed for at	- Are all incontinent patients assessed for cause of incontinence and ability to be helped by a bowel/bladder rehabilitative training program or an incontinence management program? - Are all appropriate residents involved in bladder/bowel training programs or, incontinence management and there is a schedule that shows when the program will be started? - Is there evidence of follow through on all shifts? - For residents not on bowel/bladder retraining programs, the plan of care should address specific measures for managing incontinence with a view to prevention of skin and other problems and maintenance of resident dignity.	Nursing Services 405.1124(e) Dietetic Services 405.1125(c)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F131 (cont'd)	- When a resident puts on his/her call bell for toileting assistance, how long is it before assistance is given/ - Observe pre-meal toileting. - Privacy provided. - Schedule for toileting should allow for resident's normal sleep pattern, to avoid disrupted sleep.	Ask Nurses Aides and Charge Nurse: + Will you describe this resident's bowel/bladder (B/B) training program? + How long has it been in effect? + When will you evaluate the results? + If this program is not successful - What assessment was done to determine B/B status - For residents not on B/B retraining programs what is the facility program for managing incontinence?	at least 7 days for the cause of incontinence and when appropriate an intensive bowel and bladder B/B training program should be instituted. - A trial B/B training program is suggested for all residents with incontinance problems. - I & O		
Catheter Care F132 SNF 405.1124(c) Each resident with a urinary catheter receives proper routine care including periodic evaluation	The indwelling catheter should promote a continuous flow of urine unless ordered otherwise. The surveyor should also observe for the following: - Ample supplies for catheter insertion and care. - Proper positioning of the tubing and drainage bag. - Cleaniness of the	Ask Resident: - What is the tubing/catheter for? - Why do you have one? - Does it cause any discomfort? - If it does, what is done about it? - How do you feel about having the catheter? - Is any special care given in relation to the catheter?	The surveyor should verify that there is a physicians order for an indwelling catheter, including the type and frequency of catheter care. If irrigation is ordered, the order should include type of solution and frequency of irrigation. The record should also indicate the color, consistency, and amount of urinary drainage.	*The facility should follow accepted professional standards in their catheter care. There should be medical reasons for catheter insertion - staff convenience cannot be justification. Direct care staff should know signs and symtoms of urinary tract	Infection Control 405.1135(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F132 (cont'd)	tubing and drainage bag. - Color and consistency of urine in bag. - Availability and accuracy of documentation on the I&O sheet if ordered or policy. - Proper equipment for ambulation - leg bag if resident is ambulating. (if ordered) - Availability of fluids. - When indicated monitor intake to ensure adequate intake and output or conformance with physician orders. - How many observed residents are on catheter care?	Ask Nursing Aide and Charge Nurse: - How do you routinely position and secure catheters and drainage bags? - How often is each part of the system changed? - What are the indications for insertion of the catheter? - What is the facility's procedure for routine catheter care? - How do you observe for U.T.I.'s in residents with indwelling catheters? - What is the facility's procedure for the cleansing and storage of reusable catheter equipment and drainage receptacles? - How do you care for catheter tubing?	- Assessment should address: + Need for an indwelling catheter. + Resultant problems or limitations. - Plan of Care should address: + Type of catheter and type and frequency of care. + For irrigation, the rationale, the type of solution, amount, and frequency of irrigation. + Frequency of symptoms which would precipitate catheter change. + Time frames of catheter change and responsible staff. + Appropriate increase in oral fluid intake. - Intervention The record must reflect: + When and by whom the catheter was inserted and for what reason. + Any special care provided + New problems or changes + Only appropriately trained staff should deliver catheter care. + Only licensed staff should insert	infections (U.T.I.s) and these should be reported and treated promptly. "The Center for Disease Control has developed standards for catheter care which may be used but it is not a requirement.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F132 (cont'd)			indwelling catheter. + The specific type and size of equipment used should be noted. + Signs and symptoms of urinary tract infections (UTI) should be acted upon and documented as to follow-up. - Evaluation/Reevaluation The record should reflect that the resident: + Is assessed for UTI. + Has no abdominal distention. - Notes should also include: + The color and odor of urine and the development of any problems after insertion of indwelling catheter. + Verify that catheter is patent.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCES
Injections F133 SNF 1124(c)	- Observe for preparation of injection - i.e maintenence of sterility; correct dilution, handwashing, before preparation, etc. - Observe injection site for: + Redness + Discoloration + Swelling + Lesions - Observe for proper technique when injection is given + correct site + correct needle size + correct volume of drug + sterility maintained - Resident is observed for any adverse reaction - What is the disposal method for used needles or syringes?	Ask Nurse: - What is your plan for alternating injection sites? Show me. - What is the medication for and what are potential adverse reactions? - Is there nonspecific pain at the injection site or shooting pains down a limb? - Is there skin irritations or lumps under the skin? - If adverse reaction occur, how soon are they reported? - Could this be given by any other route? Ask Resident: Suggested questions are: 1. What kind of medicine do you receive by injection/shot? Why do you need that medicine? 2. Do you have pain or numbness at or around your injection site? 3. Who gives the injection? 4. Do you receive your injection according to a schedule?	- Physician order sheet - Nursing notes for: + Resident response to medication if appropriate + Any problems noted at injection site + Any other adverse reactions + Site of injection - Plan of care + Rotation of injection site + Care for any special problems related to the injection. - Infection Control: reports for any infections connected with injections.	- Is the medication administered according to the physicians order? - Is proper technique used in preparation and administration including site rotation? - Does the nurse administering the medication know the expected action of the drug? - If infection control reports show infections at injection sites. - Is the resident's response to the medication noted in the progress notes?	Staff Development 405.1121(h) 442.314 Infection Control 405.1135(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCES
Parenteral Fluids F133 SNF 405.1124(c)	The surveyor should observe that parenteral fluids are administered with safe, aseptic technique providing fluids as ordered by the physician. Safety and comfort measures are to be taken insuring maximum protection and optimum hydration of the resident. The surveyor should note the following items: - Labeling of the solution bottle/bag. - Rate of infusion/cc/ml per hour. - Date and time started --additives, if any. - Any signs of swelling or redness at site; - Site dressing is clean, dry and dated. - Accurate I&O of parental and P.O. fluids - If splint (armboard) is used, it is applied to prevent movement but not impede circulation. - Positioning of I.V. tubing. - Comfort of restraint used to allow for maximum resident freedom while preventing movement of I.V. site.	Ask Resident: - Why do you have this tube in your (arm)(leg)? - Is it comfortable? - Is there a way it would be more comfortable? - How long has it been in? - How much longer will it stay in? Ask Appropriate Staff: - Why the resident is receiving I.V. therapy? - What the drip rate is (the amount of fluid to be received per hour). - How often the dressing is changed. - How often the tubing is changed. - What are possible side effects? - How often is the site checked? - How often is the infusion checked for drip rate and the remaining volume to be administered? Ask Nursing Aide - What are your responsibilities when caring for a resident receiving IV fluids? - What training have you had?	- Physician's order for parental therapy specifying type of fluid, rate of infusion/hour, and additives, if any, is available and current. - Twenty-four hour I&O record. - Nursing documentation indicates physician's orders are being followed. - Any adverse reactions are noted in the medical record. - Record indicates: + Infusion started by whom; cite time, rate of flow + Note is made of observation of pain or swelling at infusion site. + The need or reason for parenteral fluids. + Response to the therapy. + Problems and limitations encountered by the resident as a result of receiving parenteral fluids. - Plan of Care* The plan of care should include + Type, rate of infusion /hour, and additives (if ordered).	- Is the parenteral fluid administered according to the physician's order and in accordance with accepted nursing practice? - Are infiltrations noted in a timely manner before a large amount of fluid infiltrates? - Is the facility procedure for care of the IV site and tubing changes followed for all patients unless contraindicated? - Does documentation reflect what the patient received, any problems, and his/her response to the parenteral fluid? - Have any adverse effects been caused by administration of IV fluid? - If yes, were these preventable?	Resident Care Policies 405.1121(1) Infection Control 405.1135(b) Patient Care Management 405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F133 (cont'd)			specified goals for correction, time frames, and responsible staff. - Documentation must include time administered and by whom, the amount of fluid infused, and any other special care administered as a result of IV therapy (i.e., mouth care, assistance with ADLs, etc.). - The record must reflect: + Conditions of site and any infiltrations, phlebitis, necrosis, etc. noted, along with measures taken to correct these. + The resident's response to therapy + Changes in laboratory studies *Plan of care would not be modified for a one-time IV infusion.		
Colostomy/Ileostomy F133 SNF 405.1124(c)	The surveyor should ascertain that the facility is providing appropriate nursing care to those residents who have had bowel surgery resulting in a colostomy or ileostomy. It is recommended that the surveyor, with the resi-	Ask Resident: - Why was the ostomy performed? - How do you feel about the ostomy? - Does it ever cause you problems (e.i., pain, skin problems, odors accidents)? If so, what	The surveyor should determine that: - Colostomy irrigations, if ordered, are documented as performed by the resident or appropriately trained staff. - In the case of sigmoid colostomy regular patterns of bowel elimination are	Compliance would be indicated if residents are physically and emotionally comfortable with the ostomy with minimal or no skin problems. If residents are not comfortable with the ostomy, are having skin or other problems, the facility	Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Colostomy/Ileostomy F133 (cont'd)	dents permission, observe care being given to determine that proper techniques are being used. The following steps should be taken to assure that proper ostomy care is being provided. - The ostomy dressing should be changed or the bag emptied and thoroughly cleaned promptly after each bowel evacuation or more frequently, if drainage continues. - The peristomal skin should be cleansed and dried, and appropriate measures taken to prevent excoriation and infection. - The resident's privacy should be considered while providing care. - The resident should be provided with information and instruction in self-care at the appropriate level of understanding. - The resident should be observed for signs of withdrawal, disgust anxiety, or other emotional responses which may be related to his/	does staff do about it? - What does the staff generally do with or for the ostomy? Are they consistent and timely? - Has staff talked to you about doing some of the care for this? If so, what was the outcome? If not, is this something you'd be interested in learning more about? Ask Staff: - If nurses aid: + How did you learn to take care of colostomies? + What do you do if the skin around the colostomy becomes red or sore? + Do you ever teach the residents to care for their own colostomies? - If nurse (RN or LPN) + What is the procedure if the resident becomes constipated? Ask Other Nursing Staff: - Is there a facility procedure for ostomy care? - Do you have skin problems with your	documented as established through management of diet, fluid intake, exercise, and the use of prescribed laxatives, suppositories, and/or irrigations. - Ostomy care is documented in the resident's record along with a description of the excreta. - Problems in irregularity, skin breakdown, or other observable concerns are documented and reported to the physician. - Documentation indicates that nursing measures are taken to assist the resident who is experiencing problems in understanding and/or accepting the presence of the ostomy. - Documentation of nursing measures to maintain skin integrity. - Assessment The assessment should indicate: + Needs, problems, and limitations as a result of an ostomy. + Specific degree of	should be responding to these and correcting them as reasonable. Care plans should indicate specific goals in relation to problems and specific interventions for reaching these goals. When available an enterostomal therapy nurse should be involved in developing the care plan for residents with urinary and intestinal stomas.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Colostomy/Ileostomy F133 (cont'd)	her acceptance of the colostomy/ileostomy. - The surveyor should observe the staff giving ostomy care to verify that proper technique is used.	ostomy residents? - What do you do when skin becomes excoreated? - What teaching do you do with the residents? - What in general is the response to this teaching?	self-care performed or assistance needed. + Special skin care needs. + Special dietary needs. + Emotional support. + Medications and treatments if needed. - Plan of Care The plan of care should clearly address: + Specific goals to overcome or improve the problems(s) identified. + Methods to accomplish the goal (training, assistance, supervision, treatments, emotional support). + Services necessary and who will perform the services. + Time frame for accomplishing goals.		Social Services 405.1130(a) 442.334(a)(b)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 SNF 405.1124(c)	- Aerosol Compressor or IPPB (Intermittent Positive Pressure Breathing Machine) The surveyor must determine that the facility is providing respiratory therapy as ordered by the physician. Observation for this indicator should focus on the necessary equipment as well as on the resident. In order to determine that the necessary equipment is available, the surveyor must look for the following: + Aerosol compressor or IPPB Machine. Check that the machine is clean and operable. + Tubing – If tubing is not attached to the machine, ask to see it. Check that it is stored dry and with consideration for cleanliness. + Nebulizer Cup – should be attached to tubing. It is filled with either the prescribed medicine or distilled water only if about to be used. It should not be	While interviewing the resident, observe for sounds of congestion. Note color of lips and nail beds. Ask Resident: - Do you ever feel short of breath? - If yes, what is done when this occurs? - Is the therapy helping you to feel better? - Are there any problems with it? - If so, how does the staff respond? - Is the therapy consistently performed – both concerning time and method of providing it. Ask Staff: - What is the reason the resident is getting this therapy? - What are the expected results? - Can you demonstrate how you use the equipment? - How often is the equipment cleaned? - What are the infection control procedures in regard to use of res-	The surveyor should determine that: - Respiratory/oxygen therapy is performed or administered by appropriately trained staff. - There is a physician's order for therapy, and it is specific as to rate of delivery, etc. - If the physician's order is for prn therapy, it should specify for what symptoms. - Any information gained from resident or staff is verified in the record. - Assessment + The assessment should address both the need or reason for therapy and any problems or limitations which result from the need for therapy. - Plan of Care The surveyor should note: + The kind, amount, frequency, and/or duration of therapy based on the physician's order. + Specific goals to overcome to improve any identified	Only qualified (trained) personnel should administer/assist with respiratory therapy. Therapy must be provided as ordered. The effectiveness of the therapy must be periodically evaluated and therapy revised as appropriate. Effective infection control measures must be practiced. Needed safety precaution for the use of oxygen must be practiced. Equipment should be available and in working order.	Staff Development 405.1121 (h) 442.314 Infection Control 405.1135(b) Patient Care Management 405.1124(d) 442.341

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	stored wet. If it is not attached to the tubing, ask to see it. The mouthpiece is connected to the nebulizer cup. The surveyor should also check that all involved equipment is clean. - Oxygen Therapy The surveyor must establish that the facility is meeting the oxygen needs of the resident. When the facility does not have wall units, check that: + There are enough cylinders for oxygen delivery. + There should be flow meters and regulators for tanks in use. + A wrench should be attached or stored close by. + If using large cylinders (size G or H), look for a carrier since these tanks cannot be transported without it. + The cylinder at the resident's bedside should either be on	piratory equipment? - What training was given you in the use of this equipment? - Where is the emergency oxygen supply?	problems and/or limitations. + Specific methods to accomplish the goals (observation, supervision, training, etc.). + Who is responsible to perform therapy or assist in accomplishment of goal. - Intervention - The record should display evidence that: + The plan of care is functional + The therapy was administered in accordance with physician's order for the specified reason(s) by an appropriately trained staff member + Change in condition is documented and acted upon promptly. - Evaluation/Reevaluation The record should reflect: + The resident's response to therapy. + If response was undesirable, evidence of further intervention. + Any progress, deterioration, or development of new problems.		Physical Environment 405.1134 (1) Medical Records 405.1132 442.318

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	the carrier, sitting on a metal skirt, or otherwise secured. + There should be other necessary equipment available such as humidifiers, nebulizers, masks, nasal cannulas, T-pieces, etc., all should be dry and clean when stored. + Check to see that non bed-bound residents are not limited to their own chair/room when using oxygen (portable units will prevent social isolation. + Water reservoir is appropriately filled per manufacturers instructions. + Check to make certain the tank is not empty and that any tank is labeled as such. + Check for good oral hygiene of resident. + The room should be posted with a "No Smoking" sign. - Residents on respirators: + Are alarm systems turned on?	Residents on Respirators Ask Staff (all levels): - What training have you had in caring for	+ Based on the above information, possible modification of goals.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Respiratory Therapy F133 (cont'd)	+ Is sufficient Oxygen supply available? + Is the ventilator accessible to an emergency outlet? + Is the resident in a location that allows for frequent observation by staff? + How does the resident communicate with staff? + What level of staff (aide, LPN, RN) caring for the resident? + Is such equipment at bedside? + Is there reserve back-up equipment? + What is the condition of the residents skin around intubation tube/tracheostomy. + Does the care given use appropriate technique in caring of the patient?	residents on respirators? - Can you show me how the alarm system works? - What is your procedure for pulmonary care? - What is your procedure for changing tubing and the water reservoir? - What happens if the power goes off?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tracheostomy Care F133 SNF 405.1124(c)	Satisfactory tracheostomy care is a procedure which promotes a clean, unobstructed air passageway and maintains the skin integrity surrounding the tracheostomy site. The surveyor should determine whether: - Adequate supplies are available for the care of the tracheostomy such as tracheostomy kits, hydrogen peroxide, normal saline or sterile water, suction machine, catheter, sterile gloves, and clean dressings. - The resident is breathing without difficulty and is comfortable. - The dressing is clean, dry, and intact; the cannula is clean, in the proper position, and secured. - The skin surrounding trach is clean and dry with no redness or inflammation. - The resident has adequate oral hygiene. - An extra tube, the same size as the one in	Resident interviews must be guided by the resident's communication ability. Ask Resident: - How long will you have it? - What care can you do for yourself? - What do you need help with? - Who helps you? - Is someone always available to suction him/her when needed? - Is the suction equipment always available in working order? - Is the dressing kept clean and comfortable? - Is the tube kept clean and changed as needed? - How often are the tubes and dressings changed? - Does he/she feel confident in the personnel caring for his trach- - What is communicating with staff and other residents like? - Are staff patient and do they allow you enough time to express your needs/thoughts/feelings? [- May I observe your tracheostomy care?] Ask Staff: - Why does resident have	- The surveyor should determine that tracheostomy care is done as scheduled and as needed following the proper procedure. - Any special solutions that are needed should be addressed in the physician's orders. - Assessment - The record should reflect that the need for tracheostomy care was assessed in terms of: + Frequency + Skin integrity surrounding the tracheostomy, noting redness, inflammation, and/or excoriations. - Plan of Care should include: + Specific times of trach care and the responsible, appropriate trained person performing this task. + Specific problems relating to skin and breathing as well as the goals set to overcome these problems listing the appropriate personnel responsible. + Time frames for resolving problems	Stoma and surrounding skin should be in good condition and if not, there should be treatment directed to resolving this problem. All staff caring for the tracheostomy must be trained and emergency procedures must be known. All needed equipment must be available and in working order. Resident must at all times have readily available a means of communicating with the staff in an emergency.	Infection Control 405.1135 (b) Training 405.1121(h) 442.314 Patient Care Management 405.1124(d) Physicians Services 405.1123(b) Social Services 405.1130(a)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tracheostomy Care F133 (cont'd)	place, is available at bedside. - Does resident have an adequate method of communicating with the staff? - Does staff allow enough time for residents to communicate?	tracheostomy? - What training were you given to enable you to care for tracheostomies? - What is the procedure for tracheostomy care? - How often is the tube changed? - What do you do if the tube comes out? - May I watch you do a dressing change? - If not convenient, describe what you do. [- How do you communicate with a tracheostomized resident?]	listed in goals. + Plan for periodic assessment of appropriateness of residents own self care re: teaching or nursing assuming more responsibility as appropriate. - Intervention - The surveyor should look for documentation of: + Trach care and oral hygiene administration, including responsible personnel, time and date, and effects. + Any problems or changes noted in resident condition (e.g., redness, swelling, tracheal obstruction). + Emotional response to tracheostomy. - Evaluation/Reevaluation + Resident is or is not benefiting from trach care and skin care. + If problems are noted, the progress notes and plans for care should indicate changes in treatment. + Resident's emotional response to care of the tracheostomy should be evaluated,		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tracheostomy Care F133 (cont'd)			since this may require additional care planning.		
Suctioning F133 SNF 405.1124(c)	Suctioning is necessary for any resident who is unable to cough up secretions that are obstructing his airway. Suctioning may occur via the oral or nasal route, or stoma route with sterile technique. Attempts should be made to observe a resident being suctioned should such an opportunity arise. If so, observe that a clean/aseptic technique is observed throughout and that the resident tolerated the procedure. There should not be bloody aspirant, cyanosis, or broncho-spasm. Check that equipment is in good working order, frequency of procedure, etc. Resident observations which indicate need for intervention include: - Secretions are draining from a resident's mouth or trach and the resident is unable to	Ask Resident: - How are you feeling now after the suctioning? Does the suctioning seem to help? - Has staff explained to you the need for suctioning? Why do you need to be suctioned? How often? - Who performs the suctioning (i.e., nurses or nurses aides)? Do you feel safe with the staff performing the suctioning? - Does everyone do it about the same way? Ask Staff: - When and where did you learn to suction? - Tell me what procedure you use when you suction a resident. - Do you always have enough suction machines and catheters? - How frequently is suction tubing changed? - What provisions do you have for suctioning if the electricity is lost?	- Assessment – The record should reflect that: + The resident is frequently observed for suctioning needs. + Any limitations a resident has as a result of his suctioniong needs should be specifically noted. + Any problems resulting must be specified. - Plan of Care should include: + Awareness of the resident's suctioning needs, goals, approaches, and responsible staff needed to improve the problem or at least to maintain the resident at his present status without further deterioration. The plan must clearly indicate specific approaches towards: - Prevention of skin problems around the trach if one exists. - Correction of any existing skin pro-	- All equipment must be available and in working order. - All staff caring for the resident must know what to do in an emergency. - Current professionally accepted standards of care must be maintained.	Infection Control 405.1135(b) Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Suctioning F133 (cont'd)	cough or clear himself. - There are audible crackles or wheezes and/or diminished breath sounds. - The resident is dyspneic. - Restlessness or agitation may also be an indication that suctioning is needed. Upon completion of suctioning above symptoms should, in most cases, be relieved. The surveyor should observe that the resident is positioned to facilitate breathing (usually at a 45 degree angle). Check to see that the facility has an ample supply of suction machines and suction catheters to meet the needs of residents requiring them and that they are clean and properly stored.	- Where are your emergency electrical outlets? - What is your procedure for disposing of the secretions from suctioning? - How often does Mrs./Mr. need to be suctioned? - May I observe you when you suction Mrs./Mr.?	blems. - Provision of good oral hygiene including a rigid schedule for mouth care, schedules, or procedures for maintaining clean equipment at bedside, as well as disposal of used (dirty) equipment. - Route of suctioning (i.e., oral/nasal/trach). - Intervention - The record should indicate clearly that: + The plan of care is being implemented. Documentation should reflect: + The number of times the resident required suctioning, for what specific reason, and by whom the resident was suctioned. + Any special treatment the resident received in conjunction with suctioning		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Suctioning F133 (cont'd)			(i.e., oral hygiene, skin care, etc.). - Evaluation/Reevaluation The record should reflect: + How well the resident tolerates suctioning procedures. + Any bloody aspirant, cardiac arrhythmia, cyanosis, or bronchospasm. + Further interventions utilized to overcome or improve these. + The amount of sputum as well as its color and consistency. + Any progress or lack of progress, deterioration, and/or the development of new problems. + The evaluation should determine whether goals are being reached or if new goals must be addressed.		
Tube Feedings F133 SNF 405.1124(c)	- Staff use proper technique in administering feedings and medications. Check to see that staff checks for location of tube before feeding and that tubing	If the resident is able to be interviewed, suggested questions may be: Do you feel comfortable/safe with all the staff who perform the feeding?	Tube Feeding Review: - Plan of care - Must document tube placement and formula potency prior to each feeding.	- Has the feeding been ordered by a physician? - Is tube feeding nutritionally adequate? - Have attempts been made to discontinue tube feeding if indicated?	Nursing Services 405.1124(d)(f) 442.338(a)(2) Meal Service 442.331(c)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tube Feedings F133 (cont'd)	is irrigated before and after addition of medication. - The tube is clean and formula flows freely. - The equipment is clean and protected. If dressings are ordered, they are in place, clean, and dry. - The nasal tube is securely but comfortably secured on the face with skin maintained intact and without irritation. - The skin around the gastrostomy is kept clean and free from irritation or infection. It should be checked carefully for leakage of gastric contents. - A resident who has a N/G tube for a prolonged period of time should be observed for possible complications, such as nasal erosion, sinusitis, esophagitis, gastric ulceration, and pulmonary infection. - Resident is fed slowly with head elevated to 45° during feeding and at least 1 hour post-feeding.	If not, what happens? Are you losing or gaining weight? What is your goal? Ask Staff: - Please describe how you would carry out a resident's tube feeding.	- In the case of continuous feeding, tube placement must be documented at least every 4 hours. - Naso gastric tube must be secured in a manner that avoids creating pressure on the nose and nasopharynx. - Identify frequency, amt. of feeding based on the physician's order and time span over which each feeding is accomplished. - Medication and treatment records. - Fluid intake records. - Number of calories as well as amount of additional water. - Documentation present regarding removal and reinsertion of tubes. - Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed.	- Is skin free from irritation; mouth care is given several times daily? (More frequent mouth care in the case of continuous feeding.) - Have changes in resident condition been noted and addressed (weight loss, constipation, diarrhea, skin condition)? - Have observed problems been coordinated with other departments and resolved? - Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate? - Varied supplements as preferences allow?	Dietetic Services 405.1125(c)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Tube Feedings F133 (cont'd)	- Supplies for mouth care are in evidence, observe if possible for technique; mouth shows evidence of good care (i.e., moist, clean.)				
Nursing Services F137 SNF (405.1124) ICF (442.338) B. Twenty-four hour nursing. F137 1. Assigned duties consistent with their education and experience/ based on the characteristics of the resident load. F138 2. Weekly time schedules are maintained. F139 3. There is a sufficient number of nursing staff	Are personnel performing duties that are allowed under the State Nurse Practice Act? Do you observe care being rendered in an appropriate, competent manner? Does the time schedule posted indicate that at least the minimum required personnel are scheduled and actually on duty? What is the usual response time before a call bell is answered? In SNF's is an RN on duty during the day? Are licensed staff and aide staff functioning in appropriate roles? Where are staff spending their time?	Ask Resident: - Do residents generally feel that people taking care of them know what they are doing? - If no, explain. - Are your treatments done in a consistent manner? - If no, explain. - Do you feel that there are enough people here to take care of you? - If no, explain. - How long do you usually wait for help when you put your call light on? - Is there anything that doesn't get done as often as it should? Ask Staff: - Do you feel qualified to do all the work you are assigned to do? - If no, explain. - Do you feel you have enough training to keep up with the care the residents require?	- Review progress notes to determine who is giving care. - Review care plan to determine who the facility has assigned to care responsibility to. - Check staffing sheets for minimal requirements and time and attendance for actual staffing. - Review charts maintained for ADL medications, I & O, restraints, etc., to assure that sufficient staff are available for carrying out responsibilities as specified in patient care plans.	All nursing personnel must function within their State Nursing Practice Act. Levels of staffing meet at least minimum requirements. Nursing care needs must be identified by the facility & documentation, resident and staff interviews should determine if these needs are met. All nursing staff should have education or training to prepare them for the care they perform.	Patient Rights 405.1121(k)(g) Patient Care Policies 405.1121(1) Medical Records 405.1132(c) 442.318(a)(c) Patient Care Management 405.1124(d) 442.341 Staff Development 405.1121(h) 442.314

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F139 (cont'd) available to meet the total needs of all residents.	Check for staff who are actually on duty.	- If no, what else do you need?			
F140 4. There is a registered nurse on the day tour of duty 7 days a week (for SNF only). Intent That all residents are cared for by personnel qualified to provide the care & that sufficient numbers & classifications of personnel are available.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Patient Care Management F167 SNF 405.1124(d) F168 ICF 442.341 F169 A. Each resident's needs are addressed in a written plan of care which demonstrates that the plans of all services are integrated, consonant with the physician's plan of medical care, and is implemented shortly after admission. F170 B. Each professional service identifies needs,	Observe resident level of physical, mental, emotional and social functioning. Note problems, potential problems, needs, using observation/interview/record review work sheet.	Ask Resident: - Are you aware that you have a plan of care? - Did you participate in developing a plan of care? - Do you/your family know what the plan is and details? (e.g., diet, ambulation, dressing, etc.) - Do you attend and participate in plan of care meetings? - Who else attends the plan of care meetings? - When did you last attend the meeting for your plan of care? - Does the staff assist you in achieving the goals on the plan of care? If not, who does or why not? - Do you have all necessary assistive devices and equipment? - Is there anything that is not part of your plan of care that you think should be included? - What happens if you question any treatment or procedure? Can you give an example?	Review: - Plan of care The content of the plan of care is of primary importance rather than the format. Separate care plans are not required for each discipline, but may be accepted if there is evidence that the various disciplines coordinate their planning. - Nursing assessment/reassessments and notes. - Physician orders. - Physician notes. - Assessments/evaluations and progress notes from all professional disciplines as appropriate. - Medication and treatment records as applicable. - Lab reports, as applicable.	- Are all resident's needs/problems identified? - Is the plan developed to meet these needs? - Does the plan demonstrate an interdisciplinary approach, and include: + Goals stated in measurable/observable terms? + Approaches (staff action) to meet the resident action goals? + Responsible disciplines/staff responsible for approachs to assist resident in achieving goal/goals? + Is plan being reassessed and changed as needed to reflect current status? + Does plan of care accurately reflect information gained from observation, interview and record review?	Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Resident Rights 405.1121(k) 442.311 24 Hour Nursing Service 405.1124 442.338 Specialized Rehabilitation Services 405.1126 442.343 Training 405.1121(h) 442.314 Resident Rooms 405.1134(e) 442.325 442.326 Infection Control 405.1135 442.328 442.324

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 170 (cont'd) goals, plans, and evaluates the effectiveness of interventions plus institutes changes in the plan of care in a timely manner. INTENT The intent is to assure that the facility identifies the resident's (with residents/family input if applicable) needs through the coordinated efforts of all disciplines.		Ask Staff: - What is your input into resident's plan of care? - What aspect of the resident plan of care are you carrying out? - What is this particular resident's plan of care? - How do you assist the resident in carrying out the plan of care? - Who attends the care planning meeting? - Is the plan of care useful to you in caring for the resident? - Is there anything the resident needs that is not addressed in the plan of care? - How often is it reassessed?			Social Services 405.1130 405.1130(a) 442.344(d) Activities 405.1131 442.345 Dietetic Services 442.1135 442.332

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Restorative Nursing Activities of Daily Living F17_176 SNF 405.1124(e) ICF 442.342 442.343(a)(c) INTENT To assist the resident to attain or maintain his/her maximum level of independence and function?	A. Observe residents in need of assistance. 1. Is needed assistance provided? 2. Is resident provided assistance and instruction, as appropriate, in all ADL's to increase his/her level of independence? 3. Does staff minimize pain/discomfort while assisting resident? 4. Is resident taught transfer techniques? 5. Is resident assisted to toilet in timely manner? 6. Resident personal equipment available & within reach? Glasses Hearing aids Dentures [Artificial larynx]	Ask Resident: - What assistance do you need with bathing and/or dressing? Who helps you? - Does the staff plan with you your dressing/bathing schedule? - Do the nursing and activities staff coordinate your schedule so that you have the opportunity to participate in favorite activities? - Are you able to dress/bathe at times convenient for you? - Are you bathed consistently? (i.e., on the day(s) scheduled does the bath get performed?) - Where are you bathed? (bed, shower, tub?) - Are there adequate clothes available for you to wear? - Do they come back from laundry in appropriate condition? - How do you get in and out of bed? - If staff assists you, do they seem to be able to do their job appropriately? Do you always feel safe when	Review: - Plan of care + Reflects assessment, goals, methods to reach goals, service providers, evaluation, and achievement. + Addresses restorative nursing assessment, program initiation, implementation and evaluation of the progress over a reasonable time period. Professional judgement determines the assessment of appropriate time frames. + Identifies planning for potential discharge for all residents to determine a disposition on home care or an alternate level of care. - Nursing Notes + Demonstrate evidence of assessment, intervention, response to treatments/teaching and their progress toward independence, a maintenance level or a deterioration. + Provide evidence of interdisciplinary conferences.	Are patient needs identified? Verify that the plan of care addresses resident needs and is implemented as scheduled and that all appropriate information is documented. If goals are not reached, has a reevaluation been performed and goals revised? Does restorative nursing assist the resident to acquire a higher level of independence? Is sufficient time allowed to resident for learning to increase his/her level of independence? Are assistive devices used regularly as per plan and are they in good repair? Is there an assessment, and if appropriate, a plan for each ADL that the resident needs to gain independece in? Maintenance goals should be noted as appropriate.	Physicians Services 405.1124(a)(b) Nursing Services 405.1124(a)(b)(c) 442.342 Dietetic Services 405.1125(a) 442.331(c) Activities 405.1131(a)(b) 442.345(a)(b) Specialized Rehab. Services 405.1126 442.343(e)(1)(2)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)		being helped?			
	Prosthetic devices (eg. braces, artificial extremities).	- Are staff members encouraging you to do things for yourself?			
	Adaptive equipment (e.g., built-up spoon, reachers).	- Do you have any problems getting to the bathroom on time?			
ADL's (cont'd)	Orthotic devices (eg. splints, AFO's).	- Do you have any problems with leakage when you sneeze, laugh or at any other particular time?			
	Restraints (eg. vest, waist, wrist, ankle, mitts, nets, geri-chairs).	- How does the staff help you with these problems?			
	Grooming items (eg. comb, brush, shaver).	- Are they aware of the problems?			
	Oral hygiene (eg. toothbrush, tooth-paste, mouthwash, denture cup).	- Do you bowels move regularly?			
	Self-feeding devices.	- If not, what do you/ staff do about this?			
	Assistive devices for special sensory loss needs (eg. communication boards, large print books, magnifiers, writing tablets, picture cards, talking books).	Are you able to feed yourself?			
		- Are you able to get to the dining room by yourself? If not, why? In that case, what does staff do about this?			
		- How long have you been up today?			
		- Do you usually lie down for a rest?			
	Training/re-training	- If you need help getting into or out of bed, is staff available to help you when you need it?			
	Prosthetic management	- Where do you spend most of your time - in your chair, wheelchair or in bed?			
	Stroke adapted ADL's				
	Self-injections of medications				
	Bowel/Bladder				
	Self-feeding				
	Self grooming				
	Ambulation				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)	Colostomy/Ileostomy Care Respiratory Care (oxygen inhalation) Speech Mobility Upper extremity dressing Lower extremity dressing Observe at mealtime whether staff encourages/guides residents in self-feeding or feeds the residents.	Does anyone move your arms or legs or help you with exercises? - Have your sleeping habits changed since you came to the nursing home? If yes, in what way? - Are you able to get help during the night if needed? + What kind of help is needed? + Is staff response timely? - Do you feel there are adequate care supplies at this facility? - If not, can you give me an example of why you feel this way? - Is your family involved in assisting you or if learning to help you? - Do you feel there is adequate staff at this facility? - If not, can you give me an example of why you feel this way? - Does staff assist and/or encourage activities (e.g., R.O.M., ambulation ADL, communication programs, feeding)? - How often does staff assist in activities? - Is there anything resident would like to do			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)		for himself/herself that staff is doing? - Is resident comfortable (e.g. free from pain)? - Is your cane/walker/ crutches comfortable for you to use? - Did anyone measure you so you have the right size cane/walker/crutches? - Did anyone show you the correct way to use your cane/walker/crutches? - If the facility arranged so that you can get around easily? Ask Activities Staff Do you provide information to nursing staff about time and place of activities, plus names of residents who are to attend or those who might be interested in attending? Chair-bound Resident Ask Resident: - Does he/she know why he/she is in a chair? - Is resident assisted to use bathroom? - Is resident comfortable? - Does he/she see therapist? (O.T., Speech, P.T.) and how often? - Does resident go to a			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171–176 (cont'd)		therapy area or does therapist come to resident? - Is able to reach items needed? Ask Nurses Aide –Who give you information about the time and place of activities and which residents are to attend? How are you given this information? –How do you encourage a resident to do the most for themself? Wheelchair Resident Ask Resident: - Does he/she know why he/she needs a wheelchair? - Is resident trained and/or encouraged in independent W/C ambulation and activity? - Does resident know how to lock and unlock wheelchair? Ask Staff: - How is a resident set up for independent W/C ambulation? - Nurse Aide - has resident received instruction in transfer techniques? For Bed Bound Resident In addition to appropriate interview questions above:			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F171-176 (cont'd)		Ask Resident: - How do you spend your day? - Can you do some things for yourself? - Does the staff give you a chance to learn self-care skills? Ask Nurse: - If the resident had access to a recliner chair, would he/she be able to be out of bed? - Is the time out of bed coordinated with the activity schedule and necessary care? Ask Nurses Aide: - Does this resident do any self-care? Why not? - If no, has anyone tried to teach him/her to do some care?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Positioning F175 SNF 405.1124(e) Intent To assure that the resident is positioned at all times to promote maximum therapeutic benefit and comfort, as well as safety.	Observe residents in bed, chairs, restrained, or in "protective devices" for - body alignment - positioning - contractures (when did they occur and what is being done)? - ROM program (observe extent & technique of provider) - Assistive devices (overhead pulleys, slings, splints, etc.) - Turning/repositioning schedule and adherence to the schedule. - Devices to maintain positioning, i.e., sandbags, extra pillows, etc. Specific Observations for the Bed Resident (as appropriate to condition). Positioning/body alignment Resting splints & correct application Foot positioning boards Trapeze Hand rolls Elbow/leg splints & correct application Restraints Siderails (padded) Special mattresses	Ask Resident: - How often are you turned/repositioned by the staff? - Is that often enough? - Are you comfortable now? Do you have any pain or discomfort? Where? - How long have you had joint stiffness (contractures)? - What kinds of exercise do you do every day, including range of motion (ROM)? How long does the exercise last and how frequently do you exercise each week? - Do you wear special devices? How often? Consistently? - Are they always applied and removed appropriately and promptly? How Often? - By whom? Bed Rest Resident Ask Resident: - Why do you have to stay in bed? - How often does staff get you OOB? - Do they know how to get you up? - Who sets you up and/or assists you in bedside ADL's? - Does staff, therapist check positioning, supportive devices?	- MD orders for non-nsq interventions/treatments. - Plan of care should include at a minimum: + Restorative goals + specific joints to be exercised + devices to be used in positioning + frequency of treatment or repositioning + resident teaching information + resident teaching information + services responsible for carrying out the procedures + time frames for reaching goals - Nursing progress notes indicate: + Plan has been implemented + Progress toward goals + Response to information from reevaluation - Look for actual turning/repositioning schedule	Plan of care should be complete (addressing resident positioning needs) and plan is implemented on a daily basis. Care givers are knowledgeable re plan content Residents are turned as scheduled. In good body alignment with proper assistive devices & equipment. Contractures are prevented and/or treated. Plan is reviewed, reevaluated and revised at least quarterly, but must be done as often as patient condition dictates: Ask aide assigned to demonstrate the hand holds he/she uses for ROM. If aide doesn't know, ROM is probably not being done. Do it "at bath time" is not sufficient.	Rehabilitative Services 405.1126(h) 442.343(c)(2) MD Orders Activities Resident Rights Nursing-Staffing Inservice Social Service Dietary

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	Blankets/pillows Clean, smooth linen Clean, appropriate bed wear Turning schedules ROM schedule O.O.B. (as tolerated) Water available All adaptive devices are clean and in good repair. All assistive supportive devices are clean and in good repair. Specific Observation for the OOB Resident in Chair (geri-chair, lounge chair in room, as appropriate to condition) Arrangement of room facilitates residents optimal independence (e.g., independent eating, grooming, T.V., radio, water). Positioning/body alignment. Blankets/lap robe, pillows, foot stool. Hand rolls, splints. Clean, dry attire. Pressure relief device. Restraints, with release & activity schedule. Call bell available.	- When? - Does staff answer call bells propmtly? How soon? - Is resident able to reach items (e.g., water call bell, urinal, emesis basin, tissues)? - How much confidence do you have when the nurses are helping you transfer, or turn and so on? - Does resident go to therapy area or does therapist come to resident? Bed Rest Resident Ask Staff: - How often is position changed? - What activity is done at the time (e.g., R.O.M., toileting, OOB, grooming? - What can resident do independently? - Is equipment available? - Who maintains and cleans the equipment? - What is the schedule for this? - What training have you had to learn to position patients correctly?			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	Specific Observation for the Wheel Chair Resident (as appropriate to condition, including deliberate alterations made to equipment for specific reasons.) - Proper fit - Good working condition - Appropriate arm rest, footrest, leg support, lap tray, - Proper positioning - Pressure relief aids, (e.g., gel flotation pads, egg crate mattress, sheepskin) - Set up for independent W/C ambulation - Functional adapted toilet area - Transfer techniques Observe how staff wheel the resident (e.g., do they inform before starting movement)? Are patients moved wheeling forward and facing elevator doors? Observe staff for: - verbal cues - physical support - body mechanics Specific Observation for the Ambulatory Resident (as appropriate to condition) - Gait (steady/unsteady) - Appropriate devices for	- Was there any part of your orientation when you first came to work here that addressed positioning? - Do you have any periodic reviews/updates on positioning? Chair Bound Resident Ask Staff: - How often is resident repositioned/taken out of chair? - What is the activity at time of repositioning and/or release of the restraint? - What can resident do independently? Ambulatory Resident Ask Staff: Is resident encouraged to independently ambulate to and from activities and dining room (with or without personal assistance)? - Does resident do as much as he/she can independently? - What does resident do? - How do you know that resident is maximally independent? - If it is not working independently, how do			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F175 (cont'd)	ambulation (e.g., cane, crutches, hemi-sling - Posture - Appropriate staff assistance in ambulation - Grab bars (halls, bath/shower area) - Functionally adapted toilet area	you deal with it? - Is there something resident would like to do that he/she is not allowed to do (e.g., shave self, apply make-up, style own hair)? - What training have you had in learning to position residents and do range of motion? - What opportunity do you have for ongoing training? - Who does the actual training? Check question placement under Interviewing. May be more appropriate for resident's rights section. Observe wheeling technique used by staff.			
Nursing Services G. Administration of Drugs F183-184 SNF 405.1124(g) ICF 442.337 F186 1. The patient is identified prior to administration of a drug.	Observe a drug pass with at least 20 residents receiving medication. See SOM Appendix N. Transmittal No. 174 for details of the Surveyor Methodology for Detecting Medication Errors. - Observe medication administration techniques (e.g., hand-	Ask Resident - Do you always receive your medication on time? - If not, what is the problem? - Do you receive the correct medication? - What does it look like? - Who explained your medications to you? - What reactions do you have? - What happens if you have a question or refuse to take your medication? - Who gives you your medication? - Do your medications change in appearance?	Review the medication administration record. (as appropriate) See S.O.M. Appendix N, Transmittal No. 174 for details of the record review.	If the combined total of significant & non-significant errors is 5% or above, a deficiency is present. Any significant error is cause for a deficiency. See Appendix N for details.	Physician Services 405.1124(b)(7) Pharmaceutical Services Supervision 405.1127(a) 442.336(a)(b)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F187 2. Drugs and biologicals are administered as soon after doses are prepared. F188 b. Administered by same person who prepared the doses for administration except under single unit dose packet distribution system. Exception: ICF residents may self administer medications with their physician's permission.	washing, pouring of dosage, position of resident).	- Do the nurses stay with you when you take your medication? - Do any of the medications bother you? Ask Staff: - Do you generally have available the medications you need? - Are there any problems in administering medications? Note drug doses refused by resident and how handled by staff.			

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Conformance with Physician Drug Orders F189 F190 F191 SNF 405.1124(h) ICF 442.334(a) Drugs are administered in accordance with written orders of the attending physician. Intent All residents receive medications as ordered by the physician.	Combine with observation of drug pass.		- Review the latest recap of the physicians orders - Review the medication administration record (as appropriate) - See S.O.M. Appendix N, Transmittal No. 174 for details of the record review.	See Appendix N for details	Physician Services 405.1123(b)(7)

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SURVEY AREA CROSS REFERENCE	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	
DIETETIC SERVICES (Condition of Participation) F193 SNF (405.1125)	o <u>Specific Observations which might be indicative of possible nutrition problems:</u> Clinical – underweight/ overweight – dehydration – edema – cracked lips – pallor – dull or dry hair – swollen or red tongue – bleeding gums – decubitus ulcers – infections o Physiologic factors which may affect intake: – Swallowing difficulties – Vomiting – Food intolerance – Poor dentition – Sore mouth – Constipation – Diarrhea – Inability to feed self – Decreased visual and olfactory acuity – Unable to communicate – Loss of appetite o Psychological/Social – Confusion	Ask dietary manager to explain the procedure for making substitutions and recording the changes. – Is menu usually followed? <u>Ask Resident:</u> 1. How are your meals? 2. Are there foods you are not allowed to have? 3. Are you on a special diet? 4. Do you receive foods that are not appropriate for your diet? If so, what do you and the staff do about that? 5. What time do you receive breakfast, lunch and supper? Do you always receive a meal at mealtime? If not, why? What happens then? 6. Do you like the taste of the food? 7. Is the temperature appropriate (i.e., milk chilled, coffee hot, etc.)? 8. Do you get enough to eat? What do you do if you're still hungry after a meal?	<u>Review Nutrition assessment for the following documentation:</u> o Usual/ideal body weight/ height o Dietary allergies/ sensitivities, ability to chew and swallow regular foods without difficulty. o Full or partial dentures o Mental and emotional condition o Physical appearance, skin condition o Appetite and food preference. o Vitamin and mineral supplements. o Food and fluid intake in measurable terms and frequency of meals. o Degree of assistance needed in eating, related mobility, vision, or other identified problems. o Medications (e.g., diuretics, insulin, antibiotics, etc.) o Related laboratory findings (e.g., fasting blood sugar, cholesterol, sodium, potassium, hemoglobin, BUN, serum albumin, transferrin or creatinine-height index if available).	o Were physician diet orders followed? o Did nursing plan for feeding and assistance at mealtime? o Is there rehabilitative use of assistive devices, if appropriate? o Is modification of consistency of meals made if resident has a problem or change in condition? o Are between meal and bedtime snacks provided as needed? o Is socialization at meals provided? o Has dietitian provided counseling of resident and family as needed (related to diet)? o Usual body weight is maintained/supported? o Is there evidence that the plan is being carried out (e.g., documentation in the resident's chart, observation by the surveyor, and resident/staff interviews)? If the resident refuses meals or does not respond to intervention, the notes in the chart should indicate efforts to intervene or provide counseling.	<u>Physician Services</u> 405.1123 442.346 <u>Medical Records</u> 405.1132 442.318 <u>Nursing Services</u> 405.1124(e)(f) <u>Specialized Rehabilitative Services</u> 405.1126 <u>Patient Care Management</u> 405.1124(d)
A. Menus and Nutritional Adequacy F194 SNF (405.1125(b)) F194 ICF 442.332(a)(1)					
F196 Menus are planned and followed to meet the nutritional needs of each resident in accordance with physicians' orders and, to the extent medically possible, based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196(cont'd) <u>Intent</u> Ensures that each resident receives food in the amount, kind, and consistency to support optimal nutritional status.	- Excessive food likes and dislikes - Refusal to eat o <u>Selected biochemical changes which might indication changes in nutritional stutus</u>: - Visceral protein status o serum albumin o transferrin o BUN o Serum electrolytes During mealtime observe the resident for: - adherence to food preferences - adequate space for eating - self-feeding skills - proper position for eating - ability to eat foods served - use of adaptive feeding devices - amount of food actually eaten - protection of resident's clothes - amount of time resident is allowed to chew and swallow - Assistance provided as needed to and from dining area - All beverages are covered]	9. Do you receive nourishment in the evening? Do you have a choice about what you want to eat? 10. Do you receive medicines during meals? If yes, do you know what it is or what it is for? 11. Do you get food from outside of facility that you buy or family brings? How often? What kind of food? 12. How often does anyone from the kitchen come to ascertain your feelings and opinions on the food service, your portion size, etc.? 13. Where do you eat (e.g., dining room, your room, etc.)? Is this your choice? Do you have a choice of where you eat? 14. How often have you seen a therapist for your swallowing difficulties?" "How has the therapist instructed you/staff/family on methods to improve your swallowing? <u>Ask Dietician</u> - Describe the meal planning input you receive from residents.	o Food/drug interactions o Mental/emotional assessment as it relates to resident's food habits. Review: o Plan of Care o Nursing Notes Review: o Physicians orders o Progress notes o Notes from other professional disciplines as appropriate. Nutritional status depends not only on adequacy of menu planning but also whether the resident eats the food and how the body uses it. While the surveyor is not responsible for individual nutritional assessments of residents, when specific information is needed during the survey to make a compliance decision, the surveyor will utilize the following minimum assessment guideline: <u>Menu Evaluation</u> o Adequate in energy and nutrients - Protein - Calories	Is there evidence that the resident's progress is regularly observed (e.g., awareness of food and fluid intake such as acceptance of foods, food consumed, and resident's appetite)? o Is fluid intake for resident encouraged, Foley catheter, problem feeders monitored? o Is there general evidence as to whether poor resident conditions are due to poor care or whether the facility has taken appropriate measures to prevent or resolve problems. o Is there indication of progress toward desired outcomes? If not, is the evidence of re-evaluation available within specified time frames? o When the antropometric and clinical data do not correlate with dietary data, (food intake, dietary supplements) the surveyor should take note that the problem may not be nutritional.	<u>Nursing Services</u> -405.1124(f)

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196(cont'd)	Assistance being provided in case of choking, incontinence, falling, or other emergencies. Nursing Staff supervision of dining areas including residents' rooms during meal times.		- Vitamin C - Calcium Selected evaluation of residents for in depth review: A check list can be used to evaluate daily menus for basic foods: (use standard serving protions) Daily food plan should include: MILK GROUP 1 pt milk MEAT GROUP 5 equivalents:* 1 equivalent equals 1 oz. of meat (edible portion) weighed after cooking (this includes eggs, dried peas, beans, nuts, and all meat, fish and poultry). VEGETABLE AND FRUIT GROUP 5 services or more, including a dark green or deep yellow vegetable for vitamin A value every other day and a citrus fruit or other fruit rich in Vitamin C daily.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)	Observe serving portions sizes on all menu items: MILK GROUP - 1 pint daily Source of: Protein Calcium Phosphorus B Complex MEAT GROUP - 5 lean meat equivalents (1 meat equivalent = 1 oz meat, poultry, fish, cheese & eggs; also dried peas, beans, and nuts). Source of: Protein Iron Vitamin B12 VEGETABLE AND FRUIT GROUP - 5 servings or more (1/2 cup = 1 serving) Source of: Vitamin A,C, B6, Folacin, Fiber BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP - 7 servings (1 serving = 1 slice bread; 1/2 cup other; 3/4 cup flake-type cereal).		BREAD-CEREAL-POTATO-LEGUME-PASTA GROUP 7 servings FATS AND SWEETS (Without this group the diet contains 1,415 Kcal) Diets should be adapted from facility's currently approved diet manual. Menus are dated and contain minimum portion sizes. Are substitutions noted on the file copy? Are substitutions made within the same food group i.e., meat for another source of protein in the meat group, or vegetable of similar nutritional value?		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)	FATS AND SWEETS (to increase caloric intake) IODIZED SALT (unless contraindicated) Adequate fiber in diet		o Documentation of decision to withdraw or begin artificial feeding and hydration. Check menus for variety Are they specific (i.e., states kinds of fruit, juice, vegetable)? DIETARY SERVICES SELECTED NUTRITIONAL REQUIREMENT RECORD REVIEW N.B. The basal energy expenditure (BEE) and calorie requirement using Harris-Benedic formula recognizes the variation in energy needs for individuals. 1. Anthropometry- Weight /Height NOTE: The following sample formulas and guidelines are not the only acceptable guides available. The surveyor should ask to use the assessment guidelines used by the facility before using the ones provided here. o Important indicator of nutritional outcomes. o Disease state can have adverse effect on desired body weight.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			2. Weight for Height Calculation Females: Allow 100 lbs. for first 5 ft. of height plus 5 lbs. for each additional inch Males: Allow 106 lbs. for first 5 ft. of height plus 6 lbs. for each additional inch Estimating Caloric Needs 1. FORMULA: Harris-Benedict Equation Men: 66 + (13.7 x Wt. in Kg) + (5 x Ht. in cm) - (6.8 x Age)=BEE Women; 65.5 + 9.6 X Wt. in Kg.) + (1.7 x Ht. in cm) - (4.7 x Age)=BEE Parenteral Anabolic: 1.75 x BEE Oral Anabolic: 1.5 x BEE (Kcals)		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Oral Maintenance: 1.20 x BEE (Kcals) Metric Conversions (Approx) pounds (lb.) x 0.45 = kilograms (Kg) inches (in.) x 2.5 = centimeters (cm) Estimating Protein Needs 1. Allow 0.8 gram protein per kilogram of ideal body weight. 2. Increase to 1.2 – 1.5 gm/kg for patients with depleted protein stores (decubitus, draining wounds, fractures, etc.). Fluid Requirement Based on actual body weight: Over 55 years with no major cardiac or renal diseases: (NOTE: 2.2 lbs. equals 1 kg of body weight)		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F196 (cont'd)			Example: 120 lbs/2.2 lbs. = 54.5 kg (55 kgs) 55 kg x 30 cc = 1,650 cc/day Note: Isotonic Standard Tube Feeding = Approximately 80% water. Amputation % of Body Weight Leg 20% Below Knees 10% Arm 6% At Elbow 3.6% Suggested Standards for Evaluating Significance of Weight Loss % of body weight loss Inter- val / Significant Loss / Severe Loss 1 week 1-2% 2% 1 month 5% 5% 3 months 7 1/2% 7 1/2% 6 months 10% 10% From Blackburn, et al: "Nutritional and Metabolic Assessment of the Hospitalized Patient: JPEN vol. 1, 1977.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS			CROSS REFERENCE
				Mild Deficiency	Moderate Deficiency	Severe Deficiency	
F196 (cont'd)			Lab Indices for Visceral Proteins				
			Albumin g/dl	3.5–3.2	3.2–2.8	2.8	
			Total Lymphocyte Count (cu/mm)	1800–1500	1500–900	900	
			Transferrin (If Available)	200–180	180–160	160	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
B. Therapeutic Diets F197 SNF 405.1125(c)	System for the provision of diets: o Dietetic service Kardex or file o Therapeutic menus o Nourishment preparation and service o Adequacy of nourishment o Individual menus or diet cards	Ask Staff: o Number, type of therapeutic diets? o Time of nourishment activity, who's responsible? o Nourishment provided for day of survey?	Review: - Physician diet orders in medical record - Nurses' Kardex - Dietary Kardex - Therapeutic diet menu - Diet cards		Nursing Services 405.1124 405.1124(c) (d.) Patient care plan (f.) Supervision of patient nutrition
F198 ICF 442.332(b)(1)(2)					
F199 1. Therapeutic diets are prescribed by the attending physician.	SPECIAL FEEDINGS: The surveyor should also attempt to observe that: o Staff use proper technique in administering feedings and medications. Check to see that staff checks for location of tube before feeding and that tubing is irrigated before and after addition of medication. o Unused milk-based tube feeding should be discarded in a timely manner	The surveyor should interview staff regarding their knowledge of the feeding schedule and training in administering tube feedings. Some residents having difficulty in speaking or swallowing with the tube in place (i.e., poor toleration). The surveyor should inquire if mouth feeding was attempted. Ask Resident: If the resident is able to be interviewed, suggested questions may be: 1. How long have you been fed by this tube? 2. When was the last time you tried to eat by mouth? What happened? 3. How often do you receive the feeding? Is this consistent?	Note: - Consider appropriateness of special diet-updated and reviewed since admission. - Progress notes reflect reevaluation of resident's progress on diet. Selected number of residents on therapeutic diets should be considered for indepth reviews. Tube Feeding Review: - Plan of Care - Identify frequency, amt. of feeding based on the physician's order and the time span over which each feeding is accomplished. - Medication and treatment records - Fluid intake records - Number of calories as	On Pureed diets: o Ordered by physician o Prepared fresh daily o Same calories and/or food groups as if served whole. Pureed foods are coordinated with general/regular menu. On Tube Feeding: o Has the feeding been ordered by physician? o Is tube feeding nutritionally adequate? o Have attempts been made to progress tube feeding if indicated? o Have changes in resident condition been noted and addressed.	
F182 2. Therapeutic menus are planned in writing, prepared, and served as ordered with supervision from the dietician and advice from the attending physician whenever necessary.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197–199 (cont'd)		4. Does the staff help you in feeding? Do you feel comfortable/safe with all the staff who perform the feeding? If not, what happens? 5. Are you losing or gaining weight? What is your goal? 6. How often is the tube changed? Who does this? Do you feel comfortable/safe with all staff who perform this procedure? Interview staff regarding knowledge of diabetic diets. o What nourishment does the diabetic patient receive? o If diabetic patient refuses the meal, what is done to supplement the meal? If resident is able to be interviewed, suggested questions: 1. How long have you been on your diabetic diet? 2. Do your know some of foods you must avoid? What are they?	well as amount of additional water – Periodic reassessment of ability to swallow – Record should indicate measures taken to prevent diarrhea and constipation and to treat if they have developed. Diabetic Diets Review: o Pertinent Laboratory data: – urinary glucose – serum glucose o Wt. gain/losses	weight loss, constipation, diarrhea, skin condition)? o Have observed problems been coordinated with other departments and resolved? o Is feeding being monitored to ensure that feeding is occurring at the ordered/appropriate rate? o Varied nourishments as preferences allow? On Diabetic Diets and Other Therapeutic Diets o Ordered by Physician o Varied, nutritionally adequate o Individualized to suit resident o Re-evaluation indicates diet meets objectives. If not appropriate, documentation is provided o Laboratory results support diagnosis o Between meals nourishment provided as needed and recorded in measurable amounts.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd) F198 Therapeutic diets prescribed by the attending physician	Observe tray/meal service: o Low sodium diets are palatable (taste) o Sugar sources on diabetic diet trays o Salt sources on sodium restricted diet trays.	3. Do you receive a nourishment between meals or before going go bed?			
		FOR THE RESIDENT WITH DECUBITUS ULCERS			
F199 Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.	Functioning system to provide the needed nutrients: - Resident's general appearance - Meal service + Food acceptance + Adherence to food preferences - Food supplement + Type to support + Method of service + Assistance provided + Timely provision as ordered - Portion sizes - Conforms to physicians orders	Ask Staff: 1. Regarding knowledge of dietary needs. 2. What do you do when this resident refuses milk, meats, bread, etc.? 3. What nourishments are provided to this resident? How often? 4. What happens when a weight loss is noticed with this resident? Ask Resident: 1. Has anyone talked with you about the importance of eating your meals? 2. Do you get foods that you don't eat on your tray? 3. When do you feel hungry? 4. Do you get between meal nourishments?	1. Identify residents with conditions that immobilize or prevent voluntary body movement. 2. Identify location, number, size and depth of decubitus ulcers. 3. Calculations of kilocaloric and protein levels as needed. 4. Micronutrient need assessment and recommendation. 5. Progress notes. + monitor weight + monitor healing of decubitus ulcers. 6. Pertinent Laboratory Data + Hemoglobin/Hematocrit + Serum Albumin + Total Lymphocyte Count 7. Fluid Intake + sufficient to maintain hydration	A system is in place to provide the type and amount of nutritional support needed by the residents who have developed decubitus ulcers. Food and supplementation are provided in a method to ensure intake of nutrients needed by residents with decubitus ulcers. Nutritional intervention is assessed and reassessed to ensure appropriate intervention for acceptable health care outcome.	Nursing Service 405.1124 (d) Patient Care Plan (f) Supervision of Patient Nutrition

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F197-199 (cont'd) F198 Therapeutic diets prescribed by the attending physician F199 Therapeutic menus are planned in writing, prepared and served as ordered with supervision from the dietician and advice from the physician whenever necessary.	RENAL REVIEW System in place for the the correct provision of renal diets. – Individualized menu – Dietary Staff Utilize menu when serving diets.	Interview Staff regarding knowledge of renal diets: 1. What foods should be restricted when a patient has kidney problems? 2. What nourishments are given to these patients? 3. Are fluids restricted? Ask Resident: 1. Are you on a special diet? 2. What foods must you avoid? 3. Do you feel hungry? 4. Do you eat everything at mealtimes? 5. Are the foods the kitchen sends you the correct ones for your diet? 6. Has the dietitian explained your diet to you?	Renal Patient Diet Review – Pertinent Laboratory Data + Serum Sodium + BUN + Serum Potassium + Albumin + Hematocrit + Creatinine – Pertinent Medications + Vitamin/Mineral + Supplements – Weight gains/losses	On Renal Diets – Ordered by physician – Written menu nutritionally complete in so far as medically possible, including calories – Individualized to suit resident – Laboratory testing as needed – Coordination with dialysis unit to determine effectiveness of diet	Nursing Service 405.1124 (d) Patient Care Plan (f) Supervision of Patient Nutrition

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Preparation F204 SNF 405.1125(e)	Observe: o Feeding assistance is provided or not provided by staff o Length of time residents sit and wait for meal service		Review: o Plan of Care o Progress notes o Notes from other professional disciplines to determine rehabilitation potential to self feed, use of assistance devices; o Record of food substitution to determine alternate choice provided o Standardized recipes	The facility has kitchen and dietetic service areas adequate to meet the food service needs. These areas are properly ventilated, arranged, and equipped for sanitary refrigeration, storage, and preparation of food. Equipment and storage areas are clean, well maintained, within proper temperatures ranges, and safe	
F205 1. Food is prepared by methods that conserve its nutritive value and flavor.	o Food is served soon after cooking or refrigerated o Trays are free of spillage of foods or liquids o Foods are appropriately covered and kept at a proper temperature			Proper temperatures: (Fahrenheit) Frozen food storage -- 0 or below Cold food storage -- 40-45 degrees Hot food holding equipment -- 140 degress minimum	
F206 2. Meals are palatable, served at proper temperatures. They are cut, ground, chopped, pureed or in a form which meets individual resident needs.	o Cooking and service utensils are clean, sanitary and greaseless o Refrigerated foods must be covered o Leftover and pre-cooked foods must be dated and labeled o All cooked food stored above raw meats in refrigerator				
F207 3. If a resident refuses food served, appropriate substitutes of similar nutritive value are offered.	o Temperature gauge on or in refrigerator to record temperature o Shelving to allow air circulation o Food not stored in refrigerator must be stored off the floor (This is applicable to food stored in walk-in refrigerator and freezer.)			Dishwasher wash cycle -- 150 - 160 degrees Dishwasher rinse cycle -- 160-180 degrees or a color change in thermopaper; or adherence to manufacturers recommendations	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F207 (Cont'd) INTENT To provide foods that are safe and nutritious SNF 495.1125(e)	- No rust on shelves - No dripping or spillage on shelves and floors - Degree to which diet modification is communicated with residents ensurate with residents tolerance and capability - Residents for meal satisfaction - Observe appearance of food color, texture, aroma, and flavor - Less than 75% of meal is consumed - Type of substitutions provided		- Progress notes - Diet card - Day's menu substitute record	Dietary personnel are clean and free of infectious disease. They practice acceptable techniques and procedures to keep foods at proper temperatures and protected against contamination. Is dietary information pertinent to dietary modification? Has resident been assessed for eating program to maintain independence? The food substitute is of similar nutritive value as the refused item (e.g., milk refused, alternate of calcium rich food should be provided.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Frequency F208 SNF 405.1124(d)	o Menus as under A on page 63 o Who serves nourishments o Nourishment list and schedule	Interview various residents about the nourishment service: o Are nourishments offered routinely? o At what time are they offered? o By whom? o What kind of nourishments are offered?	Review o Menu as under A o Nourishment List	Three meals or their equivalent are served daily with not more than a 14-hour span between the evening meal and breakfast. The nourishment service is more difficult to evaluate: must find evidence that patients are offered nourishments on a planned basis and documented.	
F209 ICF 442.331(a)					
F210 1. At least three meals are served daily at regular hours with not more than a 14-hour span between a substantial evening meal and breakfast.					
F211 2. To the extent medically possible, bedtime nourishments are offered to all residents					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
E. Staffing F212 SNF 405.1125 (a)	- Food service personnel are on duty for all defined dietary responsibilities: - Supervision - Food Preparation - Dishwashing - Cleaning	- Interview personnel to verify that they are aware of their responsibilities and job descriptions.		- From an assessment of the total dietetic service operation: + The dietetic supervisor is capable of the overall management and supervision of the dietetic service. + There are dietetic personnel on duty over a 12-hour period who demonstrate ability to perform tasks adequately. + Dietetic personnel receive appropriate orientation and training consistent with their duties and responsibilities. There is evidence that the dietetic staff are knowledgeable about food service policies and procedures and apply these accepted professionals practices in their daily work. + Services provided are consistent with the size, scope and facilities available.	
F213 1. Food service personnel are on duty daily over a period of 12 or more hours. Intent Persons are providing services commensurate with their level of training; and at the level of sophistication needed by the residents.	- Duty Schedules				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
SPECIALIZED REHABILITATIVE SERVICES F214 SNF 405.1126 F215 SNF 405.1126(b) F216 ICF 442.343 A. PLAN OF CARE ICF442.343(e)(1)(2) F217 Rehabilitative services are provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapist(s) and the nursing service. B. THERAPY F218 ICF442.343(a)(c)(d) Therapy is provided according to orders of the attending physician in accordance with accepted	OBSERVE RESIDENTS As per "Restorative Nursing Activities of Daily Living" SNF 405.1124(e)2(b) ALSO: OBSERVE RESIDENTS IN THERAPY AREAS: - Is privacy provided during treatment, as applicable (e.g., cubicle curtains, room dividers, one to one area)? - Is there appropriate, courteous resident/staff interaction? - Are therapy areas appropriate to treatment given (e.g., small, quiet area for speech/ language/ hearing test and sessions, large for P.T., exercise and therapy groups, O.T; perceptual testing/splinting, A.D.L. adaptations area, as applicable)? - Is equipment clean and in good working condition? Is it operating as per manufacturer instructions (e.g., hydrocollator temp., parafin, whirlpool, etc.)?	ASK RESIDENT: (or ask staff, if resident has severe communication problem): - Are you receiving any kind of therapy? P.T.? O.P.? Speech? - What kinds of therapist(s) are working with you on your swallowing problem? - What kinds of therapists have instructed you on how to improve your swallowing? - How do the methods to improve swallowing help you? - How often do you see the therapist? - What happens if the therapist is absent for scheduled treatments? - Where do you receive your therapy? - How long have you been receiving therapy? - Do other staff members assist with therapy? Who and in what way? - Are you in a comfortable environment (room temperature, privacy, etc.)? - Do you have input into developing or revising your therapy treatments? -What things did you do immediately before entering this facility, that you are unable to do now? ASK THERAPY STAFF: - How many days/hours per week do you provide therapy? - Do you participate in the development of the resident's overall plan of care? In what way? - Do you utilize P.T.	REVIEW: - Plan of care - Doctors' orders - Nursing assessment and progress notes - Aide assignment sheets - Therapy assessments/ evaluations (includes a minimum of): + name, age, date, diagnoses + referring physician and reason for referral + history, precautions, limitations + objective documentation (e.g., tests, measurements) + rehabilitation potential - Treatment plan (includes a minimum of): + specific rehabilitation needs and objectives + treatment to meet specific measureable rehabilitative goals + type, amount, frequency, duration, modalities + name of therapist(s) who will provide treatment + restorative nursing follow-thru (recommendations for plan of care)	- Are rehabilitation services integrated with restorative nursing? - Do therapists participate in development of resident plan of care? - Do observations and interview indicate that services are provided in conjunction with 24 hour nursing, and in accordance with the overall plan of care regarding restorative nursing and specialized rehabilitation services?	Nursing Services 405.1124 442.338 442.319 442.341 Physician Services 405.1123 442.346 Medical Records 405.1132 442.318 Activities Program 405.1131 442.345 Resident Rights 405.1121(k) 442.311 Training 405.1121(h) 442.311 Infection Control 405.1135 442.315 442.327 442.328

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F218 (cont'd) professional practices by qualified therapists or qualified assistants. C. PROGRESS ICF 442.343(f)	- Are assistive devices being provided as needed? - Do assistive devices fit well, function and are used properly (e.g., wheelchairs, crutches, braces, glasses, hearing aids, canes, artificial limbs assistive eating devices)? - Is staff responsive to resident expressions of discomfort? - How are the prescribed treatments and training meeting the needs of the resident? - Are parallel bars sturdy and well secured to floor? Are systems designed for weight lifting sturdy and well secured; if attached to wall with rigging and hand grips in good conditions? - Are nonverbal residents provided with means of communication (e.g., writing tablets and utensils, picture cards)? - Are visually impaired residents provided with	"aides" In what way (if interviewing the registered physical therapist)? - How do you assure carryover of therapeutics in your absence? - How often do you provide inservice to staff? What topics are covered? - Do you have opportunities to attend inservices? - How do you communicate patient progress/regression, etc. with physician, nursing personnel, family, other disciplines? - How many residents currently are receiving P.T., O.T., Speech-language pathology and audiology therapy (SLP/AT). - Do you utilize the services of a certified occupational/therapy assistant (if interviewing the registered occupational therapist)? - If so, in what way? - Is space available for the conduction of your therapy? - Is equipment readily available to meet resident needs? - Is there a coordinated interdisciplinary	+ identifies modalities that will be delegated to non-skill staff - Progress notes indicate that plan of rehabilitation care has been re-evaluated by the physician and therapist as necessary but at least every 30 days. - Communication with physician: + 2 week progress after initiation + monthly progress + discharge summary - Treatment documentation: + frequency + summary	Physical Environment 405.1134 442.324 442.325 442.326 442.328 442.329 442.330 Dietetic Services 405.1125(e) 442.329 442.331(c)
F219 1. A report of the resident's progress is communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. EXCEPTION: ICF resident's progress must be reviewed regularly.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
	magnifiers and large print books? - Is equipment such as whirlpool cleaned between patients?	approach toward rehabilitation of the geriatric resident evident in your facility? In what way do you see this?			
F220 2. The resident's progress is thereafter reviewed regularly and the plan of rehabilitative care is reevaluated as necessary. But at least every 30 days by the physician and therapist. EXCEPTION ICF resident's plan must be revised as necessary INTENT Therapy services are provided that will assist the resident to attain his/her optimal level of function.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Pharmaceutical Services F221 SNF 405.1127	- Observe residents for excess sedation or adverse effects: + drooling + shuffling gait + involuntary movements of limbs, tongue, facial muscles + loss of affect + drowsiness + postural abnormalities + pill rolling movement - Observe for depression aggitation	Ask Resident: - Are you aware of the medications you are taking—use, frequency, contraindications? - Has your physician discussed the medications you are taking with you? - How many medications are you taking? - How do you feel the medication helps you? - How do medications bother you? (e.g., make you feel nauseated or dizzy) - Have you told anyone about this? Ask Staff: - How often does the pharmacist review the resident's medications? - To whom does he report any irregularities? - When the pharmacist reports irregularities, what is done about it? - To whom do you report any problems about medication? - Do you feel the residents are receiving the proper medications, amount and kind? - Is the pharmacist available to you for consultation?	Review medical record: - to see if pharmacist or nurse has reviewed a drug regimen on a monthly basis. - for evidence that the reviewer has reported irregularities to the physician or other who has authority to correct the irregularities for evidence that the irregularities have been evaluated. - review nurses notes, progress notes, care plan, etc. for any adverse reaction to medication and indication that corrective action was taken. - screen the drug therapy of the residents included in the sample using the indicators (forms if prepared) outlined in SOM Appendix N Transmittal #174. - review pharmacists drug regimen monthly reports to determine if pharmacist has commented on potential irregularities, screened out through this process (need full year).	Reviews were performed in the facility. There was evidence of a review performed on every resident whose record was reviewed indepth. In records reviewed, the average prescription utilization was not substantially over 6.1 If it is, review for appropriateness. Apparent irregularities were identified and reported. * Refer to SOM Appendix N in 174 for further information on drug regimen review.	Physicians Services 405.1123(b) 442.346 Nursing Services 405.1124 442.338
F222 A. Supervision F223 ICF 442.336(a)(b) F224 SNF 405.1127(a) The pharmacist reviews the drug regimen of each resident at least monthly & reports any irregularities to the medical director and administrator. A registered nurse may be utilized to perform this monthly review for ICF residents. Also the attending or staff physician must review medication quarterly.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F224 (cont'd)		- Where does the pharmacist perform his drug regimen review?			
B. Labeling of Drugs and Biologicals F225 SNF 405.1127(c) F226 ICF 442.333 F227 The labeling of drugs and biologicals is based on currently accepted professional principles and includes the appropriate accessory and cautionary instructions as well as an expiration date when applicable. INTENT To assure that residents receive medications as ordered and that they are monitored for possible side effects.	Observe labels of medications for residents observed on drug pass tour for: - name of drug - dosage form - strength of drug - quantity of drug - expiration date - presence of a control number - appropriate accessory or cautionary statement				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Laboratory and Radiological Services F228 SNF 405.1128	Observe symptoms of targeted residents, e.g., drainage, odors, jaundice, fevers, edema, etc.	Ask Nursing/Rehabilitative Staff: - What do you do when you think a resident needs laboratory work done – blood work, cultures, etc.? - How long does it take to get lab results back? - What do you do with the results when they do come back? - Do you have any problems with your laboratory services? - How are lab specimens stored? - Do you have any instruction from the lab regarding collection and storage of specimens?	Review the physician's order sheet to see if: - orders for lab services are signed - that there are orders for tests that have been done. Nursing progress notes are reviewed for documentation of physician notification of lab results. Physician progress notes or other documentation indicating that the physician is aware of lab results. There are lab reports on the medical record for all tests ordered (except if just performed).	There must be signed physician orders for all lab/radiology services performed. Record results of all testing in the medical record. There is documentation in nursing or physician notes to indicate the results of lab tests were promptly communicated to the physician. When lab tests are performed the resident should be informed of significant findings and the possible therapeutic alternatives.	Nursing Services 405.1124(a)(b)(c) 442.343 Physician Services 405.1123(b)
F229 SNF 405.1128 (a) A. Provision of Services F230 1. All services are provided only on the orders of a physician.					
F231 2. The attending physician is notified promptly of findings.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F232 3. Signed and dated reports of a clinical laboratory, x-ray and other diagnostic services are filled with the patient's medical record. INTENT To assure that lab tests are performed as ordered and findings are reported to physicians are made aware of symptoms that may require lab tests.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Social Services F233 SNF 405.1130	Observe resident for: - level of alertness - behavior exhibited (disoriented, confused, uncooperative, disruptive, aggressive, anxious, withdrawn, isolated, lonely). - personal appearance - apparent disabilities - apparent vision and/or hearing problems they exhibit as you talk to them - interaction to staff, other residents, family, visitors - participation in group activities - independence in activities, decision making - Therapeutic staff intervention: constructive reaction to resident's behavior - resident's participation on policy making bodies and committees of facility, e.g., resident councils.	- How long have you been in the facility? - Can you explain to me why you are here? - Have you had any problem adjusting to the facility i.e., loss of independence? - Have you had any other problems? - Has staff been helpful, e.g., financial? - Do you have any family or any other visitors? - Do they have any problems with which this facility has not been helpful? - If exhibiting disruptive depressed, agitated, anxious, etc. behavior- I noticed that you are upset (quiet, nervous, unhappy) today, Can you tell me what has bothered you? - Does staff respond to your suggestions about your own care? - Did you participate in planning what care you will get and who will give it to you? - Do you make use of the dining, activity, community room, and/or outdoor area?	Review medical records of residents selected for in-depth review to determine that: - Assessment and plan of care identifies residents medically related social and emotional needs and/or problems. - Resident's family and home situation, information related to medical and nursing requirements, and community resources are considered in making decisions regarding the residents care. - Medical records contain current specific information signed and dated which highlights the social and emotional needs of the ressident and significant findings and actions are entered promptly in the medical record. - Social service notes address the following, if applicable: + losses due to aging + relationship with staff and other residents + mental status + behavior problems + adjustment to the facility + illness	The residents social and emotional needs are identified. The plan of care addresses those needs. The plan of care is being followed, reviewed and revised as necessary. The family's needs and concerns are addressed if applicable. There is referral to appropriate agencies if necessary. Sufficient space is provided for private meetings and discussions. While it is not a program requirement a social worker or other staff may contribute to the resident's care plans by indicating personal strengths that can be used to build upon.	Nursing Services SNF 405.1124 ICF 442.338 Activities SNF 405.1131 ICF 442.345(a)(c)(d) Physicians Services SNF 405.1123(b) ICF 442.346 Patient Care Management SNF 1124(d) ICF 442.346 Physical Environment SNF 405.1130(b) ICF 442.344(c)
F234 SNF 405.1130(a) F235 ICF 442.344(d) A. Plan F236 The medically related social and emotional needs of the residents are identified. B. Provision of Services F237 1. Services are provided to meet the social and emotional needs by the facility or by referral to an appropriate social agency.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)					
F238 2. If financial assistance is indicated, arrangements are made promptly for referral to an appropriate agency.		- Can you tell me about your life here? What do you do in a usual day? - Are things like getting up, bathing, dressing, eating, done at the same time for everyone? - If you could change some things about living here, what would you change? Ask Social Worker/Nurse -When the social worker is readily available, delete "ask the nurse". -How often is the resident seen by a social worker?" - Who is responsible for identifying the resident's: + social and emotional needs + family and home situation + problems and needs + financial needs - How are needs identified and reported? - Does resident participate in the development of his/her care plan? - Ask nursing how often the social worker sees resident. - Does the social worker discuss residents needs/problems with nursing staff if there is a need for nursing to be involved?	- Plan of care, social service notes, reflect the current status of the resident. - There is evidence that the residents mental status has been considered when plan of care was developed. - Vision and hearing problems have been addressed. - Plan of care addresses residents needs as observed by the surveyor and stated by the resident. - Notes and plan indicate that needs have been re-evaluated and care plan changed as necessary. - There is evidence that the problems and needs of the family have been addressed. - There are indications that a referral has been made to the appropriate agency and a statement describing why. - There is documentation from the outside agency indicating what actions were taken and any plan for follow-up.		

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)		- How is physician notified and involved in plan of care? - Ask social service staff their role, function, and what services they provide. - Ask staff what referral services are available. - If services are being provided by outside resource, are resources documented work service? - Ask social service staff about their background and education. - If there is a consultant ask staff: + How often does the person come? + How long do they stay? + What does the person do while in the facility? + What assistance, consultation is being provided? + Ask social service staff if adequate space is provided for them by the facility to conduct private interviews and meetings.	- The time period between date of referral and date of services is reasonable and if not, there is evidence of follow-thru by staff. - The outside agency has documented their involvement and activities. - Plan of care demonstrates awareness of behavior, articulates the reasons for it, and indicates in the plan of care an approach to the behavior. - Assessment should contain: + a flexible approach to each resident (should be individualized). + awareness of a mental status evaluation. + resident history. + family availability for planning, resident support, etc. + identification of problems resulting from placement. + recent social adjustment. + discharge planning. - The record reflects	- There is documentation of collaboration between nursing and social work for meeting emotional needs.	Patient Care Management 405.1124(d)

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F233-238 (cont'd)			Social Service intervention with family and resident, i.e., grief and bereavement counseling. - Review integrated plan of care for: + Plan for concerted social services. + Plan for supportive services for adjustment. - Adjustment goals. - Interventions for specific conditions.		
Activities F239 SNF 405.1131 F240 SNF 405.1131(b) F241 ICF 442.345 F242 1. An ongoing program of meaningful activities is provided based on identified needs and	General level of activities throughout the facility, as well as in specifically designated areas. How many residents are lying on their beds or sitting in chairs staring at the walls during waking hours? What is the level of residents interest in activities they are doing? Are residents positioned correctly for activity?	- How does he/she spend the day? - Of the activities resident has during the week, what does he/she enjoy most/least? - If has none, why? - Has staff asked about his/her interests? Suggested specific activities or people to get acquainted with in response to interests? - What organized activities has he/she participated in this past week? - How does resident find out about upcoming programs or happenings?	Activities Assessment Interests of the resident (past and present) are identified as to resident's current capabilities and necessary adaptations to pursue their interests. Documentation that information about social history, medical problems and limitations impacting residents' activities have been communicated to activities personnel and used in assessment and development of activities portion of care plan.	Are each resident's personal interests known? If not, what actions are being taken to identify them? Residents in facility 60 days should not be without some identified interests. Are each resident's needs identified? If not, what actions are being taken to identify them? Have medical contraindications been identified in the care plans? Needs and contraindications of residents in the facility more than 30 days should be known and/or have a plan of action.	Nursing Services 405.1124 442.319 Social Services 405.1130 442.344 Special Rehabilitative Services 405.1126 442.363 Physician Services 405.1123 442.329

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F242-(cont'd) interests of each resident. It is designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any.	Are needed personal equipment (e.g., splints, glasses) and adaptations for limitations and safety (e.g., cardholder, goggles, footrests) used in activities?	- Does resident get out of facility to activities? - Does resident have problems getting to activities? If so, does the staff assist? - Does the staff encourage residents to go to activities? - Does resident participate in Resident Council? - Does resident have free choice of activities? - What kind of activities do bedfast residents engage in? Ask Resident: - Have you ever had difficulty in having private visits? Give examples.	- Needs of the resident in the following areas are identified: + social interaction + creative expression + work and service opportunities + intellectual stimulation or activities adaptation + physical exercise + spiritual or religious expression - Plan of care Used all available information about: + interests + needs + indications and contraindications for activities from other assessments + physician orders and progress notes	Does each resident's activities promote his physical, social and mental well-being?	Physical Environment 405.1134 442.329 Infection Control 405.1135 442.328 Resident Rights 405.1121(k) 405.311 Medical Records 405.1132 405.318 Patient Care Management 405.1124(d) 442.341
F243 2. Unless contraindicated by the attending physician, all residents are encouraged to participate in activities.					
F244 3. The activities promote the physical, social and mental well being of the residents.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F245 4. Equipment is maintained in good working order. F246 5. Supplies and equipment for activities of interest are available. INTENT Each resident has individual and/or group activities to meet activities needs through his interests daily.	Is lighting adequate throughout the facility for activities in which residents are engaged? Do men and women have activities of interest to them? Do residents communicate with each other in activities? Are methods of communicating upcoming activities appropriate to the resident populations? Specific observation for physically impaired/alert residents: Activities adapted to meet specific needs of the resident. Alert residents have activities of interest and at their cognitive functional level. Specific observations for confused/disoriented, emotionally disturbed and mentally retarded residents: There are current calendars, clocks and patients	Ask Nursing/Activity Staff - Do they know the interests of residents under their care? TV programs they like? Activities they want to participate in today/this week? - Do they know the personal equipment needed (e.g., glasses, hearing aids, reacher)? - Do they know the adaptive equipment used by residents for specific activities (e.g., talking books, built up tools)? - Do they talk to residents to identify new interests and report these and "dislikes" to activities personnel? How? - What is staff's involvement with individual and group activities of residents in their care? - How do they determine interests of residents who have difficulty communicating? - What activities does resident participate in regularly? Which activities does he/she enjoy most/least?	Activities notes spell out implementation of plan, resident's reactions to specific activities, approaches, and people. Residents' participation in individual and group self-started and organized structured and unstructured activities timespent. Evaluation of plan of care for: changes in interests; changes in precautions, changes in needs, new problems, approaches, etc. Plans are revised as needed.	Are equipment and supplies to meet residents interests available and maintained in good working order? Are residents evaluated periodically with emphasis on participation levels and desire for new activities? Are plans readjusted if they do not reach desired outcomes? Residents in the facility more than 60 days should have at least two activities per week of interest to them personally.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F246 (cont'd)	and patients names or symbols visible to all the residents. Staff consistently use techniques such as reality orientation, empathy, and/or validation therapy as per each individual's needs. Resident has familiar items if available in room (e.g., family pictures, artwork, afghan, chair from home). Residents in restraints have activities of interest geared to their abilities when restrained (e.g., table-top activity, music, radio, reading and writing material; when out of restraints (e.g., walks, exercise, group, toileting). Small group and one-on-one involvement with staff reinforcing appropriate responses. Staff reaction to resident behavior during activities (e.g., crying, whining, demanding, non-verbal, agression,	- If he/she does not participate, why? - Which activities appear to relax/calm the resident? Excite him/her? - How does staff manage maladaptive behavior (e.g., abusive, disruptive, combative)? - Is direct care staff involved in resident activities? How? When (weekends, evenings)? - Does resident have one-to-one assistance in activities? - How many residents have few activities a day of interest to them as individuals? - Why do these residents have so little interest? - What is your plan to find more activities of interest to them that will meet their needs? - What types of residents seem not to be interested in activities? - How many (who) residents have only passive activities?			

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 246 (cont'd.)	loudness). Specific observation for comatose or terminally ill resident: - Appropriate items for sensory enrichment in room (e.g., TV, radio, adequate lighting) - Resident placed in supportive living environment (e.g., around people, in hall, activities room, sunshine, fresh air), when appropriate to the resident needs and consistent with the resident's choice. Specific observation of environment for conducting activity program: - Adequate lighting. - Functional area is appropriate for activities of interest (e.g., religious services, arts and crafts, cooking, reading, TV watching, card playing, parties, discussion groups, gardening).	- How do you adapt activities for needs of residents who are: - confused/disoriented - emotionally disturbed - mentally retarded - physically impaired but alert - terminally ill? - Are community volunteers utilized in the activities program? In what way? - Are the residents encouraged to offer suggestions for new activities? If so, what activities have been instituted as a result? - How they manage maladaptive behavior (e.g., abusive, disruptive, combative)? - How do they help depressed residents (e.g., tearful, emotionally labile)?		Resident may refuse to participate in activity. However if the activities are part of a diagnostic or therapeutic program, the resident is responsible for assisting in the selection of mutually acceptable alternative activities.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F246 (cont'd)	- Multi-purpose room use and timing of activities does not conflict. - Outdoor activity area. - Functional furniture, indoors and outdoors. - Evidence of free choice activities: - newspapers - magazines - record player - radios - games - TV's - reading - sewing - personal visits - church services - Activities, equipment and supplies are appropriate and sufficient to meet interest of residents. - Activities equipment and supplies sufficient for conducting activities. - Activities equipment clean, safe, and in working order. - Residents rooms contain independent project materials, as appropriate. - Residents have access to the total activity environment (e.g., lobby, sunroom, day-room, porch, dining room).				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
MEDICAL RECORDS					
F247 SNF 405.1132				All information required is present in the record. Does the record document all observable resident needs/problems?	
Content					
F248 SNF 405.1132(c)					
F249 ICF 442.318(a)(c)					
F250 1. The medical record contains sufficient information to identify the resident clearly to justify diagnoses and treatment and to document results accurately.					
F251 2. The medical record contains the following information.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F251 (cont'd) a. Identification information.					
F252 b. Admission data including past medical social history.					
F253 c. Transfer form, discharge summary from any transferring facility.					
F254 d. Report of resident's attending physician.					
F255 e. Report of physical examinations.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F256 f. Reports of physicians' periodic evaluations and progress notes.					
F257 g. Diagnostic reports and therapeutic orders.					
F258 h. Reports of treatments.					
F259 i. Medications administered.					
F260 j. An overall plan of care setting forth goals to be accomplished through each service's designed activities, therapies and treatments.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F261 k. Assessments and goals of each service's plan of care.					
F262 l. Treatments and services rendered.					
F263 m. Progress notes.					
F264 n. All symptoms and other indications of illness or injury including date, time and action taken regarding each problem.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F264 (cont'd) INTENT Brings together all resident information. Reflects the care being given to the residents and helps all care givers to make decisions on care needed.					
TRANSFER AGREEMENT F265 SNF 405.1133		Ask Staff: - What is the routine information you provide to a new facility when you transfer a resident? - Who provides this?	Review information on medical record of resident who was temporarily transferred and is again back in the facility.	All pertinent resident information must be documented on the medical record at the time of transfer.	Patient Rights 404.1121(k) 442.311
F266 SNF 405.1133(a)			Look at physician and nursing progress notes of above residents to determine if the timeliness of transfer was consistent with accepted standards of care.	The resident was not injured in any way by a delay in the transfer process.	
F267 ICF 442.316			Does facility have an agreement with a hospital? Not required if hospital under same ownership, direction and in same campus.		
F268 A. Whenever the physician determines that a transfer is medically appropriate between a					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F 268 (cont'd) hospital or a facility providing more specialized care and the nursing facility, admission to the new facility shall be effected in a timely manner.			Is transfer form complete with all data, with appropriate signatures? Does the medical record indicate that adequate and pertinent aspects of the discharge planning portion of the patient care plan accompany the patient on transfer?		
F269 B. Information necessary for providing care and treatment to transferred individuals is provided.					
PHYSICAL ENVIRONMENT F270 SNF 405.1134					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F271 A. Nursing Unit SNF 405.1134(d)				Medication preparation and storage areas provide adequate space and light to prepare medication and to store medication and needed supplies.	Nursing Service 405.1124(g) 442.337 Infection Control 405.1135
F272 1. Unit properly equipped for preparation and storage of drugs and biologicals.	There is adequate light to prepare medications. There is sufficient space to prepare medications for administration in a safe and effective manner.	Ask Nursing Staff: - What do you use the medication room (area) for? - Where is the handwashing sink? - Do you have enough, convenient storage area for I.V. fluids and medications needing refrigeration. - Where are the keys for the medication room and unit dose carts? - Do you feel you have adequate storage space for supplies and equipment? - If no, what problems does that cause? - Does the resident call system function properly? Ask Residents: - Do the call bells in your room and in the toilets and bathing areas always work?		Light is available when and where the medication cart is in use. A medication refrigerator is available and does not contain patient or employee snacks. Juice, etc., used in administering medication is allowed. Clean and dirty areas must be separated, preferably in separate rooms. Storage space must be available for bulky items and supplies so that they can be stored without blocking corridors and exits. Medications are protected from unauthorized use. Call bells must be in working order and must be present in all resident bedrooms, toilets and	Governing Body 442.325 Resident Rooms 405.1134(e) 442.325
F273 2. Utility and storage rooms are adequate size.	There is sufficient space for storage of medications. Unit dose carts are protected from tampering and theft.				
F274 3. The unit is equipped to register resident calls with a functioning communications system from resident areas including rooms and toilets and bathing facility.	Medications are stored in a locked area. Refrigeration facilities are available for medications. There is sufficient storage space for I.V. fluids. Handwashing facilities are readily accessible either in the medication preparation area or adjacent to it.				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE

F274 (cont'd)	Audible call system is on and working. Long cords are available for chair bound patients.	- If no:
		  - How often is it that they do not work?
		  - How long does it take to get them fixed?
				bathing areas.
				
				Audible signals, if in the system, must be in working order and turned on.	

B. Dining and activities area F275 SNF 405.1134(g) F276 ICF 442.329	Area is clean and well maintained. There is sufficient space between tables to allow for safe passage of wheelchairs and residents with walkers, canes and other assistive devices.	Ask Residents: - Is there enough room between tables to allow you to feel safe in getting to your table? - Can you sit comfortably in your wheelchair at the table? - How is the lighting and ventilation level for you? - Are sitting preferences permitted? - Do you go to the dining room for meals?		Regulations clearly set out conditions for compliance. Refer to the regulations.	Dietetic Services 405.1125 442.331 Patient Activities 405.1131 442.345
F277 1. The facility provides one or more clean, orderly, and appropriately furnished rooms of adequate size, designed for resident dining and resident activities.	Table height or design allows residents in wheelchairs to sit a normal distance from the table. Lighting and ventilation in the dining/activity areas is provided according to recommended standards. A multi-purpose room should not be used for storage of items such as beds, mattresses, boxes, etc.				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F278 2. Dining and activity rooms are well lighted and ventilated.	Are dining areas utilized at meal service?				
F279 3. Any multi-purpose room used for dining and resident activities has sufficient space to accommodate all activities and prevent their interference with each other.					
F280 SNF 405.1134(e) Indicators C&D apply to SNFs					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
C. Resident Rooms F281 ICF 442.325	Observe rooms and furnishings for maintenance, cleanliness and safety. Look for dust/dirt on lights, high surfaces, under heating units, and in corners. Use a flashlight.	Ask Residents: - Is your room kept clean? Who cleans it? When, and how often? - Is your bed, chair, and other furniture and fixtures kept in good repair? - Do you feel you have enough privacy? - What personal belongings are you allowed to have? - Is the lighting in your room sufficient for you? - Is your chair comfortable? - When do you permit staff to clean you room? - When do you ask staff not to clean you room?		Refer to the regulations.	Resident Rights 405.1121(k)(1)(5) (9)(13) 442.311(a)(d)(2) (g)(1)(2) (6)(k) Physical Environment 405.1134(d)(e) 442.326
F282 1. Single rooms have at least 100 sq. ft.	Are beds, lights, plumbing all in working order?				
F283 2. Multiple resident rooms have no more that 4 residents and at least 80 sq. feet per resident.	Observe for all regulatory requirements as noted to the left. Are privacy curtains present, and appropriate to maintain resident privacy?				
F284 3. Each room is equipped with or conveniently located near toilet and bathing facilities.	Test several call lights. Are call lights within reach, including emergency lights in toilets and bathing areas? Are toilet and bathing facilities appropriate in number, size, and design to meet resident needs? What personal belongings do residents have in their rooms? Is there				

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F285 4. There is a capability of maintaining privacy in each.	sufficient storage and security for their belongings?				
F286 5. There is adequate storage space for each resident.					
F287 6. There is a comfortable and functioning bed and chair, plus a functional cabinet and light.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F288 7. The resident call system functions in resident rooms.					
F289 8. Each room is designed and equipped for adequate nursing care and the comfort and privacy of residents.					
F290 9. Each room is at or above grade level.					
F291 10. Each room has direct access to a corridor and outside exposure. Exception: Not required for ICF residents.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
D. Toilet and bath facilities F292 ICF 442.326 F293 1. Facilities are clean, sanitary and free of odors.	Are there adequate numbers of toilets, baths, and showers for the residents that are accessible to, and functional for all residents? Are these conveniently located in or near resident rooms? Check for water on floors of bath and shower rooms.	Ask Residents: - When was your last bath? The one before? - What safety precautions are used for getting in and out of the bathtub? - What equipment is needed to get in and out of the tub, and how do you feel about it? - How do you get your wheelchair into the toilet or bathroom?	Bathing schedule for patients in your indepth review.	Privacy is maintained for residents in toilet and bathing areas. Toilet and bathing areas are clean. Water is removed from floors immediately upon completion of bathing. Hot water is within the acceptable temperature range.	
F294 2. Facilities have safe and comfortable hot water temperatures.	Is privacy provided? Are facilities clean, sanitary and free of unpleasant odors?	- When, if ever, do you refuse to be bathed?		Soap, toilet paper and towels are available in the bathrooms. Grab bars are present and securely fastened to the wall.	
F295 3. Facilities maintain privacy.	Are bathrooms equipped with soap, toilet tissue, towels, etc.? Hot water is between 110-120 degrees or the acceptable State level. Hot water temperature control must be maintained. Single use, disposable towels should be available for handwashing purposes.			Ventilation and lighting systems are correctly functioning.	
F296 4. Facilities have grab bars and other safe guards against slipping.	Note also condition of grab bars, plumbing and fixtures. Bath areas are not used for storage.			Plumbing and other fixtures are in good condition.	

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F297 5. Facilities have fixtures in good condition.					
F298 6. The resident call system functions in toilet and bath facilities.			Facility has appropriate arrangements for providing social services, either using: – outside resources (contract or consultant services) – qualified facility personnel under a clearly defined plan.	Refer to regulations.	
E. Social Service Area	Does the social worker have a locked file available?	Ask Resident: – Does the social worker see you in a private room or in your own room? – If in your own room, do you feel that you have enough privacy?			
F299 SNF 405.1130(b) ICF 442.344	Where are social service interviews and clerical functions performed?				
F300 1. Ensures privacy for social service interviewing.	Are rooms in areas easily accessible to residents?				
F301 2. Adequate space for clerical and interviewing functions is provided.					
F302 3. Facilities are easily accessible to residents and staff.					

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SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F. Therapy areas F303 SNF 405.1126(a)	Therapy areas are accessible to all residents needing the facilities. Space allows for safe maneuvering of residents and equipment and staff.	Ask Resident: - Do you feel that the equipment you use is safe? - Do you have enough room for your treatment? Ask Therapy Staff: - Is your equipment adequately maintained? - Do you have enough room to safely and adequately provide treatment?	Refer to regulations.		
F304 ICF 442.328(a)	All residents are able to be observed and supervised during therapy.				
F305 1. Space is adequate for proper use of equipment by all residents receiving treatment	Equipment has labels (stickers, etc.) to indicate proper maintenance. All equipment fastened to floor and walls is secure.				
G. Facilities for Special care F307 SNF 405.1134(f)	Are therapy areas properly ventilated to effectively reduce heat, moisture and odors? Are private rooms available that meet regulatory criteria.	Ask Supervisory personnel: - What room(s) do you use for isolation? - What is your procedure if the room is already occupied when you need it for isolation? - Will you show me the signs you use to identify the isolation room?		Rooms meeting the regulatory requirements are available in the facility. There is a procedure that is implemented when an isolation is needed, but it is already occupied.	Resident Rights 405.1121(k)(4) 442.311(c)(2) Infection Control 405.1135(b)
F308 ICF 442.328(b)	If a resident is infected and in isolation, are precautionary signs posted, and are they legible and understandable?			Isolation signs are visable and clearly convey their intended message.	

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F309 1. Single rooms with private toilet and handwashing facilities are available for isolating residents.					
F310 2. Precautionary signs are used to identify these rooms when in use.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
H. Common Resident Areas F311 SNF 405.1134(j)	Use senses - sight, hearing, olfactory when surveying common areas as lounges, lobby, corridors. Note levels of lighting for both reading and non-reading areas. Is it bright enough but without glare?	Ask Residents: - Do you think that the lounges and corridors are usually clean? - Do they have any unpleasant odors? - Is the lighting level comfortable for you to read? Is it adequate for you to feel safe walking?		- Floors and furniture should appear clean - free of gross contamination. - Residents should have lighting bright enough to safely negotiate corridors, lounges, etc., and in reading area, be bright enough to read. But the brightness should be free of glare. Remember, the elderly need a higher level of lighting as their sight diminishes.	Infection Control 405.1135(c)
F312 ICF 442.324	Are areas clean and without offensive odors? Do background sound levels allow for ease of communication and comfort for residents/visitors? Do residents seem comfortable with the room temperature - note the use of several layers of clothing, many residents fanning themselves, etc.	- Do you have any difficulty with the noise level? - Is the temperature usually comfortable for you? - Do you feel there is adequate ventilation? - Are there handrails in all of the corridors? - Are they securely fastened to the wall?		- Except for times when a louder level of sound is necessary for communication, sounds should be unobtrusive and "comfortable". - Room temperature comfort levels vary widely, and in general the elderly will require a higher temperature for comfort than younger people. Use information from resident interviews and your observations to determine if the temperature is "comfortable" for most residents. - All corridors in	
F313 1. All common resident areas are clean, sanitary and free of odors.					
F314 2. Provision is made for adequate and comfortable lighting levels in all areas.	Are handrails on each side of the corridor and are they secure? Are smoking/no smoking areas designated?	Ask Supervisory Staff: - If there is a water main break or other interruption in the water supply, how do you obtain water for essential areas and duties?			
F315 3. There is limitation of sounds at comfort levels.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F316 4. A comfortable room temperature is maintained.				resident-used areas are equipped with handrails on each side. These rails securely fastened provide the residents with a firm support. - Supervisory staff are able to tell you how they will obtain water for drinking, cleaning/ bathing of residents, and other essential functions if their normal water supply is interrupted.	
F317 5. There is adequate ventilation thru windows or mechanical measures or a combination of both.					
F318 6. Corridors are equipped with firmly secured handrails on each side.					
F319 7. Staff are aware of procedures to ensure water to all essential areas in the event of loss of normal supply.					Disaster Preparedness 405.1136 442.313

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
I. Maintenance of Building and Equipment F320 SNF 405.1134(i)	- Ceiling and floor tile in good condition - Paint in good repair - No holes in walls - Look for rat and other rodent trails outside and inside - Preventive maintenance program for all equipment is followed - Wheelchairs not stored in hallways, bathrooms, etc. - Window screens are in good repair - Check overbed tables, wheelchairs, etc., for cleanliness and operation	Ask Staff: - How many housekeeping staff are available? - How late are housekeepers on duty during the week? - How is weekend coverage different? Ask Resident: - What if any problems have you had with special equipment you need to use?			Physical Environment 405.1134(d)
F321 1. The interior and exterior of the building are clean and orderly.					
F322 2. All essential mechanical and electrical equipment is maintained in safe operating condition.					
F323 3. Sufficient storage space is available and used for equipment to ensure that the facility is orderly and safe.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F324 4. Resident care equipment is clean and maintained in safe operating condition.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Indicator J applies to ICFs. J. Dietetic Service Area F326 SNF 405.1134(h)	Observe for - needed space to carry out routine operations - maintenance of working surfaces equipment, utensils, and serving dishes	Ask Staff: - What have you been trained to do? - What type of dishwasher machine do you have? How does it operate?	The proper temperature for the Dishwasher wash cycle is 150-160 degrees Fahrenheit. The dishwasher rinse cycle is acceptable at temperature of 180 degrees Fahrenheit or when there is a change in the temperature-sensitive tape (thermolabel). The individual manufacturers' specifications may countermand these instructions, particulary in the case of chemical sanitization.		Dietetic Services 405.1125(g) 442.331(b)
F327 1. Kitchen and dietetic service areas are adequate to insure proper, timely service for all patients.	- operable dish washer machine. - 3-sink method of pot/dish washing properly carried out/or written procedure posted - operable and clean exhaust fan - stored dishes and pots are free of baked-on food particles and chipped/cracked surfaces				
F328 2. Kitchen areas are properly ventilated, arranged, and equipped for storage and preparation of food as well as for dish and utensil cleaning, and refuse storage and removal.	- food stored off floor - protective covers for fluorescent lights - handwashing sink readily accessible				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Indicator K applies to ICF K. Dieteary Staff Hygiene F329 SNF 405.1125(f)	Observe the following: - cleanliness of hands, fingernails, hair, clothing - use of hair restraint - whether employees wash hands with soap and water after using the toilet, smoking, blowing their nose, touching raw meat, poultry or eggs - employees using hands to mix food when utensils could be used - employees using the same spoon more than once for tasting food while preparing, cooking, or serving.	Ask Staff: - What happens when you report to work with a cold, a cut or sore on your hand? - Where is handwashing sink for dietary staff? - Do you use disposable plastic hand covers? If so, when? - Where are your serving utensils located? - What are temperatures for the refrigerators and freezers? Who is responsible for checking temperatures? - Do you have thermometers to check water and food temperatures? (ask them to demonstrate how they take temperatures)			Dietetic Services 405.1125(e)(f)(g)
F330 1. Dietetic service personnel practice hygenic food handling techniques.					
Indicator L applies to ICf L. Dietary Sanitary Conditions F331 SNF 405.1125(g)	Verify that: - hot foods are 140 degrees or above - cold foods are 45 degrees or lower (*note: food held for more than 2–3 hours between 60 and 125 degrees may not be safe to eat) - cooked meats held longer than 72 hours are used, discarded or put in the freezer				
F332 1. Food is stored, refrigerated, prepared, distributed, and served under sanitary conditions.					
F333 2. Waste is disposed of properly.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F333 (cont'd)	- check that the refrigerators are equipped with an accurate thermometer - food does not have an "off" or bad odor - cracked eggs are discarded - foods are dated and then stored as to their preparation date. Observe that waste is in covered containers, bagged and tied for disposal, and that dumpsters are covered.				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
L. Emergency Power F334 SNF 405.1134(b)	Is an emergency generator available? Test generator under full load conditions.			As per regulations and covered by the Life Safety Code surveyor	
F335 1. An emergency source of electrical power necessary to protect the health and safety of residents is available.	Check items of emergency power: - lighting - fire detection - alarms - extinguishing systems - life support systems Transfer time from normal power to emergency power to occur within 10 seconds.				
F336 2. Emergency power is adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life support systems.	Check for gounded extension cords at nurses stations. Where are emergency outlets?				

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F337 3. Emergency power is provided by an emergency generator located on the premises where life support systems are used.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
Infection Control F338 SNF 405.1135	- Observation of dressing technique to identify if infection control principles are being adhered to: - sterile technique - sterile/clean field - disposal of dressing - handwashing - use of gloves	Ask Staff: - What type of dressing changes are you performing? - How often are dressings changed? - Why is resident on isolation/precautions? - Do laundry/housekeeping personnel/aides know procedures?	Review records of residents selected for indepth review for infection.	Compliance will be based mainly on your observations. Deficiencies will be cited if you see: - breaks in aseptic or isolation technique - clutter or unclean conditions that would cause unsafe conditions - inadequate supplies of linen to provide proper care and comfort for residents - inadequate techniques for handling clean and dirty linen - evidence of insect or rodent infestation - use flash light to check for roaches in closets, cabinets.	Nursing Services 405.1124 442.338
A. Infection Control F339 SNF 405.1135(b)					
F340 Aseptic and isolation techniques are followed by all personnel.	- Observation of isolation precautions: - signs - linen, double bagged - soiled linen, double bagged - gowns/masks - gloves - handwashing - disposable dishes - information for visitors	Ask Resident: - Do you know why you have dressings? - Do you know why you are on isolation/precautions? - Do you have clean linen when you need it?			
B. Sanitation F341 SNF 405.1135(c)					
F342 The facility maintains a safe, clean, and orderly interior.	- Procedures followed by: - Laundry - Housekeeping How is dirty linen transported to laundry or holding area?				
C. Linen F343 SNF 405.1135(d)	Do aides wash hands after cleaning dirty linen? How do aides handle clean/dirty linen while changing beds?				

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F344 ICF 442.327					
F345 1. The facility has available at all times a quantity of linen essential for proper care and comfort of residents.					
F346 2. Linens are handled: stored, processed, and transported in such a manner as to prevent the spread of infection.					
D. Pest Control F347 SNF 405.1135(e)	Look for evidence of insect or rodent presence (mouse or rat droppings, roaches, ants, flies	Ask Staff: - Have you seen insects (roaches, ants, flies, etc.)?			
F348 ICF 442.315(c)	around trash) - Screen doors closed - Windows that can be opened have screens that are in good repair	- Have you seen rodents and/or droppings? - What foods are residents permitted to keep in their rooms?			
F349 The facility is maintained free from insects and rodents.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
DISASTER PREPAREDNESS F350 SNF 405.1136 F351 SNF 405.1136(a) F352 ICF 442.313	- Disaster plan is located at each nursing station. - Evacuation plans posted in each smoke compartment.	Ask Residents: - Do you know what to do in case of fire? - How often do you rehearse it? Ask Staff: - What are your responsibilities at a fire drill? - What is the facilities disaster plan? (Specify types, [(e.g., fire, flood, etc.)] - How you undergone disaster training? - Have you participated in a fire disaster drill? When? - How frequently are drills held? - Have you been trained/ instructed in the use of fire equipment, fire containment methods? - Have you been trained in transfer or casualties and routes? - How would staff meet emotional needs of residents during/following a "disaster", e.g., fire		A disaster plan is available and facility staff know their roles.	Physical Environment 405.1134(a)(b) 442.321
Indicators A and B apply to ICFs.					
A. Disaster Plan					
F353 1. Facility staff are aware of plans, procedures to be followed for fire, explosion, or other disaster.					
F354 2. Facility staff are knowledgeable about evacuation routes.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F355 3. Facility staff are aware of their specific responsibilities in regard to evaluation and protection of residents.					
F356 4. Facility staff are aware of methods of containing fire.					
B. Drills F357 SNF 405.1136(b)					
F358 1. All employees are trained as part of their employment orientation in all aspects of preparedness for any disaster.					

LONG TERM CARE SURVEY

SURVEY AREA	OBSERVATION	INTERVIEWING	RECORD REVIEW	EVALUATION FACTORS	CROSS REFERENCE
F359 2. Facility staff participate in ongoing training and drills in all procedures so that each employee promtly and correctly carries out a specific role in case of a disaster. INTENT To ensure a clean, safe environment for residents.					

Subpart D—Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs

SOURCE: 57 FR 34012, July 31, 1992, unless otherwise noted.

§ 488.201 Reconsideration.

(a) *Right to reconsideration.* (1) A national accreditation organization dissatisfied with a determination that its accreditation requirements do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements is entitled to a reconsideration as provided in this subpart.

(2) A State dissatisfied with a determination that the requirements it imposes on laboratories in that State and under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements is entitled to a reconsideration as provided in this subpart.

(b) *Eligibility for reconsideration.* CMS will reconsider any determination to deny, remove or not renew the approval of deeming authority to private accreditation organizations, or any determination to deny, remove or not renew the approval of a State laboratory program for the purpose of exempting the State's laboratories from CLIA requirements, if the accreditation organization or State files a written request for a reconsideration in accordance with paragraphs (c) and (d) of this section.

(c) *Manner and timing of request for reconsideration.* (1) A national accreditation organization or a State laboratory program described in paragraph (b), dissatisfied with a determination with respect to its deeming authority, or, in the case of a State, a determination with respect to the exemption of the laboratories in the State from CLIA requirements, may request a reconsideration of the determination by filing a request with CMS either directly by its authorized officials or through its legal representative. The request must be filed within 60 days of the receipt of notice of an adverse determination or nonrenewal as provided in subpart A of part 488 or subpart E of part 493, as applicable.

(2) Reconsideration procedures are available after the effective date of the decision to deny, remove, or not renew the approval of an accreditation organization or State laboratory program.

(d) *Content of request.* The request for reconsideration must specify the findings or issues with which the accreditation organization or State disagrees and the reasons for the disagreement.

[57 FR 34012, July 31, 1992, as amended at 58 FR 61843, Nov. 23, 1993]

§ 488.203 Withdrawal of request for reconsideration.

A requestor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

§ 488.205 Right to informal hearing.

In response to a request for reconsideration, CMS will provide the accreditation organization or the State laboratory program the opportunity for an informal hearing as described in § 488.207 that will—

(a) Be conducted by a hearing officer appointed by the Administrator of CMS; and

(b) Provide the accreditation organization or State laboratory program the opportunity to present, in writing or in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew deeming authority or the exemption of a State's laboratories from CLIA requirements.

§ 488.207 Informal hearing procedures.

(a) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(b) The informal reconsideration hearing will be conducted in accordance with the following procedures—

(1) The hearing is open to CMS and the organization requesting the reconsideration, including—

(i) Authorized representatives;

(ii) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts); and

(iii) Legal counsel;

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action;

(3) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissable under the usual rules of court procedures;

(4) Either party may call witnesses from among those individuals specified in paragraph (b)(1) of this section; and

(5) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

§ 488.209 Hearing officer's findings.

(a) Within 30 days of the close of the hearing, the hearing officer will present the findings and recommendations to the accreditation organization or State laboratory program that requested the reconsideration.

(b) The written report of the hearing officer will include—

(1) Separate numbered findings of fact; and

(2) The legal conclusions of the hearing officer.

§ 488.211 Final reconsideration determination.

(a) The hearing officer's decision is final unless the Administrator, within 30 days of the hearing officer's decision, chooses to review that decision.

(b) The Administrator may accept, reject or modify the hearing officer's findings.

(c) Should the Administrator choose to review the hearing officer's decision, the Administrator will issue a final reconsideration determination to the accreditation organization or State laboratory program on the basis of the hearing officer's findings and recommendations and other relevant information.

(d) The reconsideration determination of the Administrator is final.

(e) A final reconsideration determination against an accreditation organization or State laboratory program will be published by CMS in the FEDERAL REGISTER.

Subpart E—Survey and Certification of Long-Term Care Facilities

SOURCE: 59 FR 56238, Nov. 10, 1994, unless otherwise noted.

§ 488.300 Statutory basis.

Sections 1819 and 1919 of the Act establish requirements for surveying SNFs and NFs to determine whether they meet the requirements for participation in the Medicare and Medicaid programs.

§ 488.301 Definitions.

As used in this subpart—

Abbreviated standard survey means a survey other than a standard survey that gathers information primarily through resident-centered techniques on facility compliance with the requirements for participation. An abbreviated standard survey may be premised on complaints received; a change of ownership, management, or director of nursing; or other indicators of specific concern.

Abuse means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish.

Deficiency means a SNF's or NF's failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.

Dually participating facility means a facility that has a provider agreement in both the Medicare and Medicaid programs.

Extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during a standard survey.

Facility means a SNF or NF, or a distinct part SNF or NF, in accordance with § 483.5 of this chapter.

Immediate family means husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild.

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Misappropriation of resident property means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

Neglect means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

Noncompliance means any deficiency that causes a facility to not be in substantial compliance.

Nurse aide means an individual, as defined in § 483.75(e)(1) of this chapter.

Nursing facility (NF) means a Medicaid nursing facility.

Paid feeding assistant means an individual who meets the requirements specified in § 483.35(h)(2) of this chapter and who is paid to feed residents by a facility, or who is used under an arrangement with another agency or organization.

Partial extended survey means a survey that evaluates additional participation requirements subsequent to finding substandard quality of care during an abbreviated standard survey.

Skilled nursing facility (SNF) means a Medicare nursing facility.

Standard survey means a periodic, resident-centered inspection which gathers information about the quality of service furnished in a facility to determine compliance with the requirements for participation.

Substandard quality of care means one or more deficiencies related to participation requirements under § 483.13, Resident behavior and facility practices, § 483.15, Quality of life, or § 483.25, Quality of care of this chapter, which constitute either immediate jeopardy to resident health or safety; a pattern of or widespread actual harm that is not immediate jeopardy; or a widespread potential for more than minimal harm, but less than immediate jeopardy, with no actual harm.

Substantial compliance means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

Validation survey means a survey conducted by the Secretary within 2 months following a standard survey, abbreviated standard survey, partial extended survey, or extended survey for the purpose of monitoring State survey agency performance.

[59 FR 56238, Nov. 10, 1994, as amended at 68 FR 55539, Sept. 26, 2003]

§ 488.303 State plan requirement.

(a) A State plan must provide that the requirements of this subpart and subpart F of this part are met, to the extent that those requirements apply to the Medicaid program.

(b) A State may establish a program to reward, through public recognition, incentive payments, or both, nursing facilities that provide the highest quality care to Medicaid residents. For purposes of section 1903(a)(7) of the Social Security Act, proper expenses incurred by a State in carrying out such a program are considered to be expenses necessary for the proper and efficient administration of the State plan.

(c) A State must conduct periodic educational programs for the staff and residents (and their representatives) of NFs in order to present current regulations, procedures, and policies under this subpart and subpart F of this part.

(d) Required remedies for a non-State operated NF. A State must establish, in addition to termination of the provider agreement, the following remedies or an approved alternative to the following remedies for imposition against a non-State operated NF:

(1) Temporary management.

(2) Denial of payment for new admissions.

(3) Civil money penalties.

(4) Transfer of residents.

(5) Closure of the facility and transfer of residents.

(6) State monitoring.

(e) Optional remedies for a non-State operated NF. A State may establish the following remedies for imposition against a non-State operated NF:

(1) Directed plan of correction.

(2) Directed in-service training.

(3) Alternative or additional State remedies.

(f) Alternative or additional State remedies. If a State uses remedies that are in addition to those specified in paragraph (d) or (e) of this section, or alternative to those specified in paragraph (d) of this section (other than termination of participation), it must—

(1) Specify those remedies in the State plan; and

(2) Demonstrate to CMS's satisfaction that those alternative remedies are as effective in deterring noncompliance and correcting deficiencies as the remedies listed in paragraphs (d) and (e) of this section.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.305 Standard surveys.

(a) For each SNF and NF, the State survey agency must conduct standard surveys that include all of the following:

(1) A case-mix stratified sample of residents;

(2) A survey of the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and the physical environment;

(3) An audit of written plans of care and residents' assessments to determine the accuracy of such assessments and the adequacy of such plans of care; and

(4) A review of compliance with residents' rights requirements set forth in sections 1819(c) and 1919(c) of the Act.

(b) The State survey agency's failure to follow the procedures set forth in this section will not invalidate otherwise legitimate determinations that a facility's deficiencies exist.

§ 488.307 Unannounced surveys.

(a) *Basic rule.* All standard surveys must be unannounced.

(b) *Review of survey agency's scheduling and surveying procedures.* (1) CMS reviews on an annual basis each State survey agency's scheduling and surveying procedures and practices to ensure that survey agencies avoid giving notice of a survey through the scheduling procedures and the conduct of the surveys.

(2) CMS takes corrective action in accordance with the nature and complexity of the problem when survey agencies are found to have notified a SNF or NF through their scheduling or procedural policies. Sanctions for inadequate survey performance are in accordance with § 488.320.

(c) *Civil money penalties.* An individual who notifies a SNF or NF, or causes a SNF or NF to be notified, of the time or date on which a standard survey is scheduled to be conducted is subject to a Federal civil money penalty not to exceed $2,000.

§ 488.308 Survey frequency.

(a) *Basic period.* The survey agency must conduct a standard survey of each SNF and NF not later than 15 months after the last day of the previous standard survey.

(b) *Statewide average interval.* (1) The statewide average interval between standard surveys must be 12 months or less, computed in accordance with paragraph (d) of this section.

(2) CMS takes corrective action in accordance with the nature of the State survey agency's failure to ensure that the 12-month statewide average interval requirement is met. CMS's corrective action is in accordance with § 488.320.

(c) *Other surveys.* The survey agency may conduct a survey as frequently as necessary to—

(1) Determine whether a facility complies with the participation requirements; and

(2) Confirm that the facility has corrected deficiencies previously cited.

(d) *Computation of statewide average interval.* The statewide average interval is computed at the end of each Federal fiscal year by comparing the last day of the most recent standard survey for each participating facility to the last day of each facility's previous standard survey.

(e) *Special surveys.* (1) The survey agency may conduct a standard or an abbreviated standard survey to determine whether certain changes have caused a decline in the quality of care furnished by a SNF or a NF, within 60 days of a change in the following:

(i) Ownership;

(ii) Entity responsible for management of a facility (management firm);

(iii) Nursing home administrator; or

(iv) Director of nursing.

(2) The survey agency must review all complaint allegations and conduct a standard or an abbreviated standard survey to investigate complaints of violations of requirements by SNFs and NFs if its review of the allegation concludes that—

(i) A deficiency in one or more of the requirements may have occurred; and

(ii) Only a survey can determine whether a deficiency or deficiencies exist.

(3) The survey agency does not conduct a survey if the complaint raises issues that are outside the purview of Federal participation requirements.

§ 488.310 Extended survey.

(a) *Purpose of survey.* The purpose of an extended survey is to identify the policies and procedures that caused the facility to furnish substandard quality of care.

(b) *Scope of extended survey.* An extended survey includes all of the following:

(1) Review of a larger sample of resident assessments than the sample used in a standard survey.

(2) Review of the staffing and in-service training.

(3) If appropriate, examination of the contracts with consultants.

(4) A review of the policies and procedures related to the requirements for which deficiencies exist.

(5) Investigation of any participation requirement at the discretion of the survey agency.

(c) *Timing and basis for survey.* The survey agency must conduct an extended survey not later than 14 calendar days after completion of a standard survey which found that the facility had furnished substandard quality of care.

§ 488.312 Consistency of survey results.

CMS does and the survey agency must implement programs to measure accuracy and improve consistency in the application of survey results and enforcement remedies.

§ 488.314 Survey teams.

(a) *Team composition.* (1) Surveys must be conducted by an interdisciplinary team of professionals, which must include a registered nurse.

(2) Examples of professionals include, but are not limited to, physicians, physician assistants, nurse practitioners, physical, speech, or occupational therapists, registered professional nurses, dieticians, sanitarians, engineers, licensed practical nurses, or social workers.

(3) The State determines what constitutes a professional, subject to CMS approval.

(4) Any of the following circumstances disqualifies a surveyor for surveying a particular facility:

(i) The surveyor currently works, or, within the past two years, has worked as an employee, as employment agency staff at the facility, or as an officer, consultant, or agent for the facility to be surveyed.

(ii) The surveyor has any financial interest or any ownership interest in the facility.

(iii) The surveyor has an immediate family member who has a relationship with a facility described in paragraphs (a)(4)(i) or paragraph (a)(4)(ii) of this section.

(iv) The surveyor has an immediate family member who is a resident in the facility to be surveyed. For purposes of this section, an immediate family member is defined at § 488.301 of this part.

(b) *CMS training.* CMS provides comprehensive training to surveyors, including at least the following:

(1) Application and interpretation of regulations for SNFs and NFs.

(2) Techniques and survey procedures for conducting standard and extended surveys.

(3) Techniques for auditing resident assessments and plans of care.

(c) *Required surveyor training.* (1) Except as specified in paragraph (c)(3) of

this section, the survey agency may not permit an individual to serve as a member of a survey team unless the individual has successfully completed a training and testing program prescribed by the Secretary.

(2) The survey agency must have a mechanism to identify and respond to in-service training needs of the surveyors.

(3) The survey agency may permit an individual who has not completed a training program to participate in a survey as a trainee if accompanied onsite by a surveyor who has successfully completed the required training and testing program.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.318 Inadequate survey performance.

(a) CMS considers survey performance to be inadequate if the State survey agency—

(1) Indicates a pattern of failure to—

(i) Identify deficiencies and the failure cannot be explained by changed conditions in the facility or other case specific factors;

(ii) Cite only valid deficiencies;

(iii) Conduct surveys in accordance with the requirements of this subpart; or

(iv) Use Federal standards, protocols, and the forms, methods and procedures specified by CMS in manual instructions; or

(2) Fails to identify an immediate jeopardy situation.

(b) Inadequate survey performance does not—

(1) Relieve a SNF or NF of its obligation to meet all requirements for program participation; or

(2) Invalidate adequately documented deficiencies.

§ 488.320 Sanctions for inadequate survey performance.

(a) *Annual assessment of survey performance.* CMS assesses the performance of the State's survey and certification program annually.

(b) *Sanctions for inadequate survey performance.* When a State demonstrates inadequate survey performance, as specified in § 488.318, CMS notifies the survey agency of the inadequacy and takes action in accordance with paragraphs (c) and (d) of this section.

(c) *Medicaid facilities.* (1) For a pattern of failure to identify deficiencies in Medicaid facilities, CMS—

(i) Reduces FFP, as specified in paragraph (e) of this section, and if appropriate;

(ii) Provides for training of survey teams.

(2) For other survey inadequacies in Medicaid facilities, CMS provides for training of survey teams.

(d) *Medicare facilities.* For all survey inadequacies in Medicare facilities, CMS—

(1) Requires that the State survey agency submit a plan of correction;

(2) Provides for training of survey teams;

(3) Provides technical assistance on scheduling and procedural policies;

(4) Provides CMS-directed scheduling; or

(5) Initiates action to terminate the agreement between the Secretary and the State under section 1864 of the Act, either in whole or in part.

(e) *Reduction of FFP.* In reducing FFP for inadequate survey performance, CMS uses the formula specified in section 1919(g)(3)(C) of the Act, that is 33 percent multiplied by a fraction—

(1) The numerator of which is equal to the total number of residents in the NFs that CMS found to be noncompliant during validation surveys for that quarter; and

(2) The denominator of which is equal to the total number of residents in the NFs in which CMS conducted validation surveys during that quarter.

(f) *Appeal of FFP reduction.* When a State is dissatisfied with CMS's determination to reduce FFP, the State may appeal the determination to the Departmental Appeals Board, using the procedures specified in 45 CFR part 16.

§ 488.325 Disclosure of results of surveys and activities.

(a) *Information which must be provided to public.* As provided in sections 1819(g)(5) and 1919(g)(5) of the Act, the following information must be made available to the public, upon the public's request, by the State or CMS for all surveys and certifications of SNFs and NFs:

(1) Statements of deficiencies and providers' comments.

(2) A list of isolated deficiencies that constitute no actual harm, with the potential for minimal harm.

(3) Approved plans of correction.

(4) Statements that the facility did not submit an acceptable plan of correction or failed to comply with the conditions of imposed remedies.

(5) Final appeal results.

(6) Notice of termination of a facility.

(7) Medicare and Medicaid cost reports.

(8) Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in § 420.201 of this chapter.

(9) Names of individuals with direct or indirect ownership interest in a SNF or NF, as defined in § 420.201 of this chapter, who have been found guilty by a court of law of a criminal offense in violation of Medicare or Medicaid law.

(b) *Charge to public for information.* CMS and the State may charge the public for specified services with respect to requests for information in accordance with—

(1) Section 401.140 of this chapter, for Medicare; or

(2) State procedures, for Medicaid.

(c) *How public can request information.* The public may request information in accordance with disclosure procedures specified in 45 CFR part 5.

(d) *When information must be disclosed.* The disclosing agency must make available to the public, upon the public's request, information concerning all surveys and certifications of SNFs and NFs, including statements of deficiencies, separate listings of any isolated deficiencies that constitute no actual harm, with the potential for minimal harm, and plans of correction (which contain any provider response to the deficiency statement) within 14 calendar days after each item is made available to the facility.

(e) *Procedures for responding to requests.* The procedures and time periods for responding to requests are in accordance with—

(1) Section 401.136 of this chapter for documents maintained by CMS; and

(2) State procedures for documents maintained by the State.

(f) *Information that must be provided to the State's long-term care ombudsman.* The State must provide the State's long-term care ombudsman with the following:

(1) A statement of deficiencies reflecting facility noncompliance, including a separate list of isolated deficiencies that constitute no harm with the potential for minimal harm.

(2) Reports of adverse actions specified at § 488.406 imposed on a facility.

(3) Written response by the provider.

(4) A provider's request for an appeal and the results of any appeal.

(g) *Information which must be provided to State by a facility with substandard quality of care.* (1) To provide for the notice to physicians required under sections 1819(g)(5)(C) and 1919(g)(5)(C) of the Act, not later than 10 working days after receiving a notice of substandard quality of care, a SNF or NF must provide the State with a list of—

(i) Each resident in the facility with respect to which such finding was made; and

(ii) The name and address of his or her attending physician.

(2) Failure to disclose the information timely will result in termination of participation or imposition of alternative remedies.

(h) *Information the State must provide to attending physician and State board.* Not later than 20 calendar days after a SNF or NF complies with paragraph (g) of this section, the State must provide written notice of the noncompliance to—

(1) The attending physician of each resident in the facility with respect to which a finding of substandard quality of care was made; and

(2) The State board responsible for licensing the facility's administrator.

(i) *Access to information by State Medicaid fraud control unit.* The State must provide access to any survey and certification information incidental to a SNF's or NF's participation in Medicare or Medicaid upon written request by the State Medicaid fraud control unit established under part 1007, of this title, consistent with current State laws.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.330 Certification of compliance or noncompliance.

(a) *General rules*—(1) *Responsibility for certification.* (i) The State survey agency surveys all facilities for compliance or noncompliance with requirements for long term care facilities. The survey by the State survey agency may be followed by a Federal validation survey.

(A) The State certifies the compliance or noncompliance of non-State operated NFs. Regardless of the State entity doing the certification, it is final, except in the case of a complaint or validation survey conducted by CMS, or CMS review of the State's findings.

(B) CMS certifies the compliance or noncompliance of all State-operated facilities.

(C) The State survey agency certifies the compliance or noncompliance of a non-State operated SNF, subject to the approval of CMS.

(D) The State survey agency certifies compliance or noncompliance for a dually participating SNF/NF. In the case of a disagreement between CMS and the State survey agency, a finding of noncompliance takes precedence over that of compliance.

(ii) In the case of a validation survey, the Secretary's determination as to the facility's noncompliance is binding, and takes precedence over a certification of compliance resulting from the State survey.

(2) *Basis for certification.* (i) Certification by the State is based on the survey agency findings.

(ii) Certification by CMS is based on either the survey agency findings (in the case of State-operated facilities), or, in the case of a validation survey, on CMS's own survey findings.

(b) *Effect of certification*—(1) *Certification of compliance.* A certification of compliance constitutes a determination that the facility is in substantial compliance and is eligible to participate in Medicaid as a NF, or in Medicare as a SNF, or in Medicare and Medicaid as a dually participating facility.

(2) *Certification of noncompliance.* A certification of noncompliance requires denial of participation for prospective providers and enforcement action for current providers in accordance with subpart F of this part. Enforcement action must include one of the following:

(i) Termination of any Medicare or Medicaid provider agreements that are in effect.

(ii) Application of alternative remedies instead of, or in addition to, termination procedures.

(c) *Notice of certification of noncompliance and resulting action.* The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f), and resulting action is issued by CMS, except when the State is taking the action for a non-State operated NF.

(d) *Content of notice of certification of noncompliance.* The notice of certification of noncompliance is sent in accordance with the timeframes specified in § 488.402(f) and includes information on all of the following:

(1) Nature of noncompliance.

(2) Any alternative remedies to be imposed under subpart F of this part.

(3) Any termination or denial of participation action to be taken under this part.

(4) The appeal rights available to the facility under this part.

(5) Timeframes to be met by the provider and certifying agency with regard to each of the enforcement actions or appeal procedures addressed in the notice.

(e) *Appeals.* (1) Notwithstanding any provision of State law, the State must impose remedies promptly on any provider of services participating in the Medicaid program—

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may be requested by the provider of services.

(2) CMS imposes remedies promptly on any provider of services participating in the Medicare or Medicaid program or any provider of services participating in both the Medicare and Medicaid programs—

(i) After promptly notifying the facility of the deficiencies and impending remedy or remedies; and

(ii) Except for civil money penalties, during any pending hearing that may

be requested by the provider of services.

(3) The provisions of part 498 of this chapter apply when the following providers request a hearing on a denial of participation, or certification of noncompliance leading to an enforcement remedy (including termination of the provider agreement), except State monitoring:

(i) All State-operated facilities;

(ii) SNFs and dually participating SNF/NFs; and

(iii) Any other facilities subject to a CMS validation survey or CMS review of the State's findings.

(4) The provisions of part 431 of this chapter apply when a non-State operated Medicaid NF, which has not received a CMS validation survey or CMS review of the State's findings, requests a hearing on the State's denial of participation, termination of provider agreement, or certification of noncompliance leading to an alternative remedy, except State monitoring.

(f) *Provider agreements.* CMS or the Medicaid agency may execute a provider agreement when a prospective provider is in substantial compliance with all the requirements for participation for a SNF or NF, respectively.

(g) *Special rules for Federal validation surveys.* (1) CMS may make independent certifications of a NF's, SNF's, or dually participating facility's noncompliance based on a CMS validation survey.

(2) CMS issues the notice of actions affecting facilities for which CMS did validation surveys.

(3) For non-State-operated NFs and non-State-operated dually participating facilities, any disagreement between CMS and the State regarding the timing and choice of remedies is resolved in accordance with § 488.452.

(4) Either CMS or the survey agency, at CMS's option, may revisit the facility to ensure that corrections are made.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.331 Informal dispute resolution.

(a) *Opportunity to refute survey findings.* (1) For non-Federal surveys, the State must offer a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(2) For Federal surveys, CMS offers a facility an informal opportunity, at the facility's request, to dispute survey findings upon the facility's receipt of the official statement of deficiencies.

(b)(1) Failure of the State or CMS, as appropriate, to complete informal dispute resolution timely cannot delay the effective date of any enforcement action against the facility.

(2) A facility may not seek a delay of any enforcement action against it on the grounds that informal dispute resolution has not been completed before the effective date of the enforcement action.

(c) If a provider is subsequently successful, during the informal dispute resolution process, at demonstrating that deficiencies should not have been cited, the deficiencies are removed from the statement of deficiencies and any enforcement actions imposed solely as a result of those cited deficiencies are rescinded.

(d) *Notification.* Upon request, CMS does and the State must provide the facility with written notification of the informal dispute resolution process.

§ 488.332 Investigation of complaints of violations and monitoring of compliance.

(a) *Investigation of complaints.* (1) The State survey agency must establish procedures and maintain adequate staff to investigate complaints of violations of participation requirements.

(2) The State survey agency takes appropriate precautions to protect a complainant's anonymity and privacy, if possible.

(3) If arrangements have been made with other State components for investigation of complaints, the State must have a means of communicating information among appropriate entities, and the State survey agency retains responsibility for the investigation process.

(4) If, after investigating a complaint, the State has reason to believe that an identifiable individual neglected or abused a resident, or misappropriated a resident's property, the

State survey agency must act on the complaint in accordance with § 488.335.

(b) *On-site monitoring.* The State survey agency conducts on-site monitoring on an as necessary basis when—

(1) A facility is not in substantial compliance with the requirements and is in the process of correcting deficiencies;

(2) A facility has corrected deficiencies and verification of continued substantial compliance is needed; or

(3) The survey agency has reason to question the substantial compliance of the facility with a requirement of participation.

(c) *Composition of the investigative team.* A State may use a specialized team, which may include an attorney, auditor and appropriate health professionals, to identify, survey, gather and preserve evidence, and administer remedies to noncompliant facilities.

§ 488.334 Educational programs.

A State must conduct periodic educational programs for the staff and residents (and their representatives) of SNFs and NFs in order to present current regulations, procedures, and policies on the survey, certification and enforcement process under this subpart and subpart F of this part.

§ 488.335 Action on complaints of resident neglect and abuse, and misappropriation of resident property.

(a) *Investigation.* (1) The State must review all allegations of resident neglect and abuse, and misappropriation of resident property and follow procedures specified in § 488.332.

(2) If there is reason to believe, either through oral or written evidence that an individual used by a facility to provide services to residents could have abused or neglected a resident or misappropriated a resident's property, the State must investigate the allegation.

(3) The State must have written procedures for the timely review and investigation of allegations of resident abuse and neglect, and misappropriation of resident property.

(b) *Source of complaints.* The State must review all allegations regardless of the source.

(c) *Notification*—(1) *Individuals to be notified.* If the State makes a preliminary determination, based on oral or written evidence and its investigation, that the abuse, neglect or misappropriation of property occurred, it must notify in writing—

(i) The individuals implicated in the investigation; and

(ii) The current administrator of the facility in which the incident occurred.

(2) *Timing of the notice.* The State must notify the individuals specified in paragraph (c)(1) of this section in writing within 10 working days of the State's investigation.

(3) *Contents of the notice.* The notice must include the—

(i) Nature of the allegation(s);

(ii) Date and time of the occurrence;

(iii) Right to a hearing;

(iv) Intent to report the substantiated findings in writing, once the individual has had the opportunity for a hearing, to the nurse aide registry or appropriate licensure authority;

(v) Fact that the individual's failure to request a hearing in writing within 30 days from the date of the notice will result in reporting the substantiated findings to the nurse aide registry or appropriate licensure authority.

(vi) Consequences of waiving the right to a hearing;

(vii) Consequences of a finding through the hearing process that the alleged resident abuse or neglect, or misappropriation of resident property did occur; and

(viii) Fact that the individual has the right to be represented by an attorney at the individual's own expense.

(d) *Conduct of hearing.* (1) The State must complete the hearing and the hearing record within 120 days from the day it receives the request for a hearing.

(2) The State must hold the hearing at a reasonable place and time convenient for the individual.

(e) *Factors beyond the individual's control.* A State must not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(f) *Report of findings.* If the finding is that the individual has neglected or abused a resident or misappropriated resident property or if the individual waives the right to a hearing, the State

must report the findings in writing within 10 working days to—

(1) The individual;

(2) The current administrator of the facility in which the incident occurred; and

(3) The administrator of the facility that currently employs the individual, if different than the facility in which the incident occurred;

(4) The licensing authority for individuals used by the facility other than nurse aides, if applicable; and

(5) The nurse aide registry for nurse aides. Only the State survey agency may report the findings to the nurse aide registry, and this must be done within 10 working days of the findings, in accordance with § 483.156(c) of this chapter. The State survey agency may not delegate this responsibility.

(g) *Contents and retention of report of finding to the nurse aide registry.* (1) The report of finding must include information in accordance with § 483.156(c) of this chapter.

(2) The survey agency must retain the information as specified in paragraph (g)(1) of this section, in accordance with the procedures specified in § 483.156(c) of this chapter.

(h) *Survey agency responsibility.* (1) The survey agency must promptly review the results of all complaint investigations and determine whether or not a facility has violated any requirements in part 483, subpart B of this chapter.

(2) If a facility is not in substantial compliance with the requirements in part 483, subpart B of this chapter, the survey agency initiates appropriate actions, as specified in subpart F of this part.

[59 FR 56238, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

Subpart F—Enforcement of Compliance for Long-Term Care Facilities with Deficiencies

SOURCE: 59 FR 56243, Nov. 10, 1994, unless otherwise noted.

§ 488.400 Statutory basis.

Sections 1819(h) and 1919(h) of the Act specify remedies that may be used by the Secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any others available under State or Federal law, and, except for civil money penalties, are imposed prior to the conduct of a hearing.

§ 488.401 Definitions.

As used in this subpart—

New admission means a resident who is admitted to the facility on or after the effective date of a denial of payment remedy and, if previously admitted, has been discharged before that effective date. Residents admitted before the effective date of the denial of payment, and taking temporary leave, are not considered new admissions, nor subject to the denial of payment.

Plan of correction means a plan developed by the facility and approved by CMS or the survey agency that describes the actions the facility will take to correct deficiencies and specifies the date by which those deficiencies will be corrected.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.402 General provisions.

(a) *Purpose of remedies.* The purpose of remedies is to ensure prompt compliance with program requirements.

(b) *Basis for imposition and duration of remedies.* When CMS or the State chooses to apply one or more remedies specified in § 488.406, the remedies are applied on the basis of noncompliance found during surveys conducted by CMS or by the survey agency.

(c) *Number of remedies.* CMS or the State may apply one or more remedies for each deficiency constituting noncompliance or for all deficiencies constituting noncompliance.

(d) *Plan of correction requirement.* (1) Except as specified in paragraph (d)(2) of this section, regardless of which remedy is applied, each facility that has deficiencies with respect to program requirements must submit a plan of correction for approval by CMS or the survey agency.

(2) *Isolated deficiencies.* A facility is not required to submit a plan of correction when it has deficiencies that are isolated and have a potential for minimal harm, but no actual harm has occurred.

(e) *Disagreement regarding remedies.* If the State and CMS disagree on the decision to impose a remedy, the disagreement is resolved in accordance with § 488.452.

(f) *Notification requirements*—(1) Except when the State is taking action against a non-State operated NF, CMS or the State (as authorized by CMS) gives the provider notice of the remedy, including the—

(i) Nature of the noncompliance;

(ii) Which remedy is imposed;

(iii) Effective date of the remedy; and

(iv) Right to appeal the determination leading to the remedy.

(2) When a State is taking action against a non-State operated NF, the State's notice must include the same information required by CMS in paragraph (f)(1) of this section.

(3) *Immediate jeopardy—2 day notice.* Except for civil money penalties and State monitoring imposed when there is immediate jeopardy, for all remedies specified in § 488.406 imposed when there is immediate jeopardy, the notice must be given at least 2 calendar days before the effective date of the enforcement action.

(4) *No immediate jeopardy—15 day notice.* Except for civil money penalties and State monitoring, notice must be given at least 15 calendar days before the effective date of the enforcement action in situations in which there is no immediate jeopardy.

(5) *Date of enforcement action.* The 2- and 15-day notice periods begin when the facility receives the notice.

(6) *Civil money penalties.* For civil money penalties, the notices must be given in accordance with the provisions of §§ 488.434 and 488.440.

(7) *State monitoring.* For State monitoring, no prior notice is required.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.404 Factors to be considered in selecting remedies.

(a) *Initial assessment.* In order to select the appropriate remedy, if any, to apply to a facility with deficiencies, CMS and the State determine the seriousness of the deficiencies.

(b) *Determining seriousness of deficiencies.* To determine the seriousness of the deficiency, CMS considers and the State must consider at least the following factors:

(1) Whether a facility's deficiencies constitute—

(i) No actual harm with a potential for minimal harm;

(ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;

(iii) Actual harm that is not immediate jeopardy; or

(iv) Immediate jeopardy to resident health or safety.

(2) Whether the deficiencies—

(i) Are isolated;

(ii) Constitute a pattern; or

(iii) Are widespread.

(c) *Other factors which may be considered in choosing a remedy within a remedy category.* Following the initial assessment, CMS and the State may consider other factors, which may include, but are not limited to the following:

(1) The relationship of the one deficiency to other deficiencies resulting in noncompliance.

(2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

§ 488.406 Available remedies.

(a) *General.* In addition to the remedy of termination of the provider agreement, the following remedies are available:

(1) Temporary management.

(2) Denial of payment including—

(i) Denial of payment for all individuals, imposed by CMS, to a—

(A) Skilled nursing facility, for Medicare;

(B) State, for Medicaid; or

(ii) Denial of payment for all new admissions.

(3) Civil money penalties.

(4) State monitoring.

(5) Transfer of residents.

(6) Closure of the facility and transfer of residents.

(7) Directed plan of correction.
(8) Directed in-service training.
(9) Alternative or additional State remedies approved by CMS.

(b) *Remedies that must be established.* At a minimum, and in addition to termination of the provider agreement, the State must establish the following remedies or approved alternatives to the following remedies:

(1) Temporary management.
(2) Denial of payment for new admissions.
(3) Civil money penalties.
(4) Transfer of residents.
(5) Closure of the facility and transfer of residents.
(6) State monitoring.

(c) *State plan requirement.* If a State wishes to use remedies for noncompliance that are either additional or alternative to those specified in paragraphs (a) or (b) of this section, it must—

(1) Specify those remedies in the State plan; and

(2) Demonstrate to CMS's satisfaction that those remedies are as effective as the remedies listed in paragraph (a) of this section, for deterring noncompliance and correcting deficiencies.

(d) *State remedies in dually participating facilities.* If the State's remedy is unique to the State plan and has been approved by CMS, then that remedy, as imposed by the State under its Medicaid authority, may be imposed by CMS against the Medicare provider agreement of a dually participating facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.408 Selection of remedies.

(a) *Categories of remedies.* In this section, the remedies specified in § 488.406(a) are grouped into categories and applied to deficiencies according to how serious the noncompliance is.

(b) *Application of remedies.* After considering the factors specified in § 488.404, as applicable, if CMS and the State choose to impose remedies, as provided in paragraphs (c)(1), (d)(1) and (e)(1) of this section, for facility noncompliance, instead of, or in addition to, termination of the provider agreement, CMS does and the State must follow the criteria set forth in paragraphs (c)(2), (d)(2), and (e)(2) of this section, as applicable.

(c) *Category 1.* (1) Category 1 remedies include the following:

(i) Directed plan of correction.
(ii) State monitoring.
(iii) Directed in-service training.

(2) CMS does or the State must apply one or more of the remedies in Category 1 when there—

(i) Are isolated deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) Is a pattern of deficiencies that constitutes no actual harm with a potential for more than minimal harm but not immediate jeopardy.

(3) Except when the facility is in substantial compliance, CMS or the State may apply one or more of the remedies in Category 1 to any deficiency.

(d) *Category 2.* (1) Category 2 remedies include the following:

(i) Denial of payment for new admissions.
(ii) Denial of payment for all individuals imposed only by CMS.
(iii) Civil money penalties of $50–3,000 per day.
(iv) Civil money penalty of $1,000-$10,000 per instance of noncompliance.

(2) CMS applies one or more of the remedies in Category 2, or, except for denial of payment for all individuals, the State must apply one or more of the remedies in Category 2 when there are—

(i) Widespread deficiencies that constitute no actual harm with a potential for more than minimal harm but not immediate jeopardy; or

(ii) One or more deficiencies that constitute actual harm that is not immediate jeopardy.

(3) CMS or the State may apply one or more of the remedies in Category 2 to any deficiency except when—

(i) The facility is in substantial compliance; or

(ii) CMS or the State imposes a civil money penalty for a deficiency that constitutes immediate jeopardy, the penalty must be in the upper range of penalty amounts, as specified in § 488.438(a).

(e) *Category 3.* (1) Category 3 remedies include the following:

(i) Temporary management.

(ii) Immediate termination.

(iii) Civil money penalties of $3,050–$10,000 per day.

(iv) Civil money penalty of $1,000–$10,000 per instance of noncompliance.

(2) When there are one or more deficiencies that constitute immediate jeopardy to resident health or safety—

(i) CMS does and the State must do one or both of the following:

(A) Impose temporary management; or

(B) Terminate the provider agreement;

(ii) CMS and the State may impose a civil money penalty of $3,050–$10,000 per day or $1,000–$10,000 per instance of noncompliance, in addition to imposing the remedies specified in paragraph (e)(2)(i) of this section.

(3) When there are widespread deficiencies that constitute actual harm that is not immediate jeopardy, CMS and the State may impose temporary management, in addition to Category 2 remedies.

(f) *Plan of correction.* (1) Except as specified in paragraph (f)(2) of this section, each facility that has a deficiency with regard to a requirement for long term care facilities must submit a plan of correction for approval by CMS or the State, regardless of—

(i) Which remedies are imposed; or

(ii) The seriousness of the deficiencies.

(2) When there are only isolated deficiencies that CMS or the State determines constitute no actual harm with a potential for minimal harm, the facility need not submit a plan of correction.

(g) *Appeal of a certification of noncompliance.* (1) A facility may appeal a certification of noncompliance leading to an enforcement remedy.

(2) A facility may not appeal the choice of remedy, including the factors considered by CMS or the State in selecting the remedy, specified in § 488.404.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.410 Action when there is immediate jeopardy.

(a) If there is immediate jeopardy to resident health or safety, the State must (and CMS does) either terminate the provider agreement within 23 calendar days of the last date of the survey or appoint a temporary manager to remove the immediate jeopardy. The rules for appointment of a temporary manager in an immediate jeopardy situation are as follows:

(1) CMS does and the State must notify the facility that a temporary manager is being appointed.

(2) If the facility fails to relinquish control to the temporary manager, CMS does and the State must terminate the provider agreement within 23 calendar days of the last day of the survey, if the immediate jeopardy is not removed. In these cases, State monitoring may be imposed pending termination.

(3) If the facility relinquishes control to the temporary manager, the State must (and CMS does) notify the facility that, unless it removes the immediate jeopardy, its provider agreement will be terminated within 23 calendar days of the last day of the survey.

(4) CMS does and the State must terminate the provider agreement within 23 calendar days of the last day of survey if the immediate jeopardy has not been removed.

(b) CMS or the State may also impose other remedies, as appropriate.

(c)(1) In a NF or dually participating facility, if either CMS or the State finds that a facility's noncompliance poses immediate jeopardy to resident health or safety, CMS or the State must notify the other of such a finding.

(2) CMS will or the State must do one or both of the following:

(i) Take immediate action to remove the jeopardy and correct the noncompliance through temporary management.

(ii) Terminate the facility's participation under the State plan. If this is done, CMS will also terminate the facility's participation in Medicare if it is a dually participating facility.

(d) The State must provide for the safe and orderly transfer of residents when the facility is terminated.

(e) If the immediate jeopardy is also substandard quality of care, the State survey agency must notify attending

physicians and the State board responsible for licensing the facility administrator of the finding of substandard quality of care, as specified in § 488.325(h).

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.412 Action when there is no immediate jeopardy.

(a) If a facility's deficiencies do not pose immediate jeopardy to residents' health or safety, and the facility is not in substantial compliance, CMS or the State may terminate the facility's provider agreement or may allow the facility to continue to participate for no longer than 6 months from the last day of the survey if—

(1) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility's provider agreement;

(2) The State has submitted a plan and timetable for corrective action approved by CMS; and

(3) The facility in the case of a Medicare SNF or the State in the case of a Medicaid NF agrees to repay to the Federal government payments received after the last day of the survey that first identified the deficiencies if corrective action is not taken in accordance with the approved plan of correction.

(b) If a facility does not meet the criteria for continuation of payment under paragraph (a) of this section, CMS will and the State must terminate the facility's provider agreement.

(c) CMS does and the State must deny payment for new admissions when a facility is not in substantial compliance 3 months after the last day of the survey.

(d) CMS terminates the provider agreement for SNFs and NFs, and stops FFP to a State for a NF for which participation was continued under paragraph (a) of this section, if the facility is not in substantial compliance within 6 months of the last day of the survey.

[59 FR 56243, Nov. 10, 1994; 60 FR 50118, Sept. 28, 1995]

§ 488.414 Action when there is repeated substandard quality of care.

(a) *General.* If a facility has been found to have provided substandard quality of care on the last three consecutive standard surveys, as defined in § 488.305, regardless of other remedies provided—

(1) CMS imposes denial of payment for all new admissions, as specified in § 488.417, or denial of all payments, as specified in § 488.418;

(2) The State must impose denial of payment for all new admissions, as specified in § 488.417; and

(3) CMS does and the State survey agency must impose State monitoring, as specified in § 488.422, until the facility has demonstrated to the satisfaction of CMS or the State, that it is in substantial compliance with all requirements and will remain in substantial compliance with all requirements.

(b) *Repeated noncompliance.* For purposes of this section, repeated noncompliance is based on the repeated finding of substandard quality of care and not on the basis that the substance of the deficiency or the exact tag number for the deficiency was repeated.

(c) *Standard surveys to which this provision applies.* Standard surveys completed by the State survey agency on or after October 1, 1990, are used to determine whether the threshold of three consecutive standard surveys is met.

(d) *Program participation.* (1) The determination that a certified facility has repeated instances of substandard quality of care is made without regard to any variances in the facility's program participation (that is, any standard survey completed for Medicare, Medicaid or both programs will be considered).

(2) Termination would allow the count of repeated substandard quality of care surveys to start over.

(3) Change of ownership. (i) A facility may not avoid a remedy on the basis that it underwent a change of ownership.

(ii) In a facility that has undergone a change of ownership, CMS does not and the State may not restart the count of repeated substandard quality of care surveys unless the new owner can demonstrate to the satisfaction of CMS or the State that the poor past performance no longer is a factor due to the change in ownership.

(e) *Facility alleges corrections or achieves compliance after repeated substandard quality of care is identified.* (1) If a penalty is imposed for repeated substandard quality of care, it will continue until the facility has demonstrated to the satisfaction of CMS or the State that it is in substantial compliance with the requirements and that it will remain in substantial compliance with the requirements for a period of time specified by CMS or the State.

(2) A facility will not avoid the imposition of remedies or the obligation to demonstrate that it will remain in compliance when it—

(i) Alleges correction of the deficiencies cited in the most recent standard survey; or

(ii) Achieves compliance before the effective date of the remedies.

§ 488.415 Temporary management.

(a) *Definition.* Temporary management means the temporary appointment by CMS or the State of a substitute facility manager or administrator with authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in the facility's operation.

(b) *Qualifications.* The temporary manager must—

(1) Be qualified to oversee correction of deficiencies on the basis of experience and education, as determined by the State;

(2) Not have been found guilty of misconduct by any licensing board or professional society in any State;

(3) Have, or a member of his or her immediate family have, no financial ownership interest in the facility; and

(4) Not currently serve or, within the past 2 years, have served as a member of the staff of the facility.

(c) *Payment of salary.* The temporary manager's salary—

(1) Is paid directly by the facility while the temporary manager is assigned to that facility; and

(2) Must be at least equivalent to the sum of the following—

(i) The prevailing salary paid by providers for positions of this type in what the State considers to be the facility's geographic area;

(ii) Additional costs that would have reasonably been incurred by the provider if such person had been in an employment relationship; and

(iii) Any other costs incurred by such a person in furnishing services under such an arrangement or as otherwise set by the State.

(3) May exceed the amount specified in paragraph (c)(2) of this section if the State is otherwise unable to attract a qualified temporary manager.

(d) *Failure to relinquish authority to temporary management*—(1) *Termination of provider agreement.* If a facility fails to relinquish authority to the temporary manager as described in this section, CMS will or the State must terminate the provider agreement in accordance with § 488.456.

(2) *Failure to pay salary of temporary manager.* A facility's failure to pay the salary of the temporary manager is considered a failure to relinquish authority to temporary management.

(e) *Duration of temporary management.* Temporary management ends when the facility meets any of the conditions specified in § 488.454(c).

§ 488.417 Denial of payment for all new admissions.

(a) *Optional denial of payment.* Except as specified in paragraph (b) of this section, CMS or the State may deny payment for all new admissions when a facility is not in substantial compliance with the requirements, as defined in § 488.401, as follows:

(1) *Medicare facilities.* In the case of Medicare facilities, CMS may deny payment to the facility.

(2) *Medicaid facilities.* In the case of Medicaid facilities—

(i) The State may deny payment to the facility; and

(ii) CMS may deny payment to the State for all new Medicaid admissions to the facility.

(b) *Required denial of payment.* CMS does or the State must deny payment for all new admissions when—

(1) The facility is not in substantial compliance, as defined in § 488.401, 3 months after the last day of the survey identifying the noncompliance; or

(2) The State survey agency has cited a facility with substandard quality of

care on the last three consecutive standard surveys.

(c) *Resumption of payments: Repeated instances of substandard quality of care.* When a facility has repeated instances of substandard quality of care, payments to the facility or, under Medicaid, CMS payments to the State on behalf of the facility, resume on the date that—

(1) The facility achieves substantial compliance as indicated by a revisit or written credible evidence acceptable to CMS (for all facilities except non-State operated NFs against which CMS is imposing no remedies) or the State (for non-State operated NFs against which CMS is imposing no remedies); and

(2) CMS (for all facilities except non-State operated NFs against which CMS is imposing no remedies) or the State (for non-State operated NFs against which CMS is imposing no remedies) believes that the facility is capable of remaining in substantial compliance.

(d) *Resumption of payments: No repeated instances of substandard quality of care.* When a facility does not have repeated instances of substandard quality of care, payments to the facility or, under Medicaid, CMS payments to the State on behalf of the facility, resume prospectively on the date that the facility achieves substantial compliance, as indicated by a revisit or written credible evidence acceptable to CMS (under Medicare) or the State (under Medicaid).

(e) *Restriction.* No payments to a facility or, under Medicaid, CMS payments to the State on behalf of the facility, are made for the period between the date that the—

(1) Denial of payment remedy is imposed; and

(2) Facility achieves substantial compliance, as determined by CMS or the State.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.418 Secretarial authority to deny all payments.

(a) *CMS option to deny all payment.* If a facility has not met a requirement, in addition to the authority to deny payment for all new admissions as specified in § 488.417, CMS may deny any further payment for all Medicare residents in the facility and to the State for all Medicaid residents in the facility.

(b) *Prospective resumption of payment.* Except as provided in paragraphs (d) and (e) of this section, if the facility achieves substantial compliance, CMS resumes payment prospectively from the date that it verifies as the date that the facility achieved substantial compliance.

(c) *Restriction on payment after denial of payment is imposed.* If payment to the facility or to the State resumes after denial of payment for all residents, no payment is made for the period between the date that—

(1) Denial of payment was imposed; and

(2) CMS verifies as the date that the facility achieved substantial compliance.

(d) *Retroactive resumption of payment.* Except when a facility has repeated instances of substandard quality of care, as specified in paragraph (e) of this section, when CMS or the State finds that the facility was in substantial compliance before the date of the revisit, or before CMS or the survey agency received credible evidence of such compliance, payment is resumed on the date that substantial compliance was achieved, as determined by CMS.

(e) *Resumption of payment—repeated instances of substandard care.* When CMS denies payment for all Medicare residents for repeated instances of substandard quality of care, payment is resumed when—

(1) The facility achieved substantial compliance, as indicated by a revisit or written credible evidence acceptable to CMS; and

(2) CMS believes that the facility will remain in substantial compliance.

§ 488.422 State monitoring.

(a) A State monitor—

(1) Oversees the correction of deficiencies specified by CMS or the State survey agency at the facility site and protects the facility's residents from harm;

(2) Is an employee or a contractor of the survey agency;

(3) Is identified by the State as an appropriate professional to monitor cited deficiencies;

(4) Is not an employee of the facility;

(5) Does not function as a consultant to the facility; and

(6) Does not have an immediate family member who is a resident of the facility to be monitored.

(b) A State monitor must be used when a survey agency has cited a facility with substandard quality of care deficiencies on the last 3 consecutive standard surveys.

(c) State monitoring is discontinued when—

(1) The facility has demonstrated that it is in substantial compliance with the requirements, and, if imposed for repeated instances of substandard quality of care, will remain in compliance for a period of time specified by CMS or the State; or

(2) Termination procedures are completed.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.424 Directed plan of correction.

CMS, the State survey agency, or the temporary manager (with CMS or State approval) may develop a plan of correction and CMS, the State, or the temporary manager require a facility to take action within specified timeframes.

§ 488.425 Directed inservice training.

(a) *Required training.* CMS or the State agency may require the staff of a facility to attend an inservice training program if—

(1) The facility has a pattern of deficiencies that indicate noncompliance; and

(2) Education is likely to correct the deficiencies.

(b) *Action following training.* After the staff has received inservice training, if the facility has not achieved substantial compliance, CMS or the State may impose one or more other remedies specified in § 488.406.

(c) *Payment.* The facility pays for directed inservice training.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.426 Transfer of residents, or closure of the facility and transfer of residents.

(a) *Transfer of residents, or closure of the facility and transfer of residents in an emergency.* In an emergency, the State has the authority to—

(1) Transfer Medicaid and Medicare residents to another facility; or

(2) Close the facility and transfer the Medicaid and Medicare residents to another facility.

(b) *Required transfer when a facility's provider agreement is terminated.* When the State or CMS terminates a facility's provider agreement, the State arranges for the safe and orderly transfer of all Medicare and Medicaid residents to another facility.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.430 Civil money penalties: Basis for imposing penalty.

(a) CMS or the State may impose a civil money penalty for either the number of days a facility is not in substantial compliance with one or more participation requirements or for each instance that a facility is not in substantial compliance, regardless of whether or not the deficiencies constitute immediate jeopardy.

(b) CMS or the State may impose a civil money penalty for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.432 Civil money penalties: When a penalty is collected.

(a) *When facility requests a hearing.* (1) A facility must request a hearing on the determination of the noncompliance that is the basis for imposition of the civil money penalty within the time specified in one of the following sections:

(i) Section 498.40 of this chapter for a

(A) SNF;

(B) Dually participating facility;

(C) State-operated NF; or

(D) Non-State operated NF against which CMS is imposing remedies.

(ii) Section 431.153 of this chapter for a non-State operated NF that is not

subject to imposition of remedies by CMS.

(2)(i) If a facility requests a hearing within the time specified in paragraph (a)(1) of this section, for a civil money penalty imposed per day, CMS or the State initiates collection of the penalty when there is a final administrative decision that upholds CMS's or the State's determination of noncompliance after the facility achieves substantial compliance or is terminated.

(ii) If a facility requests a hearing for a civil money penalty imposed per instance of noncompliance within the time specified in paragraph (a)(1) of this section, CMS or the State initiates collection of the penalty when there is a final administrative decision that upholds CMS's or the State's determination of noncompliance.

(b) When a facility does not request a hearing for a civil money penalty imposed per day. (1) If a facility does not request a hearing in accordance with paragraph (a) of this section, CMS or the State initiates collection of the penalty when the facility—

(i) Achieves substantial compliance; or

(ii) Is terminated.

(2) When a facility does not request a hearing for a civil money penalty imposed per instance of noncompliance. If a facility does not request a hearing in accordance with paragraph (a) of this section, CMS or the State initiates collection of the penalty when the time frame for requesting a hearing expires.

(c) When a facility waives a hearing. (1) If a facility waives, in writing, its right to a hearing as specified in § 488.436, for a civil money penalty imposed per day, CMS or the State initiates collection of the penalty when the facility—

(i) Achieves substantial compliance; or (ii) Is terminated.

(2) If a facility waives, in writing, its right to a hearing as specified in § 488.436, for a civil money penalty imposed per instance of noncompliance, CMS or the State initiates collection of the penalty upon receipt of the facility's notification.

(d) Accrual and computation of penalties for a facility that—

(1) Requests a hearing or does not request a hearing are specified in § 488.440;

(2) Waives its right to a hearing in writing, are specified in §§ 488.436(b) and 488.440.

(e) The collection of civil money penalties is made as provided in § 488.442.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.434 Civil money penalties: Notice of penalty.

(a) *CMS notice of penalty.* (1) CMS sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.

(2) *Content of notice.* The notice that CMS sends includes—

(i) The nature of the noncompliance;

(ii) The statutory basis for the penalty;

(iii) The amount of penalty per day of noncompliance or the amount of the penalty per instance of noncompliance;

(iv) Any factors specified in § 488.438(f) that were considered when determining the amount of the penalty;

(v) The date of the instance of noncompliance or the date on which the penalty begins to accrue;

(vi) When the penalty stops accruing, if applicable;

(vii) When the penalty is collected; and

(viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in § 488.436.

(b) *State notice of penalty.* (1) The State must notify the facility in accordance with State procedures for all non-State operated NFs when the State takes the action.

(2) The State's notice must—

(i) Be in writing; and

(ii) Include, at a minimum, the information specified in paragraph (a)(2) of this section.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13360, Mar. 18, 1999]

§ 488.436 Civil money penalties: Waiver of hearing, reduction of penalty amount.

(a) *Waiver of a hearing.* The facility may waive the right to a hearing, in writing, within 60 days from the date of the notice imposing the civil money penalty.

(b) *Reduction of penalty amount.* (1) If the facility waives its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, CMS or the State reduces the civil money penalty amount by 35 percent.

(2) If the facility does not waive its right to a hearing in accordance with the procedures specified in paragraph (a) of this section, the civil money penalty is not reduced by 35 percent.

[59 FR 56243, Nov. 10, 1994; 62 FR 44221, Aug. 20, 1997]

§ 488.438 Civil money penalties: Amount of penalty.

(a) *Amount of penalty.* (1) The penalties are within the following ranges, set at $50 increments:

(i) *Upper range—$3,050–$10,000.* Penalties in the range of $3,050–$10,000 per day are imposed for deficiencies constituting immediate jeopardy, and as specified in paragraph (d)(2) of this section.

(ii) *Lower range—$50–$3,000.* Penalties in the range of $50–$3,000 per day are imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm.

(2) *Per instance penalty.* When penalties are imposed for an instance of noncompliance, the penalties will be in the range of $1,000-$10,000 per instance.

(b) *Basis for penalty amount.* The amount of penalty is based on CMS's or the State's assessment of factors listed in paragraph (f) of this section.

(c) *Decreased penalty amounts.* Except as specified in paragraph (d)(2) of this section, if immediate jeopardy is removed, but the noncompliance continues, CMS or the State will shift the penalty amount imposed per day to the lower range.

(d) *Increased penalty amounts.* (1) Before a hearing requested in accordance with § 488.432(a), CMS or the State may propose to increase the per day penalty amount for facility noncompliance which, after imposition of a lower level penalty amount, becomes sufficiently serious to pose immediate jeopardy.

(2) CMS does and the State must increase the per day penalty amount for any repeated deficiencies for which a lower level penalty amount was previously imposed, regardless of whether the increased penalty amount would exceed the range otherwise reserved for nonimmediate jeopardy deficiencies.

(3) Repeated deficiencies are deficiencies in the same regulatory grouping of requirements found at the last survey, subsequently corrected, and found again at the next survey.

(e) *Review of the penalty.* When an administrative law judge or State hearing officer (or higher administrative review authority) finds that the basis for imposing a civil money penalty exists, as specified in § 488.430, the administrative law judge or State hearing officer (or higher administrative review authority) may not—

(1) Set a penalty of zero or reduce a penalty to zero;

(2) Review the exercise of discretion by CMS or the State to impose a civil money penalty; and

(3) Consider any factors in reviewing the amount of the penalty other than those specified in paragraph (f) of this section.

(f) *Factors affecting the amount of penalty.* In determining the amount of penalty, CMS does or the State must take into account the following factors:

(1) The facility's history of noncompliance, including repeated deficiencies.

(2) The facility's financial condition.

(3) The factors specified in § 488.404.

(4) *The facility's degree of culpability. Culpability* for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13360, Mar. 18, 1999; 68 FR 46072, Aug. 4, 2003]

§ 488.440 Civil money penalties: Effective date and duration of penalty.

(a)(1) The per day civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by CMS or the State.

(2) A civil money penalty for each instance of noncompliance is imposed in a specific amount for that particular deficiency .

(b) The per day civil money penalty is computed and collectible, as specified in §§ 488.432 and 488.442, for the number of days of noncompliance until the date the facility achieves substantial compliance, or, if applicable, the date of termination when—

(1) CMS's or the State's decision of noncompliance is upheld after a final administrative decision;

(2) The facility waives its right to a hearing in accordance with § 488.436; or

(3) The time for requesting a hearing has expired and CMS or the State has not received a hearing request from the facility.

(c) The entire penalty, whether imposed on a per day or per instance basis, is due and collectible as specified in the notice sent to the provider under paragraphs (d) and (e) of this section.

(d)(1) When a civil money penalty is imposed on a per day basis and the facility achieves substantial compliance, CMS does or the State must send a separate notice to the facility containing the following information:

(i) The amount of penalty per day.

(ii) The number of days involved.

(iii) The total amount due.

(iv) The due date of the penalty.

(v) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(2) When a civil money penalty is imposed for an instance of noncompliance, CMS does or the State must send a separate notice to the facility containing the following information:

(i) The amount of the penalty.

(ii) The total amount due.

(iii) The due date of the penalty.

(iv) The rate of interest assessed on the unpaid balance beginning on the due date, as provided in § 488.442.

(e) In the case of a facility for which the provider agreement has been terminated and on which a civil money penalty was imposed on a per day basis, CMS does or the State must send this penalty information after the—

(1) Final administrative decision is made;

(2) Facility has waived its right to a hearing in accordance with § 488.436; or

(3) Time for requesting a hearing has expired and CMS or the state has not received a hearing request from the facility.

(f) *Accrual of penalties when there is no immediate jeopardy.* (1) In the case of noncompliance that does not pose immediate jeopardy, the daily accrual of per day civil money penalties is imposed for the days of noncompliance prior to the notice specified in § 488.434 and an additional period of no longer than 6 months following the last day of the survey.

(2) After the period specified in paragraph (f)(1) of this section, if the facility has not achieved substantial compliance, CMS terminates the provider agreement and the State may terminate the provider agreement.

(g)(1) In a case when per day civil money penalties are imposed, when a facility has deficiencies that pose immediate jeopardy, CMS does or the State must terminate the provider agreement within 23 calendar days after the last day of the survey if the immediate jeopardy remains.

(2) The accrual of the civil money penalty imposed on a per day basis stops on the day the provider agreement is terminated.

(h)(1) If an on-site revisit is necessary to confirm substantial compliance and the provider can supply documentation acceptable to CMS or the State agency that substantial compliance was achieved on a date preceding the revisit, penalties imposed on a per day basis only accrue until that date of correction for which there is written credible evidence.

(2) If an on-site revisit is not necessary to confirm substantial compliance, penalties imposed on a per day basis only accrue until the date of correction for which CMS or the State receives and accepts written credible evidence.

[59 FR 56243, Nov. 10, 1994, as amended at 64 FR 13361, Mar. 18, 1999]

§ 488.442 Civil money penalties: Due date for payment of penalty.

(a) *When payments are due for a civil money penalty imposed on a per day basis*—(1) *After a final administrative decision.* A civil money penalty payment is due 15 days after a final administrative decision is made when—

(i) The facility achieves substantial compliance before the final administrative decision; or

(ii) The effective date of termination occurs before the final administrative decision.

(2) *When no hearing was requested.* A civil money penalty payment is due 15 days after the time period for requesting a hearing has expired and a hearing request was not received when—

(i) The facility achieved substantial compliance before the hearing request was due; or

(ii) The effective date of termination occurs before the hearing request was due.

(3) *After a request to waive a hearing.* A civil money penalty payment is due 15 days after receipt of the written request to waive a hearing when—

(i) The facility achieved substantial compliance before CMS or the State received the written waiver of hearing; or

(ii) The effective date of termination occurs before CMS or the State received the written waiver of hearing.

(4) *After substantial compliance is achieved.* A civil money penalty payment is due 15 days after substantial compliance is achieved when—

(i) The final administrative decision is made before the facility came into substantial compliance;

(ii) The facility did not file a timely hearing request before it came into substantial compliance; or

(iii) The facility waived its right to a hearing before it came into substantial compliance;

(5) *After the effective date of termination.* A civil money penalty payment is due 15 days after the effective date of termination, if before the effective date of termination—

(i) The final administrative decision was made;

(ii) The time for requesting a hearing has expired and the facility did not request a hearing; or

(iii) The facility waived its right to a hearing.

(6) In the cases specified in paragraph (a)(4) of this section, the period of noncompliance may not extend beyond 6 months from the last day of the survey.

(b) When payments are due for a civil money penalty imposed for an instance of noncompliance. Payment of a civil money penalty is due 15 days after one of the following dates:

(1) The final administrative decision is made;

(2) The time for requesting a hearing has expired and the facility did not request a hearing; or

(3) The facility waived its right to a hearing.

(c) *Deduction of penalty from amount owed.* The amount of the penalty, when determined, may be deducted from any sum then or later owing by CMS or the State to the facility.

(d) *Interest*—(1) *Assessment.* Interest is assessed on the unpaid balance of the penalty, beginning on the due date.

(2) *Medicare interest.* Medicare rate of interest is the higher of—

(i) The rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date of the notice of the penalty amount due (published quarterly in the FEDERAL REGISTER by HHS under 45 CFR 30.13(a)); or

(ii) The current value of funds (published annually in the FEDERAL REGISTER by the Secretary of the Treasury, subject to quarterly revisions).

(3) *Medicaid interest.* The interest rate for Medicaid is determined by the State.

(e) *Penalties collected by CMS.* Civil money penalties and corresponding interest collected by CMS from—

(1) Medicare-participating facilities are deposited as miscellaneous receipts of the United States Treasury; and

(2) Medicaid-participating facilities are returned to the State.

(f) *Collection from dually participating facilities.* Civil money penalties collected from dually participating facilities are deposited as miscellaneous receipts of the United States Treasury and returned to the State in proportion commensurate with the relative proportions of Medicare and Medicaid beds

at the facility actually in use by residents covered by the respective programs on the date the civil money penalty begins to accrue.

(g) *Penalties collected by the State.* Civil money penalties collected by the State must be applied to the protection of the health or property of residents of facilities that the State or CMS finds noncompliant, such as—

(1) Payment for the cost of relocating residents to other facilities;

(2) State costs related to the operation of a facility pending correction of deficiencies or closure; and

(3) Reimbursement of residents for personal funds or property lost at a facility as a result of actions by the facility or by individuals used by the facility to provide services to residents.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13361, Mar. 18, 1999]

§ 488.444 Civil money penalties: Settlement of penalties.

(a) CMS has authority to settle cases at any time prior to a final administrative decision for Medicare-only SNFs, State-operated facilities, or other facilities for which CMS's enforcement action prevails, in accordance with § 488.330.

(b) The State has the authority to settle cases at any time prior to the evidentiary hearing decision for all cases in which the State's enforcement action prevails.

§ 488.450 Continuation of payments to a facility with deficiencies.

(a) *Criteria.* (1) CMS may continue payments to a facility not in substantial compliance for the periods specified in paragraph (c) of this section if the following criteria are met:

(i) The State survey agency finds that it is more appropriate to impose alternative remedies than to terminate the facility;

(ii) The State has submitted a plan and timetable for corrective action approved by CMS; and

(iii) The facility, in the case of a Medicare SNF, or the State, in the case of a Medicaid NF, agrees to repay the Federal government payments received under this provision if corrective action is not taken in accordance with the approved plan and timetable for corrective action.

(2) CMS or the State may terminate the SNF or NF agreement before the end of the correction period if the criteria in paragraph (a)(1) of this section are not met.

(b) *Cessation of payments.* If termination is not sought, either by itself or along with another remedy or remedies, or any of the criteria set forth in paragraph (a)(1) of this section are not met or agreed to by either the facility or the State, the facility or State will receive no Medicare or Federal Medicaid payments, as applicable, from the last day of the survey.

(c) *Period of continued payments.* If the conditions in paragraph (a)(1) of this section are met, CMS may continue payments to a Medicare facility or to the State for a Medicaid facility with noncompliance that does not constitute immediate jeopardy for up to 6 months from the last day of the survey.

(d) *Failure to achieve substantial compliance.* If the facility does not achieve substantial compliance by the end of the period specified in paragraph (c) of this section,

(1) CMS will—

(i) Terminate the provider agreement of the Medicare SNF in accordance with § 488.456; or

(ii) Discontinue Federal funding to the SNF for Medicare; and

(iii) Discontinue FFP to the State for the Medicaid NF.

(2) The State may terminate the provider agreement for the NF.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 488.452 State and Federal disagreements involving findings not in agreement in non-State operated NFs and dually participating facilities when there is no immediate jeopardy.

The following rules apply when CMS and the State disagree over findings of noncompliance or application of remedies in a non-State operated NF or dually participating facility:

(a) *Disagreement over whether facility has met requirements.* (1) The State's finding of noncompliance takes precedence when—

(i) CMS finds that a NF or a dually participating facility is in substantial compliance with the participation requirements; and

(ii) The State finds that a NF or dually participating facility has not achieved substantial compliance.

(2) CMS's findings of noncompliance take precedence when—

(i) CMS finds that a NF or a dually participating facility has not achieved substantial compliance; and

(ii) The State finds that a NF or a dually participating facility is in substantial compliance with the participation requirements.

(3) When CMS's survey findings take precedence, CMS may—

(i) Impose any of the alternative remedies specified in § 488.406;

(ii) Terminate the provider agreement subject to the applicable conditions of § 488.450; and

(iii) Stop FFP to the State for a NF.

(b) *Disagreement over decision to terminate.* (1) CMS's decision to terminate the participation of a facility takes precedence when—

(i) Both CMS and the State find that the facility has not achieved substantial compliance; and

(ii) CMS, but not the State, finds that the facility's participation should be terminated. CMS will permit continuation of payment during the period prior to the effective date of termination not to exceed 6 months, if the applicable conditions of § 488.450 are met.

(2) The State's decision to terminate a facility's participation and the procedures for appealing such termination, as specified in § 431.153(c) of this chapter, takes precedence when—

(i) The State, but not CMS, finds that a NF's participation should be terminated; and

(ii) The State's effective date for the termination of the NF's provider agreement is no later than 6 months after the last day of survey.

(c) *Disagreement over timing of termination of facility.* The State's timing of termination takes precedence if it does not occur later than 6 months after the last day of the survey when both CMS and the State find that—

(1) A facility is not in substantial compliance; and

(2) The facility's participation should be terminated.

(d) *Disagreement over remedies.* (1) When CMS or the State, but not both, establishes one or more remedies, in addition to or as an alternative to termination, the additional or alternative remedies will also apply when—

(i) Both CMS and the State find that a facility has not achieved substantial compliance; and

(ii) Both CMS and the State find that no immediate jeopardy exists.

(2) *Overlap of remedies.* When CMS and the State establish one or more remedies, in addition to or as an alternative to termination, only the CMS remedies apply when both CMS and the State find that a facility has not achieved substantial compliance.

(e) Regardless of whether CMS's or the State's decision controls, only one noncompliance and enforcement decision is applied to the Medicaid agreement, and for a dually participating facility, that same decision will apply to the Medicare agreement.

§ 488.454 Duration of remedies.

(a) Except as specified in paragraphs (b) and (d) of this section, alternative remedies continue until—

(1) The facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or

(2) CMS or the State terminates the provider agreement.

(b) In the cases of State monitoring and denial of payment imposed for repeated substandard quality of care, remedies continue until—

(1) CMS or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance; or

(2) CMS or the State terminates the provider agreement.

(c) In the case of temporary management, the remedy continues until—

(1) CMS or the State determines that the facility has achieved substantial compliance and is capable of remaining in substantial compliance;

(2) CMS or the State terminates the provider agreement; or

(3) The facility which has not achieved substantial compliance reassumes management control. In this case, CMS or the State initiates termination of the provider agreement and may impose additional remedies.

(d) In the case of a civil money penalty imposed for an instance of noncompliance, the remedy is the specific amount of the civil money penalty imposed for the particular deficiency.

(e) If the facility can supply documentation acceptable to CMS or the State survey agency that it was in substantial compliance and was capable of remaining in substantial compliance, if necessary, on a date preceding that of the revisit, the remedies terminate on the date that CMS or the State can verify as the date that substantial compliance was achieved and the facility demonstrated that it could maintain substantial compliance, if necessary.

[59 FR 56243, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995, as amended at 64 FR 13361, Mar. 18, 1999]

§ 488.456 Termination of provider agreement.

(a) *Effect of termination.* Termination of the provider agreement ends—

(1) Payment to the facility; and

(2) Any alternative remedy.

(b) *Basis for termination.* (1) CMS and the State may terminate a facility's provider agreement if a facility—

(i) Is not in substantial compliance with the requirements of participation, regardless of whether or not immediate jeopardy is present; or

(ii) Fails to submit an acceptable plan of correction within the timeframe specified by CMS or the State.

(2) CMS and the State terminate a facility's provider agreement if a facility—

(i) Fails to relinquish control to the temporary manager, if that remedy is imposed by CMS or the State; or

(ii) Does not meet the eligibility criteria for continuation of payment as set forth in § 488.412(a)(1).

(c) *Notice of termination.* Before terminating a provider agreement, CMS does and the State must notify the facility and the public—

(1) At least 2 calendar days before the effective date of termination for a facility with immediate jeopardy deficiencies; and

(2) At least 15 calendar days before the effective date of termination for a facility with non-immediate jeopardy deficiencies that constitute noncompliance.

(d) *Procedures for termination.* (1) CMS terminates the provider agreement in accordance with procedures set forth in § 489.53 of this chapter; and

(2) The State must terminate the provider agreement of a NF in accordance with procedures specified in parts 431 and 442 of this chapter.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

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AUTHORITY: Secs. 1102, 1819, 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

SOURCE: 45 FR 22937, Apr. 4, 1980, unless otherwise noted.

Subpart A—General Provisions

§ 489.1 Statutory basis.

This part implements section 1866 of the Social Security Act. Section 1866 specifies the terms of provider agreements, the grounds for terminating a provider agreement, the circumstances under which payment for new admissions may be denied, and the circumstances under which payment may be withheld for failure to make timely utilization review. The following other sections of that Act are also pertinent.

(a) Section 1861 defines the services covered under Medicare and the providers that may be reimbursed for furnishing those services.

(b) Section 1864 provides for the use of State survey agencies to ascertain whether certain entities meet the conditions of participation.

(c) Section 1871 authorizes the Secretary to prescribe regulations for the administration of the Medicare program.

(d) Although section 1866 of the Act speaks only to providers and provider agreements, the effective date rules in this part are made applicable also to the approval of suppliers that meet the requirements specified in § 489.13.

(e) Section 1861(o)(7) of the Act requires each HHA to provide CMS with a surety bond.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 24492, July 3, 1986; 62 FR 43936, Aug. 18, 1997; 63 FR 312, Jan. 5, 1998]

§ 489.2 Scope of part.

(a) Subpart A of this part sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare. Subpart B of this part specifies the basic commitments and limitations that the provider must agree to as part of an agreement to provide services. Subpart C specifies the limitations on allowable charges to beneficiaries for deductibles, coinsurance, copayments, blood, and services that must be part of the provider agreement. Subpart D of this part specifies how incorrect collections are to be handled. Subpart F sets forth the circumstances and procedures for denial of payments for new admissions and for withholding of payment as an alternative to termination of a provider agreement.

(b) The following providers are subject to the provisions of this part:

(1) Hospitals.

(2) Skilled nursing facilities (SNFs).

(3) Home health agencies (HHAs).

(4) Clinics, rehabilitation agencies, and public health agencies.

(5) Comprehensive outpatient rehabilitation facilities (CORFs).

(6) Hospices.

(7) Critical access hospital (CAHs).

(8) Community mental health centers (CMHCs).

(9) Religious nonmedical health care institutions (RNHCIs).

(c)(1) Clinics, rehabilitation agencies, and public health agencies may enter into provider agreements only for furnishing outpatient physical therapy, and speech pathology services.

(2) CMHCs may enter into provider agreements only to furnish partial hospitalization services.

[45 FR 22937, Apr. 4, 1980, as amended at 47 FR 56297, Dec. 15, 1982; 48 FR 56036, Dec. 15, 1983; 51 FR 24492, July 3, 1986; 58 FR 30676, May 26, 1993; 59 FR 6578, Feb. 11, 1994; 62 FR 46037, Aug. 29, 1997; 68 FR 66720, Nov. 28, 2003]

§ 489.3 Definitions.

For purposes of this part—

Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Provider agreement means an agreement between CMS and one of the providers specified in § 489.2(b) to provide services to Medicare beneficiaries and to comply with the requirements of section 1866 of the Act.

[48 FR 39837, Sept. 1, 1983, as amended at 51 FR 24492, July 3, 1986; 54 FR 5373, Feb. 2, 1989; 59 FR 56250, Nov. 10, 1994; 60 FR 50119, Sept. 28, 1995]

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter. The RNHCIs must meet the conditions for coverage, conditions for participation and the requirements set forth in this section and elsewhere in this chapter.

(b) In order to participate in the Medicare program, the provider must meet the applicable civil rights requirements of:

(1) Title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under, any program or activity receiving Federal financial assistance (section 601);

(2) Section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR part 84, which provides that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subject to discrimination under any program or activity receiving Federal financial assistance;

(3) The Age Discrimination Act of 1975, as implemented by 45 CFR part 90, which is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Discrimination Act also permits federally assisted programs and activities, and recipients of Federal funds, to continue to use certain age distinctions, and factors other than age, that meet the requirements of the Age Discrimination Act and 45 CFR part 90; and

(4) Other pertinent requirements of the Office of Civil Rights of HHS.

(c) In order for a hospital, SNF, HHA, hospice, or RNHCI to be accepted, it must also meet the advance directives requirements specified in subpart I of this part.

(d) The State survey agency will ascertain whether the provider meets the conditions of participation or requirements (for SNFs) and make its recommendations to CMS.

(e) In order for a home health agency to be accepted, it must also meet the surety bond requirements specified in subpart F of this part.

(f) In order for a home health agency to be accepted as a new provider, it must also meet the capitalization requirements specified in subpart B of this part.

[58 FR 61843, Nov. 23, 1993, as amended at 59 FR 6578, Feb. 11, 1994; 63 FR 312, Jan. 5, 1998; 68 FR 66720, Nov. 28, 2003]

§ 489.11 Acceptance of a provider as a participant.

(a) *Action by CMS.* If CMS determines that the provider meets the requirements, it will send the provider—

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) *Action by provider.* If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to CMS, together with a written statement indicating whether it has been adjudged insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) *Notice of acceptance.* If CMS accepts the agreement, it will return one copy to the provider with a written notice that—

(1) Indicates the dates on which it was signed by the provider's representative and accepted by CMS; and

(2) Specifies the effective date of the agreement.

[45 FR 22937, Apr. 4, 1980, as amended at 59 FR 56251, Nov. 10, 1994; 62 FR 43937, Aug. 18, 1997]

§ 489.12 Decision to deny an agreement.

(a) *Bases for denial.* CMS may refuse to enter into an agreement for any of the following reasons:

(1) Principals of the prospective provider have been convicted of fraud (see § 420.204 of this chapter);

(2) The prospective provider has failed to disclose ownership and control interests in accordance with § 420.206 of this chapter; or

(3) The prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(b) [Reserved]

(c) *Compliance with civil rights requirements.* CMS will not enter into a provider agreement if the provider fails to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90, subject to the provisions of § 489.10.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986; 54 FR 4027, Jan. 27. 1989; 59 FR 6578, Feb. 11, 1994; 59 FR 56251, Nov. 10, 1994]

§ 489.13 Effective date of agreement or approval.

(a) *Applicability*—(1) *General rule.* Except as provided in paragraph (a)(2) of this section, this section applies to Medicare provider agreements with, and supplier approval of, entities that, as a basis for participation in Medicare—

(i) Are subject to survey and certification by CMS or the State survey agency; or

(ii) Are deemed to meet Federal requirements on the basis of accreditation by an accrediting organization whose program has CMS approval at the time of accreditation survey and accreditation decision.

(2) *Exceptions.* (i) For an agreement with a community mental health center (CMHC) or a Federally qualified health center (FQHC), the effective date is the date on which CMS accepts a signed agreement which assures that the CMHC or FQHC meets all Federal requirements.

(ii) A Medicare supplier approval of a laboratory is effective only while the laboratory has in effect a valid CLIA certificate issued under part 493 of this chapter, and only for the specialty and subspecialty tests it is authorized to perform.

(b) *All Federal requirements are met on the date of survey.* The agreement or approval is effective on the date the survey (including the Life Safety Code survey, if applicable) is completed, if on that date the provider or supplier meets all applicable Federal requirements as set forth in this chapter. (If the agreement or approval is time-limited, the new agreement or approval is effective on the day following expiration of the current agreement or approval.)

(c) *All Federal requirements are not met on the date of survey.* If on the date the survey is completed the provider or supplier fails to meet any of the requirements specified in paragraph (b) of this section, the following rules apply:

(1) For an agreement with an SNF, the effective date is the date on which—

(i) The SNF is in substantial compliance (as defined in § 488.301 of this chapter) with the requirements for participation; and

(ii) CMS or the State survey agency receives from the SNF, if applicable, an approvable waiver request.

(2) For an agreement with, or an approval of, any other provider or supplier, (except those specified in paragraph (a)(2) of this section), the effective date is the earlier of the following:

(i) The date on which the provider or supplier meets all requirements.

(ii) The date on which a provider or supplier is found to meet all conditions of participation or coverage, but has lower level deficiencies, and CMS or the State survey agency receives an acceptable plan of correction for the lower level deficiencies, or an approvable waiver request, or both. (The date of receipt is the effective date regardless of when CMS approves the plan of correction or the waiver request, or both.)

(d) *Accredited provider or supplier requests participation in the Medicare program*—(1) *General rule.* If the provider or supplier is currently accredited by a national accrediting organization whose program had CMS approval at the time of accreditation survey and accreditation decision, and on the basis of accreditation, CMS has deemed the provider or supplier to meet Federal requirements, the effective date depends on whether the provider or supplier is subject to requirements in addition to those included in the accrediting organization's approved program.

(i) *Provider or supplier subject to additional requirements.* If the provider or supplier is subject to additional requirements, the effective date of the agreement or approval is the date on which the provider or supplier meets all requirements, including the additional requirements.

(ii) *Provider or supplier not subject to additional requirements.* For a provider or supplier that is not subject to additional requirements, the effective date is the date of the provider's or supplier's initial request for participation if on that date the provider or supplier met all Federal requirements.

(2) *Special rule: Retroactive effective date.* If a provider or supplier meets the requirements of paragraphs (d)(1) and (d)(1)(i) or (d)(1)(ii) of this section, the effective date may be retroactive for up to one year to encompass dates on which the provider or supplier furnished, to a Medicare beneficiary, covered services for which it has not been paid.

[62 FR 43936, Aug. 18, 1997]

§ 489.18 Change of ownership or leasing: Effect on provider agreement.

(a) *What constitutes change of ownership*—(1) *Partnership.* In the case of a partnership, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law, constitutes change of ownership.

(2) *Unincorporated sole proprietorship.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* The merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation constitutes change of ownership. Transfer of corporate stock or the merger of another corporation into the provider corporation does not constitute change of ownership.

(4) *Leasing.* The lease of all or part of a provider facility constitutes change of ownership of the leased portion.

(b) *Notice to CMS.* A provider who is contemplating or negotiating a change of ownership must notify CMS.

(c) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, the existing provider agreement will automatically be assigned to the new owner.

(d) *Conditions that apply to assigned agreements.* An assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued including, but not limited to, the following:

(1) Any existing plan of correction.

(2) Compliance with applicable health and safety standards.

(3) Compliance with the ownership and financial interest disclosure requirements of part 420, subpart C, of this chapter.

(4) Compliance with civil rights requirements set forth in 45 CFR Parts 80, 84, and 90.

(e) *Effect of leasing.* The provider agreement will be assigned to the lessee only to the extent of the leased portion of the facility.

[45 FR 22937, Apr. 4, 1980, as amended at 59 FR 56251, Nov. 10, 1994]

Subpart B—Essentials of Provider Agreements

§ 489.20 Basic commitments.

The provider agrees to the following:

(a) To limit its charges to beneficiaries and to other individuals on their behalf, in accordance with provisions of subpart C of this part.

(b) To comply with the requirements of subpart D of this part for the return or other disposition of any amounts incorrectly collected from a beneficiary or any other person in his or her behalf.

(c) To comply with the requirements of § 420.203 of this chapter when it hires certain former employees of intermediaries.

(d) In the case of a hospital or a CAH that furnishes services to Medicare beneficiaries, either to furnish directly or to make arrangements (as defined in § 409.3 of this chapter) for all Medicare-covered services to inpatients and outpatients of a hospital or a CAH except the following:

(1) Physicians' services that meet the criteria of § 415.102(a) of this chapter for payment on a reasonable charge basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act, that are furnished after December 31, 1990.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Certified nurse-midwife services, as defined in section 1861(ff) of the Act, that are furnished after December 31, 1990.

(5) Qualified psychologist services, as defined in section 1861(ii) of the Act, that are furnished after December 31, 1990.

(6) Services of an anesthetist, as defined in § 410.69 of this chapter.

(e) In the case of a hospital or CAH that furnishes inpatient hospital services or inpatient CAH services for which payment may be made under Medicare, to maintain an agreement with a QIO for that organization to review the admissions, quality, appropriateness, and diagnostic information related to those inpatient services. The requirement of this paragraph (e) applies only if, for the area in which the hospital or CAH is located, there is a QIO that has a contract with CMS under part B of title XI of the Act.

(f) To maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented.

(g) To bill other primary payers before Medicare.

(h) If the provider receives payment for the same services from Medicare and another payer that is primary to Medicare, to reimburse Medicare any overpaid amount within 60 days.

(i) If the provider receives, from a payer that is primary to Medicare, a payment that is reduced because the provider failed to file a proper claim—

(1) To bill Medicare for an amount no greater than would have been payable as secondary payment if the primary insurer's payment had been based on a proper claim; and

(2) To charge the beneficiary only: (i) The amount it would have been entitled to charge if it had filed a proper claim and received payment based on such a claim; and

(ii) An amount equal to any primary payment reduction attributable to failure to file a proper claim, but only if the provider can show that—

(A) It failed to file a proper claim solely because the beneficiary, for any reason other than mental or physical incapacity, failed to give the provider the necessary information; or

(B) The beneficiary, who was responsible for filing a proper claim, failed to do so for any reason other than mental or physical incapacity.

(j) In the State of Oregon, because of a court decision, and in the absence of a reversal on appeal or a statutory clarification overturning the decision, hospitals may bill liability insurers first. However, if the liability insurer does not pay ''promptly'', as defined in § 411.50 of this chapter, the hospital

must withdraw its claim or lien and bill Medicare for covered services.

(k) In the case of home health agencies that provide home health services to Medicare beneficiaries under subpart E of part 409 and subpart C f part 410 of this chapter, to offer to furnish catheters, catheter supplies, ostomy bags, and supplies related to ostomy care to any individual who requires them as part of their furnishing of home health services.

(l) In the case of a hospital as defined in § 489.24(b) to comply with § 489.24.

(m) In the case of a hospital as defined in § 489.24(b), to report to CMS or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of § 489.24(e).

(n) In the case of inpatient hospital services, to participate in any health plan contracted for under 10 U.S.C. 1079 or 1086 or 38 U.S.C. 613, in accordance with § 489.25.

(o) In the case of inpatient hospital services, to admit veterans whose admission has been authorized under 38 U.S.C. 603, in accordance with § 489.26.

(p) To comply with § 489.27 of this part concerning notification of Medicare beneficiaries of their rights associated with the termination of Medicare services.

(q) In the case of a hospital as defined in § 489.24(b)—

(1) To post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area), a sign (in a form specified by the Secretary) specifying rights of individuals under Section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and

(2) To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital participates in the Medicaid program under a State plan approved under title XIX.

(r) In the case of a hospital as defined in § 489.24(b) (including both the transferring and receiving hospitals), to maintain—

(1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer;

(2) A list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition; and

(3) A central log on each individual who comes to the emergency department, as defined in § 489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

(s) In the case of an SNF, either to furnish directly or make arrangements (as defined in § 409.3 of this chapter) for all Medicare-covered services furnished to a resident (as defined in § 411.15(p)(3) of this chapter) of the SNF, except the following:

(1) Physicians' services that meet the criteria of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Services performed under a physician's supervision by a physician assistant who meets the applicable definition in section 1861(aa)(5) of the Act.

(3) Services performed by a nurse practitioner or clinical nurse specialist who meets the applicable definition in section 1861(aa)(5) of the Act and is working in collaboration (as defined in section 1861(aa)(6) of the Act) with a physician.

(4) Services performed by a certified nurse-midwife, as defined in section 1861(gg) of the Act.

(5) Services performed by a qualified psychologist, as defined in section 1861(ii) of the Act.

(6) Services performed by a certified registered nurse anesthetist, as defined in section 1861(bb) of the Act.

(7) Dialysis services and supplies, as defined in section 1861(s)(2)(F) of the Act, and those ambulance services that are furnished in conjunction with them.

(8) Erythropoietin (EPO) for dialysis patients, as defined in section 1861(s)(2)(O) of the Act.

(9) Hospice care, as defined in section 1861(dd) of the Act.

(10) An ambulance trip that initially conveys an individual to the SNF to be admitted as a resident, or that conveys an individual from the SNF in connection with one of the circumstances specified in §411.15(p)(3)(i) through (p)(3)(iv) of this chapter as ending the individual's status as an SNF resident.

(11) The transportation costs of electrocardiogram equipment (HCPCS code R0076), but only with respect to those electrocardiogram test services furnished during 1998.

(12) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020; J9040–J9151; J9170–J9185; J9200–J9201; J9206–J9208; J9211; J9230–J9245; and J9265–J9600; and, as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534.

(13) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262; 36489; 36530–36535; 36640; 36823; and 96405–96542.

(14) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440.

(15) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340; L5500–L5611; L5613–L5986; L5988; L6050–L6370; L6400–6880; L6920–L7274; and L7362–L7366, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(t) Hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under section 18(b) of the Occupational Safety and Health Act) must comply with the bloodborne pathogens (BBP) standards under 29 CFR 1910.1030. A hospital that fails to comply with the BBP standards may be subject to a civil money penalty in accordance with section 17 of the Occupational Safety and Health Act of 1970, including any adjustments of the civil money penalty amounts under the Federal Civil Penalties Inflation Adjustment Act, for a violation of the BBP standards. A civil money penalty will be imposed and collected in the same manner as civil money penalties under section 1128A(a) of the Social Security Act.

[45 FR 22937, Apr. 4, 1980, as amended at 48 FR 39837, Sept. 1, 1983; 49 FR 323, Jan. 3, 1984; 54 FR 41747, Oct. 11, 1989; 57 FR 36018, Aug. 12, 1992; 58 FR 30677, May 26, 1993; 59 FR 32120, June 22, 1994; 60 FR 63189, Dec. 8, 1995; 62 FR 46037, Aug. 29, 1997; 63 FR 26312, May 12, 1998; 65 FR 18548, Apr. 7, 2000; 65 FR 46796, July 31, 2000; 66 FR 39601, July 31, 2001; 68 FR 16669, Apr. 4, 2003; 68 FR 43942, July 25, 2003; 68 FR 46072, Aug. 4, 2003; 69 FR 49272, Aug. 11, 2004; 70 FR 45055, Aug. 4, 2005; 71 FR 9471, Feb. 24, 2006]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, in §489.20, paragraphs (l) through (r) were added. Paragraphs (m), (r)(2) and (r)(3) contain information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§489.21 Specific limitations on charges.

Except as specified in subpart C of this part, the provider agrees not to charge a beneficiary for any of the following:

(a) Services for which the beneficiary is entitled to have payment made under Medicare.

(b) Services for which the beneficiary would be entitled to have payment made if the provider—

(1) Had in its files the required certification and recertification by a physician relating to the services furnished to the beneficiary;

(2) Had furnished the information required by the intermediary in order to determine the amount due the provider on behalf of the individual for the period with respect to which payment is to be made or any prior period;

(3) Had complied with the provisions requiring timely utilization review of long stay cases so that a limitation on days of service has not been imposed under section 1866(d) of the Act (see subpart K of part 405 and part 482 of this chapter for utilization review requirements); and

(4) Had obtained, from the beneficiary or a person acting on his or her behalf, a written request for payment to be made to the provider, and had

properly filed that request. (If the beneficiary or person on his or her behalf refuses to execute a written request, the provider may charge the beneficiary for all services furnished to him or her.)

(c) Inpatient hospital services furnished to a beneficiary who exhausted his or her Part A benefits, if CMS reimburses the provider for those services.

(d) Custodial care and services not reasonable and necessary for the diagnosis or treatment of illness or injury, if—

(1) The beneficiary was without fault in incurring the expenses; and

(2) The determination that payment was incorrect was not made until after the third year following the year in which the payment notice was sent to the beneficiary.

(e) Inpatient hospital services for which a beneficiary would be entitled to have payment made under Part A of Medicare but for a denial or reduction in payments under regulations at § 412.48 of this chapter or under section 1886(f) of the Act.

(f) Items and services furnished to a hospital inpatient (other than physicians' services as described in § 415.102(a) of this chapter or the services of an anesthetist as described in § 405.553(b)(4) of this chapter) for which Medicare payment would be made if furnished by the hospital or by other providers or suppliers under arrangements made with them by the hospital. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the hospital for the item or service, and is also prohibited.

(g) [Reserved]

(h) Items and services (other than those described in §§ 489.20(s)(1) through (15)) required to be furnished under § 489.20(s) to a resident of an SNF (defined in § 411.15(p) of this chapter), for which Medicare payment would be made if furnished by the SNF or by other providers or suppliers under arrangements made with them by the SNF. For this purpose, a charge by another provider or supplier for such an item or service is treated as a charge by the SNF for the item or service, and is also prohibited.

[49 FR 324, Jan. 3, 1984, as amended at 51 FR 22052, June 17, 1986; 52 FR 27765, July 23, 1987; 60 FR 63189, Dec. 8, 1995; 64 FR 41683, July 30, 1999; 65 FR 46796, July 31, 2000; 65 FR 62646, Oct. 19, 2000; 66 FR 39601, July 31, 2001]

§ 489.22 Special provisions applicable to prepayment requirements.

(a) A provider may not require an individual entitled to hospital insurance benefits to prepay in part or in whole for inpatient services as a condition of admittance as an inpatient, except where it is clear upon admission that payment under Medicare, Part A cannot be made.

(b) A provider may not deny covered inpatient services to an individual entitled to have payment made for those services on the ground of inability or failure to pay a requested amount at or before admission.

(c) A provider may not evict, or threaten to evict, an individual for inability to pay a deductible or a coinsurance amount required under Medicare.

(d) A provider may not charge an individual for (1) its agreement to admit or readmit the individual on some specified future date for covered inpatient services; or (2) for failure to remain an inpatient for any agreed-upon length of time or for failure to give advance notice of departure from the provider's facilities.

[45 FR 22937, Apr. 4, 1980, as amended at 68 FR 46072, Aug. 4, 2003]

§ 489.23 Specific limitation on charges for services provided to certain enrollees of fee-for-service FEHB plans.

A provider that furnishes inpatient hospital services to a retired Federal worker age 65 or older who is enrolled in a fee-for-service FEHB plan and who is not covered under Medicare Part A, must accept, as payment in full, an amount that approximates as closely as possible the Medicare inpatient hospital prospective payment system (PPS) rate established under part 412. The payment to the provider is composed of a payment from the FEHB plan and a payment from the enrollee. This combined payment approximates

the Medicare PPS rate. The payment from the FEHB plan approximates, as closely as possible, the Medicare PPS rate minus any applicable enrollee deductible, coinsurance, or copayment amount. The payment from the enrollee is equal to the applicable deductible, coinsurance, or copayment amount.

[62 FR 56111, Oct. 29, 1997]

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

(a) *Applicability of provisions of this section.* (1) In the case of a hospital that has an emergency department, if an individual (whether or not eligible for Medicare benefits and regardless of ability to pay) ''comes to the emergency department'', as defined in paragraph (b) of this section, the hospital must—

(i) Provide an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examination must be conducted by an individual(s) who is determined qualified by hospital bylaws or rules and regulations and who meets the requirements of §482.55 of this chapter concerning emergency services personnel and direction; and

(ii) If an emergency medical condition is determined to exist, provide any necessary stabilizing treatment, as defined in paragraph (d) of this section, or an appropriate transfer as defined in paragraph (e) of this section. If the hospital admits the individual as an inpatient for further treatment, the hospital's obligation under this section ends, as specified in paragraph (d)(2) of this section.

(2) *Nonapplicability of provisions of this section.* Sanctions under this section for inappropriate transfer during a national emergency do not apply to a hospital with a dedicated emergency department located in an emergency area, as specified in section 1135(g)(1) of the Act.

(b) *Definitions.* As used in this subpart—

Capacity means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits.

Comes to the emergency department means, with respect to an individual who is not a patient (as defined in this section), the individual—

(1) Has presented at a hospital's dedicated emergency department, as defined in this section, and requests examination or treatment for a medical condition, or has such a request made on his or her behalf. In the absence of such a request by or on behalf of the individual, a request on behalf of the individual will be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs examination or treatment for a medical condition;

(2) Has presented on hospital property, as defined in this section, other than the dedicated emergency department, and requests examination or treatment for what may be an emergency medical condition, or has such a request made on his or her behalf. In the absence of such a request by or on behalf of the individual, a request on behalf of the individual will be considered to exist if a prudent layperson observer would believe, based on the individual's appearance or behavior, that the individual needs emergency examination or treatment;

(3) Is in a ground or air ambulance owned and operated by the hospital for purposes of examination and treatment for a medical condition at a hospital's dedicated emergency department, even if the ambulance is not on hospital grounds. However, an individual in an ambulance owned and operated by the hospital is not considered to have ''come to the hospital's emergency department'' if—

(i) The ambulance is operated under communitywide emergency medical service (EMS) protocols that direct it to transport the individual to a hospital other than the hospital that owns

the ambulance; for example, to the closest appropriate facility. In this case, the individual is considered to have come to the emergency department of the hospital to which the individual is transported, at the time the individual is brought onto hospital property;

(ii) The ambulance is operated at the direction of a physician who is not employed or otherwise affiliated with the hospital that owns the ambulance; or

(4) Is in a ground or air nonhospital-owned ambulance on hospital property for presentation for examination and treatment for a medical condition at a hospital's dedicated emergency department. However, an individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department, even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. The hospital may direct the ambulance to another facility if it is in ''diversionary status,'' that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff disregards the hospital's diversion instructions and transports the individual onto hospital property, the individual is considered to have come to the emergency department.

Dedicated emergency department means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

(1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;

(2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

(3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.

Emergency medical condition means—

(1) A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in—

(i) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(ii) Serious impairment to bodily functions; or

(iii) Serious dysfunction of any bodily organ or part; or

(2) With respect to a pregnant woman who is having contractions—

(i) That there is inadequate time to effect a safe transfer to another hospital before delivery; or

(ii) That transfer may pose a threat to the health or safety of the woman or the unborn child.

Hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act.

Hospital property means the entire main hospital campus as defined in § 413.65(b) of this chapter, including the parking lot, sidewalk, and driveway, but excluding other areas or structures of the hospital's main building that are not part of the hospital, such as physician offices, rural health centers, skilled nursing facilities, or other entities that participate separately under Medicare, or restaurants, shops, or other nonmedical facilities.

Hospital with an emergency department means a hospital with a dedicated emergency department as defined in this paragraph (b).

Inpatient means an individual who is admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services as described in § 409.10(a) of this chapter with the expectation that he or she will remain at least overnight and occupy a bed even though the situation later develops that the individual can be discharged

or transferred to another hospital and does not actually use a hospital bed overnight.

Labor means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital medical staff bylaws and State law, certifies that, after a reasonable time of observation, the woman is in false labor.

Participating hospital means (1) a hospital or (2) a critical access hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Patient means—

(1) An individual who has begun to receive outpatient services as part of an encounter, as defined in §410.2 of this chapter, other than an encounter that the hospital is obligated by this section to provide;

(2) An individual who has been admitted as an inpatient, as defined in this section.

Stabilized means, with respect to an ''emergency medical condition'' as defined in this section under paragraph (1) of that definition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility or, with respect to an ''emergency medical condition'' as defined in this section under paragraph (2) of that definition, that the woman has delivered the child and the placenta.

To stabilize means, with respect to an ''emergency medical condition'' as defined in this section under paragraph (1) of that definition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that, with respect to an ''emergency medical condition'' as defined in this section under paragraph (2) of that definition, the woman has delivered the child and the placenta.

Transfer means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (i) has been declared dead, or (ii) leaves the facility without the permission of any such person.

(c) *Use of dedicated emergency department for nonemergency services.* If an individual comes to a hospital's dedicated emergency department and a request is made on his or her behalf for examination or treatment for a medical condition, but the nature of the request makes it clear that the medical condition is not of an emergency nature, the hospital is required only to perform such screening as would be appropriate for any individual presenting in that manner, to determine that the individual does not have an emergency medical condition.

(d) *Necessary stabilizing treatment for emergency medical conditions*—(1) *General.* Subject to the provisions of paragraph (d)(2) of this section, if any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(i) Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition.

(ii) For transfer of the individual to another medical facility in accordance with paragraph (e) of this section.

(2) *Exception: Application to inpatients.* (i) If a hospital has screened an individual under paragraph (a) of this section and found the individual to have an emergency medical condition, and admits that individual as an inpatient in good faith in order to stabilize the emergency medical condition, the hospital has satisfied its special responsibilities under this section with respect to that individual.

(ii) This section is not applicable to an inpatient who was admitted for

elective (nonemergency) diagnosis or treatment.

(iii) A hospital is required by the conditions of participation for hospitals under Part 482 of this chapter to provide care to its inpatients in accordance with those conditions of participation.

(3) *Refusal to consent to treatment.* A hospital meets the requirements of paragraph (d)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

(4) *Delay in examination or treatment.* (i) A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (d)(1) of this section in order to inquire about the individual's method of payment or insurance status.

(ii) A participating hospital may not seek, or direct an individual to seek, authorization from the individual's insurance company for screening or stabilization services to be furnished by a hospital, physician, or nonphysician practitioner to an individual until after the hospital has provided the appropriate medical screening examination required under paragraph (a) of this section, and initiated any further medical examination and treatment that may be required to stabilize the emergency medical condition under paragraph (d)(1) of this section.

(iii) An emergency physician or nonphysician practitioner is not precluded from contacting the individual's physician at any time to seek advice regarding the individual's medical history and needs that may be relevant to the medical treatment and screening of the patient, as long as this consultation does not inappropriately delay services required under paragraph (a) or paragraphs (d)(1) and (d)(2) of this section.

(iv) Hospitals may follow reasonable registration processes for individuals for whom examination or treatment is required by this section, including asking whether an individual is insured and, if so, what that insurance is, as long as that inquiry does not delay screening or treatment. Reasonable registration processes may not unduly discourage individuals from remaining for further evaluation.

(5) *Refusal to consent to transfer.* A hospital meets the requirements of paragraph (d)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) does not consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

(e) *Restricting transfer until the individual is stabilized*—(1) *General.* If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless—

(i) The transfer is an appropriate transfer (within the meaning of paragraph (e)(2) of this section); and

(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer,

after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its bylaws or rules and regulations) has signed a certification described in paragraph (e)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which—

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility—

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (e)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (g) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

(3) A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (e)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.

(f) *Recipient hospital responsibilities.* A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers, which, for purposes of this subpart, means hospitals meeting the requirements of referral centers found at § 412.96 of this chapter) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual. This requirement applies to any participating hospital with specialized capabilities, regardless of

whether the hospital has a dedicated emergency department.

(g) *Termination of provider agreement.* If a hospital fails to meet the requirements of paragraph (a) through (f) of this section, CMS may terminate the provider agreement in accordance with § 489.53.

(h) *Consultation with Quality Improvement Organizations (QIOs)*—(1) *General.* Except as provided in paragraph (h)(3) of this section, in cases where a medical opinion is necessary to determine a physician's or hospital's liability under section 1867(d)(1) of the Act, CMS requests the appropriate QIO (with a contract under Part B of title XI of the Act) to review the alleged section 1867(d) violation and provide a report on its findings in accordance with paragraph (h)(2)(iv) and (v) of this section. CMS provides to the QIO all information relevant to the case and within its possession or control. CMS, in consultation with the OIG, also provides to the QIO a list of relevant questions to which the QIO must respond in its report.

(2) *Notice of review and opportunity for discussion and additional information.* The QIO shall provide the physician and hospital reasonable notice of its review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. When a QIO receives a request for consultation under paragraph (h)(1) of this section, the following provisions apply—

(i) The QIO reviews the case before the 15th calendar day and makes its tentative findings.

(ii) Within 15 calendar days of receiving the case, the QIO gives written notice, sent by certified mail, return receipt requested, to the physician or the hospital (or both if applicable).

(iii)(A) The written notice must contain the following information:

(*1*) The name of each individual who may have been the subject of the alleged violation.

(*2*) The date on which each alleged violation occurred.

(*3*) An invitation to meet, either by telephone or in person, to discuss the case with the QIO, and to submit additional information to the QIO within 30 calendar days of receipt of the notice, and a statement that these rights will be waived if the invitation is not accepted. The QIO must receive the information and hold the meeting within the 30-day period.

(*4*) A copy of the regulations at 42 CFR 489.24.

(B) For purposes of paragraph (h)(2)(iii)(A) of this section, the date of receipt is presumed to be 5 days after the certified mail date on the notice, unless there is a reasonable showing to the contrary.

(iv) The physician or hospital (or both where applicable) may request a meeting with the QIO. This meeting is not designed to be a formal adversarial hearing or a mechanism for discovery by the physician or hospital. The meeting is intended to afford the physician and/or the hospital a full and fair opportunity to present the views of the physician and/or hospital regarding the case. The following provisions apply to that meeting:

(A) The physician and/or hospital has the right to have legal counsel present during that meeting. However, the QIO may control the scope, extent, and manner of any questioning or any other presentation by the attorney. The QIO may also have legal counsel present.

(B) The QIO makes arrangements so that, if requested by CMS or the OIG, a verbatim transcript of the meeting may be generated. If CMS or OIG requests a transcript, the affected physician and/or the affected hospital may request that CMS provide a copy of the transcript.

(C) The QIO affords the physician and/or the hospital an opportunity to present, with the assistance of counsel, expert testimony in either oral or written form on the medical issues presented. However, the QIO may reasonably limit the number of witnesses and length of such testimony if such testimony is irrelevant or repetitive. The physician and/or hospital, directly or through counsel, may disclose patient records to potential expert witnesses without violating any non-disclosure requirements set forth in part 476 of this chapter.

(D) The QIO is not obligated to consider any additional information provided by the physician and/or the hospital after the meeting, unless, before the end of the meeting, the QIO requests that the physician and/or hospital submit additional information to support the claims. The QIO then allows the physician and/or the hospital an additional period of time, not to exceed 5 calendar days from the meeting, to submit the relevant information to the QIO.

(v) Within 60 calendar days of receiving the case, the QIO must submit to CMS a report on the QIO's findings. CMS provides copies to the OIG and to the affected physician and/or the affected hospital. The report must contain the name of the physician and/or the hospital, the name of the individual, and the dates and times the individual arrived at and was transferred (or discharged) from the hospital. The report provides expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there were any medical utilization or quality of care issues involved in the case.

(vi) The report required under paragraph (h)(2)(v) of this section should not state an opinion or conclusion as to whether section 1867 of the Act or § 489.24 has been violated.

(3) If a delay would jeopardize the health or safety of individuals or when there was no screening examination, the QIO review described in this section is not required before the OIG may impose civil monetary penalties or an exclusion in accordance with section 1867(d)(1) of the Act and 42 CFR part 1003 of this title.

(4) If the QIO determines after a preliminary review that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, as defined by paragraph (b) of this section, then the QIO may, at its discretion, return the case to CMS and not meet the requirements of paragraph (h) except for those in paragraph (h)(2)(v).

(i) *Release of QIO assessments.* Upon request, CMS may release a QIO assessment to the physician and/or hospital, or the affected individual, or his or her representative. The QIO physician's identity is confidential unless he or she consents to its release. (See §§ 476.132 and 476.133 of this chapter.)

(j) *Availability of on-call physicians.* (1) Each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians.

(2) The hospital must have written policies and procedures in place—

(i) To respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control; and

(ii) To provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

[59 FR 32120, June 22, 1994, as amended at 62 FR 46037, Aug. 29, 1997; 65 FR 18548, Apr. 7, 2000; 65 FR 59748, Oct. 6, 2000; 66 FR 1599, Jan. 9, 2001; 66 FR 59923, Nov. 30, 2001; 68 FR 53262, Sept. 9, 2003; 71 FR 48143, Aug. 18, 2006]

EFFECTIVE DATE NOTE: At 59 FR 32120, June 22, 1994, § 489.24 was added. Paragraphs (d) and (g) contain information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 489.25 Special requirements concerning CHAMPUS and CHAMPVA programs.

For inpatient services, a hospital that participates in the Medicare program must participate in any health plan contracted under 10 U.S.C. 1079 or 1086 (Civilian Health and Medical Program of the Uniformed Services) and under 38 U.S.C. 613 (Civilian Health and Medical Program of the Veterans Administration) and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full, less applicable deductible, patient cost-share, and noncovered items. Hospitals must meet the requirements of 32 CFR

part 199 concerning program benefits under the Department of Defense. This section applies to inpatient services furnished to beneficiaries admitted on or after January 1, 1987.

[59 FR 32123, June 22, 1994]

§ 489.26 Special requirements concerning veterans.

For inpatient services, a hospital that participates in the Medicare program must admit any veteran whose admission is authorized by the Department of Veterans Affairs under 38 U.S.C. 603 and must meet the requirements of 38 CFR part 17 concerning admissions practices and payment methodology and amounts. This section applies to services furnished to veterans admitted on and after July 1, 1987.

[59 FR 32123, June 22, 1994]

§ 489.27 Beneficiary notice of discharge rights.

(a) A hospital that participates in the Medicare program must furnish each Medicare beneficiary, or an individual acting on his or her behalf, the notice of discharge rights required under section 1866(a)(1)(M) of the Act. The hospital must provide timely notice during the course of the hospital stay. For purposes of this paragraph, the course of the hospital stay begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission. The hospital must be able to demonstrate compliance with this requirement.

(b) *Notification by other providers.* Other providers that participate in the Medicare program must furnish each Medicare beneficiary, or authorized representative, applicable CMS notices in advance of the termination of Medicare services, including the notices required under §§ 405.1202 and 422.624 of this chapter.

[68 FR 16669, Apr. 4, 2003, as amended at 69 FR 69268, Nov. 26, 2004]

§ 489.28 Special capitalization requirements for HHAs.

(a) *Basic rule.* An HHA entering the Medicare program on or after January 1, 1998, including a new HHA as a result of a change of ownership, if the change of ownership results in a new provider number being issued, must have available sufficient funds, which we term ''initial reserve operating funds,'' to operate the HHA for the three month period after its Medicare provider agreement becomes effective, exclusive of actual or projected accounts receivable from Medicare or other health care insurers.

(b) *Standard.* Initial reserve operating funds are sufficient to meet the requirement of this section if the total amount of such funds is equal to or greater than the product of the actual average cost per visit of three or more similarly situated HHAs in their first year of operation (selected by CMS for comparative purposes) multiplied by the number of visits projected by the HHA for its first three months of operation—or 22.5 percent (one fourth of 90 percent) of the average number of visits reported by the comparison HHAs—whichever is greater.

(c) *Method.* CMS, through the intermediary, will determine the amount of the initial reserve operating funds using reported cost and visit data from submitted cost reports for the first full year of operation from at least three HHAs that the intermediary serves that are comparable to the HHA that is seeking to enter the Medicare program, considering such factors as geographic location and urban/rural status, number of visits, provider-based versus free-standing, and proprietary versus non-proprietary status. The determination of the adequacy of the required initial reserve operating funds is based on the average cost per visit of the comparable HHAs, by dividing the sum of total reported costs of the HHAs in their first year of operation by the sum of the HHAs' total reported visits. The resulting average cost per visit is then multiplied by the projected visits for the first three months of operation of the HHA seeking to enter the program, but not less than 90 percent of average visits for a three month period for the HHAs used in determining the average cost per visit.

(d) *Required proof of availability of initial reserve operating funds.* The HHA must provide CMS with adequate proof

of the availability of initial reserve operating funds. Such proof, at a minimum, will include a copy of the statement(s) of the HHA's savings, checking, or other account(s) that contains the funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and that the funds are immediately available to the HHA. In some cases, an HHA may have all or part of the initial reserve operating funds in cash equivalents. For the purpose of this section, cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and that present insignificant risk of changes in value. A cash equivalent that is not readily convertible to a known amount of cash as needed during the initial three month period for which the initial reserve operating funds are required does not qualify in meeting the initial reserve operating funds requirement. Examples of cash equivalents for the purpose of this section are Treasury bills, commercial paper, and money market funds. As with funds in a checking, savings, or other account, the HHA also must be able to document the availability of any cash equivalents. CMS later may require the HHA to furnish another attestation from the financial institution that the funds remain available, or, if applicable, documentation from the HHA that any cash equivalents remain available, until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization. The officer of the HHA who will be certifying the accuracy of the information on the HHA's cost report must certify what portion of the required initial reserve operating funds is non-borrowed funds, including funds invested in the business by the owner. That amount must be at least 50 percent of the required initial reserve operating funds. The remainder of the reserve operating funds may be secured through borrowing or line of credit from an unrelated lender.

(e) *Borrowed funds.* If borrowed funds are not in the same account(s) as the HHA's own non-borrowed funds, the HHA also must provide proof that the borrowed funds are available for use in operating the HHA, by providing, at a minimum, a copy of the statement(s) of the HHA's savings, checking, or other account(s) containing the borrowed funds, accompanied by an attestation from an officer of the bank or other financial institution that the funds are in the account(s) and are immediately available to the HHA. As with the HHA's own (that is, non-borrowed) funds, CMS later may require the HHA to establish the current availability of such borrowed funds, including furnishing an attestation from a financial institution or other source, as may be appropriate, and to establish that such funds will remain available until a date when the HHA will have been surveyed by the State agency or by an approved accrediting organization.

(f) *Line of credit.* If the HHA chooses to support the availability of a portion of the initial reserve operating funds with a line of credit, it must provide CMS with a letter of credit from the lender. CMS later may require the HHA to furnish an attestation from the lender that the HHA, upon its certification into the Medicare program, continues to be approved to borrow the amount specified in the letter of credit.

(g) *Provider agreement.* CMS does not enter into a provider agreement with an HHA unless the HHA meets the initial reserve operating funds requirement of this section.

[63 FR 312, Jan. 5, 1998]

Subpart C—Allowable Charges

§ 489.30 Allowable charges: Deductibles and coinsurance.

(a) *Part A deductible and coinsurance.* The provider may charge the beneficiary or other person on his or her behalf:

(1) The amount of the inpatient hospital deductible or, if less, the actual charges for the services;

(2) The amount of inpatient hospital coinsurance applicable for each day the individual is furnished inpatient hospital services after the 60th day, during a benefit period; and

(3) The posthospital SNF care coinsurance amount.

(4) In the case of durable medical equipment (DME) furnished as a home

health service, 20 percent of the customary charge for the service.

(b) *Part B deductible and coinsurance.* (1) The basic allowable charges are the $75 deductible and 20 percent of the customary (insofar as reasonable) charges in excess of that deductible.

(2) For hospital outpatient services, the allowable deductible charges depend on whether the hospital can determine the beneficiary's deductible status.

(i) If the hospital is unable to determine the deductible status, it may charge the beneficiary its full customary charges up to $75.

(ii) If the beneficiary provides official information as to deductible status, the hospital may charge only the unmet portion of the deductible.

(3) In either of the cases discussed in paragraph (b)(2) of this section, the hospital is required to file with the intermediary, on a form prescribed by CMS, information as to the services, charges, and amounts collected.

(4) The intermediary must reimburse the beneficiary if reimbursement is authorized and credit the expenses to the beneficiary's deductible if the deductible has not yet been met.

(5) In the case of DME furnished as a home health service under Medicare Part B, the coinsurance is 20 percent of the customary (insofar as reasonable) charge for the services, with the following exception: If the DME is used DME purchased by or on behalf of the beneficiary at a price at least 25 percent less than the reasonable charge for comparable new equipment, no coinsurance is required.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 41350, Nov. 14, 1986]

§ 489.31 Allowable charges: Blood.

(a) *Limitations on charges.* (1) A provider may charge the beneficiary (or other person on his or her behalf) only for the first three pints of blood or units of packed red cells furnished under Medicare Part A during a calendar year, or furnished under Medicare Part B during a calendar year.

(2) The charges may not exceed the provider's customary charges.

(3) The provider may not charge for any whole blood or packed red cells in any of the circumstances specified in § 409.87(c)(2) of this chapter.

(b) *Offset for excessive charges.* If the charge exceeds the cost to the provider, that excess will be deducted from any Medicare payments due the provider.

[56 FR 23022, May 20, 1991, as amended at 57 FR 36018, Aug. 12, 1992]

§ 489.32 Allowable charges: Noncovered and partially covered services.

(a) *Services requested by beneficiary.* If services furnished at the request of a beneficiary (or his or her representative) are more expensive than, or in excess of, services covered under Medicare—

(1) A provider may charge the beneficiary an amount that does not exceed the difference between—

(i) The provider's customary charges for the services furnished; and

(ii) The provider's customary charges for the kinds and amounts of services that are covered under Medicare.

(2) A provider may not charge for the services unless they have been requested by the beneficiary (or his or her representative) nor require a beneficiary to request services as a condition of admission.

(3) To avoid misunderstanding and disputes, a provider must inform any beneficiary who requests a service for which a charge will be made that there will be a specified charge for that service.

(b) *Services not requested by the beneficiary.* For special provisions that apply when a provider customarily furnishes more expensive services, see § 413.35 of this chapter.

[45 FR 22937, Apr. 4, 1980, as amended at 51 FR 34833, Sept. 30, 1986]

§ 489.34 Allowable charges: Hospitals participating in State reimbursement control systems or demonstration projects.

A hospital receiving payment for a covered hospital stay under either a State reimbursement control system approved under 1886(c) of the Act or a demonstration project authorized under section 402(a) of Pub. L. 90–248 (42 U.S.C. 1395b–1) or section 222(a) of Pub. L. 92–603 (42 U.S.C. 1395b–1 (note)) and that would otherwise be subject to the

prospective payment system set forth in part 412 of this chapter may charge a beneficiary for noncovered services as follows:

(a) For the custodial care and medically unnecessary services described in § 412.42(c) of this chapter, after the conditions of § 412.42(c)(1) through (c)(4) are met; and

(b) For all other services in accordance with the applicable rules of this subpart C.

[54 FR 41747, Oct. 11, 1989]

§ 489.35 Notice to intermediary.

The provider must inform its intermediary of any amounts collected from a beneficiary or from other persons on his or her behalf.

Subpart D—Handling of Incorrect Collections

§ 489.40 Definition of incorrect collection.

(a) As used in this subpart, ''incorrect collections'' means any amounts collected from a beneficiary (or someone on his or her behalf) that are not authorized under subpart C of this part.

(b) A payment properly made to a provider by an individual not considered entitled to Medicare benefits will be deemed to be an ''incorrect collection'' when the individual is found to be retroactively entitled to benefits.

§ 489.41 Timing and methods of handling.

(a) *Refund.* Prompt refund to the beneficiary or other person is the preferred method of handling incorrect collections.

(b) *Setting aside.* If the provider cannot refund within 60 days from the date on the notice of incorrect collection, it must set aside an amount, equal to the amount incorrectly collected, in a separate account identified as to the individual to whom the payment is due. This amount incorrectly collected must be carried on the provider's records in this manner until final disposition is made in accordance with the applicable State law.

(c) *Notice to, and action by, intermediary.* (1) The provider must notify the intermediary of the refund or setting aside required under paragraphs (a) and (b) of this section.

(2) If the provider fails to refund or set aside the required amounts, they may be offset against amounts otherwise due the provider.

§ 489.42 Payment of offset amounts to beneficiary or other person.

(a) In order to carry out the commitment to refund amounts incorrectly collected, CMS may determine that amounts offset in accordance with § 489.41 are to be paid directly to the beneficiary or other person from whom the provider received the incorrect collection, if:

(1) CMS finds that the provider has failed, following written request, to refund the amount of the incorrect collection to the beneficiary or other person; and

(2) The provider agreement has been terminated in accordance with the provisions of subpart E of this part.

(b) Before making a determination to make payment under paragraph (a) of this section, CMS will give written notice to the provider (1) explaining that an incorrect collection was made and the amount; (2) requesting the provider to refund the incorrect collection to the beneficiary or other person; and (3) advising of CMS's intention to make a determination under paragraph (a) of this section.

(c) The notice will afford an authorized official of the provider an opportunity to submit, within 20 days from the date on the notice, written statement or evidence with respect to the incorrect collection and/or offset amounts. CMS will consider any written statement or evidence in making a determination.

(d) Payment to a beneficiary or other person under the provisions of paragraph (a) of this section:

(1) Will not exceed the amount of the incorrect collection; and

(2) May be considered as payment made to the provider.

Subpart E—Termination of Agreement and Reinstatement After Termination

§ 489.52 Termination by the provider.

(a) *Notice to CMS.* (1) A provider that wishes to terminate its agreement must send CMS written notice of its intent.

(2) The notice may state the intended date of termination which must be the first day of a month.

(b) *Termination date.* (1) If the notice does not specify a date, or the date is not acceptable to CMS, CMS may set a date that will not be more than 6 months from the date on the provider's notice of intent.

(2) CMS may accept a termination date that is less than 6 months after the date on the provider's notice if it determines that to do so would not unduly disrupt services to the community or otherwise interfere with the effective and efficient administration of the Medicare program.

(3) A cessation of business is deemed to be a termination by the provider, effective with the date on which it stopped providing services to the community.

(c) *Public notice.* (1) The provider must give notice to the public at least 15 days before the effective date of termination.

(2) The notice must be published in one or more local newspapers and must—

(i) Specify the termination date; and

(ii) Explain to what extent services may continue after that date, in accordance with the exceptions set forth in § 489.55.

§ 489.53 Termination by CMS.

(a) *Basis for termination of agreement with any provider.* CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider:

(1) It is not complying with the provisions of title XVIII and the applicable regulations of this chapter or with the provisions of the agreement.

(2) It places restrictions on the persons it will accept for treatment and it fails either to exempt Medicare beneficiaries from those restrictions or to apply them to Medicare beneficiaries the same as to all other persons seeking care.

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter. In the case of an RNHCI no longer meets the conditions for coverage, conditions of participation and requirements set forth elsewhere in this chapter.

(4) It fails to furnish information that CMS finds necessary for a determination as to whether payments are or were due under Medicare and the amounts due.

(5) It refuses to permit examination of its fiscal or other records by, or on behalf of CMS, as necessary for verification of information furnished as a basis for payment under Medicare.

(6) It failed to furnish information on business transactions as required in § 420.205 of this chapter.

(7) It failed at the time the agreement was entered into or renewed to disclose information on convicted individuals as required in § 420.204 of this chapter.

(8) It failed to furnish ownership information as required in § 420.206 of this chapter.

(9) It failed to comply with civil rights requirements set forth in 45 CFR parts 80, 84, and 90.

(10) In the case of a hospital or a critical access hospital as defined in section 1861(mm)(1) of the Act that has reason to believe it may have received an individual transferred by another hospital in violation of § 489.24(d), the hospital failed to report the incident to CMS or the State survey agency.

(11) In the case of a hospital requested to furnish inpatient services to CHAMPUS or CHAMPVA beneficiaries or to veterans, it failed to comply with § 489.25 or § 489.26, respectively.

(12) It failed to furnish the notice of discharge rights as required by § 489.27.

(13) It refuses to permit photocopying of any records or other information by, or on behalf of CMS, as necessary to determine or verify compliance with participation requirements.

(14) The hospital knowingly and willfully fails to accept, on a repeated basis, an amount that approximates the Medicare rate established under

the inpatient hospital prospective payment system, minus any enrollee deductibles or copayments, as payment in full from a fee-for-service FEHB plan for inpatient hospital services provided to a retired Federal enrollee of a fee-for-service FEHB plan, age 65 or older, who does not have Medicare Part A benefits.

(15) It had its enrollment in the Medicare program revoked in accordance to § 424.535 of this chapter.

(b) *Termination of agreements with certain hospitals.* In the case of a hospital or critical access hospital that has an emergency department, as defined in § 489.24(b), CMS may terminate the provider agreement if—

(1) The hospital fails to comply with the requirements of § 489.24 (a) through (e), which require the hospital to examine, treat, or transfer emergency medical condition cases appropriately, and require that hospitals with specialized capabilities or facilities accept an appropriate transfer; or

(2) The hospital fails to comply with § 489.20(m), (q), and (r), which require the hospital to report suspected violations of § 489.24(e), to post conspicuously in emergency departments or in a place or places likely to be noticed by all individuals entering the emergency departments, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments, (that is, entrance, admitting area, waiting room, treatment area), signs specifying rights of individuals under this subpart, to post conspicuously information indicating whether or not the hospital participates in the Medicaid program, and to maintain medical and other records related to transferred individuals for a period of 5 years, a list of on-call physicians for individuals with emergency medical conditions, and a central log on each individual who comes to the emergency department seeking assistance.

(c) *Notice of termination*—(1) *Timing: Basic rule.* Except as provided in paragraph (c)(2) of this section, CMS gives the provider notice of termination at least 15 days before the effective date of termination of the provider agreement.

(2) *Timing exceptions: Immediate jeopardy situations*—(i) *Hospital with emergency department.* If CMS finds that a hospital with an emergency department is in violation of § 489.24, paragraphs (a) through (e), and CMS determines that the violation poses immediate jeopardy to the health or safety of individuals who present themselves to the hospital for emergency services, CMS—

(A) Gives the hospital a preliminary notice indicating that its provider agreement will be terminated in 23 days if it does not correct the identified deficiencies or refute the finding; and

(B) Gives a final notice of termination, and concurrent notice to the public, at least 2 , but not more than 4, days before the effective date of termination of the provider agreement.

(ii) *Skilled nursing facilities (SNFs).* For an SNF with deficiencies that pose immediate jeopardy to the health or safety of residents, CMS gives notice at least 2 days before the effective date of termination of the provider agreement.

(3) *Content of notice.* The notice states the reasons for, and the effective date of, the termination, and explains the extent to which services may continue after that date, in accordance with § 489.55.

(4) *Notice to public.* CMS concurrently gives notice of the termination to the public.

(d) *Appeal by the provider.* A provider may appeal the termination of its provider agreement by CMS in accordance with part 498 of this chapter.

[51 FR 24492, July 3, 1986, as amended at 52 FR 22454, June 12, 1987; 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 59 FR 32123, June 22, 1994; 59 FR 56251, Nov. 10, 1994; 60 FR 45851, Sept. 1, 1995; 60 FR 50119, Sept. 28, 1995; 62 FR 43937, Aug. 18, 1997; 62 FR 46037, Aug. 29, 1997; 62 FR 56111, Oct. 29, 1997; 68 FR 66720, Nov. 28, 2003; 69 FR 49272, Aug. 11, 2004; 71 FR 20781, Apr. 21, 2006]

§ 489.54 Termination by the OIG.

(a) *Basis for termination.* (1) The OIG may terminate the agreement of any provider if the OIG finds that any of the following failings can be attributed to that provider.

(i) It has knowingly and willfully made, or caused to be made, any false

statement or representation of a material fact for use in an application or request for payment under Medicare.

(ii) It has submitted, or caused to be submitted, requests for Medicare payment of amounts that substantially exceed the costs it incurred in furnishing the services for which payment is requested.

(iii) It has furnished services that the OIG has determined to be substantially in excess of the needs of individuals or of a quality that fails to meet professionally recognized standards of health care. The OIG will not terminate a provider agreement under paragraph (a) if CMS has waived a disallowance with respect to the services in question on the grounds that the provider and the beneficiary could not reasonably be expected to know that payment would not be made. (The rules for determining such lack of knowledge are set forth in §§ 405.330 through 405.334 of this chapter.)

(b) *Notice of termination.* The OIG will give the provider notice of termination at least 15 days before the effective date of termination of the agreement, and will concurrently give notice of termination to the public.

(c) *Appeal by the provider.* A provider may appeal a termination of its agreement by the OIG in accordance with subpart O of part 405 of this chapter.

(d) *Other applicable rules.* The termination of a provider agreement by the OIG is subject to the additional procedures specified in §§ 1001.105 through 1001.109 of this title for notice and appeals.

[51 FR 24492, July 3, 1986, as amended at 51 FR 34788, Sept. 30, 1986]

§ 489.55 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services and hospice care furnished under a plan established before the effective date of termination.[1]

[50 FR 37376, Sept. 13, 1985]

§ 489.57 Reinstatement after termination.

When a provider agreement has been terminated by CMS under § 489.53, or by the OIG under § 489.54, a new agreement with that provider will not be accepted unless CMS or the OIG, as appropriate, finds—

(a) That the reason for termination of the previous agreement has been removed and there is reasonable assurance that it will not recur; and

(b) That the provider has fulfilled, or has made satisfactory arrangements to fulfill, all of the statutory and regulatory responsibilities of its previous agreement.

[51 FR 24493, July 3, 1986]

Subpart F—Surety Bond Requirements for HHAs

SOURCE: 63 FR 313, Jan. 5, 1998, unless otherwise noted.

§ 489.60 Definitions.

As used in this subpart unless the context indicates otherwise—

Assessment means a sum certain that CMS may assess against an HHA in lieu of damages under Titles XI, XVIII, or XXI of the Social Security Act or under regulations in this chapter.

Assets includes but is not limited to any listing that identifies Medicare beneficiaries to whom home health services were furnished by a participating or formerly participating HHA.

Civil money penalty means a sum certain that CMS has the authority to impose on an HHA as a penalty under Titles XI, XVIII, or XXI of the Social Security Act or under regulations in this chapter.

Participating home health agency means a ''home health agency'' (HHA), as that term is defined by section 1861(o) of the Social Security Act, that

[1] For termination before July 18, 1984, payment was available through the calendar year in which the termination was effective.

also meets the definition of a ''provider'' set forth at § 400.202 of this chapter.

Rider means a notice issued by a Surety that a change in the bond has occurred or will occur.

Surety bond means one or more bonds issued by one or more surety companies under 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225, provided the bond otherwise meets the requirements of this section.

Unpaid civil money penalty or assessment means a civil money penalty or assessment imposed by CMS on an HHA under Titles XI, XVIII, or XXI of the Social Security Act, plus accrued interest, that, after the HHA or Surety has exhausted all administrative appeals, remains unpaid (because the civil money penalty or assessment has not been paid to, or offset or compromised by, CMS) and is not the subject of a written arrangement, acceptable to CMS, for payment by the HHA. In the event a written arrangement for payment, acceptable to CMS, is made, an *unpaid civil money penalty or assessment* also means such civil money penalty or assessment, plus accrued interest, that remains due 60 days after the HHA's default on such arrangement.

Unpaid claim means a Medicare overpayment for which the HHA is responsible, plus accrued interest, that, 90 days after the date of the agency's notice to the HHA of the overpayment, remains due (because the overpayment has not been paid to, or recouped or compromised by, CMS) and is not the subject of a written arrangement, acceptable to CMS, for payment by the HHA. In the event a written arrangement for payment, acceptable to CMS, is made, an *unpaid claim* also means a Medicare overpayment for which the HHA is responsible, plus accrued interest, that remains due 60 days after the HHA's default on such arrangement.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.61 Basic requirement for surety bonds.

Except as provided in § 489.62, each HHA that is a Medicare participating HHA, or that seeks to become a Medicare participating HHA, must obtain a surety bond (and furnish to CMS a copy of such surety bond) that meets the requirements of this subpart F and CMS's instructions.

§ 489.62 Requirement waived for Government-operated HHAs.

An HHA operated by a Federal, State, local, or tribal government agency is deemed to have provided CMS with a comparable surety bond under State law, and CMS therefore waives the requirements of this subpart with respect to such an HHA if, during the preceding 5 years the HHA has—

(a) Not had any unpaid claims or unpaid civil money penalties or assessments; and

(b) Not had any of its claims referred by CMS to the Department of Justice or the General Accounting Office in accordance with part 401 of this chapter.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.63 Parties to the bond.

The surety bond must name the HHA as Principal, CMS as Obligee, and the surety company (and its heirs, executors, administrators, successors and assignees, jointly and severally) as Surety.

§ 489.64 Authorized Surety and exclusion of surety companies.

(a) An HHA may obtain a surety bond required under § 489.61 only from an authorized Surety.

(b) An authorized Surety is a surety company that—

(1) Has been issued a Certificate of Authority by the U.S. Department of the Treasury in accordance with 31 U.S.C. 9304 to 9308 and 31 CFR parts 223, 224, and 225 as an acceptable surety on Federal bonds and the Certificate has neither expired nor been revoked; and

(2) Has not been determined by CMS to be an unauthorized Surety for the purpose of an HHA obtaining a surety bond under this section.

(c) CMS determines that a surety company is an unauthorized Surety under this section—

(1) If, upon request by CMS, the surety company fails to furnish timely confirmation of the issuance of, and the validity and accuracy of information appearing on, a surety bond an

HHA presents to CMS that shows the surety company as Surety on the bond;

(2) If, upon presentation by CMS to the surety company of a request for payment on a surety bond and of sufficient evidence to establish the surety company's liability on the bond, the surety company fails to timely pay CMS in full the amount requested, up to the face amount of the bond; or

(3) For other good cause.

(d) Any determination CMS makes under paragraph (c) of this section is effective immediately when notice of the determination is published in the FEDERAL REGISTER and remains in effect until a notice of reinstatement is published in the FEDERAL REGISTER.

(e) Any determination CMS makes under paragraph (c) of this section does not affect the Surety's liability under any surety bond issued by a surety company to an HHA before notice of such determination is published in accordance with paragraph (d) of this section.

(f) A determination by CMS that a surety company is an unauthorized Surety under this section is not a debarment, suspension, or exclusion for the purposes of Executive Order No. 12549 (3 CFR, 1986 comp., p. 189).

§ 489.65 Amount of the bond.

(a) *Basic rule.* The amount of the surety bond must be $50,000 or 15 percent of the Medicare payments made by CMS to the HHA in the HHA's most recent fiscal year for which a cost report has been accepted by CMS, whichever is greater.

(b) *Computation of the 15 percent: Participating HHA.* The 15 percent is computed as follows:

(1) For the initial bond—on the basis of Medicare payments made by CMS to the HHA in the HHA's most recent fiscal year as shown in the HHA's most recent cost report that has been accepted by CMS. If the initial bond will cover less than a full fiscal year, the computation of the 15 percent will be based on the number of months of the fiscal year that the bond will cover.

(2) For subsequent bonds—on the basis of Medicare payments made by CMS in the most recent fiscal year for which a cost report has been accepted. However, if payments in the first six months of the current fiscal year differ from such an amount by more than 25 percent, then the amount of the bond is 15 percent of such payments projected on an annualized basis.

(c) *Computation of 15 percent: An HHA that seeks to become a participating HHA by obtaining assets or ownership interest.* For an HHA that seeks to become a participating HHA by purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent is computed on the basis of Medicare payments made by CMS to the participating or formerly participating HHA in the most recent fiscal year that a cost report has been accepted.

(d) *Change of ownership.* For an HHA that undergoes a change of ownership the 15 percent is computed on the basis of Medicare payments made by CMS to the HHA for the most recently accepted cost report.

(e) *An HHA that seeks to become a participating HHA without obtaining assets or ownership interest.* For an HHA that seeks to become a participating HHA without purchasing the assets or the ownership interest of a participating or formerly participating HHA, the 15 percent computation does not apply.

(f) *Exception to the basic rule.* If an HHA's overpayment in the most recently accepted cost report exceeds 15 percent of annual payments, CMS may require the HHA to secure a bond in an amount up to or equal to the amount of overpayment, provided the amount of the bond is not less than $50,000.

(g) *Expiration of the 15 percent provision.* For an annual surety bond, or for a rider on a continuous surety bond, that is required to be submitted on or after June 1, 2005, notwithstanding any reference in this subpart to 15 percent as a basis for determining the amount of the bond, the amount of the bond or rider, as applicable, must be $50,000 or such amount as CMS specifies in accordance with paragraph (f) of this section, whichever amount is greater.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.66 Additional requirements of the surety bond.

The surety bond that an HHA obtains under this subpart must meet the following additional requirements:

(a) The bond must guarantee that within 30 days of receiving written notice from CMS of an unpaid claim or unpaid civil money penalty or assessment, which notice contains sufficient evidence to establish the Surety's liability under the bond, the Surety will pay CMS, up to the stated amount of the bond—

(1) The full amount of any unpaid claim, plus accrued interest, for which the HHA is responsible; and

(2) The full amount of any unpaid civil money penalty or assessment imposed by CMS on the HHA, plus accrued interest.

(b) The bond must provide the following:

(1) The Surety is liable for unpaid claims, unpaid civil money penalties, and unpaid assessments that are discovered when the surety bond is in effect, regardless of when the payment, overpayment, or other event giving rise to the claim, civil money penalty, or assessment occurred, provided CMS makes a written demand for payment from the Surety during, or within 90 days after, the term of the bond.

(2) If the HHA fails to furnish a bond meeting the requirements of this subpart F for the year following expiration of the term of an annual bond, or if the HHA fails to submit a rider when a rider is required to be submitted under this subpart, or if the HHA's provider agreement is terminated, the last bond or rider, as applicable, submitted by the HHA to CMS, which bond or applicable rider meets the requirements of this subpart, remains effective and the Surety remains liable for unpaid claims, civil money penalties, and assessments that—

(i) CMS determines or imposes on or asserts against the HHA based on overpayments or other events that took place during or prior to the term of the last bond or rider; and

(ii) Were determined or imposed during the 2 years following the date the HHA failed to submit a bond or required rider or the date the HHA's provider agreement is terminated, whichever is later.

(c) The bond must provide that the Surety's liability to CMS under the bond is not extinguished by any action of the HHA, the Surety, or CMS, including but not necessarily limited to any of the following actions:

(1) Action by the HHA or the Surety to terminate or limit the scope or term of the bond. The Surety's liability may be extinguished, however, when—

(i) The Surety furnishes CMS with notice of such action not later than 10 days after receiving notice from the HHA of action by the HHA to terminate or limit the scope of the bond, or not later than 60 days before the effective date of such action by the Surety; or

(ii) The HHA furnishes CMS with a new bond that meets the requirements of this subpart.

(2) The Surety's failure to continue to meet the requirements of § 489.64(a) or CMS's determination that the surety company is an unauthorized Surety under § 489.64(b).

(3) Termination of the HHA's provider agreement.

(4) Any action by CMS to suspend, offset, or otherwise recover payments to the HHA.

(5) Any action by the HHA to—

(i) Cease operation;

(ii) Sell or transfer any asset or ownership interest;

(iii) File for bankruptcy; or

(iv) Fail to pay the Surety.

(6) Any fraud, misrepresentation, or negligence by the HHA in obtaining the surety bond or by the Surety (or by the Surety's agent, if any) in issuing the surety bond, except that any fraud, misrepresentation, or negligence by the HHA in identifying to the Surety (or to the Surety's agent) the amount of Medicare payments upon which the amount of the surety bond is determined will not cause the Surety's liability to CMS to exceed the amount of the bond.

(7) The HHA's failure to exercise available appeal rights under Medicare or to assign such rights to the Surety.

(d) The bond must provide that actions under the bond may be brought by CMS or by CMS's fiscal intermediaries.

(e) The bond must provide the Surety's name, street address or post office box number, city, state, and zipcode to which the CMS notice provided for in paragraph (a) of this section is to be sent.

[63 FR 313, Jan. 5, 1998, as amended at 63 FR 29655, June 1, 1998]

§ 489.67 Term and type of bond.

(a) Each participating HHA that does not meet the criteria for waiver under § 489.62 must submit to CMS in a form as CMS may specify, a surety bond for a term beginning January 1, 1998. If an annual bond is submitted for the initial term, it must be effective through the end of the HHA's current fiscal year.

(b) *Type of bond.* The type of bond required to be submitted by an HHA under this subpart may be either—

(1) An annual bond (that is, a bond that specifies an effective annual period corresponding to the HHA's fiscal year); or

(2) A continuous bond (that is, a bond that remains in full force and effect from term to term unless it is terminated or canceled as provided for in the bond or as otherwise provided by law) that is updated by the Surety, via the issuance of a rider, for a particular fiscal year for which the bond amount has changed or will change.

(c) *HHA that seeks to become a participating HHA.* (1) An HHA that seeks to become a participating HHA must submit a surety bond with its enrollment application (Form CMS–855, OMB number 0938–0685). The term of the initial surety bond must be effective from the effective date of provider agreement as specified in § 489.13 of this part. However, if the effective date of the provider agreement is less than 30 days before the end of the HHA's current fiscal year, the HHA may obtain a bond effective through the end of the next fiscal year, provided the amount of the bond is the greater of $75,000 or 20 percent of the amount determined from the computation specified in § 489.65(c) as applicable.

(2) An HHA that seeks to become a participating HHA through the purchase or transfer of assets or ownership interest of a participating or formerly participating HHA must also ensure that the surety bond is effective from the date of such purchase or transfer.

(d) *Change of ownership.* An HHA that undergoes a change of ownership must submit the surety bond to CMS not later than the effective date of the change of ownership and the bond must be effective from the effective date of the change of ownership through the remainder of the HHA's fiscal year.

(e) *Government-operated HHA that loses its waiver.* A government-operated HHA that, as of January 1, 1998, meets the criteria for waiver under § 489.62 but thereafter is determined by CMS to not meet such criteria, must submit a surety bond to CMS within 60 days after it receives notice from CMS that it no longer meets the criteria for waiver.

(f) *Change of Surety.* An HHA that obtains a replacement surety bond from a different Surety to cover the remaining term of a previously obtained bond must submit the new surety bond to CMS within 30 days of obtaining the bond from the new Surety.

(Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh))

[63 FR 315, Jan. 5, 1998, as amended at 63 FR 10731, Mar. 4, 1998; 63 FR 29656, June 1, 1998; 63 FR 41171, July 31, 1998]

§ 489.68 Effect of failure to obtain, maintain, and timely file a surety bond.

(a) The failure of a participating HHA to obtain, file timely, and maintain a surety bond in accordance with this subpart F and CMS's instructions is sufficient under § 489.53(a)(1) for CMS to terminate the HHA's provider agreement.

(b) The failure of an HHA seeking to become a participating HHA to obtain and file timely a surety bond in accordance with this Subpart F and CMS's instructions is sufficient under § 489.12(a)(3) for CMS to refuse to enter into a provider agreement with the HHA.

§ 489.69 Evidence of compliance.

(a) CMS may at any time require an HHA to make a specific showing of

being in compliance with the requirements of this Subpart F and may require the HHA to submit such additional evidence as CMS considers sufficient to demonstrate the HHA's compliance.

(b) If requested by CMS to do so, the failure of an HHA to timely furnish sufficient evidence to CMS to demonstrate compliance with the requirements of this Subpart F is sufficient for CMS to terminate the HHA's provider agreement under §489.53(a)(1) or to refuse to enter into a provider agreement with the HHA under §489.12(a)(3), as applicable.

§ 489.70 Effect of payment by the Surety.

A Surety's payment to CMS under a bond for an unpaid claim or an unpaid civil money penalty or assessment, constitutes—

(a) Collection of the unpaid claim or unpaid civil money penalty or assessment (to the extent the Surety's payment on the bond covers such unpaid claim, civil money penalty, or assessment); and

(b) A basis for termination of the HHA's provider agreement under §489.53(a)(1).

§ 489.71 Surety's standing to appeal Medicare determinations.

A Surety has standing to appeal any matter that the HHA could appeal, provided the Surety satisfies all jurisdictional and procedural requirements that would otherwise have applied to the HHA, and provided the HHA is not, itself, actively pursuing its appeal rights under this chapter, and provided further that, with respect to unpaid claims, the Surety has paid CMS all amounts owed to CMS by the HHA on such unpaid claims, up to the amount of the bond.

[63 FR 29656, June 1, 1998]

§ 489.72 Effect of review reversing determination.

In the event a Surety has paid CMS on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and to the extent the HHA that obtained such bond (or the Surety under §489.71) is subsequently successful in appealing the determination that was the basis of the unpaid claim or unpaid civil money penalty or assessment that caused the Surety to pay CMS under the bond, CMS will refund to the Surety the amount the Surety paid to CMS to the extent such amount relates to the matter that was successfully appealed by the HHA (or by the Surety), provided all review, including judicial review, has been completed on such matter. Any additional amounts owing as a result of the appeal will be paid to the HHA.

§ 489.73 Effect of conditions of payment.

If a Surety has paid an amount to CMS on the basis of liability incurred under a bond obtained by an HHA under this subpart F, and CMS subsequently collects from the HHA, in whole or in part, on such unpaid claim, civil money penalty, or assessment that was the basis for the Surety's liability, CMS reimburses the Surety such amount as CMS collected from the HHA, up to the amount paid by the Surety to CMS, provided the Surety has no other liability to CMS under the bond.

(Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh))

[63 FR 29656, June 1, 1998]

§ 489.74 Incorporation into existing provider agreements.

The requirements of this subpart F are deemed to be incorporated into existing HHA provider agreements effective January 1, 1998.

[63 FR 315, Jan. 5, 1998. Redesignated at 63 FR 29656, June 1, 1998]

Subparts G–H [Reserved]

Subpart I—Advance Directives

SOURCE: 57 FR 8203, Mar. 6, 1992, unless otherwise noted.

§ 489.100 Definition.

For purposes of this part, *advance directive* means a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of

health care when the individual is incapacitated.

§ 489.102 Requirements for providers.

(a) Hospitals, critical access hospitals, skilled nursing facilities, nursing facilities, home health agencies, providers of home health care (and for Medicaid purposes, providers of personal care services), hospices, and religious nonmedical health care institutions must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care, or patient care in the case of a patient in a religious nonmedical health care institution, by or through the provider and are required to:

(1) Provide written information to such individuals concerning—

(i) An individual's rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. Providers are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. Providers are to update and disseminate amended information as soon as possible, but no later than 90 days from the effective date of the changes to State law; and

(ii) The written policies of the provider or organization respecting the implementation of such rights, including a clear and precise statement of limitation if the provider cannot implement an advance directive on the basis of conscience. At a minimum, a provider's statement of limitation should:

(A) Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians;

(B) Identify the state legal authority permitting such objection; and

(C) Describe the range of medical conditions or procedures affected by the conscience objection.

(2) Document in a prominent part of the individual's current medical record, or patient care record in the case of an individual in a religious nonmedical health care institution, whether or not the individual has executed an advance directive;

(3) Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(4) Ensure compliance with requirements of State law (whether statutory or recognized by the courts of the State) regarding advance directives. The provider must inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency;

(5) Provide for education of staff concerning its policies and procedures on advance directives; and

(6) Provide for community education regarding issues concerning advance directives that may include material required in paragraph (a)(1) of this section, either directly or in concert with other providers and organizations. Separate community education materials may be developed and used, at the discretion of providers. The same written materials do not have to be provided in all settings, but the material should define what constitutes an advance directive, emphasizing that an advance directive is designed to enhance an incapacitated individual's control over medical treatment, and describe applicable State law concerning advance directives. A provider must be able to document its community education efforts.

(b) The information specified in paragraph (a) of this section is furnished:

(1) In the case of a hospital, at the time of the individual's admission as an inpatient.

(2) In the case of a skilled nursing facility at the time of the individual's admission as a resident.

(3)(i) In the case of a home health agency, in advance of the individual coming under the care of the agency. The HHA may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(ii) In the case of personal care services, in advance of the individual coming under the care of the personal care services provider. The personal care provider may furnish advance directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided.

(4) In the case of a hospice program, at the time of initial receipt of hospice care by the individual from the program.

(c) The providers listed in paragraph (a) of this section—

(1) Are not required to provide care that conflicts with an advance directive.

(2) Are not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive and State law allows any health care provider or any agent of such provider to conscientiously object.

(d) Prepaid or eligible organizations (as specified in sections 1833(a)(1)(A) and 1876(b) of the Act) must meet the requirements specified in § 417.436 of this chapter.

(e) If an adult individual is incapacitated at the time of admission or at the start of care and is unable to receive information (due to the incapacitating conditions or a mental disorder) or articulate whether or not he or she has executed an advance directive, then the provider may give advance directive information to the individual's family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The provider is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.

[57 FR 8203, Mar. 6, 1992, as amended at 59 FR 45403, Sept. 1, 1994; 60 FR 33294, June 27, 1995; 62 FR 46037, Aug. 29, 1997; 64 FR 67052, Nov. 30, 1999; 68 FR 66720, Nov. 28, 2003]

§ 489.104 Effective dates.

These provisions apply to services furnished on or after December 1, 1991 payments made under section 1833(a)(1)(A) of the Act on or after December 1, 1991, and contracts effective on or after December 1, 1991.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

Sec.
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491.2 Definitions.
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491.11 Program evaluation.

AUTHORITY: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

Subpart A—Rural Health Clinics: Conditions for Certification; and FQHCs Conditions for Coverage

§ 491.1 Purpose and scope.

This subpart sets forth the conditions that rural health clinics or FQHCs must meet in order to qualify for reimbursement under Medicare (title XVIII of the Social Security Act) and that rural health clinics must meet in order to qualify for reimbursement under Medicaid (title XIX of the Act).

[57 FR 24982, June 12, 1992]

§ 491.2 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by the clinic's staff.

FQHC means an entity as defined in § 405.2401(b).

Nurse practitioner means a registered professional nurse who is currently licensed to practice in the State, who

meets the State's requirements governing the qualifications of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

(2) Has satisfactorily completed a formal 1 academic year educational program that:

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program; or

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (2) of this definition, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding the effective date of this subpart.

Physician means a doctor of medicine or osteopathy legally authorized to practice medicine or surgery in the State.

Physician assistant means a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians; or

(2) Has satisfactorily completed a program for preparing physician's assistants that:

(i) Was at least 1 academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation; or

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (2) of this definition and assisted primary care physicians for a total of 12 months during the 18-month period that ended on December 31, 1986.

Rural area means an area that is not delineated as an urbanized area by the Bureau of the Census.

Rural health clinic or clinic means a clinic that is located in a rural area designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care and treatment of mental diseases, and meets all other requirements of this subpart.

Shortage area means a defined geographic area designated by the Department as having either a shortage of personal health services (under section 1302(7) of the Public Health Service Act) or a shortage of primary medical care manpower (under section 332 of that Act).

Secretary means the Secretary of Health and Human Services, or any official to whom he has delegated the pertinent authority.

[71 FR 55345, Sept. 22, 2006]

§ 491.3 Certification procedures.

A rural health clinic will be certified for participation in Medicare in accordance with subpart S of 42 CFR part 405. The Secretary will notify the State Medicaid agency whenever he has certified or denied certification under Medicare for a prospective rural health clinic in that State. A clinic certified under Medicare will be deemed to meet the standards for certification under Medicaid.

[71 FR 55346, Sept. 22, 2006]

§ 491.4 Compliance with Federal, State and local laws.

The rural health clinic or FQHC and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Licensure of clinic or center.* The clinic or center is licensed pursuant to applicable State and local law.

(b) *Licensure, certification or registration of personnel.* Staff of the clinic or center are licensed, certified or registered in accordance with applicable State and local laws.

[57 FR 24982, June 12, 1992]

§ 491.5 Location of clinic.

(a) *Basic requirements.* (1) An RHC is located in a rural area that is designated as a shortage area.

(2) An FQHC is located in a rural or urban area that is designated as either a shortage area or an area that has a medically underserved population.

(3) Both the RHC and the FQHC may be permanent or mobile units.

(i) *Permanent unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a permanent structure.

(ii) *Mobile unit.* The objects, equipment, and supplies necessary for the provision of the services furnished directly by the clinic or center are housed in a mobile structure, which has fixed, scheduled location(s).

(iii) *Permanent unit in more than one location.* If clinic or center services are furnished at permanent units in more than one location, each unit is independently considered for approval as a rural health clinic or for approval as an FQHC.

(b) *Exceptions.* (1) CMS does not disqualify an RHC approved under this subpart if the area in which it is located subsequently fails to meet the definition of a rural, shortage area.

(2) A private, nonprofit facility that meets all other conditions of this subpart except for location in a shortage area will be certified if, on July 1, 1977, it was operating in a rural area that is determined by the Secretary (on the basis of the ratio of primary care physicians to the general population) to have an insufficient supply of physicians to meet the needs of the area served.

(3) Determinations on these exceptions will be made by the Secretary upon application by the facility.

(c) *Criteria for designation of rural areas.* (1) Rural areas are areas not delineated as urbanized areas in the last census conducted by the Census Bureau.

(2) Excluded from the rural area classification are:

(i) Central cities of 50,000 inhabitants or more;

(ii) Cities with at least 25,000 inhabitants which, together with contiguous areas having stipulated population density, have combined populations of 50,000 and constitute, for general economic and social purposes, single communities;

(iii) Closely settled territories surrounding cities and specifically designated by the Census Bureau as urban.

(3) Included in the rural area classification are those portions of extended cities that the Census Bureau has determined to be rural.

(d) *Criteria for designation of shortage areas.* (1) The criteria for determination of shortage of personal health services (under section 1302(7) of the Public Health Services Act), are:

(i) The ratio of primary care physicians practicing within the area to the resident population;

(ii) The infant mortality rate;

(iii) The percent of the population 65 years of age or older; and

(iv) The percent of the population with a family income below the poverty level.

(2) The criteria for determination of shortage of primary medical care manpower (under section 332(a)(1)(A) of the Public Health Services Act) are:

(i) The area served is a rational area for the delivery of primary medical care services;

(ii) The ratio of primary care physicians practicing within the area to the resident population; and

(iii) The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area.

(e) *Medically underserved population.* A medically underserved population includes the following:

(1) A population of an urban or rural area that is designated by PHS as having a shortage of personal health services.

(2) A population group that is designated by PHS as having a shortage of personal health services.

(f) *Requirements specific to FQHCs.* An FQHC approved for participation in

Medicare must meet one of the following criteria:

(1) Furnish services to a medically underserved population.

(2) Be located in a medically underserved area, as demonstrated by an application approved by PHS.

CROSS REFERENCE: See 42 CFR 110.203(g) (41 FR 45718, Oct. 15, 1976) and 42 CFR Part 5 (42 FR 1586, Jan. 10, 1978).

[43 FR 5375, Feb. 8, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, and amended at 57 FR 24982, June 12, 1992; 61 FR 14658, Apr. 3, 1996; 68 FR 74816, Dec. 24, 2003; 71 FR 55346, Sept. 22, 2006]

§ 491.6 Physical plant and environment.

(a) *Construction.* The clinic or center is constructed, arranged, and maintained to insure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Maintenance.* The clinic or center has a preventive maintenance program to ensure that:

(1) All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

(2) Drugs and biologicals are appropriately stored; and

(3) The premises are clean and orderly.

(c) *Emergency procedures.* The clinic or center assures the safety of patients in case of non-medical emergencies by:

(1) Training staff in handling emergencies;

(2) Placing exit signs in appropriate locations; and

(3) Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic or center is located.

[57 FR 24983, June 12, 1992]

§ 491.7 Organizational structure.

(a) *Basic requirements.* (1) The clinic or center is under the medical direction of a physician, and has a health care staff that meets the requirements of § 491.8.

(2) The organization's policies and its lines of authority and responsibilities are clearly set forth in writing.

(b) *Disclosure.* The clinic or center discloses the names and addresses of:

(1) Its owners, in accordance with section 1124 of the Social Security Act (42 U.S.C. 132 A–3);

(2) The person principally responsible for directing the operation of the clinic or center; and

(3) The person responsible for medical direction.

[57 FR 24983, June 12, 1992]

§ 491.8 Staffing and staff responsibilities.

(a) *Staffing.* (1) The clinic or center has a health care staff that includes one or more physicians. Rural health clinic staffs must also include one or more physician's assistants or nurse practitioners.

(2) The physician member of the staff may be the owner of the rural health clinic, an employee of the clinic or center, or under agreement with the clinic or center to carry out the responsibilities required under this section.

(3) The physician assistant, nurse practitioner, nurse-midwife, clinical social worker, or clinical psychologist member of the staff may be the owner or an employee of the clinic or center, or may furnish services under contract to the center.

(4) The staff may also include ancillary personnel who are supervised by the professional staff.

(5) The staff is sufficient to provide the services essential to the operation of the clinic or center.

(6) A physician, nurse practitioner, physician assistant, nurse-midwife, clinical social worker, or clinical psychologist is available to furnish patient care services at all times the clinic or center operates. In addition, for rural health clinics, a nurse practitioner or a physician assistant is available to furnish patient care services at least 60 percent of the time the clinic operates.

(b) *Physician responsibilities.* (1) The physician:

(i) Except for services furnished by a clinical psychologist in an FQHC, which State law permits to be provided without physician supervision, provides medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician's assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the clinic's or center's written policies and the services provided to Federal program patients; and

(iii) Periodically reviews the clinic's or center's patient records, provides medical orders, and provides medical care services to the patients of the clinic or center.

(2) A physician is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances), to provide the medical direction, medical care services, consultation and supervision described in paragraph (b)(1) of this section and is available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the clinic or center.

(c) *Physician assistant and nurse practitioner responsibilities.* (1) The physician assistant and the nurse practitioner members of the clinic's or center's staff:

(i) Participate in the development, execution and periodic review of the written policies governing the services the clinic or center furnishes;

(ii) Participate with a physician in a periodic review of the patients' health records.

(2) The physician assistant or nurse practitioner performs the following functions, to the extent they are not being performed by a physician:

(i) Provides services in accordance with the clinic's or center's policies;

(ii) Arranges for, or refers patients to, needed services that cannot be provided at the clinic or center; and

(iii) Assures that adequate patient health records are maintained and transferred as required when patients are referred.

[57 FR 24983, June 12, 1992, as amended at 61 FR 14658, Apr. 3, 1996; 68 FR 74817, Dec. 24, 2003; 71 FR 55346, Sept. 22, 2006]

§ 491.9 Provision of services.

(a) *Basic requirements.* (1) All services offered by the clinic or center are furnished in accordance with applicable Federal, State, and local laws; and

(2) The clinic or center is primarily engaged in providing outpatient health services and meets all other conditions of this subpart.

(3) The laboratory requirements in paragraph (c)(2) of this section apply to RHCs, but do not apply to FQHCs.

(b) *Patient care policies.* (1) The clinic's or center's health care services are furnished in accordance with appropriate written policies which are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician assistants or nurse practitioners. At least one member is not a member of the clinic or center staff.

(3) The policies include:

(i) A description of the services the clinic or center furnishes directly and those furnished through agreement or arrangement.

(ii) Guidelines for the medical management of health problems which include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the clinic or center.

(iii) Rules for the storage, handling, and administration of drugs and biologicals.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (b)(2) of this section and reviewed as necessary by the clinic or center.

(c) *Direct services*—(1) *General.* The clinic or center staff furnishes those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory.* These requirements apply to RHCs but not to FQHCs. The RHC provides laboratory services in accordance with part 493 of this chapter, which implements the provisions of section 353 of the Public Health Service

Act. The RHC provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

(i) Chemical examinations of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Emergency*. The clinic or center provides medical emergency procedures as a first response to common life-threatening injuries and acute illness and has available the drugs and biologicals commonly used in life saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) *Services provided through agreements or arrangements*. (1) The clinic or center has agreements or arrangements with one or more providers or suppliers participating under Medicare or Medicaid to furnish other services to its patients, including:

(i) Inpatient hospital care;

(ii) Physician(s) services (whether furnished in the hospital, the office, the patient's home, a skilled nursing facility, or elsewhere); and

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic or center.

(2) If the agreements are not in writing, there is evidence that patients referred by the clinic or center are being accepted and treated.

[57 FR 24983, June 12, 1992, as amended at 58 FR 63536, Dec. 2, 1993]

§ 491.10 Patient health records.

(a) *Records system*. (1) The clinic or center maintains a clinical record system in accordance with written policies and procedures.

(2) A designated member of the professional staff is responsible for maintaining the records and for insuring that they are completely and accurately documented, readily accessible, and systematically organized.

(3) For each patient receiving health care services, the clinic or center maintains a record that includes, as applicable:

(i) Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;

(iii) All physician's orders, reports of treatments and medications, and other pertinent information necessary to monitor the patient's progress;

(iv) Signatures of the physician or other health care professional.

(b) *Protection of record information*. (1) The clinic or center maintains the confidentiality of record information and provides safeguards against loss, destruction or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the clinic or center and the conditions for release of information.

(3) The patient's written consent is required for release of information not authorized to be released without such consent.

(c) *Retention of records*. The records are retained for at least 6 years from date of last entry, and longer if required by State statute.

(Secs. 1102, 1833 and 1902(a)(13), Social Security Act; 49 Stat. 647, 91 Stat. 1485 (42 U.S.C. 1302, 13951 and 1396a(a)(13)))

[43 FR 30529, July 14, 1978. Redesignated at 50 FR 33034, Aug. 16, 1985, as amended at 57 FR 24984, June 12, 1992]

§ 491.11 Program evaluation.

(a) The clinic or center carries out, or arranges for, an annual evaluation of its total program.

(b) The evaluation includes review of:

(1) The utilization of clinic or center services, including at least the number of patients served and the volume of services;

(2) A representative sample of both active and closed clinical records; and

(3) The clinic's or center's health care policies.

(c) The purpose of the evaluation is to determine whether:

(1) The utilization of services was appropriate;

(2) The established policies were followed; and

(3) Any changes are needed.

(d) The clinic or center staff considers the findings of the evaluation and takes corrective action if necessary.

[71 FR 55346, Sept. 22, 2006]

PART 493—LABORATORY REQUIREMENTS

Subpart A—General Provisions

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Subpart B—Certificate of Waiver

493.35 Application for a certificate of waiver.
493.37 Requirements for a certificate of waiver.
493.39 Notification requirements for laboratories issued a certificate of waiver.

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493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.
493.45 Requirements for a registration certificate.
493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.
493.49 Requirements for a certificate of compliance.
493.51 Notification requirements for laboratories issued a certificate of compliance.
493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Subpart D—Certificate of Accreditation

493.55 Application for registration certificate and certificate of accreditation.
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493.602 Scope of subpart.
493.606 Applicability of subpart.
493.638 Certificate fees.
493.639 Fee for revised certificate.
493.643 Fee for determination of program compliance.
493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.
493.646 Payment of fees.
493.649 Methodology for determining fee amount.

Subpart G [Reserved]

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

493.801 Condition: Enrollment and testing of samples.
493.803 Condition: Successful participation.
493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (INCLUDING THE SUBCATEGORY), HIGH COMPLEXITY, OR ANY COMBINATION OF THESE TESTS

493.821 Condition: Microbiology.
493.823 Standard; Bacteriology.
493.825 Standard; Mycobacteriology.
493.827 Standard; Mycology.
493.829 Standard; Parasitology.
493.831 Standard; Virology.
493.833 Condition: Diagnostic immunology.
493.835 Standard; Syphilis serology.
493.837 Standard; General immunology.
493.839 Condition: Chemistry.
493.841 Standard; Routine chemistry.
493.843 Standard; Endocrinology.
493.845 Standard; Toxicology.
493.849 Condition: Hematology.
493.851 Standard; Hematology.
493.853 Condition: Pathology.
493.855 Standard; Cytology: gynecologic examinations.
493.857 Condition: Immunohematology.
493.859 Standard; ABO group and D (Rho) typing.
493.861 Standard; Unexpected antibody detection.
493.863 Standard; Compatibility testing.
493.865 Standard; Antibody identification.

Subpart I—Proficiency Testing Programs for Nonwaived Testing

493.901 Approval of proficiency testing programs.
493.903 Administrative responsibilities.
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PROFICIENCY TESTING PROGRAMS BY SPECIALTY AND SUBSPECIALTY

493.909 Microbiology.
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493.913 Mycobacteriology.
493.915 Mycology.
493.917 Parasitology.
493.919 Virology.
493.921 Diagnostic immunology.
493.923 Syphilis serology.
493.927 General immunology.
493.929 Chemistry.
493.931 Routine chemistry.
493.933 Endocrinology.
493.937 Toxicology.
493.941 Hematology (including routine hematology and coagulation).
493.945 Cytology; gynecologic examinations.
493.959 Immunohematology.

Subpart J—Facility Administration for Nonwaived Testing

493.1100 Condition: Facility administration.
493.1101 Standard: Facilities.
493.1103 Standard: Requirements for transfusion services.
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Subpart K—Quality System for Nonwaived Testing

493.1200 Introduction.
493.1201 Condition: Bacteriology.
493.1202 Condition: Mycobacteriology.
493.1203 Condition: Mycology.
493.1204 Condition: Parasitology.
493.1205 Condition: Virology.
493.1207 Condition: Syphilis serology.
493.1208 Condition: General immunology.
493.1210 Condition: Routine chemistry.
493.1211 Condition: Urinalysis.
493.1212 Condition: Endocrinology.
493.1213 Condition: Toxicology.
493.1215 Condition: Hematology.
493.1217 Condition: Immunohematology.
493.1219 Condition: Histopathology.
493.1220 Condition: Oral pathology.
493.1221 Condition: Cytology.
493.1225 Condition: Clinical cytogenetics.
493.1226 Condition: Radiobioassay.
493.1227 Condition: Histocompatibility.

GENERAL LABORATORY SYSTEMS

493.1230 Condition: General laboratory systems.
493.1231 Standard: Confidentiality of patient information.
493.1232 Standard: Specimen identification and integrity.
493.1233 Standard: Complaint investigations.
493.1234 Standard: Communications.
493.1235 Standard: Personnel competency assessment policies.
493.1236 Standard: Evaluation of proficiency testing performance.
493.1239 Standard: General laboratory systems quality assessment.

PREANALYTIC SYSTEMS

493.1240 Condition: Preanalytic systems.
493.1241 Standard: Test request.
493.1242 Standard: Specimen submission, handling, and referral.
493.1249 Standard: Preanalytic systems quality assessment.

ANALYTIC SYSTEMS

493.1250 Condition: Analytic systems.

493.1251 Standard: Procedure manual.
493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.
493.1253 Standard: Establishment and verification of performance specifications.
493.1254 Standard: Maintenance and function checks.
493.1255 Standard: Calibration and calibration verification procedures.
493.1256 Standard: Control procedures.
493.1261 Standard: Bacteriology.
493.1262 Standard: Mycobacteriology.
493.1263 Standard: Mycology.
493.1264 Standard: Parasitology.
493.1265 Standard: Virology.
493.1267 Standard: Routine chemistry.
493.1269 Standard: Hematology.
493.1271 Standard: Immunohematology.
493.1273 Standard: Histopathology.
493.1274 Standard: Cytology.
493.1276 Standard: Clinical cytogenetics.
493.1278 Standard: Histocompatibility.
493.1281 Standard: Comparison of test results.
493.1282 Standard: Corrective actions.
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493.1289 Standard: Analytic systems quality assessment.

POSTANALYTIC SYSTEMS

493.1290 Condition: Postanalytic systems.
493.1291 Standard: Test report.
493.1299 Standard: Postanalytic systems quality assessment.

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493.1351 General.

LABORATORIES PERFORMING PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES

493.1353 Scope.
493.1355 Condition: Laboratories performing PPM procedures; laboratory director.
493.1357 Standard; laboratory director qualifications.
493.1359 Standard; PPM laboratory director responsibilities.
493.1361 Condition: Laboratories performing PPM procedures; testing personnel.
493.1363 Standard; PPM testing personnel qualifications.
493.1365 Standard; PPM testing personnel responsibilities.

LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING

493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
493.1405 Standard; Laboratory director qualifications.
493.1406 Standard; Laboratory director qualifications on or before February 28, 1992.
493.1407 Standard; Laboratory director responsibilities.
493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.
493.1411 Standard; Technical consultant qualifications.
493.1413 Standard; Technical consultant responsibilities.
493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.
493.1417 Standard; Clinical consultant qualifications.
493.1419 Standard; Clinical consultant responsibilities.
493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.
493.1423 Standard; Testing personnel qualifications.
493.1425 Standard; Testing personnel responsibilities.

LABORATORIES PERFORMING HIGH COMPLEXITY TESTING

493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
493.1443 Standard; Laboratory director qualifications.
493.1445 Standard; Laboratory director responsibilities.
493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.
493.1449 Standard; Technical supervisor qualifications.
493.1451 Standard; Technical supervisor responsibilities.
493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.
493.1455 Standard; Clinical consultant qualifications.
493.1457 Standard; Clinical consultant responsibilities.
493.1459 Condition: Laboratories performing high complexity testing; general supervisor.
493.1461 Standard; General supervisor qualifications.
493.1462 General supervisor qualifications on or before February 28, 1992.
493.1463 Standard; General supervisor responsibilities.
493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.
493.1469 Standard; Cytology general supervisor qualifications.

493.1471 Standard; Cytology general supervisor responsibilities.
493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.
493.1483 Standard; Cytotechnologist qualifications.
493.1485 Standard; Cytotechnologist responsibilities.
493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
493.1489 Standard; Testing personnel qualifications.
493.1491 Technologist qualifications on or before February 28, 1992.
493.1495 Standard; Testing personnel responsibilities.

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493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.
493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.
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493.1800 Basis and scope.
493.1804 General considerations.
493.1806 Available sanctions: All laboratories.
493.1807 Additional sanctions: Laboratories that participate in Medicare.
493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.
493.1809 Limitation on Medicaid payment.
493.1810 Imposition and lifting of alternative sanctions.
493.1812 Action when deficiencies pose immediate jeopardy.
493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.
493.1816 Action when deficiencies are not at the condition level.
493.1820 Ensuring timely correction of deficiencies.
493.1826 Suspension of part of Medicare payments.
493.1828 Suspension of all Medicare payments.
493.1832 Directed plan of correction and directed portion of a plan of correction.
493.1834 Civil money penalty.
493.1836 State onsite monitoring.
493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.
493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.
493.1842 Cancellation of Medicare approval.
493.1844 Appeals procedures.
493.1846 Civil action.
493.1850 Laboratory registry.

Subpart S [Reserved]

Subpart T—Consultations

493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

AUTHORITY: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following sections 1861(s)(11) through 1861(s)(16) of the Social Security Act (42 U.S.C. 263a, 1302, 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16)).

SOURCE: 55 FR 9576, Mar. 14, 1990, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 57 FR 7139, Feb. 28, 1992, unless otherwise noted.

§ 493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under ''laboratory'' in § 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

§ 493.2 Definitions.

As used in this part, unless the context indicates otherwise—

Accredited institution means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

Accredited laboratory means a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by CMS in accordance with this part;

Adverse action means the imposition of a principal or alternative sanction by CMS.

ALJ stands for Administrative Law Judge.

Alternative sanctions means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with ''intermediate sanctions'' as used in section 1846 of the Act.

Analyte means a substance or constituent for which the laboratory conducts testing.

Approved accreditation organization for laboratories means a private, nonprofit accreditation organization that has formally applied for and received CMS's approval based on the organization's compliance with this part.

Approved State laboratory program means a licensure or other regulatory program for laboratories in a State, the requirements of which are imposed under State law, and the State laboratory program has received CMS approval based on the State's compliance with this part.

Authorized person means an individual authorized under State law to order tests or receive test results, or both.

Calibration means a process of testing and adjusting an instrument or test system to establish a correlation between the measurement response and the concentration or amount of the substance that is being measured by the test procedure.

Calibration verification means the assaying of materials of known concentration in the same manner as patient samples to substantiate the instrument or test system's calibration throughout the reportable range for patient test results.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988.

CLIA certificate means any of the following types of certificates issued by CMS or its agent:

(1) *Certificate of compliance* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable condition level requirements, or reissued before the expiration date, pending an appeal, in accordance with § 493.49, when an inspection has found the laboratory to be out of compliance with one or more condition level requirements.

(2) *Certificate for provider-performed microscopy (PPM) procedures* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with § 493.47, to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than PPM procedures and, if desired, waived tests listed in § 493.15(c).

(3) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by CMS (indicating that the laboratory is

deemed to meet applicable CLIA requirements) or reissued before the expiration date, pending an appeal, in accordance with §493.61, when a validation or complaint survey has found the laboratory to be noncompliant with one or more CLIA conditions.

(4) *Certificate of registration or registration certificate* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.45, that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by CMS or its agent; or in accordance with §493.57 to an entity that is accredited by an approved accreditation organization.

(5) *Certificate of waiver* means a certificate issued or reissued before the expiration date, pending an appeal, in accordance with §493.37, to a laboratory to perform only the waived tests listed at §493.15(c).

CLIA-exempt laboratory means a laboratory that has been licensed or approved by a State where CMS has determined that the State has enacted laws relating to laboratory requirements that are equal to or more stringent than CLIA requirements and the State licensure program has been approved by CMS in accordance with subpart E of this part.

Condition level deficiency means noncompliance with one or more condition level requirements.

Condition level requirements means any of the requirements identified as ''conditions'' in subparts G through Q of this part.

Credible allegation of compliance means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

Dentist means a doctor of dental medicine or doctor of dental surgery licensed by the State to practice dentistry within the State in which the laboratory is located.

Equivalency means that an accreditation organization's or a State laboratory program's requirements, taken as a whole, are equal to or more stringent than the CLIA requirements established by CMS, taken as whole. It is acceptable for an accreditation organization's or State laboratory program's requirements to be organized differently or otherwise vary from the CLIA requirements, as long as (1) all of the requirements taken as a whole would provide at least the same protection as the CLIA requirements taken as a whole; and (2) a finding of noncompliance with respect to CLIA requirements taken as a whole would be matched by a finding of noncompliance with the accreditation or State requirements taken as a whole.

CMS agent means an entity with which CMS arranges to inspect laboratories and assess laboratory activities against CLIA requirements and may be a State survey agency, a private, nonprofit organization other than an approved accreditation organization, a component of HHS, or any other governmental component CMS approves for this purpose. In those instances where all of the laboratories in a State are exempt from CLIA requirements, based on the approval of a State's exemption request, the State survey agency is not the CMS agent.

FDA-cleared or approved test system means a test system cleared or approved by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for invitro diagnostic use. Unless otherwise stated, this includes test systems exempt from FDA premarket clearance or approval.

HHS means the Department of Health and Human Services, or its designee.

Immediate jeopardy means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of

the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Intentional violation means knowing and willful noncompliance with any CLIA condition.

Kit means all components of a test that are packaged together.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Midlevel practitioner means a nurse midwife, nurse practitioner, or physician assistant, licensed by the State within which the individual practices, if such licensing is required in the State in which the laboratory is located.

Nonwaived test means any test system, assay, or examination that has not been found to meet the statutory criteria specified at section 353(d)(3) of the Public Health Service Act.

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

(1) A director of the laboratory if he or she meets the stated criteria; and

(2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

Owner means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

Party means a laboratory affected by any of the enforcement procedures set forth in this subpart, by CMS or the OIG, as appropriate.

Performance characteristic means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

Performance specification means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

Physician means an individual with a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine degree who is licensed by the State to practice medicine, osteopathy, or podiatry within the State in which the laboratory is located.

Principal sanction means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

Prospective laboratory means a laboratory that is operating under a registration certificate or is seeking any of the three other types of CLIA certificates.

Rate of disparity means the percentage of sample validation inspections for a specific accreditation organization or State where CMS, the State survey agency or other CMS agent finds noncompliance with one or more condition level requirements but no comparable deficiencies were cited by the accreditation organization or the State, and it is reasonable to conclude that the deficiencies were present at the time of the most recent accreditation organization or State licensure inspection.

Example: Assume the State survey agency, CMS or other CMS agent performs 200 sample validation inspections for laboratories accredited by a single accreditation organization or licensed in an exempt State during a validation review period and finds that 60

of the 200 laboratories had one or more condition level requirements out of compliance. CMS reviews the validation and accreditation organization's or State's inspections of the validated laboratories and determines that the State or accreditation organization found comparable deficiencies in 22 of the 60 laboratories and it is reasonable to conclude that deficiencies were present in the remaining 38 laboratories at the time of the accreditation organization's or State's inspection. Thirty-eight divided by 200 equals a 19 percent rate of disparity.

Referee laboratory means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

Reference range means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

Reportable range means the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response.

Sample in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

State includes, for purposes of this part, each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and a political subdivision of a State where the State, acting pursuant to State law, has expressly delegated powers to the political subdivision sufficient to authorize the political subdivision to act for the State in enforcing requirements equal to or more stringent than CLIA requirements.

State licensure means the issuance of a license to, or the approval of, a laboratory by a State laboratory program as meeting standards for licensing or approval established under State law.

State licensure program means a State laboratory licensure or approval program.

State survey agency means the State health agency or other appropriate State or local agency that has an agreement under section 1864 of the Social Security Act and is used by CMS to perform surveys and inspections.

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would have an impact on the health and safety of the general public or of individuals served by a laboratory and raises doubts as to a laboratory's compliance with any condition level requirement.

Target value for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group (''peer'' group) may be used. If the method group is less than 10 participants, ''target value'' means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Test system means the instructions and all of the instrumentation, equipment, reagents, and supplies needed to perform an assay or examination and generate test results.

Unsatisfactory proficiency testing performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

Unsuccessful participation in proficiency testing means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.

Unsuccessful proficiency testing performance means a failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

Validation review period means the one year time period during which CMS conducts validation inspections and evaluates the results of the most recent surveys performed by an accreditation organization or State laboratory program.

Waived test means a test system, assay, or examination that HHS has determined meets the CLIA statutory criteria as specified for waiver under section 353(d)(3) of the Public Health Service Act.

[57 FR 7139, Feb. 28, 1992, as amended at 57 FR 7236, Feb. 28, 1992; 57 FR 34013, July 31, 1992; 57 FR 35761, Aug. 11, 1992; 58 FR 5220, Jan. 19, 1993; 58 FR 48323, Sept. 15, 1993; 60 FR 20043, Apr. 24, 1995; 63 FR 26732, May 14, 1998; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

§ 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is CLIA-exempt.

(b) *Exception.* These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA-certified laboratory is subject to this rule.

(c) *Federal laboratories.* Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993; 60 FR 20043, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.5 Categories of tests by complexity.

(a) Laboratory tests are categorized as one of the following:

(1) Waived tests.

(2) Tests of moderate complexity, including the subcategory of PPM procedures.

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only PPM procedures, only tests of high complexity or any combination of these tests.

(c) Each laboratory must be either CLIA-exempt or possess one of the following CLIA certificates, as defined in § 493.2:

(1) Certificate of registration or registration certificate.

(2) Certificate of waiver.

(3) Certificate for PPM procedures.

(4) Certificate of compliance.

(5) Certificate of accreditation.

[60 FR 20043, Apr. 24, 1995]

§ 493.15 Laboratories performing waived tests.

(a) *Requirement.* Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems are simple laboratory examinations and procedures which—

(1) Are cleared by FDA for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

(i) Bilirubin;

(ii) Glucose;

(iii) Hemoglobin;

(iv) Ketone;

(v) Leukocytes;

(vi) Nitrite;

(vii) pH;

(viii) Protein;

(ix) Specific gravity; and

(x) Urobilinogen.

(2) Fecal occult blood;

(3) Ovulation tests—visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

(6) Hemoglobin—copper sulfate—non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) *Revisions to criteria for test categorization and the list of waived tests.* HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the FEDERAL REGISTER in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993]

§ 493.17 Test categorization.

(a) *Categorization by criteria.* Notices will be published in the FEDERAL REGISTER which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of ''1'' indicates the lowest level of complexity, and the score of ''3'' indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

NOTE: A score of ''2'' will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of ''1'' and ''3.''

(1) *Knowledge.* (i) *Score 1.* (A) Minimal scientific and technical knowledge is required to perform the test; and

(B) Knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) *Score 3.* Specialized scientific and technical knowledge is essential to perform preanalytic, analytic or postanalytic phases of the testing.

(2) *Training and experience.* (i) *Score 1.* (A) Minimal training is required for

preanalytic, analytic and postanalytic phases of the testing process; and

(B) Limited experience is required to perform the test.

(ii) *Score 3.* (A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; or

(B) Substantial experience may be necessary for analytic test performance.

(3) *Reagents and materials preparation.* (i) *Score 1.* (A) Reagents and materials are generally stable and reliable; and

(B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions.

(ii) *Score 3.* (A) Reagents and materials may be labile and may require special handling to assure reliability; or

(B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) *Characteristics of operational steps.* (i) *Score 1.* Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

(ii) *Score 3.* Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.

(5) *Calibration, quality control, and proficiency testing materials.* (i) *Score 1.* (A) Calibration materials are stable and readily available;

(B) Quality control materials are stable and readily available; and

(C) External proficiency testing materials, when available, are stable.

(ii) *Score 3.* (A) Calibration materials, if available, may be labile;

(B) Quality control materials may be labile, or not available; or

(C) External proficiency testing materials, if available, may be labile.

(6) *Test system troubleshooting and equipment maintenance.* (i) *Score 1.* (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and

(B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) *Score 3.* (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; or

(B) Maintenance requires special knowledge, skills, and abilities.

(7) *Interpretation and judgment.* (i) *Score 1.* (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and

(B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) *Score 3.* (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and

(B) Resolution of problems requires extensive interpretation and judgment.

(b) *Revisions to the criteria for categorization.* The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) *Process for device/test categorization utilizing the scoring system under § 493.17(a).* (1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both CMS and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations:

(A) When categorizing previously uncategorized new technology;

(B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(ii) Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group

may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, CMS, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.

(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the lists of tests in the FEDERAL REGISTER notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision. Test categorization is effective as of the notification to the applicant.

(5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the FEDERAL REGISTER in a notice with opportunity for comment.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993]

§ 493.19 Provider-performed microscopy (PPM) procedures.

(a) *Requirement.* To be categorized as a PPM procedure, the procedure must meet the criteria specified in paragraph (b) of this section.

(b) *Criteria.* Procedures must meet the following specifications:

(1) The examination must be personally performed by one of the following practitioners:

(i) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or an employee.

(ii) A midlevel practitioner, under the supervision of a physician or in independent practice only if authorized by the State, during the patient's visit on a specimen obtained from his or her own patient or from a patient of a clinic, group medical practice, or other health care provider of which the midlevel practitioner is a member or an employee.

(iii) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

(2) The procedure must be categorized as moderately complex.

(3) The primary instrument for performing the test is the microscope, limited to bright-field or phase-contrast microscopy.

(4) The specimen is labile or delay in performing the test could compromise the accuracy of the test result.

(5) Control materials are not available to monitor the entire testing process.

(6) Limited specimen handling or processing is required.

(c) *Provider-performed microscopy (PPM) examinations.* A laboratory may qualify to perform tests under this section if it restricts PPM examinations to one or more of the following procedures (or additional procedures added to this list as provided under paragraph (d) of this section), waived tests and no others:

(1) All direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements.

(2) All potassium hydroxide (KOH) preparations.

(3) Pinworm examinations.

(4) Fern tests.

(5) Post-coital direct, qualitative examinations of vaginal or cervical mucous.

(6) Urine sediment examinations.

(7) Nasal smears for granulocytes.

(8) Fecal leukocyte examinations.

(9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

(d) *Revisions to criteria and the list of PPM procedures.* (1) The CLIAC conducts reviews upon HHS' request and recommends to HHS revisions to the criteria for categorization of procedures.

(2) HHS determines whether a laboratory procedure meets the criteria listed under paragraph (b) of this section for a PPM procedure. Revisions to the list of PPM procedures proposed by HHS are published in the FEDERAL REGISTER

as a notice with an opportunity for public comment.

(e) *Laboratory requirements.* Laboratories eligible to perform PPM examinations must—

(1) Meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, and M of this part.

(2) Be subject to inspection as specified under subpart Q of this part.

[60 FR 20044, Apr. 24, 1995; 68 FR 50723, Aug. 22, 2003]

§ 493.20 Laboratories performing tests of moderate complexity.

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to waived tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity including the subcategory of PPM procedures.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part. Under a registration certificate or certificate of compliance, laboratories also performing PPM procedures must meet the inspection requirements at §§ 493.1773 and 493.1777.

(c) If the laboratory also performs waived tests, compliance with subparts H, J, K, and M of this part is not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.1773, and 493.1775.

[60 FR 20044, Apr. 24, 1995, as amended at 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

§ 493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in § 493.17(a).

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C or subpart D, and subparts F, H, J, K, M, and Q of this part.

(c) If the laboratory also performs tests of moderate complexity, the applicable requirements of subparts H, J, K, M, and Q of this part must be met. Under a registration certificate or certificate of compliance, PPM procedures must meet the inspection requirements at §§ 493.1773 and 493.1777.

(d) If the laboratory also performs waived tests, the requirements of subparts H, J, K, and M are not applicable to the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(e), 493.1773, and 493.1775.

[57 FR 7139, Feb. 28, 1992, as amended at 60 FR 20044, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

Subpart B—Certificate of Waiver

SOURCE: 57 FR 7142, Feb. 28, 1992, unless otherwise noted.

§ 493.35 Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in § 493.15 must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes;

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access requirements.* Laboratories that perform one or more waived tests listed in § 493.15(c) and no other tests must meet the following conditions:

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and § 493.15(e);

(2) Agree to permit announced and unannounced inspections by HHS in accordance with subpart Q of this part under the following circumstances:

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health.

(ii) To evaluate complaints from the public.

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15.

(iv) To collect information regarding the appropriateness of waiver of tests listed in § 493.15.

(e) *Denial of application.* If HHS determines that the application for a certificate of waiver is to be denied, HHS will—

(1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part;

(2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and

(3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 60 FR 20044, Apr. 24, 1995]

§ 493.37 Requirements for a certificate of waiver.

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of § 493.35.

(b) Laboratories issued a certificate of waiver—

(1) Are subject to the requirements of this subpart and § 493.15(e) of subpart A of this part; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part.

(c) Laboratories must remit the certificate of waiver fee specified in subpart F of this part.

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(e)(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a noncompliance determination resulting in HHS action to revoke, suspend, or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part.

(2) If the laboratory requests a hearing within the time specified by HHS,

it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(3) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(f) A laboratory seeking to renew its certificate of waiver must—

(1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and

(2) Meet the requirements of §§ 493.35 and 493.37.

(g) A laboratory with a certificate of waiver that wishes to perform examinations or tests not listed in the waiver test category must meet the requirements set forth in subpart C or subpart D of this part, as applicable.

[57 FR 7142, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 60 FR 20045, Apr. 24, 1995]

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under § 493.15 for which the laboratory does not have the appropriate certificate as required in subpart C or subpart D of this part, as applicable; and

(b) Within 30 days of any change(s) in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[57 FR 7142, Feb. 28, 1992, as amended at 60 FR 20045, Apr. 24, 1995]

Subpart C—Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance

SOURCE: 57 FR 7143, Feb. 28, 1992, unless otherwise noted.

§ 493.43 Application for registration certificate, certificate for provider-performed microscopy (PPM) procedures, and certificate of compliance.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing nonwaived testing must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of test procedures and examinations performed annually (excluding waived tests or tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both;

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5222, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20045, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.45 Requirements for a registration certificate.

Laboratories performing only waived tests, PPM procedures, or any combination of these tests, are not required to obtain a registration certificate.

(a) A registration certificate is required—(1) Initially for all laboratories performing test procedures of moderate complexity (other than the subcategory of PPM procedures) or high complexity, or both; and

(2) For all laboratories that have been issued a certificate of waiver or certificate for PPM procedures that intend to perform tests of moderate or high complexity, or both, in addition to those tests listed in § 493.15(c) or specified as PPM procedures.

(b) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of § 493.43;

(2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or technical supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate, as specified in subpart F of this part.

(c) Prior to the expiration of the registration certificate, a laboratory must—

(1) Remit the certificate fee specified in subpart F of this part;

(2) Be inspected by HHS as specified in subpart Q of this part; and

(3) Demonstrate compliance with the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of compliance for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

(e) A registration certificate is—

(1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter; and

(2) Not renewable; however, the registration certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.

(f) In the event of a noncompliance determination resulting in an HHS denial of a laboratory's certificate of compliance application, HHS will provide the laboratory with a statement of grounds on which the noncompliance determination is based and offer an opportunity for appeal as provided in subpart R.

(g) If the laboratory requests a hearing within the time specified by HHS, it retains its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(h) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified

in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.

[57 FR 7143, Feb. 28, 1992, as amended at 58 FR 5223, Jan. 19, 1993; 60 FR 20045, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.47 Requirements for a certificate for provider-performed microscopy (PPM) procedures.

(a) A certificate for PPM procedures is required—

(1) Initially for all laboratories performing test procedures specified as PPM procedures; and

(2) For all certificate of waiver laboratories that intend to perform only test procedures specified as PPM procedures in addition to those tests listed in § 493.15(c).

(b) HHS will issue a certificate for PPM procedures if the laboratory—

(1) Complies with the requirements of § 493.43; and

(2) Remits the fee for the certificate, as specified in subpart F of this part.

(c) Laboratories issued a certificate for PPM procedures are subject to—

(1) The notification requirements of § 493.53;

(2) The applicable requirements of this subpart and subparts H, J, K, and M of this part; and

(3) Inspection only under the circumstances specified under §§ 493.1773 and 493.1775, but are not routinely inspected to determine compliance with the requirements specified in paragraphs (c) (1) and (2) of this section.

(d) In accordance with subpart R of this part, HHS will initiate suspension, limitation, or revocation of a laboratory's certificate for PPM procedures for failure to comply with the applicable requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart may result in suspension of all or part of payments under Medicare and Medicaid, as specified in subpart R of this part.

(e) A certificate for PPM procedures is valid for a period of no more than 2 years.

[58 FR 5223, Jan. 19, 1993, as amended at 60 FR 20045, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

§ 493.49 Requirements for a certificate of compliance.

A certificate of compliance may include any combination of tests categorized as high complexity or moderate complexity or listed in § 493.15(c) as waived tests. Moderate complexity tests may include those specified as PPM procedures.

(a) HHS will issue a certificate of compliance to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, and Q of this part.

(b) Laboratories issued a certificate of compliance—

(1) Are subject to the notification requirements of § 493.51; and

(2) Must permit announced or unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints;

(iii) When HHS has substantive reason to believe that tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information regarding the appropriateness of tests listed in § 493.15 or tests categorized as moderate complexity (including the subcategory) or high complexity.

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate of compliance in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate of compliance issued under this subpart is valid for no more than 2 years.

(e) In the event of a noncompliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate of compliance, HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within 60 days of the notice of sanction, it retains its certificate of compliance or reissued certificate of compliance until a decision is made by an administrative law judge (ALJ) as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health or when the criteria at § 493.1840(a) (4) and (5) are met.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a noncompliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate of compliance must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of compliance; and

(2) Meet the requirements of § 493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate of compliance must be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time period specified by HHS, the laboratory retains its certificate of compliance or reissued certificate of compliance until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate of compliance even if there has been no appeals decision issued.

[60 FR 20045, Apr. 24, 1995, as amended at 68 FR 3702, Jan. 24, 2003]

§ 493.51 Notification requirements for laboratories issued a certificate of compliance.

Laboratories issued a certificate of compliance must meet the following conditions:

(a) Notify HHS or its designee within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Technical supervisor (laboratories performing high complexity only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate of compliance, so that compliance with requirements can be determined.

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance.

[57 FR 7143, Feb. 28, 1992, as amended at 60 FR 20046, Apr. 24, 1995]

§ 493.53 Notification requirements for laboratories issued a certificate for provider-performed microscopy (PPM) procedures.

Laboratories issued a certificate for PPM procedures must notify HHS or its designee—

(a) Before performing and reporting results for any test of moderate or high complexity, or both, in addition to tests specified as PPM procedures or any test or examination that is not specified under § 493.15(c), for which it does not have a registration certificate as required in subpart C or subpart D, as applicable, of this part; and

(b) Within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

[58 FR 5224, Jan. 19, 1993, as amended at 60 FR 20046, Apr. 24, 1995]

Subpart D—Certificate of Accreditation

SOURCE: 57 FR 7144, Feb. 28, 1992, unless otherwise noted.

§ 493.55 Application for registration certificate and certificate of accreditation.

(a) *Filing of application.* A laboratory may be issued a certificate of accreditation in lieu of the applicable certificate specified in subpart B or subpart C of this part provided the laboratory—

(1) Meets the standards of a private non-profit accreditation program approved by HHS in accordance with subpart E; and

(2) Files a separate application for each location, except as specified in paragraph (b) of this section.

(b) *Exceptions.* (1) Laboratories that are not at fixed locations, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

(3) Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—(1) Be made to HHS on a form or forms prescribed by HHS;

(2) Be signed by an owner or authorized representative of the laboratory who attests that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the Public Health Service Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of tests and examinations performed annually (excluding waived tests and tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20046, Apr. 24, 1995]

§ 493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate of compliance issued by HHS.

(a) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of § 493.55;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate specified in subpart F of this part.

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate of compliance.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of § 493.49.

(c) In accordance with subpart R of this part, HHS will initiate suspension, revocation, or limitation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid as specified in subpart R of this part.

(d) A registration certificate is valid for a period of no more than 2 years. However, it may be reissued if the laboratory is subject to subpart C of this part, as specified in § 493.57(b)(2) and compliance has not been determined by HHS before the expiration date of the registration certificate.

(e) In the event that the laboratory does not meet the requirements of this subpart, HHS will—

(1) Deny a laboratory's request for certificate of accreditation;

(2) Notify the laboratory if it must meet the requirements for a certificate as defined in subpart C of this part;

(3) Provide the laboratory with a statement of grounds on which the application denial is based;

(4) Offer an opportunity for appeal on the application denial as provided in subpart R of this part. If the laboratory requests a hearing within the time specified by HHS, the laboratory will retain its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(5) For those laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the request even if there has been no appeals decision issued.

[57 FR 7144, Feb. 28, 1992, as amended at 60 FR 20046, Apr. 24, 1995]

§ 493.61 Requirements for a certificate of accreditation.

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

(1) Meets the requirements of § 493.57 or, if applicable, § 493.49 of subpart C of this part; and

(2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must—

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of § 493.63;

(3) Comply with the requirements of the approved accreditation program;

(4) Permit random sample validation and complaint inspections as required in subpart Q of this part;

(5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;

(6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and

(7) Authorize its accreditation program to submit to HHS the results of the laboratory's proficiency testing.

(c) A laboratory failing to meet the requirements of this section—

(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program;

(2) Will be subject to full determination of compliance by HHS;

(3) May be subject to suspension, revocation or limitation of the laboratory's certificate of accreditation or certain alternative sanctions; and

(4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.

(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with § 488.11 of this chapter.

(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and

(3) Offer an opportunity for appeal as provided in subpart R of this part.

(f) If the laboratory requests a hearing within the time frame specified by HHS—

(1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.

(g) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or § 493.57.

(h) A laboratory seeking to renew its certificate of accreditation must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of accreditation;

(2) Meet the requirements of this subpart; and

(3) Submit the certificate of accreditation fee specified in subpart F of this part.

(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;

(3) The opportunity for appeal on HHS's action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.

[57 FR 7144, Feb. 28, 1992, as amended at 58 FR 5224, Jan. 19, 1993]

§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.

Laboratories issued a certificate of accreditation must:

(a) Notify HHS and the approved accreditation program within 30 days of any changes in—

(1) Ownership;

(2) Name;

(3) Location; or

(4) Director.

(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.

(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

Subpart E—Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program

SOURCE: 63 FR 26732, May 14, 1998, unless otherwise noted.

§ 493.551 General requirements for laboratories.

(a) *Applicability.* CMS may deem a laboratory to meet all applicable CLIA program requirements through accreditation by a private nonprofit accreditation program (that is, grant deemed

status), or may exempt from CLIA program requirements all State licensed or approved laboratories in a State that has a State licensure program established by law, if the following conditions are met:

(1) The requirements of the accreditation organization or State licensure program are equal to, or more stringent than, the CLIA condition-level requirements specified in this part, and the laboratory would meet the condition-level requirements if it were inspected against these requirements.

(2) The accreditation program or the State licensure program meets the requirements of this subpart and is approved by CMS.

(3) The laboratory authorizes the approved accreditation organization or State licensure program to release to CMS all records and information required and permits inspections as outlined in this part.

(b) *Meeting CLIA requirements by accreditation.* A laboratory seeking to meet CLIA requirements through accreditation by an approved accreditation organization must do the following:

(1) Obtain a certificate of accreditation as required in subpart D of this part.

(2) Pay the applicable fees as required in subpart F of this part.

(3) Meet the proficiency testing (PT) requirements in subpart H of this part.

(4) Authorize its PT organization to furnish to its accreditation organization the results of the laboratory's participation in an approved PT program for the purpose of monitoring the laboratory's PT and for making the annual PT results, along with explanatory information required to interpret the PT results, available on a reasonable basis, upon request of any person. A laboratory that refuses to authorize release of its PT results is no longer deemed to meet the condition-level requirements and is subject to a full review by CMS, in accordance with subpart Q of this part, and may be subject to the suspension or revocation of its certificate of accreditation under § 493.1840.

(5) Authorize its accreditation organization to release to CMS or a CMS agent the laboratory's PT results that constitute unsuccessful participation in an approved PT program, in accordance with the definition of ''unsuccessful participation in an approved PT program,'' as specified in § 493.2 of this part, when the laboratory has failed to achieve successful participation in an approved PT program.

(6) Authorize its accreditation organization to release to CMS a notification of the actions taken by the organization as a result of the unsuccessful participation in a PT program within 30 days of the initiation of the action. Based on this notification, CMS may take an adverse action against a laboratory that fails to participate successfully in an approved PT program.

(c) *Withdrawal of laboratory accreditation.* After an accreditation organization has withdrawn or revoked its accreditation of a laboratory, the laboratory retains its certificate of accreditation for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or the effective date of any action taken by CMS, whichever is earlier.

§ 493.553 Approval process (application and reapplication) for accreditation organizations and State licensure programs.

(a) *Information required.* An accreditation organization that applies or reapplies to CMS for deeming authority, or a State licensure program that applies or reapplies to CMS for exemption from CLIA program requirements of licensed or approved laboratories within the State, must provide the following information:

(1) A detailed comparison of the individual accreditation, or licensure or approval requirements with the comparable condition-level requirements; that is, a crosswalk.

(2) A detailed description of the inspection process, including the following:

(i) Frequency of inspections.

(ii) Copies of inspection forms.

(iii) Instructions and guidelines.

(iv) A description of the review and decision-making process of inspections.

(v) A statement concerning whether inspections are announced or unannounced.

(vi) A description of the steps taken to monitor the correction of deficiencies.

(3) A description of the process for monitoring PT performance, including action to be taken in response to unsuccessful participation in a CMS-approved PT program.

(4) Procedures for responding to and for the investigation of complaints against its laboratories.

(5) A list of all its current laboratories and the expiration date of their accreditation or licensure, as applicable.

(6) Procedures for making PT information available (under State confidentiality and disclosure requirements, if applicable) including explanatory information required to interpret PT results, on a reasonable basis, upon request of any person.

(b) *CMS action on an application or reapplication.* If CMS receives an application or reapplication from an accreditation organization, or State licensure program, CMS takes the following actions:

(1) CMS determines if additional information is necessary to make a determination for approval or denial of the application and notifies the accreditation organization or State to afford it an opportunity to provide the additional information.

(2) CMS may visit the accreditation organization or State licensure program offices to review and verify the policies and procedures represented in its application and other information, including, but not limited to, review and examination of documents and interviews with staff.

(3) CMS notifies the accreditation organization or State licensure program indicating whether CMS approves or denies the request for deeming authority or exemption, respectively, and the rationale for any denial.

(c) *Duration of approval.* CMS approval may not exceed 6 years.

(d) *Withdrawal of application.* The accreditation organization or State licensure program may withdraw its application at any time before official notification, specified at § 493.553(b)(3).

§ 493.555 Federal review of laboratory requirements.

CMS's review of an accreditation organization or State licensure program includes, but is not limited to, an evaluation of the following:

(a) Whether the organization's or State's requirements for laboratories are equal to, or more stringent than, the condition-level requirements for laboratories.

(b) The organization's or State's inspection process to determine the comparability of the full inspection and complaint inspection procedures and requirements to those of CMS, including, but not limited to, inspection frequency and the ability to investigate and respond to complaints against its laboratories.

(c) The organization's or State's agreement with CMS that requires it to do the following:

(1) Notify CMS within 30 days of the action taken, of any laboratory that has—

(i) Had its accreditation or licensure suspended, withdrawn, revoked, or limited;

(ii) In any way been sanctioned; or

(iii) Had any adverse action taken against it.

(2) Notify CMS within 10 days of any deficiency identified in an accredited or CLIA-exempt laboratory if the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public.

(3) Notify CMS, within 30 days, of all newly—

(i) Accredited laboratories (or laboratories whose areas of specialty/subspecialty testing have changed); or

(ii) Licensed laboratories, including the specialty/subspecialty areas of testing.

(4) Notify each accredited or licensed laboratory within 10 days of CMS's withdrawal of the organization's deeming authority or State's exemption.

(5) Provide CMS with inspection schedules, as requested, for validation purposes.

§ 493.557 Additional submission requirements.

(a) *Specific requirements for accreditation organizations.* In addition to the information specified in §§ 493.553 and

493.555, as part of the approval and review process, an accreditation organization applying or reapplying for deeming authority must also provide the following:

(1) The specialty or subspecialty areas for which the organization is requesting deeming authority and its mechanism for monitoring compliance with all requirements equivalent to condition-level requirements within the scope of the specialty or subspecialty areas.

(2) A description of the organization's data management and analysis system with respect to its inspection and accreditation decisions, including the kinds of routine reports and tables generated by the systems.

(3) Detailed information concerning the inspection process, including, but not limited to the following:

(i) The size and composition of individual accreditation inspection teams.

(ii) Qualifications, education, and experience requirements that inspectors must meet.

(iii) The content and frequency of training provided to inspection personnel, including the ability of the organization to provide continuing education and training to inspectors.

(4) Procedures for removal or withdrawal of accreditation status for laboratories that fail to meet the organization's standards.

(5) A proposed agreement between CMS and the accreditation organization with respect to the notification requirements specified in §493.555(c).

(6) Procedures for monitoring laboratories found to be out of compliance with its requirements. (These monitoring procedures must be used only when the accreditation organization identifies noncompliance. If noncompliance is identified through validation inspections, CMS or a CMS agent monitors corrections, as authorized at §493.565(d)).

(7) A demonstration of its ability to provide CMS with electronic data and reports in compatible code, including the crosswalk specified in §493.553(a)(1), that are necessary for effective validation and assessment of the organization's inspection process.

(8) A demonstration of its ability to provide CMS with electronic data, in compatible code, related to the adverse actions resulting from PT results constituting unsuccessful participation in PT programs as well as data related to the PT failures, within 30 days of the initiation of adverse action.

(9) A demonstration of its ability to provide CMS with electronic data, in compatible code, for all accredited laboratories, including the area of specialty or subspecialty.

(10) Information defining the adequacy of numbers of staff and other resources.

(11) Information defining the organization's ability to provide adequate funding for performing required inspections.

(12) Any facility-specific data, upon request by CMS, which includes, but is not limited to, the following:

(i) PT results that constitute unsuccessful participation in a CMS-approved PT program.

(ii) Notification of the adverse actions or corrective actions imposed by the accreditation organization as a result of unsuccessful PT participation.

(13) An agreement to provide written notification to CMS at least 30 days in advance of the effective date of any proposed change in its requirements.

(14) An agreement to disclose any laboratory's PT results upon reasonable request by any person.

(b) *Specific requirements for a State licensure program.* In addition to requirements in §§493.553 and 493.555, as part of the approval and review process, when a State licensure program applies or reapplies for exemption from the CLIA program, the State must do the following:

(1) Demonstrate to CMS that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements.

(2) Permit CMS or a CMS agent to inspect laboratories in the State.

(3) Require laboratories in the State to submit to inspections by CMS or a CMS agent as a condition of licensure or approval.

(4) Agree to pay the cost of the validation program administered in that State as specified in §§493.645(a) and 493.646(b).

(5) Take appropriate enforcement action against laboratories found by CMS

not to be in compliance with requirements equivalent to CLIA requirements.

(6) Submit for Medicare and Medicaid payment purposes, a list of the specialties and subspecialties of tests performed by each laboratory.

(7) Submit a written presentation that demonstrates the agency's ability to furnish CMS with electronic data in compatible code, including the crosswalk specified in §493.553(a)(1).

(8) Submit a statement acknowledging that the State will notify CMS through electronic transmission of the following:

(i) Any laboratory that has had its licensure or approval revoked or withdrawn or has been in any way sanctioned by the State within 30 days of taking the action.

(ii) Changes in licensure or inspection requirements.

(iii) Changes in specialties or subspecialties under which any licensed laboratory in the State performs testing.

(9) Provide information for the review of the State's enforcement procedures for laboratories found to be out of compliance with the State's requirements.

(10) Submit information that demonstrates the ability of the State to provide CMS with the following:

(i) Electronic data and reports in compatible code with the adverse or corrective actions resulting from PT results that constitute unsuccessful participation in PT programs.

(ii) Other data that CMS determines are necessary for validation and assessment of the State's inspection process requirements.

(11) Agree to provide CMS with written notification of any changes in its licensure/approval and inspection requirements.

(12) Agree to disclose any laboratory's PT results in accordance with a State's confidentiality requirements.

(13) Agree to take the appropriate enforcement action against laboratories found by CMS not to be in compliance with requirements comparable to condition-level requirements and report these enforcement actions to CMS.

(14) If approved, reapply to CMS every 2 years to renew its exempt status and to renew its agreement to pay the cost of the CMS-administered validation program in that State.

§ 493.559 Publication of approval of deeming authority or CLIA exemption.

(a) *Notice of deeming authority or exemption.* CMS publishes a notice in the FEDERAL REGISTER when it grants deeming authority to an accreditation organization or exemption to a State licensure program.

(b) *Contents of notice.* The notice includes the following:

(1) The name of the accreditation organization or State licensure program.

(2) For an accreditation organization:

(i) The specific specialty or subspecialty areas for which it is granted deeming authority.

(ii) A description of how the accreditation organization provides reasonable assurance to CMS that a laboratory accredited by the organization meets CLIA requirements equivalent to those in this part and would meet CLIA requirements if the laboratory had not been granted deemed status, but had been inspected against condition-level requirements.

(3) For a State licensure program, a description of how the laboratory requirements of the State are equal to, or more stringent than, those specified in this part.

(4) The basis for granting deeming authority or exemption.

(5) The term of approval, not to exceed 6 years.

§ 493.561 Denial of application or reapplication.

(a) *Reconsideration of denial.* (1) If CMS denies a request for approval, an accreditation organization or State licensure program may request, within 60 days of the notification of denial, that CMS reconsider its original application or application for renewal, in accordance with part 488, subpart D.

(2) If the accreditation organization or State licensure program requests a reconsideration of CMS's determination to deny its request for approval or reapproval, it may not submit a new application until CMS issues a final reconsideration determination.

(b) *Resubmittal of a request for approval—accreditation organization.* An accreditation organization may resubmit a request for approval if a final reconsideration determination is not pending and the accreditation program meets the following conditions:

(1) It has revised its accreditation program to address the rationale for denial of its previous request.

(2) It demonstrates that it can provide reasonable assurance that its accredited facilities meet condition-level requirements.

(3) It resubmits the application in its entirety.

(c) *Resubmittal of request for approval—State licensure program.* The State licensure program may resubmit a request for approval if a final reconsideration determination is not pending and it has taken the necessary action to address the rationale for any previous denial.

§ 493.563 Validation inspections—Basis and focus.

(a) *Basis for validation inspection*—(1) *Laboratory with a certificate of accreditation.* (i) CMS or a CMS agent may conduct an inspection of an accredited laboratory that has been issued a certificate of accreditation on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) CMS uses the results of these inspections to validate the accreditation organization's accreditation process.

(2) *Laboratory in a State with an approved State licensure program.* (i) CMS or a CMS agent may conduct an inspection of any laboratory in a State with an approved State licensure program on a representative sample basis or in response to a substantial allegation of noncompliance.

(ii) The results of these inspections are used to validate the appropriateness of the exemption of that State's licensed or approved laboratories from CLIA program requirements.

(b) *Validation inspection conducted on a representative sample basis.* (1) If CMS or a CMS agent conducts a validation inspection on a representative sample basis, the inspection is comprehensive, addressing all condition-level requirements, or it may be focused on a specific condition-level requirement.

(2) The number of laboratories sampled is sufficient to allow a reasonable estimate of the performance of the accreditation organization or State.

(c) *Validation inspection conducted in response to a substantial allegation of noncompliance.* (1) If CMS or a CMS agent conducts a validation inspection in response to a substantial allegation of noncompliance, the inspection focuses on any condition-level requirement that CMS determines to be related to the allegation.

(2) If CMS or a CMS agent substantiates a deficiency and determines that the laboratory is out of compliance with any condition-level requirement, CMS or a CMS agent conducts a full CLIA inspection.

(d) *Inspection of operations and offices.* As part of the validation review process, CMS may conduct an onsite inspection of the operations and offices to verify the following:

(1) The accreditation organization's representations and to assess the accreditation organization's compliance with its own policies and procedures.

(2) The State's representations and to assess the State's compliance with its own policies and procedures, including verification of State enforcement actions taken on the basis of validation inspections performed by CMS or a CMS agent.

(e) *Onsite inspection of an accreditation organization.* An onsite inspection of an accreditation organization may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the accreditation process.

(3) Evaluation of accreditation inspection results and the accreditation decision-making process.

(4) Interviews with the accreditation organization's staff.

(f) *Onsite inspection of a State licensure program.* An onsite inspection of a State licensure program office may include, but is not limited to, the following:

(1) A review of documents.

(2) An audit of meetings concerning the licensure or approval process.

(3) Evaluation of State inspection results and the licensure or approval decision-making process.

(4) Interviews with State employees.

§ 493.565 Selection for validation inspection—laboratory responsibilities.

A laboratory selected for a validation inspection must do the following:

(a) Authorize its accreditation organization or State licensure program, as applicable, to release to CMS or a CMS agent, on a confidential basis, a copy of the laboratory's most recent full, and any subsequent partial inspection.

(b) Authorize CMS or a CMS agent to conduct a validation inspection.

(c) Provide CMS or a CMS agent with access to all facilities, equipment, materials, records, and information that CMS or a CMS agent determines have a bearing on whether the laboratory is being operated in accordance with the requirements of this part, and permit CMS or a CMS agent to copy material or require the laboratory to submit material.

(d) If the laboratory possesses a valid certificate of accreditation, authorize CMS or a CMS agent to monitor the correction of any deficiencies found through the validation inspection.

§ 493.567 Refusal to cooperate with validation inspection.

(a) *Laboratory with a certificate of accreditation.* (1) A laboratory with a certificate of accreditation that refuses to cooperate with a validation inspection by failing to comply with the requirements in § 493.565—

(i) Is subject to full review by CMS or a CMS agent, in accordance with this part; and

(ii) May be subject to suspension, revocation, or limitation of its certificate of accreditation under this part.

(2) A laboratory with a certificate of accreditation is again deemed to meet the condition-level requirements by virtue of its accreditation when the following conditions exist:

(i) The laboratory withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation inspection, PT results, or notification of any adverse actions resulting from PT failure.

(ii) The laboratory withdraws any prior refusal to allow a validation inspection.

(iii) CMS finds that the laboratory meets all the condition-level requirements.

(b) *CLIA-exempt laboratory.* If a CLIA-exempt laboratory fails to comply with the requirements specified in § 493.565, CMS notifies the State of the laboratory's failure to meet the requirements.

§ 493.569 Consequences of a finding of noncompliance as a result of a validation inspection.

(a) *Laboratory with a certificate of accreditation.* If a validation inspection results in a finding that the accredited laboratory is out of compliance with one or more condition-level requirements, the laboratory is subject to—

(1) The same requirements and survey and enforcement processes applied to laboratories that are not accredited and that are found out of compliance following an inspection under this part; and

(2) Full review by CMS, in accordance with this part; that is, the laboratory is subject to the principal and alternative sanctions in § 493.1806.

(b) *CLIA-exempt laboratory.* If a validation inspection results in a finding that a CLIA-exempt laboratory is out of compliance with one or more condition-level requirements, CMS directs the State to take appropriate enforcement action.

§ 493.571 Disclosure of accreditation, State and CMS validation inspection results.

(a) *Accreditation organization inspection results.* CMS may disclose accreditation organization inspection results to the public only if the results are related to an enforcement action taken by the Secretary.

(b) *State inspection results.* Disclosure of State inspection results is the responsibility of the approved State licensure program, in accordance with State law.

(c) *CMS validation inspection results.* CMS may disclose the results of all

validation inspections conducted by CMS or its agent.

§493.573 Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure programs.

(a) *Comparability review.* In addition to the initial review for determining equivalency of specified organization or State requirements to the comparable condition-level requirements, CMS reviews the equivalency of requirements in the following cases:

(1) When CMS promulgates new condition-level requirements.

(2) When CMS identifies an accreditation organization or a State licensure program whose requirements are no longer equal to, or more stringent than, condition-level requirements.

(3) When an accreditation organization or State licensure program adopts new requirements.

(4) When an accreditation organization or State licensure program adopts changes to its inspection process, as required by §493.575(b)(1), as applicable.

(5) Every 6 years, or sooner if CMS determines an earlier review is required.

(b) *Validation review.* Following the end of a validation review period, CMS evaluates the validation inspection results for each approved accreditation organization and State licensure program.

(c) *Reapplication procedures.* (1) Every 6 years, or sooner, as determined by CMS, an approved accreditation organization must reapply for continued approval of deeming authority and a State licensure program must reapply for continued approval of a CLIA exemption. CMS provides notice of the materials that must be submitted as part of the reapplication procedure.

(2) An accreditation organization or State licensure program that does not meet the requirements of this subpart, as determined through a comparability or validation review, must furnish CMS, upon request, with the reapplication materials CMS requests. CMS establishes a deadline by which the materials must be submitted.

(d) *Notice.* (1) CMS provides written notice, as appropriate, to the following:

(i) An accreditation organization indicating that its approval may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and CMS is initiating a review of the accreditation organization's deeming authority.

(ii) A State licensure program indicating that its CLIA exemption may be in jeopardy if a comparability or validation review reveals that it is not meeting the requirements of this subpart and that a review is being initiated of the CLIA exemption of the State's laboratories.

(2) The notice contains the following information:

(i) A statement of the discrepancies that were found as well as other related documentation.

(ii) An explanation of CMS's review process on which the final determination is based and a description of the possible actions, as specified in §493.575, that CMS may impose based on the findings from the comparability or validation review.

(iii) A description of the procedures available if the accreditation organization or State licensure program, as applicable, desires an opportunity to explain or justify the findings made during the comparability or validation review.

(iv) The reapplication materials that the accreditation organization or State licensure program must submit and the deadline for that submission.

§493.575 Removal of deeming authority or CLIA exemption and final determination review.

(a) *CMS review.* CMS conducts a review of the following:

(1) A deeming authority review of an accreditation organization's program if the comparability or validation review produces findings, as described at §493.573. CMS reviews, as appropriate, the criteria described in §§493.555 and 493.557(a) to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) An exemption review of a State's licensure program if the comparability or validation review produces findings, as described at §493.573. CMS reviews, as appropriate, the criteria described in §§493.555 and 493.557(b) to reevaluate

whether the licensure program continues to meet all these criteria.

(3) A review of an accreditation organization or State licensure program, at CMS's discretion, if validation review findings, irrespective of the rate of disparity, indicate widespread or systematic problems in the organization's accreditation or State's licensure process that provide evidence that the requirements, taken as a whole, are no longer equivalent to CLIA requirements, taken as a whole.

(4) A review of the accreditation organization or State licensure program whenever validation inspection results indicate a rate of disparity of 20 percent or more between the findings of the organization or State and those of CMS or a CMS agent for the following periods:

(i) One year for accreditation organizations.

(ii) Two years for State licensure programs.

(b) *CMS action after review.* Following the review, CMS may take the following action:

(1) If CMS determines that the accreditation organization or State has failed to adopt requirements equal to, or more stringent than, CLIA requirements, CMS may give a conditional approval for a probationary period of its deeming authority to an organization 30 days following the date of CMS's determination, or exempt status to a State within 30 days of CMS's determination, both not to exceed 1 year, to afford the organization or State an opportunity to adopt equal or more stringent requirements.

(2) If CMS determines that there are widespread or systematic problems in the organization's or State's inspection process, CMS may give conditional approval during a probationary period, not to exceed 1 year, effective 30 days following the date of the determination.

(c) *Final determination.* CMS makes a final determination as to whether the organization or State continues to meet the criteria described in this subpart and issues a notice that includes the reasons for the determination to the organization or State within 60 days after the end of any probationary period. This determination is based on an evaluation of any of the following:

(1) The most recent validation inspection and review findings. To continue to be approved, the organization or State must meet the criteria of this subpart.

(2) Facility-specific data, as well as other related information.

(3) The organization's or State's inspection procedures, surveyors' qualifications, ongoing education, training, and composition of inspection teams.

(4) The organization's accreditation requirements, or the State's licensure or approval requirements.

(d) *Date of withdrawal of approval.* CMS may withdraw its approval of the accreditation organization or State licensure program, effective 30 days from the date of written notice to the organization or State of this proposed action, if improvements acceptable to CMS have not been made during the probationary period.

(e) *Continuation of validation inspections.* The existence of any validation review, probationary status, or any other action, such as a deeming authority review, by CMS does not affect or limit the conduct of any validation inspection.

(f) *Federal Register notice.* CMS publishes a notice in the FEDERAL REGISTER containing a justification for removing the deeming authority from an accreditation organization, or the CLIA-exempt status of a State licensure program.

(g) *Withdrawal of approval-effect on laboratory status*—(1) *Accredited laboratory.* After CMS withdraws approval of an accreditation organization's deeming authority, the certificate of accreditation of each affected laboratory continues in effect for 60 days after it receives notification of the withdrawal of approval.

(2) *CLIA-exempt laboratory.* After CMS withdraws approval of a State licensure program, the exempt status of each licensed or approved laboratory in the State continues in effect for 60 days after a laboratory receives notification from the State of the withdrawal of CMS's approval of the program.

(3) *Extension.* After CMS withdraws approval of an accreditation organization or State licensure program, CMS may extend the period for an additional 60 days for a laboratory if it determines that the laboratory submitted an application for accreditation to an approved accreditation organization or an application for the appropriate certificate to CMS or a CMS agent before the initial 60-day period ends.

(h) *Immediate jeopardy to patients.* (1) If at any time CMS determines that the continued approval of deeming authority of any accreditation organization poses immediate jeopardy to the patients of the laboratories accredited by the organization, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of deeming authority for that accreditation organization.

(2) If at any time CMS determines that the continued approval of a State licensure program poses immediate jeopardy to the patients of the laboratories in that State, or continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of that State licensure program.

(i) *Failure to pay fees.* CMS withdraws the approval of a State licensure program if the State fails to pay the applicable fees, as specified in §§ 493.645(a) and 493.646(b).

(j) *State refusal to take enforcement action.* (1) CMS may withdraw approval of a State licensure program if the State refuses to take enforcement action against a laboratory in that State when CMS determines it to be necessary.

(2) A laboratory that is in a State in which CMS has withdrawn program approval is subject to the same requirements and survey and enforcement processes that are applied to a laboratory that is not exempt from CLIA requirements.

(k) *Request for reconsideration.* Any accreditation organization or State that is dissatisfied with a determination to withdraw approval of its deeming authority or remove approval of its State licensure program, as applicable, may request that CMS reconsider the determination, in accordance with subpart D of part 488.

Subpart F—General Administration

SOURCE: 57 FR 7138, 7213, Feb. 28, 1992, unless otherwise noted.

§ 493.602 Scope of subpart.

This subpart sets forth the methodology for determining the amount of the fees for issuing the appropriate certificate, and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of accredited laboratories and of CLIA-exempt laboratories.

[60 FR 20047, Apr. 24, 1995]

§ 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in § 493.3.

[58 FR 5212, Jan. 19, 1993]

§ 493.638 Certificate fees.

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance, as applicable. Laboratories must also pay a fee to reapply for a certificate for PPM procedures, certificate of waiver, certificate of accreditation, or a certificate of compliance. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act.

(1) For registration certificates and certificates of compliance, the costs include issuing the certificates, collecting the fees, evaluating and monitoring proficiency testing programs, evaluating which procedures, tests or examinations meet the criteria for inclusion in the appropriate complexity category, and implementing section 353 of the PHS Act.

(2) For a certificate of waiver, the costs include issuing the certificate, collecting the fees, determining if a certificate of waiver should be issued,

evaluating which tests qualify for inclusion in the waived category, and other direct administrative costs.

(3) For a certificate for PPM procedures, the costs include issuing the certificate, collecting the fees, determining if a certificate for PPM procedures should be issued, evaluating which procedures meet the criteria for inclusion in the subcategory of PPM procedures, and other direct administrative costs.

(4) For a certificate of accreditation, the costs include issuing the certificate, collecting the fees, evaluating the programs of accrediting bodies, and other direct administrative costs.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on the category of test complexity, or on the category of test complexity and schedules or ranges of annual laboratory test volume (excluding waived tests and tests performed for quality control, quality assurance, and proficiency testing purposes) and specialties tested, with the amounts of the fees in each schedule being a function of the costs for all aspects of general administration of CLIA as set forth in § 493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to determine the amount of the fee is found in § 493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate for PPM procedures, certificate of waiver, certificate of accreditation, or certificate of compliance is the amount in effect at the time the application is received. Upon receipt of an application for a certificate, HHS or its designee notifies the laboratory of the amount of the required fee for the requested certificate.

[60 FR 20047, Apr. 24, 1995]

§ 493.639 Fee for revised certificate.

(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the following circumstances:

(1) The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory as follows:

(i) If a laboratory with a certificate of waiver wishes to perform tests in addition to those listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(ii) If a laboratory with a certificate for PPM procedures wishes to perform tests in addition to those specified as PPM procedures or listed in § 493.15(c) as waived tests, it must, as set forth in § 493.638, pay an additional fee for the appropriate certificate to cover the additional testing.

(2) A laboratory must pay a fee to cover the cost of issuing a revised certificate when—

(i) A laboratory changes its name, location, or its director; or

(ii) A laboratory deletes services or wishes to add services and requests that its certificate be changed. (An additional fee is also required under § 493.643(d) if it is necessary to determine compliance with additional requirements.)

[57 FR 7213, Feb. 28, 1992, as amended at 60 FR 20047, Apr, 24, 1995]

§ 493.643 Fee for determination of program compliance.

(a) *Fee requirement.* In addition to the fee required under § 493.638, a laboratory subject to routine inspections must pay a fee to cover the cost of determining program compliance. Laboratories issued a certificate for PPM procedures, certificate of waiver, or a certificate of accreditation are not subject to this fee for routine inspections.

(b) *Costs included in the fee.* Included in the fee for determining program compliance is the cost of evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite inspections; documenting deficiencies; evaluating laboratories' plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annually on a calendar year basis. Laboratories are inspected biennially; therefore, fees are assessed and

payable biennially. If additional expenses are incurred to conduct follow up visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform the activities.

(c) *Classification of laboratories that require inspection for purpose of determining amount of fee.* (1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the ten following schedules based on the laboratory's scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purposes).

(i) (A) *Schedule A Low Volume.* The laboratory performs not more than 2,000 laboratory tests annually.

(B) *Schedule A.* The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(ii) *Schedule B.* The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) *Schedule C.* The laboratory performs tests in no more 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(iv) *Schedule D.* The laboratory performs tests in at least 4 specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule E.* The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vi) *Schedule F.* The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(vii) *Schedule G.* The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(viii) *Schedule H.* The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(ix) *Schedule I.* The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(x) *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

(2) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assurance, and proficiency testing are excluded from the laboratory's total annual volume). Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(3) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

(A) Bacteriology.

(B) Mycobacteriology.

(C) Mycology.

(D) Parasitology.

(E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

(A) Syphilis Serology.

(B) General immunology

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

(A) Routine chemistry.

(B) Endocrinology.

(C) Toxicology.

(D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of Immunohematology, which includes one or more of the following subspecialties:

(A) ABO grouping and Rh typing.

(B) Unexpected antibody detection.

(C) Compatibility testing.

(D) Unexpected antibody identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

(A) Cytology.

(B) Histopathology.

(C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of Histocompatibility.

(ix) The specialty of Clinical Cytogenetics.

(d) *Additional fees.* (1) If after a certificate of compliance is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the laboratory holding a certificate of compliance a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate of compliance for failure to pay the assessed costs.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20047, Apr. 24, 1995; 68 FR 3702, Jan. 24, 2003]

§ 493.645 Additional fee(s) applicable to approved State laboratory programs and laboratories issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures.

(a) *Approved State laboratory programs.* State laboratory programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, CLIA-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's CLIA-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

(b) *Accredited laboratories.* (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If a laboratory issued a certificate of accreditation has been inspected and followup visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the assessed fee.

(c) If, in the case of a laboratory that has been issued a certificate of accreditation, certificate of waiver, or certificate for PPM procedures, it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the costs of these activities are not imposed upon the laboratory.

[60 FR 20047, Apr. 24, 1995]

§ 493.646 Payment of fees.

(a) Except for CLIA-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the

appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. The appropriate certificate is not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

§ 493.649 Methodology for determining fee amount.

(a) *General rule.* The amount of the fee in each schedule for compliance determination inspections is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required or, if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate of compliance is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of any certificate. HHS determines the average hourly rates for the activities of each of these entities.

(1) *State survey agencies.* The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory's participation in an approved proficiency testing program. The cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encompasses salary costs (as determined by each State's civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support staff.

(ii) Travel costs necessary to comply with each State's administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are established based on historical State requirements.

(iii) Indirect costs as negotiated by HHS.

(2) *Federal agencies.* The hourly rate for activities performed by Federal agencies is the most recent average hourly cost to HHS to staff and support a full time equivalent employee. Included in this cost are salary and fringe benefit costs, necessary administrative costs, such as printing, training, postage, express mail, supplies, equipment, computer system and building service charges associated with support services provided by organizational components such as a computer center, and any other oversight activities necessary to support the program.

(3) *HHS contractors.* The hourly rate for activities performed by HHS contractors is the average hourly rate established for contractor assistance based on an independent government cost estimate for the required workload. This rate includes the cost of contractor support to provide proficiency testing programs to laboratories that do not participate in an approved proficiency testing program, provide specialized assistance in the evaluation of laboratory performance in an approved proficiency testing program, perform assessments of cytology testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary surveyor training.

(c) *Determining number of hours.* The average number of hours used to determine the overall fee in each schedule is

HHS's estimate, based on historical experience, of the average time needed by each entity to perform the activities for which it is responsible.

[57 FR 7138 and 7213, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995]

Subpart G [Reserved]

Subpart H—Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing

SOURCE: 57 FR 7146, Feb. 28, 1992, unless otherwise noted.

§ 493.801 Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) *Standard; Enrollment.* The laboratory must—

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with § 493.1236(c)(1).

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify CMS before any change in designation; and

(4) Authorize the proficiency testing program to release to HHS all data required to—

(i) Determine the laboratory's compliance with this subpart; and

(ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

(b) *Standard; Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least

one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

[57 FR 7146, Feb. 28, 1992, as amended at 60 FR 20048, Apr. 24, 1995; 63 FR 26737, May 14, 1998; 68 FR 3702, Jan. 24, 2003]

§ 493.807 Condition: Reinstatement of laboratories performing nonwaived testing.

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

[58 FR 5228, Jan. 19, 1993, as amended at 60 FR 20048, Apr. 24, 1995]

PROFICIENCY TESTING BY SPECIALTY AND SUBSPECIALTY FOR LABORATORIES PERFORMING TESTS OF MODERATE COMPLEXITY (INCLUDING THE SUBCATEGORY), HIGH COMPLEXITY, OR ANY COMBINATION OF THESE TESTS

§ 493.821 Condition: Microbiology.

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

§ 493.823 Standard; Bacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.825 Standard; Mycobacteriology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.827 Standard; Mycology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.829 Standard; Parasitology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.831 Standard; Virology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame

for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.833 Condition: Diagnostic immunology.

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

§ 493.835 Standard; Syphilis serology.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.837 Standard; General immunology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame

for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.839 Condition: Chemistry.

The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.

§ 493.841 Standard; Routine chemistry.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.843 Standard; Endocrinology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.845 Standard; Toxicology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.849 Condition: Hematology.

The specialty of hematology, for the purpose of proficiency testing, is not

subdivided into subspecialties of testing.

§ 493.851 Standard; Hematology.

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.853 Condition: Pathology.

The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations.

§ 493.855 Standard; Cytology: gynecologic examinations.

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-

slide test. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.

(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented.

(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.

(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, CMS will initiate intermediate sanctions or limit the laboratory's certificate to exclude gynecologic cytology testing under CLIA, and, if applicable, suspend the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of this part.

[57 FR 7146, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994]

§ 493.857 Condition: Immunohematology.

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

§ 493.859 Standard; ABO group and D (Rho) typing.

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.861 Standard; Unexpected antibody detection.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.863 Standard; Compatibility testing.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.865 Standard; Antibody identification.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

Subpart I—Proficiency Testing Programs for Nonwaived Testing

SOURCE: 57 FR 7151, Feb. 28, 1992, unless otherwise noted.

§ 493.901 Approval of proficiency testing programs.

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private nonprofit organization or a Federal or State agency, or entity acting as a designated agent for the State. An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the current year. The organization, Federal, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty, subspecialty, and analyte or test for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;

(b) Demonstrate to HHS that it has—

(1) The technical ability required to—

(i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606, 640, and 820; and

(ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;

(2) A scientifically defensible process for determining the correct result for each challenge offered by the program;

(3) A program of sufficient annual challenge and with the frequency specified in §§ 493.909 through 493.959 to establish that a laboratory has met minimum performance requirements;

(4) The resources needed to provide Statewide or nationwide reports to regulatory agencies on individual's performance for gynecologic cytology and

on individual laboratory performance on testing events, cumulative reports and scores for each laboratory or individual, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis when requested;

(5) Provisions to include on each proficiency testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as by the laboratory director;

(6) A mechanism for notifying participants of the PT shipping schedule and for participants to notify the proficiency testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and

(7) A process to resolve technical, administrative, and scientific problems about program operations;

(c) Meet the specific criteria for proficiency testing programs listed by specialty, subspecialty, and analyte or test contained in §§ 493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with the information necessary to assure that the proficiency testing program meets the criteria required for approval; and

(d) Comply with all applicable packaging, shipment, and notification requirements of 42 CFR part 72.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.903 Administrative responsibilities.

The proficiency testing program must—

(a)(1) Provide HHS or its designees and participating laboratories with an electronic or a hard copy, or both, of reports of proficiency testing results and all scores for each laboratory's performance in a format as required by and approved by CMS for each CLIA-certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.

(2) Provide HHS with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within *15* working days of the testing event;

(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA-certified laboratories for the purpose of establishing a system to make the proficiency testing program's results available, on a reasonable basis, upon request of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing program's results;

(c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of §§ 493.901 through 493.959;

(d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and

(e) Provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993]

§ 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, CMS will notify the program and the program must notify all laboratories enrolled of the nonapproval and the reasons for nonapproval within 30 days of the notification.

PROFICIENCY TESTING PROGRAMS BY SPECIALTY AND SUBSPECIALTY

§ 493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these subspecialties are found at §§ 493.911 through 493.919.

§ 493.911 Bacteriology.

(a) *Types of services offered by laboratories.* In bacteriology, for proficiency testing purposes, there are five types of laboratories:

(1) Those that interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification;

(2) Those that use direct antigen techniques to detect an organism and may also interpret Gram stains or perform primary inoculation, or perform any combination of these;

(3) Those that, in addition to interpreting Gram stains, performing primary inoculations, and using direct antigen tests, also isolate and identify aerobic bacteria from throat, urine, cervical, or urethral discharge specimens to the genus level and may also perform antimicrobial susceptibility tests on selected isolated microorganisms;

(4) Those that perform the services in paragraph (a)(3) of this section and also isolate and identify aerobic bacteria from any source to the species level and may also perform antimicrobial susceptibility tests; and

(5) Those that perform the services in paragraph (a)(4) of this section and also isolate and identify anaerobic bacteria from any source.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. For the types of laboratories specified in paragraph (a) of this section, an annual program must include samples that contain organisms that are representative of the six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative bacteria, as appropriate. The specific organisms included in the samples may vary from year to year. The annual program must include samples for bacterial antigen detection, bacterial isolation and identification, Gram stain, and antimicrobial susceptibility testing.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly occurring in patient specimens or opportunistic pathogens. The program must include the following two types of samples; each type of sample must meet the 50 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens such as urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients. The program determines the reportable isolates.

(2) An approved program may vary over time. For example, the types of organisms that might be included in an approved program over time are—

Anaerobes:
Bacteroides fragilis group
Clostridium perfringens

Peptostreptococcus anaerobius
Enterobacteriaceae
Citrobacter freundii
Enterobacter aerogenes
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis
Salmonella typhimurium
Serratia marcescens
Shigella sonnei
Yersinia enterocolitica
Gram-positive bacilli:
Listeria monocytogenes
Corynebacterium species CDC Group JK
Gram-positive cocci:
Staphylococcus aureus
Streptococcus Group A
Streptococcus Group B
Streptococcus Group D (S. bovis and enterococcus)
Streptococcus pneumoniae
Gram-negative cocci:
Branhamella catarrhalis
Neisseria gonorrhoeae
Neisseria meningitidis
Miscellaneous Gram-negative bacteria:
Campylobacter jejuni
Haemophilis influenza, Type B
Pseudomonas aeruginosa

(3) For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a predetermined pattern of sensitivity or resistance to the common antimicrobial agents.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (7) of this section.

(1) The program determines staining characteristics to be interpreted by Gram stain. The program determines the reportable bacteria to be detected by direct antigen techniques or isolation. To determine the accuracy of a laboratory's response for Gram stain interpretation, direct antigen detection, identification, or antimicrobial susceptibility testing, the program must compare the laboratory's response for each sample with the response which reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of its final answer, for example, a laboratory specified in paragraph (a)(3) of this section will be evaluated on the basis of the average of its scores for paragraphs (c)(3) through (c)(6) as determined in paragraph (c)(7) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms that are reported. Therefore, the total number of correct responses for organism isolation and identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1+1)\times100=50$ percent.

(4) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which service is offered. A correct response for each antibiotic will be determined as described in §§493.911(c) (1) using criteria such as the guidelines established by the National Committee for Clinical Laboratory Standards. Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing for *Enterobacteriaceae* using amikacin, cephalothin, and tobramycin, and the organism in the proficiency testing sample is an *Enterobacteriaceae*, and the laboratory reports correct responses for two of

three antimicrobial agents, the laboratory's grade would be 2/3×100=67 percent.

(5) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The score for antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(6) The performance criteria for Gram stain is staining reaction, i.e., gram positive or gram negative. The score for Gram stain is the number of correct responses divided by the number of challenges to be tested, multiplied by 100.

(7) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(6) of this section kbased on the type of service offered by the laboratory.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.913 Mycobacteriology.

(a) *Types of services offered by laboratories.* In mycobacteriology, there are five types of laboratories for proficiency testing purposes:

(1) Those that interpret acid-fast stains and refer specimen to another laboratory appropriately certified in the subspecialty of mycobacteriology;

(2) Those that interpret acid-fast stains, perform primary inoculation, and refer cultures to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification;

(3) Those that interpret acid-fast stains, isolate and perform identification and/or antimycobacterial susceptibility of *Mycobacterium tuberculosis*, but refer other mycobacteria species to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification and/or susceptibility tests;

(4) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory appropriately certified in the subspecialty of mycobacteriology; and

(5) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS or its designee for on-site testing events. For types of laboratories specified in paragraphs (a)(1) and (a) (3) through (5) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.

(1) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). The program determines the reportable isolates and correct responses for antimycobacterial susceptibility for any designated isolate.

(2) An approved program may vary over time. For example, the types of mycobacteria that might be included in an approved program over time are—

TB
Mycobacterium tuberculosis
Mycobacterium bovis
Group I
Mycobacterium kansasii
Group II
Mycobacterium szulgai
Group III
Mycobacterium avium-intracellulare
Mycobacterium terrae
Group IV
Mycobacterium fortuitum

(3) For antimycobacterial susceptibility testing, the program must provide at least one sample per testing event that includes mycobacterium tuberculosis that has a predetermined pattern of sensitivity or resistance to the common antimycobacterial agents.

(4) For laboratories specified in paragraphs (a)(1) and (a)(2), the program must provide at least five samples per testing event that includes challenges that are acid-fast and challenges which do not contain acid-fast organisms.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (6) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain, for isolation and identification, and for antimycobacterial susceptibility. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of the average of its scores as determined in paragraph (c)(6) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be

$1 / (1 + 1) \times 100 = 50$ percent

(4) For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens. A correct response for each antibiotic will be determined as described in §493.913(c)(1). Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three antimycobacterial agents and the laboratory reports correct response for two of the three antimycobacterial agents, the laboratory's grade would be $\frac{2}{3} \times 100 = 67$ percent.

(5) The performance criterion for qualitative tests is the presence or absence of acid-fast organisms. The score for acid-fast organism detection is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(5) of this section based on the type of service offered by the laboratory.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§493.915 Mycology.

(a) *Types of services offered by laboratories.* In mycology, there are four types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:

(1) Those that isolate and identify only yeasts and/or dermatophytes to the genus level;

(2) Those that isolate and identify yeasts and/or dermatophytes to the species level;

(3) Those that isolate and perform identification of all organisms to the genus level; and

(4) Those that isolate and perform identification of all organisms to the species level.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain organisms that are representative of five major groups of fungi: Yeast or yeast-like fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

(1) An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

(2) An approved program may vary over time. As an example, the types of organisms that might be included in an approved program over time are—

Candida albicans
Candida (other species)
Cryptococcus neoformans
Sporothrix schenckii
Exophiala jeanselmei
Fonsecaea pedrosoi
Microsporum sp.
Acremonium sp.
Trichophyton sp.
Aspergillus fumigatus
Nocardia sp.
Blastomyces dermatitidis[1]
Zygomycetes sp.

[1] NOTE: Provided as a nonviable sample.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable organisms. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must deduct credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each shipment or testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be 1/(1+1)x100=50 percent.

(4) The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) or (c)(4), or both, of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5228, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.917 Parasitology.

(a) *Types of services offered by laboratories.* In parasitology there are two

types of laboratories for proficiency testing purposes—

(1) Those that determine the presence or absence of parasites by direct observation (wet mount) and/or pinworm preparations and, if necessary, refer specimens to another laboratory appropriately certified in the subspecialty of parasitology for identification;

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in parasitology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.

(1) An approved program must, before each calendar year furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(2) An approved program may vary over time. As an example, the types of parasites that might be included in an approved program over time are—

Enterobius vermicularis
Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschli
Chilomastix mesnili
Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (6) of this section.

(1) The program must determine the reportable parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in scoring a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal parasite(s), the grading system must deduct credit for these additional erroneous parasites reported and not found in rare numbers by the program's referencing process. Therefore, the total number of correct responses submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal parasite and the laboratory

reported it correctly but reported the presence of an additional parasite, which was not present, the sample grade would be

1/(1+1)×100=50 percent.

(4) The criterion for acceptable performance for qualitative parasitology examinations is presence or absence of a parasite(s).

(5) The score for parasitology is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (c)(3) through (c)(5) of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 68 FR 3702, Jan. 24, 2003]

§ 493.919 Virology.

(a) *Types of services offered by laboratories.* In virology, there are two types of laboratories for proficiency testing purposes—

(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and

(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include viral species that are the more commonly identified viruses. The specific organisms found in the samples may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.

(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as Herpes simplex, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

(c) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of correct responses determined by virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be 1/(1+1)×100=50 percent.

(4) The performance criterion for qualitative antigen tests is presence or

absence of the viral antigen. The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) and (c)(4) of this section.

[57 FR 7151, Feb. 28, 1992, as amended at 68 FR 3702, Jan. 24, 2003]

§493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these subspecialties are found at §§493.923 and 493.927.

§493.923 Syphilis serology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Evaluation of test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration, by method, that will be considered as indicating a positive response. The score for a sample in syphilis serology is the average of scores determined under paragraphs (b)(2) and (b)(3) of this section.

(2) For quantitative syphilis tests, the program must determine the correct response for each method by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria. The criterion for acceptable performance for quantitative syphilis serology tests is the target value ±1 dilution.

(3) The criterion for acceptable performance for qualitative syphilis serology tests is reactive or nonreactive.

(4) To determine the overall testing event score, the number of correct responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§493.927 General immunology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

Analyte or Test Procedure

Alpha-l antitrypsin
Alpha-fetoprotein (tumor marker)
Antinuclear antibody
Antistreptolysin O
Anti-human immunodeficiency virus (HIV)

Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc, HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis
Rheumatoid factor
Rubella

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin	Target value ±3 SD.
Alpha-fetoprotein (tumor marker).	Target value ±3 SD.
Antinuclear antibody	Target value ±2 dilutions or positive or negative.
Antistreptolysin O	Target value ±2 dilution or positive or negative.
Anti-Human Immunodeficiency virus.	Reactive or nonreactive.
Complement C3	Target value ±3 SD.
Complement C4	Target value ±3 SD.
Hepatitis (HBsAg, anti-HBc, HBeAg).	Reactive (positive) or nonreactive (negative).
IgA	Target value ±3 SD.
IgE	Target value ±3 SD.
IgG	Target value ±25%.
IgM	Target value ±3 SD.
Infectious mononucleosis	Target value ±2 dilutions or positive or negative.
Rheumatoid factor	Target value ±2 dilutions or positive or negative.
Rubella	Target value ±2 dilutions or immune or nonimmune or positive or negative.

(3) The criterion for acceptable performance for qualitative general immunology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§ 493.931 through 493.939.

§ 493.931 Routine chemistry.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at

approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

Analyte or Test Procedure

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas (pH, pO2, and pCO2)
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase, isoenzymes
Creatinine
Glucose (Excluding measurements on devices cleared by FDA for home use)
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in routine chemistry is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alanine aminotransferase (ALT/SGPT).	Target value ±20%.
Albumin	Target value ±10%.
Alkaline phosphatase	Target value ±30%.
Amylase	Target value ±30%.
Aspartate aminotransferase (AST/SGOT).	Target value ±20%.
Bilirubin, total	Target value ±0.4 mg/dL or ±20% (greater).
Blood gas pO2	Target value ±3 SD.
pCO2	Target value ±5 mm Hg or ±8% (greater).
pH	Target value ±0.04.
Calcium, total	Target value ±1.0 mg/dL.
Chloride	Target value ±5%.
Cholesterol, total	Target value ±10%.
Cholesterol, high density lipoprotein.	Target value ±30%.
Creatine kinase	Target value ±30%.
Creatine kinase isoenzymes	MB elevated (presence or absence) or Target value ±3SD.
Creatinine	Target value ±0.3 mg/dL or ±15% (greater).
Glucose (excluding glucose performed on monitoring devices cleared by FDA for home use.	Target value ±6 mg/dl or ±10% (greater).
Iron, total	Target value ±20%.
Lactate dehydrogenase (LDH).	Target value ±20%.
LDH isoenzymes	LDH1/LDH2 (+ or −) or Target value ±30%.
Magnesium	Target value ±25%.
Potassium	Target value ±0.5 mmol/L.
Sodium	Target value ±4 mmol/L.
Total Protein	Target value ±10%.
Triglycerides	Target value ±25%.
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater).
Uric acid	Target value ±17%.

(3) The criterion for acceptable performance for qualitative routine chemistry tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable

analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 68 FR 3702, Jan. 24, 2003]

§ 493.933 Endocrinology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

Analyte or Test

Cortisol
Free Thyroxine
Human Chorionic gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests)
T3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in endocrinology is either the score determined under paragraph (c)(2) or (c)(3) of this section.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Cortisol	Target value ±25%.
Free Thyroxine	Target value ±3 SD.
Human Chorionic Gonadotropin (excluding urine pregnancy tests done by visual color comparison categorized as waived tests).	Target value ±3 SD positive or negative.
T3 Uptake	Target value ±3 SD.
Triiodothyronine	Target value ±3 SD.
Thyroid-stimulating hormone	Target value ±3 SD.
Thyroxine	Target value ±20% or 1.0 mcg/dL (greater).

(3) The criterion for acceptable performance for qualitative endocrinology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.937 Toxicology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

Analyte or Test Procedure

Alcohol (blood)	Phenytoin
Blood lead	Primidone
Carbamazepine	Procainamide (and metabolite)
Digoxin	Quinidine
Ethosuximide	Theophylline
Gentamicin	Tobramycin
Lithium	Valproic Acid
Phenobarbital	

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in toxicology is the score determined under paragraph (c)(2) of this section.

(2) For quantitative toxicology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Alcohol, blood	Target Value ±25%.
Blood lead	Target Value ±10% or 4 mcg/dL (greater).
Carbamazepine	Target Value ±25%.
Digoxin	Target Value ±20% or ±0.2 ng/mL (greater).
Ethosuximide	Target Value ±20%.
Gentamicin	Target Value ±25%.
Lithium	Target Value ±0.3 mmol/L or ±20% (greater).
Phenobarbital	Target Value ±20%
Phenytoin	Target Value ±25%.
Primidone	Target Value ±25%.
Procainamide (and metabolite).	Target Value ±25%.
Quinidine	Target Value ±25%.
Tobramycin	Target Value ±25%.
Theophylline	Target Value ±25%.
Valproic Acid	Target Value ±25%.

(3) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.941 Hematology (including routine hematology and coagulation).

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS and or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

Cell identification or white blood cell differential
Erythrocyte count
Hematocrit (excluding spun microhematocrit)
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. The types of cells that might be included in an approved program over time are—

Neutrophilic granulocytes
Eosinophilic granulocytes
Basophilic granulocytes
Lymphocytes
Monocytes
Major red and white blood cell abnormalities
Immature red and white blood cells

(2) White blood cell differentials should be limited to the percentage distribution of cellular elements listed above.

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Cell identification	90% or greater consensus on identification.
White blood cell differential	Target ±3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count	Target ±6%.
Hematocrit (Excluding spun hematocrits).	Target ±6%.
Hemoglobin	Target ±7%.
Leukocyte count	Target ±15%.
Platelet count	Target ±25%.
Fibrinogen	Target ±20%.
Partial thromboplastin time	Target ±15%.
Prothrombin time	Target ±15%.

(3) The criterion for acceptable performance for the qualitative hematology test is correct cell identification.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§493.945 Cytology; gynecologic examinations.

(a) *Program content and frequency of challenge.* (1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in §§493.1105(a)(7)(i)(A) and 493.1274(f)(2). If slide preparations are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set must include at least one slide representing each of the response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.

(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in §493.855.

(b) *Evaluation of an individual's performance.* HHS approves only those programs that assess the accuracy of each individual's responses on both 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.

(1) To determine the accuracy of an individual's response on a particular challenge (slide), the program must compare the individual's response for each slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations, a 100% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations, confirmation by tissue biopsy is required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) An individual qualified as a technical supervisor under §493.1449 (b) or (k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) The criteria for acceptable performance are determined by using the

scoring system in paragraphs (b)(3) (i) and (ii) of this section.

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§ 493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449 (b) or (k) of this part.

(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.

(A) The four response categories for reporting proficiency testing results and their descriptions are as follows:

Category	Description
A	Unsatisfactory for diagnosis due to: (1) Scant cellularity. (2) Air drying. (3) Obscuring material (blood, inflammatory cells, or lubricant).
B	Normal or Benign Changes—includes: (1) Normal, negative or within normal limits. (2) Infection other than Human Papillomavirus (HPV) (e.g., *Trichomonas vaginalis,* changes or morphology consistent with *Candida* spp., *Actinomyces* spp. or *Herpes simplex* virus). (3) Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).
C	Low Grade Squamous Intraepithelial Lesion—includes: (1) Cellular changes associated with HPV. (2) Mild dysplasia/CIN–1.
D	High Grade Lesion and Carcinoma—includes: (1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN–2 and severe dysplasia/carcinoma in-situ/CIN–3. (2) Squamous cell carcinoma. (3) Adenocarcinoma and other malignant neoplasms.

(B) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (−5) points for an incorrect response on a 10-slide test set. For example, if the correct response on a slide is ''high grade squamous intraepithelial lesion'' (category ''D'' on the scoring system chart) and an examinee calls it ''normal or negative'' (category ''B'' on the scoring system chart), then the examinee's point value on that slide is calculated as minus five (−5). Each slide is scored individually in the same manner. The individual's score for the testing event is determined by adding the point value achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100.

(C) Criteria for scoring system for a 10-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	0	0
B	5	10	0	0
C	5	0	10	5
D	0	−5	5	10

(D) Criteria for scoring system for a 10-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	10	0	5	5
B	5	10	5	5
C	5	0	10	10
D	0	−5	10	10

(E) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(F) and (G) of this section, for technical supervisors and cytotechnologists, respectively, provide maximums of 5 points for a correct response and minus ten (−10) points for an incorrect response on a 20-slide test set.

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a

description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	0	0
B	2.5	5	0	0
C	2.5	0	5	2.5
D	0	−10	2.5	5

(G) Criteria for scoring system for a 20-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Examinee's response:	A	B	C	D
Correct response category:				
A	5	0	2.5	2.5
B	2.5	5	2.5	2.5
C	2.5	0	5	5
D	0	−10	5	5

[57 FR 7151, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993; 68 FR 3702, Jan. 24, 2003]

§ 493.959 Immunohematology.

(a) *Types of services offered by laboratories.* In immunohematology, there are four types of laboratories for proficiency testing purposes—

(1) Those that perform ABO group and/or D (Rho) typing;

(2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;

(3) Those that in addition to paragraph (a)(2) of this section perform compatibility testing; and

(4) Those that perform in addition to paragraph (a)(3) of this section antibody identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(c) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or Test Procedure

ABO group (excluding subgroups)
D (Rho) typing
Unexpected antibody detection
Compatibility testing
Antibody identification

(d) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (d)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory's response for unexpected antibody detection and antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

(2) *Criteria for acceptable performance.* The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group	100% accuracy.
D (Rho) typing	100% accuracy.
Unexpected antibody detection	80% accuracy.
Compatibility testing	100% accuracy.
Antibody identification	80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte} \times 100}{\text{Total number of challenges for the analyte}} = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges} \times 100}{\text{Total number of all challenges}} = \text{Testing event score}$$

Subpart J—Facility Administration for Nonwaived Testing

SOURCE: 68 FR 3703, Jan. 24, 2003, unless otherwise noted.

§ 493.1100 Condition: Facility administration.

Each laboratory that performs nonwaived testing must meet the applicable requirements under §§ 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).

§ 493.1101 Standard: Facilities.

(a) The laboratory must be constructed, arranged, and maintained to ensure the following:

(1) The space, ventilation, and utilities necessary for conducting all phases of the testing process.

(2) Contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.

(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

(e) Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.

§ 493.1103 Standard: Requirements for transfusion services.

A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities.

(a) *Arrangement for services.* The facility must have a transfusion service agreement reviewed and approved by the responsible party(ies) that govern the procurement, transfer, and availability of blood and blood products.

(b) *Provision of testing.* The facility must provide prompt ABO grouping, D(Rho) typing, unexpected antibody detection, compatibility testing, and laboratory investigation of transfusion reactions on a continuous basis through a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

(c) *Blood and blood products storage and distribution.* (1) If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient.

(d) *Investigation of transfusion reactions.* The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

§ 493.1105 Standard: Retention requirements.

(a) The laboratory must retain its records and, as applicable, slides, blocks, and tissues as follows:

(1) *Test requisitions and authorizations.* Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.

(2) *Test procedures.* Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

(3) *Analytic systems records.* Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in §§493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

(i) Records of test system performance specifications that the laboratory establishes or verifies under §493.1253 for the period of time the laboratory uses the test system but no less than 2 years.

(ii) Immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v) and (d).

(4) *Proficiency testing records.* Retain all proficiency testing records for at least 2 years.

(5) *Quality system assessment records.* Retain all laboratory quality systems assessment records for at least 2 years.

(6) *Test reports.* Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following:

(i) Immunohematology reports as specified in 21 CFR 606.160(d).

(ii) Pathology test reports for at least 10 years after the date of reporting.

(7) *Slide, block, and tissue retention*—(i) *Slides.* (A) Retain cytology slide preparations for at least 5 years from the date of examination (see §493.1274(f) for proficiency testing exception).

(B) Retain histopathology slides for at least 10 years from the date of examination.

(ii) *Blocks.* Retain pathology specimen blocks for at least 2 years from the date of examination.

(iii) *Tissue.* Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.

(b) If the laboratory ceases operation, the laboratory must make provisions to ensure that all records and, as applicable, slides, blocks, and tissue are retained and available for the time frames specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50723, Aug. 22, 2003]

Subpart K—Quality System for Nonwaived Testing

SOURCE: 68 FR 3703, Jan. 24, 2003, unless otherwise noted.

§493.1200 Introduction.

(a) Each laboratory that performs nonwaived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.

(b) The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.

(c) The various components of the laboratory's quality system are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§493.1201 Condition: Bacteriology.

If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in §§493.1230 through 493.1256, §493.1261, and §§493.1281 through 493.1299.

§493.1202 Condition: Mycobacteriology.

If the laboratory provides services in the subspecialty of Mycobacteriology,

the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1262, and §§ 493.1281 through 493.1299.

§ 493.1203 Condition: Mycology.

If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1263, and §§ 493.1281 through 493.1299.

§ 493.1204 Condition: Parasitology.

If the laboratory provides services in the subspecialty of Parasitology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1264, and §§ 493.1281 through 493.1299.

§ 493.1205 Condition: Virology.

If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1265, and §§ 493.1281 through 493.1299.

§ 493.1207 Condition: Syphilis serology.

If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1208 Condition: General immunology.

If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1210 Condition: Routine chemistry.

If the laboratory provides services in the subspecialty of Routine chemistry, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1267, and §§ 493.1281 through 493.1299.

§ 493.1211 Condition: Urinalysis.

If the laboratory provides services in the subspecialty of Urinalysis, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1212 Condition: Endocrinology.

If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1213 Condition: Toxicology.

If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1215 Condition: Hematology.

If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1269, and §§ 493.1281 through 493.1299.

§ 493.1217 Condition: Immunohematology.

If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1271, and §§ 493.1281 through 493.1299.

§ 493.1219 Condition: Histopathology.

If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1273, and §§ 493.1281 through 493.1299.

§ 493.1220 Condition: Oral pathology.

If the laboratory provides services in the subspecialty of Oral pathology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1221 Condition: Cytology.

If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256,

§ 493.1274, and §§ 493.1281 through 493.1299.

§ 493.1225 Condition: Clinical cytogenetics.

If the laboratory provides services in the specialty of Clinical cytogenetics, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1276, and §§ 493.1281 through 493.1299.

§ 493.1226 Condition: Radiobioassay.

If the laboratory provides services in the specialty of Radiobioassay, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, and §§ 493.1281 through 493.1299.

§ 493.1227 Condition: Histocompatibility.

If the laboratory provides services in the specialty of Histocompatibility, the laboratory must meet the requirements specified in §§ 493.1230 through 493.1256, § 493.1278, and §§ 493.1281 through 493.1299.

GENERAL LABORATORY SYSTEMS

§ 493.1230 Condition: General laboratory systems.

Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in §§ 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems as specified in § 493.1239 for each specialty and subspecialty of testing performed.

§ 493.1231 Standard: Confidentiality of patient information.

The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control.

§ 493.1232 Standard: Specimen identification and integrity.

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

§ 493.1233 Standard: Complaint investigations.

The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.

§ 493.1234 Standard: Communications.

The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1235 Standard: Personnel competency assessment policies.

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

§ 493.1236 Standard: Evaluation of proficiency testing performance.

(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

(b) The laboratory must verify the accuracy of the following:

(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

(2) Any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return of results).

(c) At least twice annually, the laboratory must verify the accuracy of the following:

(1) Any test or procedure it performs that is not included in subpart I of this part.

(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.

(d) All proficiency testing evaluation and verification activities must be documented.

§ 493.1239 Standard: General laboratory systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at §§ 493.1231 through 493.1236.

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all general laboratory systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

PREANALYTIC SYSTEMS

§ 493.1240 Condition: Preanalytic systems.

Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in §§ 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in § 493.1249 for each specialty and subspecialty of testing performed.

§ 493.1241 Standard: Test request.

(a) The laboratory must have a written or electronic request for patient testing from an authorized person.

(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

(c) The laboratory must ensure the test requisition solicits the following information:

(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values.

(2) The patient's name or unique patient identifier.

(3) The sex and age or date of birth of the patient.

(4) The test(s) to be performed.

(5) The source of the specimen, when appropriate.

(6) The date and, if appropriate, time of specimen collection.

(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy.

(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

(d) The patient's chart or medical record may be used as the test requisition or authorization but must be available to the laboratory at the time of testing and available to CMS or a CMS agent upon request.

(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

§ 493.1242 Standard: Specimen submission, handling, and referral.

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable:

(1) Patient preparation.

(2) Specimen collection.

(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source.

(4) Specimen storage and preservation.

(5) Conditions for specimen transportation.

(6) Specimen processing.

(7) Specimen acceptability and rejection.

(8) Specimen referral.

(b) The laboratory must document the date and time it receives a specimen.

(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS.

(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

§ 493.1249 Standard: Preanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at §§ 493.1241 through 493.1242.

(b) The preanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all preanalytic systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 3703, Aug. 22, 2003]

ANALYTIC SYSTEMS

§ 493.1250 Condition: Analytic systems.

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in §§ 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in § 493.1289 for each specialty and subspecialty of testing performed.

§ 493.1251 Standard: Procedure manual.

(a) A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

(b) The procedure manual must include the following when applicable to the test procedure:

(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in § 493.1242.

(2) Microscopic examination, including the detection of inadequately prepared slides.

(3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.

(5) Calibration and calibration verification procedures.

(6) The reportable range for test results for the test system as established or verified in § 493.1253.

(7) Control procedures.

(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.

(9) Limitations in the test methodology, including interfering substances.

(10) Reference intervals (normal values).

(11) Imminently life-threatening test results, or panic or alert values.

(12) Pertinent literature references.

(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening results, or panic, or alert values.

(14) Description of the course of action to take if a test system becomes inoperable.

(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in § 493.1105(a)(2).

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1252 Standard: Test systems, equipment, instruments, reagents, materials, and supplies.

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under § 493.1253.

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following:

(1) Water quality.

(2) Temperature.

(3) Humidity.

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following:

(1) Identity and when significant, titer, strength or concentration.

(2) Storage requirements.

(3) Preparation and expiration dates.

(4) Other pertinent information required for proper use.

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

(e) Components of reagent kits of different lot numbers must not be interchanged unless otherwise specified by the manufacturer.

§ 493.1253 Standard: Establishment and verification of performance specifications.

(a) *Applicability.* Laboratories are not required to verify or establish performance specifications for any test system used by the laboratory before April 24, 2003.

(b)(1) *Verification of performance specifications.* Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

(A) Accuracy.

(B) Precision.

(C) Reportable range of test results for the test system.

(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

(2) *Establishment of performance specifications.* Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text

book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

(i) Accuracy.

(ii) Precision.

(iii) Analytical sensitivity.

(iv) Analytical specificity to include interfering substances.

(v) Reportable range of test results for the test system.

(vi) Reference intervals (normal values).

(vii) Any other performance characteristic required for test performance.

(3) *Determination of calibration and control procedures.* The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

(c) *Documentation.* The laboratory must document all activities specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1254 Standard: Maintenance and function checks.

(a) *Unmodified manufacturer's equipment, instruments, or test systems.* The laboratory must perform and document the following:

(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

(b) *Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer.* The laboratory must do the following:

(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting.

(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

§ 493.1255 Standard: Calibration and calibration verification procedures.

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system. Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following:

(a) Perform and document calibration procedures—

(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer;

(2) Using the criteria verified or established by the laboratory as specified in § 493.1253(b)(3)—

(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and

(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and

(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

(b) Perform and document calibration verification procedures—

(1) Following the manufacturer's calibration verification instructions;

(2) Using the criteria verified or established by the laboratory under § 493.1253(b)(3)—

(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and

(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and

(3) At least once every 6 months and whenever any of the following occur:

(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance.

(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

§ 493.1256 Standard: Control procedures.

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process.

(b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in § 493.1253(b)(3).

(c) The control procedures must—

(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance.

(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must—

(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at §§ 493.1261 through 493.1278.

(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section.

(3) At least once each day patient specimens are assayed or examined perform the following for—

(i) Each quantitative procedure, include two control materials of different concentrations;

(ii) Each qualitative procedure, include a negative and positive control material;

(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively;

(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and

(v) Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

(4) For thin layer chromatography—

(i) Spot each plate or card, as applicable, with a calibrator containing all known substances or drug groups, as appropriate, which are identified by thin layer chromatography and reported by the laboratory; and

(ii) Include at least one control material on each plate or card, as applicable, which must be processed through each step of patient testing, including extraction processes.

(5) For each electrophoretic procedure include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.

(6) Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced.

(7) Over time, rotate control material testing among all operators who perform the test.

(8) Test control materials in the same manner as patient specimens.

(9) When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system.

(10) Establish or verify the criteria for acceptability of all control materials.

(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available.

(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory.

(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

(e) For reagent, media, and supply checks, the laboratory must do the following:

(1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in §493.1261(a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

(3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use.

(4) Before, or concurrent with the initial use—

(i) Check each batch of media for sterility if sterility is required for testing;

(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and

(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results.

(g) The laboratory must document all control procedures performed.

(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§493.1261 Standard: Bacteriology.

(a) The laboratory must check the following for positive and negative reactivity using control organisms:

(1) Each day of use for beta-lactamase methods other than Cefinase™.

(2) Each week of use for Gram stains.

(3) When each batch (prepared in-house), lot number (commercially prepared), and shipment of antisera is prepared or opened, and once every 6 months thereafter.

(b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s)

before, or concurrent with, initial use, using approved control organisms.

(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1262 Standard: Mycobacteriology.

(a) Each day of use, the laboratory must check all reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction and an acid-fast organism that produces a negative reaction.

(b) For antimycobacterial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(1) The laboratory must establish limits for acceptable control results.

(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(3) The results for the control organism(s) must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1263 Standard: Mycology.

(a) The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s).

(b) For antifungal susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antifungal agent(s) before, or concurrent with, initial use, using an appropriate control organism(s).

(1) The laboratory must establish limits for acceptable control results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

(3) The results for the control organism(s) must be within established limits before reporting patient results.

(c) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1264 Standard: Parasitology.

(a) The laboratory must have available a reference collection of slides or photographs and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control material that will demonstrate staining characteristics.

(d) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1265 Standard: Virology.

(a) When using cell culture to isolate or identify viruses, the laboratory must simultaneously incubate a cell substrate control or uninoculated cells as a negative control material.

(b) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1267 Standard: Routine chemistry.

For blood gas analyses, the laboratory must perform the following:

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer.

(b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing.

(c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes.

(d) Document all control procedures performed, as specified in this section.

§ 493.1269 Standard: Hematology.

(a) For manual cell counts performed using a hemocytometer—

(1) One control material must be tested each 8 hours of operation; and

(2) Patient specimens and control materials must be tested in duplicate.

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

(c) For manual coagulation tests—

(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and

(2) Patient specimens and control materials must be tested in duplicate.

(d) The laboratory must document all control procedures performed, as specified in this section.

§ 493.1271 Standard: Immunohematology.

(a) *Patient testing.* (1) The laboratory must perform ABO grouping, D(Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e).

(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(3) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.

(b) *Immunohematological testing and distribution of blood and blood products.* Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b).

(c) *Blood and blood products storage.* Blood and blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period.

(2) Inspections of the alarm system must be documented.

(d) *Retention of samples of transfused blood.* According to the laboratory's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of transfusion reactions. The laboratory must promptly dispose of blood not retained for further testing that has passed its expiration date.

(e) *Investigation of transfusion reactions.* (1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures.

(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused.

(f) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1273 Standard: Histopathology.

(a) As specified in § 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reaction(s) of the control slide with each special stain must be documented.

(b) The laboratory must retain stained slides, specimen blocks, and

tissue remnants as specified in § 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under §§ 493.1449(b), (l), or (m).

(c) An individual who has successfully completed a training program in neuromuscular pathology approved by HHS may examine and provide reports for neuromuscular pathology.

(d) Tissue pathology reports must be signed by an individual qualified as specified in paragraph (b) or, as appropriate, paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual who performed the examination and made the diagnosis.

(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results.

(f) The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1274 Standard: Cytology.

(a) *Cytology slide examination site.* All cytology slide preparations must be evaluated on the premises of a laboratory certified to conduct testing in the subspecialty of cytology.

(b) *Staining.* The laboratory must have available and follow written policies and procedures for each of the following, if applicable:

(1) All gynecologic slide preparations must be stained using a Papanicolaou or modified Papanicolaou staining method.

(2) Effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process must be used.

(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.

(c) *Control procedures.* The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following:

(1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under §§ 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section).

(i) The review must be performed by an individual who meets one of the following qualifications:

(A) A technical supervisor qualified under §§ 493.1449(b) or (k).

(B) A cytology general supervisor qualified under § 493.1469.

(C) A cytotechnologist qualified under § 493.1483 who has the experience specified in § 493.1469(b)(2).

(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information.

(iii) The review of those cases selected must be completed before reporting patient results.

(2) Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies.

(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.

(4) Records of initial examinations and all rescreening results must be documented.

(5) An annual statistical laboratory evaluation of the number of—

(i) Cytology cases examined;

(ii) Specimens processed by specimen type;

(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation);

(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison;

(v) Gynecologic cases where cytology and histology are discrepant; and

(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

(6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation and, if appropriate, corrective actions taken.

(d) *Workload limits.* The laboratory must establish and follow written policies and procedures that ensure the following:

(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

(i) The workload limit is based on the individual's performance using evaluations of the following:

(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section.

(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

(2) The maximum number of slides examined by an individual in each 24-hour period does not exceed 100 slides (one patient specimen per slide; gynecologic, nongynecologic, or both) irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and must not be employed as an individual's performance target. In addition—

(i) The maximum number of 100 slides is examined in no less than an 8-hour workday;

(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula—

$$\frac{\text{Number of hours examining slides} \times 100}{8}$$

is used to determine maximum slide volume to be examined;

(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and

(iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit.

(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

(4) Records are available to document the workload limit for each individual.

(e) *Slide examination and reporting.* The laboratory must establish and follow written policies and procedures that ensure the following:

(1) A technical supervisor confirms each gynecologic slide preparation interpreted to exhibit reactive or reparative changes or any of the following epithelial cell abnormalities:

(i) Squamous cell.

(A) Atypical squamous cells of undetermined significance (ASC-US) or cannot exclude HSIL (ASC-H).

(B) LSIL-Human papillomavirus (HPV)/mild dysplasia/cervical intraepithelial neoplasia 1 (CIN 1).

(C) HSIL-moderate and severe dysplasia, carcinoma in situ (CIS)/CIN 2 and CIN 3 or with features suspicious for invasion.

(D) Squamous cell carcinoma.

(ii) Glandular cell.

(A) Atypical cells not otherwise specified (NOS) or specified in comments (endocervical, endometrial, or glandular).

(B) Atypical cells favor neoplastic (endocervical or glandular).

(C) Endocervical adenocarcinoma in situ.

(D) Adenocarcinoma endocervical, adenocarcinoma endometrial, adenocarcinoma extrauterine, and adenocarcinoma NOS.

(iii) Other malignant neoplasms.

(2) The report of gynecologic slide preparations with conditions specified in paragraph (e)(1) of this section must be signed to reflect the technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

(3) All nongynecologic preparations are reviewed by a technical supervisor. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor who performed the review.

(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

(5) The report contains narrative descriptive nomenclature for all results.

(6) Corrected reports issued by the laboratory indicate the basis for correction.

(f) *Record and slide retention.* (1) The laboratory must retain all records and slide preparations as specified in §493.1105.

(2) Slides may be loaned to proficiency testing programs in lieu of maintaining them for the required time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of these slides.

(3) Documentation of slides loaned or referred for purposes other than proficiency testing must be maintained.

(4) All slides must be retrievable upon request.

(g) *Automated and semi-automated screening devices.* When performing evaluations using automated and semi-automated screening devices, the laboratory must follow manufacturer's instructions for preanalytic, analytic, and postanalytic phases of testing, as applicable, and meet the applicable requirements of this subpart K.

(h) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§493.1276 Standard: Clinical cytogenetics.

(a) The laboratory must have policies and procedures for ensuring accurate and reliable patient specimen identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, photographic printing, and reporting and storage of results, karyotypes, and photographs.

(b) The laboratory must have records that document the following:

(1) The media used, reactions observed, number of cells counted, number of cells karyotyped, number of chromosomes counted for each metaphase spread, and the quality of the banding.

(2) The resolution is appropriate for the type of tissue or specimen and the type of study required based on the clinical information provided to the laboratory.

(3) An adequate number of karyotypes are prepared for each patient.

(c) Determination of sex must be performed by full chromosome analysis.

(d) The laboratory report must include a summary and interpretation of the observations, number of cells counted and analyzed, and use the International System for Human Cytogenetic Nomenclature.

(e) The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§493.1278 Standard: Histocompatibility.

(a) *General.* The laboratory must meet the following requirements:

(1) An audible alarm system must be used to monitor the storage temperature of specimens (donor and recipient) and reagents. The laboratory must have an emergency plan for alternate storage.

(2) All patient specimens must be easily retrievable.

(3) Reagent typing sera inventory prepared in-house must indicate source, bleeding date and identification number, reagent specificity, and volume remaining.

(4) If the laboratory uses immunologic reagents (for example, antibodies, antibody-coated particles, or complement) to facilitate or enhance the isolation of lymphocytes, or lymphocyte subsets, the efficacy of the methods must be monitored with appropriate quality control procedures.

(5) Participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

(b) *HLA typing.* The laboratory must do the following:

(1) Use a technique(s) that is established to optimally define, as applicable, HLA Class I and II specificities.

(2) HLA type all potential transplant recipients at a level appropriate to support clinical transplant protocol and donor selection.

(3) HLA type cells from organ donors referred to the laboratory.

(4) Use HLA antigen terminology that conforms to the latest report of the World Health Organization (W.H.O.) Committee on Nomenclature. Potential new antigens not yet approved by this committee must have a designation that cannot be confused with W.H.O. terminology.

(5) Have available and follow written criteria for the following:

(i) The preparation of cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the HLA typing technique(s) performed.

(ii) Selecting typing reagents, whether prepared in-house or commercially.

(iii) Ensuring that reagents used for typing are adequate to define all HLA-A, B and DR specificities that are officially recognized by the most recent W.H.O. Committee on Nomenclature and for which reagents are readily available.

(iv) The assignment of HLA antigens.

(v) When antigen redefinition and retyping are required.

(6) Check each HLA typing by testing, at a minimum the following:

(i) A positive control material.

(ii) A negative control material in which, if applicable to the technique performed, cell viability at the end of incubation is sufficient to permit accurate interpretation of results. In assays in which cell viability is not required, the negative control result must be sufficiently different from the positive control result to permit accurate interpretation of results.

(iii) Positive control materials for specific cell types when applicable (that is, T cells, B cells, and monocytes).

(c) *Disease-associated studies.* The laboratory must check each typing for disease-associated HLA antigens using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

(d) *Antibody Screening.* The laboratory must do the following:

(1) Use a technique(s) that detects HLA-specific antibody with a specificity equivalent or superior to that of the basic complement-dependent microlymphocytotoxicity assay.

(2) Use a method that distinguishes antibodies to HLA Class II antigens from antibodies to Class I antigens to detect antibodies to HLA Class II antigens.

(3) Use a panel that contains all the major HLA specificities and common splits. If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding.

(4) Make a reasonable attempt to have available monthly serum specimens for all potential transplant recipients for periodic antibody screening and crossmatch.

(5) Have available and follow a written policy consistent with clinical transplant protocols for the frequency of screening potential transplant recipient sera for preformed HLA-specific antibodies.

(6) Check each antibody screening by testing, at a minimum the following:

(i) A positive control material containing antibodies of the appropriate isotype for the assay.

(ii) A negative control material.

(7) As applicable, have available and follow written criteria and procedures for antibody identification to the level appropriate to support clinical transplant protocol.

(e) *Crossmatching.* The laboratory must do the following:

(1) Use a technique(s) documented to have increased sensitivity in comparison with the basic complement-dependent microlymphocytotoxicity assay.

(2) Have available and follow written criteria for the following:

(i) Selecting appropriate patient serum samples for crossmatching.

(ii) The preparation of donor cells or cellular extracts (for example, solubilized antigens and nucleic acids), as applicable to the crossmatch technique(s) performed.

(3) Check each crossmatch and compatibility test for HLA Class II antigenic differences using control materials to monitor the test components and each phase of the test system to ensure acceptable performance.

(f) *Transplantation.* Laboratories performing histocompatibility testing for transfusion and transplantation purposes must do the following:

(1) Have available and follow written policies and protocols specifying the histocompatibility testing (that is, HLA typing, antibody screening, compatibility testing and crossmatching) to be performed for each type of cell, tissue or organ to be transfused or transplanted. The laboratory's policies must include, as applicable—

(i) Testing protocols for cadaver donor, living, living-related, and combined organ and tissue transplants;

(ii) Testing protocols for patients at high risk for allograft rejection; and

(iii) The level of testing required to support clinical transplant protocols (for example, antigen or allele level).

(2) For renal allotransplantation and combined organ and tissue transplants in which a kidney is to be transplanted, have available results of final crossmatches before the kidney is transplanted.

(3) For nonrenal transplantation, if HLA testing and final crossmatches were not performed prospectively because of an emergency situation, the laboratory must document the circumstances, if known, under which the emergency transplant was performed, and records of the transplant must reflect any information provided to the laboratory by the patient's physician.

(g) *Documentation.* The laboratory must document all control procedures performed, as specified in this section.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1281 Standard: Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available:

(1) Patient age.

(2) Sex.

(3) Diagnosis or pertinent clinical data.

(4) Distribution of patient test results.

(5) Relationship with other test parameters.

(c) The laboratory must document all test result comparison activities.

§493.1282 Standard: Corrective actions.

(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur:

(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in §493.1253(b), which include but are not limited to—

(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and

(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

(3) The criteria for proper storage of reagents and specimens, as specified under §493.1252(b), are not met.

§493.1283 Standard: Test records.

(a) The laboratory must maintain an information or record system that includes the following:

(1) The positive identification of the specimen.

(2) The date and time of specimen receipt into the laboratory.

(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability.

(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

(b) Records of patient testing including, if applicable, instrument printouts, must be retained.

§493.1289 Standard: Analytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in §§493.1251 through 493.1283.

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all analytic systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

POSTANALYTIC SYSTEMS

§493.1290 Condition: Postanalytic systems.

Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in §493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in §493.1299 for each specialty and subspecialty of testing performed.

§493.1291 Standard: Test report.

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or

entered manually) to final report destination, in a timely manner. This includes the following:

(1) Results reported from calculated data.

(2) Results and patient-specific data electronically reported to network or interfaced systems.

(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

(c) The test report must indicate the following:

(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number.

(2) The name and address of the laboratory location where the test was performed.

(3) The test report date.

(4) The test performed.

(5) Specimen source, when appropriate.

(6) The test result and, if applicable, the units of measurement or interpretation, or both.

(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(d) Pertinent ''reference intervals'' or ''normal'' values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in § 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(f) Test results must be released only to authorized persons and, if applicable, the individual responsible for using the test results and the laboratory that initially requested the test.

(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

(i) If a laboratory refers patient specimens for testing—

(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory;

(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and

(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

(j) All test reports or records of the information on the test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

(k) When errors in the reported patient test results are detected, the laboratory must do the following:

(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors.

(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results.

(3) Maintain duplicates of the original report, as well as the corrected report.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1299 Standard: Postanalytic systems quality assessment.

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in § 493.1291.

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff.

(c) The laboratory must document all postanalytic systems quality assessment activities.

[68 FR 3703, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

Subpart L [Reserved]

Subpart M—Personnel for Nonwaived Testing

SOURCE: 57 FR 7172, Feb. 28, 1992, unless otherwise noted.

§ 493.1351 General.

This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

[60 FR 20049, Apr. 24, 1995]

LABORATORIES PERFORMING PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES

SOURCE: 60 FR 20049, Apr. 24, 1995, unless otherwise noted.

§ 493.1353 Scope.

In accordance with § 493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed by a health care provider during a patient visit in the context of a physical examination. PPM procedures are subject to the personnel requirements in §§ 493.1355 through 493.1365.

§ 493.1355 Condition: Laboratories performing PPM procedures; laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1357 and provides overall management and direction in accordance with § 493.1359.

§ 493.1357 Standard; laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of PPM procedures as specified in § 493.19(c) and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if the licensing is required.

(b) The laboratory director must meet one of the following requirements:

(1) Be a physician, as defined in § 493.2.

(2) Be a midlevel practitioner, as defined in § 493.2, authorized by a State to practice independently in the State in which the laboratory is located.

(3) Be a dentist, as defined in § 493.2.

§ 493.1359 Standard; PPM laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the prompt, accurate, and proficient reporting of test results. The laboratory director must—

(a) Direct no more than five laboratories; and

(b) Ensure that any procedure listed under § 493.19(c)—

(1) Is personally performed by an individual who meets the qualification requirements in § 493.1363; and

(2) Is performed in accordance with applicable requirements in subparts H, J, K, and M of this part.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3713, Jan. 24, 2003; 68 FR 50724, Aug. 22, 2003]

§ 493.1361 Condition: Laboratories performing PPM procedures; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of § 493.1363 to perform the functions specified in § 493.1365 for the volume and complexity of testing performed.

§ 493.1363 Standard: PPM testing personnel qualifications.

Each individual performing PPM procedures must—

(a) Possess a current license issued by the State in which the laboratory is located if the licensing is required; and

(b) Meet one of the following requirements:

(1) Be a physician, as defined in § 493.2.

(2) Be a midlevel practitioner, as defined in § 493.2, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located.

(3) Be a dentist as defined in § 493.2 of this part.

§ 493.1365 Standard; PPM testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results. Any PPM procedure must be—

(a) Personally performed by one of the following practitioners:

(1) A physician during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group medical practice of which the physician is a member or employee.

(2) A midlevel practitioner, under the supervision of a physician or in independent practice if authorized by the State in which the laboratory is located, during the patient's visit on a specimen obtained from his or her own patient or from the patient of a clinic, group medical practice, or other health care provider, in which the midlevel practitioner is a member or an employee.

(3) A dentist during the patient's visit on a specimen obtained from his or her own patient or from a patient of a group dental practice of which the dentist is a member or an employee; and

(b) Performed using a microscope limited to a brightfield or a phase/contrast microscope.

LABORATORIES PERFORMING MODERATE COMPLEXITY TESTING

§ 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1405 of this subpart and provides overall management and direction in accordance with § 493.1407 of this subpart.

§ 493.1405 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least one year directing or supervising non-waived laboratory testing; or

(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in §493.1407; or

(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and

(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or

(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and

(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;

(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under §493.1406; or

(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5233, Jan. 19, 1993]

§493.1406 Standard; Laboratory director qualifications on or before February 28, 1992.

The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.

(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and

(b) The laboratory director must:

(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(2) Be a physician who:

(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or

(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or

(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or

(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;

(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and

(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to

HHS in one of the laboratory specialties; or

(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either:

(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or

(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or

(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.

NOTE: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

[58 FR 5233, Jan. 19, 1993]

§ 493.1407 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§ 493.1409, 493.1415, and 493.1421, respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3713, Jan. 24, 2003]

§493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.

The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart.

§493.1411 Standard; Technical consultant qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

(a) The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

(b) The technical consultant must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

NOTE: The technical consultant requirements for ''laboratory training or experience, or both'' in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1413 Standard; Technical consultant responsibilities.

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

(b) The technical consultant is responsible for—

(1) Selection of test methodology appropriate for the clinical use of the test results;

(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the

type and complexity of the laboratory services performed;

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

§493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the qualification requirements of §493.1417 of this part and provides clinical consultation in accordance with §493.1419 of this part.

§493.1417 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under §493.1405(b) (1), (2), or (3)(i); or

(b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§493.1419 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide clinical consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.

The laboratory must have a sufficient number of individuals who meet the qualification requirements of §493.1423, to perform the functions specified in §493.1425 for the volume and complexity of tests performed.

§493.1423 Standard; Testing personnel qualifications.

Each individual performing moderate complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or

(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(4)(i) Have earned a high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1425 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing moderate complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

LABORATORIES PERFORMING HIGH COMPLEXITY TESTING

§ 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.

The laboratory must have a director who meets the qualification requirements of § 493.1443 of this subpart and provides overall management and direction in accordance with § 493.1445 of this subpart.

§493.1443 Standard; Laboratory director qualifications.

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and

(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(ii) Have at least 2 years of experience directing or supervising high complexity testing; or

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution and—

(i) Be certified and continue to be certified by a board approved by HHS; or

(ii) Before February 24, 2003, must have served or be serving as a director of a laboratory performing high complexity testing and must have at least—

(A) Two years of laboratory training or experience, or both; and

(B) Two years of laboratory experience directing or supervising high complexity testing.

(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or

(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or

(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993; 59 FR 62609, Dec. 6, 1994; 62 FR 25858, May 12, 1997; 63 FR 55034, Oct. 14, 1998; 65 FR 82944, Dec. 29, 2000; 68 FR 3713, Jan. 24, 2003]

§493.1445 Standard; Laboratory director responsibilities.

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§493.1447, 493.1453, 493.1459, and 493.1487, respectively.

(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(4);

(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and

whether supervisory or director review is required prior to reporting patient test results.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.

The laboratory must have a technical supervisor who meets the qualification requirements of §493.1449 of this subpart and provides technical supervision in accordance with §493.1451 of this subpart.

§493.1449 Standard; Technical supervisor qualifications.

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—

(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification.

(c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.

(d) If the requirements of paragraph (b) of this section are not met and the

laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.

(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the speciality of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in

high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology;

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology.

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum

of 6 months experience in high complexity testing within the subspecialty of virology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.

(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology.

(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.

(j) If the requirements of paragraph (b) of this section are not met and the

laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.

(k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Meet one of the following requirements—

(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;

(2) An individual qualified under §493.1449(b) or paragraph (k)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under §493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(1) Meet one of the following requirements:

(i) (A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(ii) An individual qualified under §493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(2) For tests in dermatopathology, meet one of the following requirements:

(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(B) Meet one of the following requirements:

(*1*) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(*2*) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(*3*) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or

(ii) An individual qualified under §493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(3) For tests in ophthalmic pathology, meet one of the following requirements:

(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(B) Must meet one of the following requirements:

(*1*) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(*2*) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certitication and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or

(ii) An individual qualified under §493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or

(3) An individual qualified under §493.1449(b) or paragraph (m) (1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m) (1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric

medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay.

(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B)(*1*) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(*2*) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

(p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

NOTE: The technical supervisor requirements for ''laboratory training or experience, or both'' in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5234, Jan. 19, 1993]

§ 493.1451 Standard: Technical supervisor responsibilities.

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

(b) The technical supervisor is responsible for—

(1) Selection of the test methodology that is appropriate for the clinical use of the test results;

(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

(c) In cytology, the technical supervisor or the individual qualified under § 493.1449(k)(2)—

(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§493.1471 and 493.1485, respectively;

(2) Must establish the workload limit for each individual examining slides;

(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;

(4) Must perform the functions specified in §493.1274(d) and (e);

(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in §493.945 and achieves a passing score, as specified in §493.855; and

(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 68 FR 3714, Jan. 24, 2003]

§493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.

The laboratory must have a clinical consultant who meets the requirements of §493.1455 of this subpart and provides clinical consultation in accordance with §493.1457 of this subpart.

§493.1455 Standard; Clinical consultant qualifications.

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under §493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, §493.1443(b)(6); or

(b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993]

§493.1457 Standard; Clinical consultant responsibilities.

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

§493.1459 Condition: Laboratories performing high complexity testing; general supervisor.

The laboratory must have one or more general supervisors who are qualified under §493.1461 of this subpart to provide general supervision in accordance with §493.1463 of this subpart.

§493.1461 Standard: General supervisor qualifications.

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The general supervisor must be qualified as a—

(1) Laboratory director under §493.1443; or

(2) Technical supervisor under §493.1449.

(c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section

are not met, the individual functioning as the general supervisor must—

(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or

(2)(i) Qualify as testing personnel under § 493.1489(b)(2); and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or

(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under § 493.1462 on or before February 28, 1992.

(ii) *Exception.* An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of § 493.1462 on or before January 1, 1994.''

(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995—

(i) Meet one of the following requirements:

(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS.

(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or

(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and—

(i) Be a high school graduate or equivalent; and

(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992.

(d) For blood gas analysis, the individual providing general supervision must—

(1) Be qualified under §§ 493.1461(b) (1) or (2), or 493.1461(c); or

(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and

(ii) Have at least two years of training or experience, or both in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed:

(1) In histopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l)(1);

(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l) or (2);

(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(1)(3); and

(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(m).

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20049, Apr. 24, 1995]

§ 493.1462 General supervisor qualifications on or before February 28, 1992.

To qualify as a general supervisor under § 493.1461(c)(3), an individual

must have met or could have met the following qualifications as they were in effect on or before February 28, 1992.

(a) Each supervisor possesses a current license as a laboratory supervisor issued by the State, if such licensing exists; and

(b) The laboratory supervisor—

(1) Who qualifies as a laboratory director under §493.1406(b)(1), (2), (4), or (5) is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor; or

(2)(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(ii) Subsequent to graduation, has had at least 2 years of experience in one of the laboratory specialties in a laboratory; or

(3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(ii) Subsequent to graduation has had at least 4 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated specialty in a laboratory; or

(4)(i) Is qualified as a laboratory technologist under §493.1491; and

(ii) After qualifying as a laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience of which not less than 2 years have been spent working in the designated laboratory specialty in a laboratory; or

(5) With respect to individuals first qualifying before July 1, 1971, has had at least 15 years of pertinent full-time laboratory experience before January 1, 1968; this required experience may be met by the substitution of education for experience.

[58 FR 39155, July 22, 1993]

§493.1463 Standard: General supervisor responsibilities.

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(a) The general supervisor—(1) Must be accessible to testing personnel at all times testing is performed to provide on-site, telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

(2) Is responsible for providing day-to-day supervision of high complexity test performance by a testing personnel qualified under §493.1489;

(3) Except as specified in paragraph (c) of this section, must be onsite to provide direct supervision when high complexity testing is performed by any individuals qualified under §493.1489(b)(5); and

(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for—

(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

(3) Providing orientation to all testing personnel; and

(4) Annually evaluating and documenting the performance of all testing personnel.

(c) *Exception.* For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (a)(3) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5235, Jan. 19, 1993; 60 FR 20050, Apr. 24, 1995]

§ 493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of § 493.1469 of this subpart, and provides supervision in accordance with § 493.1471 of this subpart.

§ 493.1469 Standard: Cytology general supervisor qualifications.

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must—

(a) Be qualified as a technical supervisor under § 493.1449 (b) or (k); or

(b)(1) Be qualified as a cytotechnologist under § 493.1483; and

(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

§ 493.1471 Standard: Cytology general supervisor responsibilities.

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under § 493.1469.

(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(b) The cytology general supervisor must—

(1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under § 493.1274(c));

(3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

(4) Document the number of hours spent examining slides in each 24-hour period.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§ 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in § 493.1483 to perform the functions specified in § 493.1485.

§ 493.1483 Standard: Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of § 493.1449 (b) or (k), or—

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation or other organization approved by HHS; or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Before September 1, 1992—

(i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and

(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or

(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or

(4) Before September 1, 1994, have full-time experience of at least 2 years

or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under §493.1449(b) or (k)(1), and before January 1, 1969, must have—

(i) Graduated from high school;

(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and

(iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(5)(i) On or before September 1, 1994, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under §493.1449(b) or (k)(1); and

(ii) On or before September 1, 1995, have met the requirements in either paragraph (b)(1) or (2) of this section.

[57 FR 7172, Feb. 28, 1992, as amended at 59 FR 685, Jan. 6, 1994]

§493.1485 Standard; Cytotechnologist responsibilities.

The cytotechnologist is responsible for documenting—

(a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in §493.1274(c));

(b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

(c) The number of hours spent examining slides in each 24-hour period.

[57 FR 7172, Feb. 28, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§493.1487 Condition: Laboratories performing high complexity testing; testing personnel.

The laboratory has a sufficient number of individuals who meet the qualification requirements of §493.1489 of this subpart to perform the functions specified in §493.1495 of this subpart for the volume and complexity of testing performed.

§493.1489 Standard; Testing personnel qualifications.

Each individual performing high complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or—

(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes—

(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either—

(*1*) 24 semester hours of medical laboratory technology courses; or

(*2*) 24 semester hours of science courses that include—

(*i*) Six semester hours of chemistry;

(*ii*) Six semester hours of biology; and

(*iii*) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and

(B) Have laboratory training that includes either of the following:

(*1*) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.)

(*2*) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

(3) Have previously qualified or could have qualified as a technologist under §493.1491 on or before February 28, 1992;

(4) On or before April 24, 1995 be a high school graduate or equivalent and have either—

(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or

(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

(5)(i) Until September 1, 1997—

(A) Have earned a high school diploma or equivalent; and

(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has—

(*1*) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(*2*) The skills required for implementing all standard laboratory procedures;

(*3*) The skills required for performing each test method and for proper instrument use;

(*4*) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed;

(*5*) A working knowledge of reagent stability and storage;

(*6*) The skills required to implement the quality control policies and procedures of the laboratory;

(*7*) An awareness of the factors that influence test results; and

(*8*) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and

(ii) As of September 1, 1997, be qualified under §493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995;

(6) For blood gas analysis—

(i) Be qualified under §493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5);

(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

(7) For histopathology, meet the qualifications of §493.1449 (b) or (l) to perform tissue examinations.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 58 FR 39155, July 22, 1993; 60 FR 20050, Apr. 24, 1995]

§ 493.1491 Technologist qualifications on or before February 28, 1992.

In order to qualify as high complexity testing personnel under §493.1489(b)(3), the individual must have met or could have met the following qualifications for technologist as they were in effect on or before February 28, 1992. Each technologist must—

(a) Possess a current license as a laboratory technologist issued by the State, if such licensing exists; and

(b)(1) Have earned a bachelor's degree in medical technology from an accredited university; or

(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by the Secretary, and has successfully completed a course of training of at least 12 months in such a school; or

(3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, has at least 1 year of pertinent full-time laboratory experience or training, or both, in the specialty or subspecialty in which the individual performs tests; or

(4)(i) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—

(A) *For those whose training was completed before September 15, 1963.* At least 24 semester hours in chemistry and biology courses of which—

(*1*) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(*2*) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(B) *For those whose training was completed after September 14, 1963.*

(*1*) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(*2*) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(*3*) 3 semester hours of mathematics; and

(ii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b)(1) and (2) of this section; or

(5) With respect to individuals first qualifying before July 1, 1971, the technologist—

(i) Was performing the duties of a laboratory technologist at any time between July 1, 1961, and January 1, 1968, and

(ii) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience); or

(6) Achieves a satisfactory grade in a proficiency examination approved by HHS.

[58 FR 39155, July 22, 1993]

§493.1495 Standard; Testing personnel responsibilities.

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing high complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

(7) Except as specified in paragraph (c) of this section, if qualified under §493.1489(b)(5), perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under §493.1461.

(c) *Exception.* For individuals qualified under §493.1489(b)(5), who were performing high complexity testing on or before January 19, 1993, the requirements of paragraph (b)(7) of this section are not effective, provided that all high complexity testing performed by the individual in the absence of a general supervisor is reviewed within 24 hours by a general supervisor qualified under §493.1461.

[57 FR 7172, Feb. 28, 1992, as amended at 58 FR 5236, Jan. 19, 1993; 60 FR 20050, Apr. 24, 1995]

Subparts N–P [Reserved]

Subpart Q—Inspection

SOURCE: 57 FR 7184, Feb. 28, 1992, unless otherwise noted.

§ 493.1771 Condition: Inspection requirements applicable to all CLIA-certified and CLIA-exempt laboratories.

(a) Each laboratory issued a CLIA certificate must meet the requirements in § 493.1773 and the specific requirements for its certificate type, as specified in §§ 493.1775 through 493.1780.

(b) All CLIA-exempt laboratories must comply with the inspection requirements in §§ 493.1773 and 493.1780, when applicable.

[63 FR 26737, May 14, 1998]

§ 493.1773 Standard: Basic inspection requirements for all laboratories issued a CLIA certificate and CLIA-exempt laboratories.

(a) A laboratory issued a certificate must permit CMS or a CMS agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part. A CLIA-exempt laboratory and a laboratory that requests, or is issued a certificate of accreditation, must permit CMS or a CMS agent to conduct validation and complaint inspections.

(b) *General requirements.* As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following:

(1) Test samples, including proficiency testing samples, or perform procedures.

(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part.

(3) Permit laboratory personnel to be observed performing all phases of the total testing process (preanalytic, analytic, and postanalytic).

(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following:

(i) Specimen procurement and processing areas.

(ii) Storage facilities for specimens, reagents, supplies, records, and reports.

(iii) Testing and reporting areas.

(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires.

(c) *Accessible records and data.* A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) *Requirement to provide information and data.* A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

(e) *Reinspection.* CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results.

(f) *Complaint inspection.* CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part.

(g) *Failure to permit an inspection or reinspection.* Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part.

[63 FR 26737, May 14, 1998; 63 FR 32699, June 15, 1998]

§ 493.1775 Standard: Inspection of laboratories issued a certificate of waiver or a certificate for provider-performed microscopy procedures.

(a) A laboratory that has been issued a certificate of waiver or a certificate for provider-performed microscopy procedures is not subject to biennial inspections.

(b) If necessary, CMS or a CMS agent may conduct an inspection of a laboratory issued a certificate of waiver or a certificate for provider-performed microscopy procedures at any time during the laboratory's hours of operation to do the following:

(1) Determine if the laboratory is operated and testing is performed in a manner that does not constitute an imminent and serious risk to public health.

(2) Evaluate a complaint from the public.

(3) Determine whether the laboratory is performing tests beyond the scope of the certificate held by the laboratory.

(4) Collect information regarding the appropriateness of tests specified as waived tests or provider-performed microscopy procedures.

(c) The laboratory must comply with the basic inspection requirements of §493.1773.

[63 FR 26737, May 14, 1998]

§493.1777 Standard: Inspection of laboratories that have requested or have been issued a certificate of compliance.

(a) *Initial inspection.* (1) A laboratory issued a registration certificate must permit an initial inspection to assess the laboratory's compliance with the requirements of this part before CMS issues a certificate of compliance.

(2) The inspection may occur at any time during the laboratory's hours of operation.

(b) *Subsequent inspections.* (1) CMS or a CMS agent may conduct subsequent inspections on a biennial basis or with such other frequency as CMS determines to be necessary to ensure compliance with the requirements of this part.

(2) CMS bases the nature of subsequent inspections on the laboratory's compliance history.

(c) *Provider-performed microscopy procedures.* The inspection sample for review may include testing in the subcategory of provider-performed microscopy procedures.

(d) *Compliance with basic inspection requirements.* The laboratory must comply with the basic inspection requirements of §493.1773.

[63 FR 26738, May 14, 1998]

§493.1780 Standard: Inspection of CLIA-exempt laboratories or laboratories requesting or issued a certificate of accreditation.

(a) *Validation inspection.* CMS or a CMS agent may conduct a validation inspection of any accredited or CLIA-exempt laboratory at any time during its hours of operation.

(b) *Complaint inspection.* CMS or a CMS agent may conduct a complaint inspection of a CLIA-exempt laboratory or a laboratory requesting or issued a certificate of accreditation at any time during its hours of operation upon receiving a complaint applicable to the requirements of this part.

(c) *Noncompliance determination.* If a validation or complaint inspection results in a finding that the laboratory is not in compliance with one or more condition-level requirements, the following actions occur:

(1) A laboratory issued a certificate of accreditation is subject to a full review by CMS, in accordance with subpart E of this part and §488.11 of this chapter.

(2) A CLIA-exempt laboratory is subject to appropriate enforcement actions under the approved State licensure program.

(d) *Compliance with basic inspection requirements.* CLIA-exempt laboratories and laboratories requesting or issued a certificate of accreditation must comply with the basic inspection requirements in §493.1773.

[63 FR 26738, May 14, 1998]

Subpart R—Enforcement Procedures

SOURCE: 57 FR 7237, Feb. 28, 1992, unless otherwise noted.

§493.1800 Basis and scope.

(a) *Statutory basis.* (1) Section 1846 of the Act—

(i) Provides for intermediate sanctions that may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the conditions for Medicare coverage of their services; and

(ii) Requires the Secretary to develop and implement a range of such sanctions, including four that are specified in the statute.

(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA '88—

(i) Establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens;

(ii) Requires a Federal certification scheme to be applied to all such laboratories; and

(iii) Grants the Secretary broad enforcement authority, including—

(A) Use of intermediate sanctions;

(B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and

(C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health.

(3) Section 353 also—

(i) Provides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements;

(ii) Specifies the administrative hearing and judicial review rights of a laboratory that is sanctioned under CLIA; and

(iii) Requires the Secretary to publish annually a list of all laboratories that have been sanctioned during the preceding year.

(b) *Scope and applicability*. This subpart sets forth—

(1) The policies and procedures that CMS follows to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act; and

(2) The appeal rights of laboratories on which CMS imposes sanctions.

§ 493.1804 General considerations.

(a) *Purpose*. The enforcement mechanisms set forth in this subpart have the following purposes:

(1) To protect all individuals served by laboratories against substandard testing of specimens.

(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.

(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

(b) *Basis for decision to impose sanctions*. (1) CMS's decision to impose sanctions is based on one or more of the following:

(i) Deficiencies found by CMS or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

(ii) Unsuccessful participation in proficiency testing.

(2) CMS imposes one or more of the alternative or principal sanctions specified in §§ 493.1806 and 493.1807 when CMS or CMS's agent finds that a laboratory has condition-level deficiencies.

(c) *Imposition of alternative sanctions*. (1) CMS may impose alternative sanctions in lieu of, or in addition to principal sanctions, (CMS does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)

(2) CMS may impose alternative sanctions other than a civil money penalty after the laboratory has had an opportunity to respond, but before the hearing specified in § 493.1844.

(d) *Choice of sanction: Factors considered*. CMS bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by the State or by CMS, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(3) Whether the same condition level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g., of remedial action) in regard to the noncompliance, and their availability to the State, to other CMS agents, and to CMS.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that CMS hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendation by the State agency as to which sanction would be appropriate.

(e) *Number of alternative sanctions.* CMS may impose a separate sanction for each condition level deficiency or a single sanction for all condition level deficiencies that are interrelated and subject to correction by a single course of action.

(f) *Appeal rights.* The appeal rights of laboratories dissatisfied with the imposition of a sanction are set forth in §493.1844.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§493.1806 Available sanctions: All laboratories.

(a) *Applicability.* CMS may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) *Principal sanction.* CMS may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) *Alternative sanctions.* CMS may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

(1) Directed plan of correction, as set forth at §493.1832.

(2) State onsite monitoring as set forth at §493.1836.

(3) Civil money penalty, as set forth at §493.1834.

(d) *Civil suit.* CMS may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a CLIA-exempt laboratory that has been found with deficiencies during a validation survey), if CMS has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) *Criminal sanctions.* Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

[57 FR 7237, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993]

§493.1807 Additional sanctions: Laboratories that participate in Medicare.

The following additional sanctions are available for laboratories that are out of compliance with one or more CLIA conditions and that have approval to receive Medicare payment for their services.

(a) *Principal sanction.* Cancellation of the laboratory's approval to receive Medicare payment for its services.

(b) *Alternative sanctions.* (1) Suspension of payment for tests in one or more specific specialties or subspecialties, performed on or after the effective date of sanction.

(2) Suspension of payment for all tests in all specialties and subspecialties performed on or after the effective date of sanction.

§493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.

(a) *Suspension or revocation of any type of CLIA certificate.* When CMS suspends or revokes any type of CLIA certificate, CMS concurrently cancels the laboratory's approval to receive Medicare payment for its services.

(b) *Limitation of any type of CLIA certificate.* When CMS limits any type of CLIA certificate, CMS concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

§493.1809 Limitation on Medicaid payment.

As provided in section 1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that has a CLIA certificate or is licensed by a State whose licensure program has been approved by the Secretary under this part.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§493.1810 Imposition and lifting of alternative sanctions.

(a) *Notice of noncompliance and of proposed sanction: Content.* If CMS or its agency identifies condition level noncompliance in a laboratory, CMS or its

agent gives the laboratory written notice of the following:

(1) The condition level noncompliance that it has identified.

(2) The sanction or sanctions that CMS or its agent proposes to impose against the laboratory.

(3) The rationale for the proposed sanction or sanctions.

(4) The projected effective date and duration of the proposed sanction or sanctions.

(5) The authority for the proposed sanction or sanctions.

(6) The time allowed (at least 10 days) for the laboratory to respond to the notice.

(b) *Opportunity to respond.* During the period specified in paragraph (a)(6) of this section, the laboratory may submit to CMS or its agent written evidence or other information against the imposition of the proposed sanction or sanctions.

(c) *Notice of imposition of sanction*—(1) *Content.* CMS gives the laboratory written notice that acknowledges any evidence or information received from the laboratory and specifies the following:

(i) The sanction or sanctions to be imposed against the laboratory.

(ii) The authority and rationale for the imposing sanction or sanctions.

(iii) The effective date and duration of sanction.

(2) *Timing.* (i) If CMS or its agent determines that the deficiencies pose immediate jeopardy, CMS provides notice at least 5 days before the effective date of sanction.

(ii) If CMS or its agent determines that the deficiencies do not pose immediate jeopardy, CMS provides notice at least 15 days before the effective date of the sanction.

(d) *Duration of alternative sanctions.* An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition level deficiencies.

(2) CMS's suspension, limitation, or revocation of the laboratory's CLIA certificate becomes effective.

(e) *Lifting of alternative sanctions*—(1) *General rule.* Alternative sanctions are not lifted until a laboratory's compliance with all condition level requirements is verified.

(2) *Credible allegation of compliance.* When a sanctioned laboratory submits a credible allegation of compliance, CMS's agent determines whether—

(i) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation; or

(ii) It must revisit to verify whether the laboratory has, in fact, achieved compliance.

(3) *Compliance achieved before the date of revisit.* If during a revisit, the laboratory presents credible evidence (as determined by CMS or its agent) that it achieved compliance before the date of revisit, sanctions are lifted as of that earlier date.

§ 493.1812 Action when deficiencies pose immediate jeopardy.

If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:

(a) CMS requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, CMS suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. CMS may later revoke the certificate.

(c) In addition, if CMS has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, CMS may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, the following rules apply:

(a) *Initial action.* (1) CMS may cancel the laboratory's approval to receive Medicare payment for its services.

(2) CMS may suspend, limit, or revoke the laboratory's CLIA certificate.

(3) If CMS does not impose a principal sanction under paragraph (a)(1) or (a)(2) of this section, it imposes one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, CMS may impose the training and technical assistance requirement set forth at §493.1838 in lieu of, or in addition to, one or more alternative sanctions.

(b) *Failure to correct condition level deficiencies.* If CMS imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, CMS—

(1) Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues the Medicare payment sanctions as of the day cancellation is effective.

(2) Following a revisit which indicates that the laboratory has not corrected its condition level deficiencies, notifies the laboratory that it proposes to suspend, limit, or revoke the certificate, as specified in §493.1816(b), and the laboratory's right to hearing; and

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, while a hearing on the proposed suspension, limitation, or revocation of the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is pending.)

(c) *Action after hearing.* If a hearing decision upholds a proposed suspension, limitation, or revocation of a laboratory's CLIA certificate, CMS discontinues any alternative sanctions as of the day it makes the suspension, limitation, or revocation effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§493.1816 Action when deficiencies are not at the condition level.

If a laboratory has deficiencies, that are not at the condition level, the following rules apply:

(a) *Initial action.* The laboratory must submit a plan of correction that is acceptable to CMS in content and time frames.

(b) *Failure to correct deficiencies.* If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:

(1) CMS cancels the laboratory's approval to receive Medicare payment for its services.

(2) CMS notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's CLIA certificate and of the laboratory's right to a hearing.

§493.1820 Ensuring timely correction of deficiencies.

(a) *Timing of visits.* CMS, the State survey agency or other CMS agent may visit the laboratory at any time to evaluate progress, and at the end of the period to determine whether all corrections have been made.

(b) *Deficiencies corrected before a visit.* If during a visit, a laboratory produces credible evidence that it achieved compliance before the visit, the sanctions are lifted as of that earlier date.

(c) *Failure to correct deficiencies.* If during a visit it is found that the laboratory has not corrected its deficiencies, CMS may propose to suspend, limit, or revoke the laboratory's CLIA certificate.

(d) *Additional time for correcting lower level deficiencies* not at the condition level. If at the end of the plan of correction period all condition level deficiencies have been corrected, and there are deficiencies, that are not at the condition level, CMS may request a revised plan of correction. The revised plan may not extend beyond 12 months from the last day of the inspection that originally identified the cited deficiencies.

(e) *Persistence of deficiencies.* If at the end of the period covered by the plan of correction, the laboratory still has deficiencies, the rules of §§493.1814 and 493.1816 apply.

§ 493.1826 Suspension of part of Medicare payments.

(a) *Application.* (1) CMS may impose this sanction if a laboratory—

(i) Is found to have condition level deficiencies with respect to one or more specialties or subspecialties of tests; and

(ii) Agrees (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended.

(2) CMS suspends Medicare payment for those specialities or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

(b) *Procedures.* Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction.* This sanction continues until the laboratory corrects the condition level deficiencies or CMS cancels the laboratory's approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, CMS resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

(2) [Reserved]

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992]

§ 493.1828 Suspension of all Medicare payments.

(a) *Application.* (1) CMS may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies.

(2) CMS suspends payment for all Medicare covered laboratory services when the following conditions are met:

(i) Either—

(A) The laboratory has not corrected its condition level deficiencies included in the plan of correction within 3 months from the last date of inspection; or

(B) The laboratory has been found to have the same condition level deficiencies during three consecutive inspections; and

(ii) The laboratory has chosen (in return for not having its Medicare approval immediately cancelled), to not charge Medicare beneficiaries or their private insurance carriers for services for which Medicare payment is suspended.

(3) CMS suspends payment for services furnished on and after the effective date of sanction.

(b) *Procedures.* Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction.* (1) Suspension of payment continues until all condition level deficiencies are corrected, but never beyond twelve months.

(2) If all the deficiencies are not corrected by the end of the 12 month period, CMS cancels the laboratory's approval to receive Medicare payment for its services.

§ 493.1832 Directed plan of correction and directed portion of a plan of correction.

(a) *Application.* CMS may impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. If CMS does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition level deficiencies, it at least imposes a directed portion of a plan of correction when it imposes any of the following alternative sanctions:

(1) State onsite monitoring.

(2) Civil money penalty.

(3) Suspension of all or part of Medicare payments.

(b) *Procedures*—(1) *Directed plan of correction.* When imposing this sanction, CMS—

(i) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with § 493.1810;

(ii) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance; and

(iii) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph (b)(3) of this section.

(2) *Directed portion of a plan of correction.* CMS may decide to notify clients

of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, CMS takes the following steps—

(i) Directs the laboratory to submit to CMS, the State survey agency, or other CMS agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other timeframe specified by CMS.

(ii) Within 30 calendar days of receipt of the information, may send to each laboratory client, via the State survey agency, a notice containing the name and address of the laboratory, the nature of the laboratory's noncompliance, and the kind and effective date of the alternative sanction.

(iii) Sends to each laboratory client, via the State survey agency, notice of the recission of an adverse action within 30 days of the rescission.

(3) *Notice of imposition of a principal sanction following the imposition of an alternative sanction.* If CMS imposes a principal sanction following the imposition of an alternative sanction, and for which CMS has already obtained a list of laboratory clients, CMS may use that list to notify the clients of the imposition of the principal sanction.

(c) *Duration of a directed plan of correction.* If CMS imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) CMS cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of CMS's intent to suspend, limit, or revoke the laboratory's CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate.

§493.1834 Civil money penalty.

(a) *Statutory basis.* Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

(b) *Scope.* This section sets forth the procedures that CMS follows to impose a civil money penalty in lieu of, or in addition to, suspending, limiting, or revoking the certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures of a laboratory that is found to have condition level deficiencies.

(c) *Basis for imposing a civil money penalty.* CMS may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.

(d) *Amount of penalty*—(1) *Factors considered.* In determining the amount of the penalty, CMS takes into account the following factors:

(i) The nature, scope, severity, and duration of the noncompliance.

(ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.

(iii) The laboratory's overall compliance history including but not limited to any period of noncompliance that occurred between certifications of compliance.

(iv) The laboratory's intent or reason for noncompliance.

(v) The accuracy and extent of laboratory records and their availability to CMS, the State survey agency, or other CMS agent.

(2) *Range of penalty amount.* (i) For a condition level deficiency that poses immediate jeopardy, the range is $3,050–$10,000 per day of noncompliance or per violation.

(ii) For a condition level deficiency that does not pose immediate jeopardy, the range is $50–$3,000 per day of noncompliance or per violation.

(3) *Decreased penalty amounts.* If the immediate jeopardy is removed, but the deficiency continues, CMS shifts the penalty amount to the lower range.

(4) *Increased penalty amounts.* CMS may, before the hearing, propose to increase the penalty amount for a laboratory that has deficiencies which, after imposition of a lower level penalty

amount, become sufficiently serious to pose immediate jeopardy.

(e) *Procedures for imposition of civil money penalty*—(1) *Notice of intent.* (i) CMS sends the laboratory written notice, of CMS's intent to impose a civil money penalty.

(ii) The notice includes the following information:

(A) The statutory basis for the penalty.

(B) The proposed daily or per violation amount of the penalty.

(C) The factors (as described in paragraph (d)(1) of this section) that CMS considered.

(D) The opportunity for responding to the notice in accordance with § 493.1810(c).

(E) A specific statement regarding the laboratory's appeal rights.

(2) *Appeal rights.* (i) The laboratory has 60 days from the date of receipt of the notice of intent to impose a civil money penalty to request a hearing in accordance with § 493.1844(g).

(ii) If the laboratory requests a hearing, all other pertinent provisions of § 493.1844 apply.

(iii) If the laboratory does not request a hearing, CMS may reduce the proposed penalty amount by 35 percent.

(f) *Accrual and duration of penalty*—(1) *Accrual of penalty.* The civil money penalty begins accruing as follows:

(i) 5 days after notice of intent if there is immediate jeopardy.

(ii) 15 days after notice of intent if there is not immediate jeopardy.

(2) *Duration of penalty.* The civil money penalty continues to accrue until the earliest of the following occurs:

(i) The laboratory's compliance with condition level requirements is verified on the basis of the evidence presented by the laboratory in its credible allegation of compliance or at the time or revisit.

(ii) Based on credible evidence presented by the laboratory at the time of revisit, CMS determines that compliance was achieved before the revisit. (In this situation, the money penalty stops accruing as of the date of compliance.)

(iii) CMS suspends, limits, or revokes the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(g) *Computation and notice of total penalty amount*—(1) *Computation.* CMS computes the total penalty amount after the laboratory's compliance is verified or CMS suspends, limits, or revokes the laboratory's CLIA certificate but in no event before—

(i) The 60 day period for requesting a hearing has expired without a request or the laboratory has explicitly waived its right to a hearing; or

(ii) Following a hearing requested by the laboratory, the ALJ issues a decision that upholds imposition of the penalty.

(2) *Notice of penalty amount and due date of penalty.* The notice includes the following information:

(i) Daily or per violation penalty amount.

(ii) Number of days or violations for which the penalty is imposed.

(iii) Total penalty amount.

(iv) Due date for payment of the penalty.

(h) *Due date for payment of penalty.* (1) Payment of a civil money penalty is due 15 days from the date of the notice specified in paragraph (g)(2) of this section.

(2) CMS may approve a plan for a laboratory to pay a civil money penalty, plus interest, over a period of up to one year from the original due date.

(i) *Collection and settlement*—(1) *Collection of penalty amounts.* (i) The determined penalty amount may be deducted from any sums then or later owing by the United States to the laboratory subject to the penalty.

(ii) Interest accrues on the unpaid balance of the penalty, beginning on the due date. Interest is computed at the rate specified in § 405.378(d) of this chapter.

(2) *Settlement.* CMS has authority to settle any case at any time before the ALJ issues a hearing decision.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995; 61 FR 63749, Dec. 2, 1996]

§ 493.1836 State onsite monitoring.

(a) *Application.* (1) CMS may require continuous or intermittent monitoring of a plan of correction by the State

survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor's responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) The costs are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by CMS and the State.

(ii) The hourly rate includes salary, fringe benefits, travel, and other direct and indirect costs approved by CMS.

(b) *Procedures.* Before imposing this sanction, CMS provides notice of sanction and opportunity to respond in accordance with §493.1810.

(c) *Duration of sanction.* (1) If CMS imposes onsite monitoring, the sanction continues until CMS determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, CMS cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate of compliance, registration certificate, certificate of accreditation, or certificate for PPM procedures is effective.

[57 FR 7237, Feb. 28, 1992, as amended at 60 FR 20051, Apr. 24, 1995]

§493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory's participation in proficiency testing is unsuccessful, CMS may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance, or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§493.1806 and 493.1807.

§493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) *Adverse action based on actions of the laboratory's owner, operator or employees.* CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

(3) Failed to comply with the certificate requirements and performance standards;

(4) Failed to comply with reasonable requests by CMS for any information or work on materials that CMS concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS;

(5) Refused a reasonable request by CMS or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;

(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

(7) Failed to comply with an alternative sanction imposed under this subpart; or

(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) *Adverse action based on improper referrals in proficiency testing.* If CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, CMS suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, CMS does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in § 493.1844) that upholds suspension or limitation.

(2) *Exceptions.* CMS may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for CMS or a CMS agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) CMS may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* CMS notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

§ 493.1842 Cancellation of Medicare approval.

(a) *Basis for cancellation.* (1) CMS always cancels a laboratory's approval to receive Medicare payment for its services if CMS suspends or revokes the laboratory's CLIA certificate.

(2) CMS may cancel the laboratory's approval under any of the following circumstances:

(i) The laboratory is out of compliance with a condition level requirement.

(ii) The laboratory fails to submit a plan of correction satisfactory to CMS.

(iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, CMS gives the laboratory—

(1) Written notice of the rationale for, effective date, and effect of, cancellation;

(2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in § 493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

§ 493.1844 Appeals procedures.

(a) *General rules.* (1) The provisions of this section apply to all laboratories and prospective laboratories that are dissatisfied with any initial determination under paragraph (b) of this section.

(2) Hearings are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter, except that the authority to conduct hearings and issue decisions may be exercised by ALJs assigned to, or detailed to, the Departmental Appeals Board.

(3) Any party dissatisfied with a hearing decision is entitled to request review of the decision as specified in subpart E of part 498 of this chapter, except that the authority to review the decision may be exercised by the Departmental Appeals Board.

(4) When more than one of the actions specified in paragraph (b) of this section are carried out concurrently, the laboratory has a right to only one hearing on all matters at issue.

(b) *Actions that are initial determinations.* The following actions are initial

determinations and therefore are subject to appeal in accordance with this section:

(1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by CMS because of noncompliance with CLIA requirements.

(2) The denial of a CLIA certificate.

(3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).

(4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

(c) *Actions that are not initial determinations.* Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to, the following:

(1) The finding that a laboratory accredited by a CMS-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts H, J, K, M, and Q of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.

(2) The finding that a laboratory determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition level.

(3) The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.

(4) The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.

(5) The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.

(6) The determination that a laboratory's deficiencies pose immediate jeopardy.

(7) The amount of the civil money penalty assessed per day or for each violation of Federal requirements.

(d) *Effect of pending appeals*—(1) *Alternative sanctions.* The effective date of an alternative sanction (other than a civil money penalty) is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(2) *Suspension, limitation, or revocation of a laboratory's CLIA certificate*—(i) *General rule.* Except as provided in paragraph (d)(2)(ii) of this section, suspension, limitation, or revocation of a CLIA certificate is not effective until after a hearing decision by an ALJ is issued.

(ii) *Exceptions.* (A) If CMS determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a CLIA certificate is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(B) CMS may suspend or limit a laboratory's CLIA certificate before an ALJ hearing or hearing decision if the laboratory has refused a reasonable request for information (including but not limited to billing information), or for work on materials, or has refused permission for CMS or a CMS agent to inspect the laboratory or its operation.

(3) *Cancellation of Medicare approval.* The effective date of the cancellation of a laboratory's approval to receive Medicare payment for its services is not delayed because the laboratory has appealed and the hearing or hearing decision is pending.

(4) *Effect of ALJ decision.* (i) An ALJ decision is final unless, as provided in paragraph (a)(3) of this section, one of the parties requests review by the Departmental Appeals Board within 60 days, and the Board reviews the case and issues a revised decision.

(ii) If an ALJ decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation.

(e) *Appeal rights for prospective laboratories*—(1) *Reconsideration.* Any prospective laboratory dissatisfied with a denial of a CLIA certificate, or of approval for Medicare payment for its services, may initiate the appeals process by requesting reconsideration in accordance with §§498.22 through 498.25 of this chapter.

(2) *Notice of reopening.* If CMS reopens an initial or reconsidered determination, CMS gives the prospective laboratory notice of the revised determination in accordance with § 498.32 of this chapter.

(3) *ALJ hearing.* Any prospective laboratory dissatisfied with a reconsidered determination under paragraph (e)(1) of this section or a revised reconsidered determination under § 498.30 of this chapter is entitled to a hearing before an ALJ, as specified in paragraph (a)(2) of this section.

(4) *Review of ALJ hearing decisions.* Any prospective laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board as provided in paragraph (a)(3) of this section.

(f) *Appeal rights of laboratories*—(1) *ALJ hearing.* Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

(2) *Review of ALJ hearing decisions.* Any laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board, as provided in paragraph (a)(3) of this section.

(3) *Judicial review.* Any laboratory dissatisfied with the decision to impose a civil money penalty or to suspend, limit, or revoke its CLIA certificate may, within 60 days after the decision becomes final, file with the U.S. Court of Appeals of the circuit in which the laboratory has its principal place of business, a petition for judicial review.

(g) *Notice of adverse action.* (1) If CMS suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for its services, CMS gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at § 493.1832. In addition, CMS notifies the general public each time one of these principal sanctions is imposed.

(2) The notice to the laboratory—

(i) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the appeal rights if any; and

(ii) When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no longer authorized to perform, and that are no longer covered under Medicare.

(3) The notice to other entities includes the same information except the information about the laboratory's appeal rights.

(h) *Effective date of adverse action.* (1) When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of the notice.

(2) When CMS determines that the laboratory's deficiencies do not pose immediate jeopardy, the effective date of the adverse action is at least 15 days after the date of the notice.

[57 FR 7237, Feb. 28, 1992; 57 FR 35761, Aug. 11, 1992, as amended at 68 FR 3714, Jan. 24, 2003]

§ 493.1846 Civil action.

If CMS has reason to believe that continuation of the activities of any laboratory, including a State-exempt laboratory, would constitute a significant hazard to the public health, CMS may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory if CMS deems it necessary. Upon proper showing, the court shall issue a temporary injunction or restraining order without bond against continuation of the activity.

§ 493.1850 Laboratory registry.

(a) Once a year CMS makes available to physicians and to the general public specific information (including information provided to CMS by the OIG) that is useful in evaluating the performance of laboratories, including the following:

(1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.

(2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions.

(3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with the circumstances of each case and the penalties imposed.

(4) A list of laboratories on which alternative sanctions have been imposed, showing—

(i) The effective date of the sanctions;

(ii) The reasons for imposing them;

(iii) Any corrective action taken by the laboratory; and

(iv) If the laboratory has achieved compliance, the verified date of compliance.

(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(6) All appeals and hearing decisions.

(7) A list of laboratories against which CMS has brought suit under §493.1846 and the reasons for those actions.

(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.

(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

Subpart S [Reserved]

Subpart T—Consultations

SOURCE: 57 FR 7185, Feb. 28, 1992, unless otherwise noted.

§493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

(a) HHS will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this part 493.

(b) The Clinical Laboratory Improvement Advisory Committee will be comprised of individuals involved in the provision of laboratory services, utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS.

(c) HHS will designate specialized subcommittees as necessary.

(d) The Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS, will review and make recommendations concerning:

(1) Criteria for categorizing nonwaived testing;

(2) Determination of waived tests;

(3) Personnel standards;

(4) Facility administration and quality systems standards.

(5) Proficiency testing standards;

(6) Applicability to the standards of new technology; and

(7) Other issues relevant to part 493, if requested by HHS.

(f) HHS will be responsible for providing the data and information, as necessary, to the members of the Clinical Laboratory Improvement Advisory Committee.

[57 FR 7185, Feb. 28, 1992, as amended at 58 FR 5237, Jan. 19, 1993; 60 FR 20051, Apr. 24, 1995; 68 FR 3714, Jan. 24, 2003]

PART 494 [RESERVED]

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 52 FR 22446, June 12, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 498.1 Statutory basis.

(a) Section 1866(h) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Sections 1128 (a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare and section 1128(f) provides for hearing and judicial review for exclusions.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e)–(f) [Reserved]

(g) Although § 1866(h) of the Act is silent regarding appeal rights for suppliers and practitioners, the rules in this part include procedures for review of determinations that affect those two groups.

(h) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected entity has had notice and opportunity for a hearing.

(i) Section 1819(h) of the Act—

(1) Provides that, for SNFs found to be out of compliance with the requirements for participation, specified remedies may be imposed instead of, or in addition to, termination of the facility's Medicare provider agreement; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on SNFs.

(j) Section 1891(e) of the Act provides that, for home health agencies (HHAs) found to be out of compliance with the conditions of participation, specified remedies may be imposed instead of, or in addition to, termination of the HHA's Medicare provider agreement.

(k) Section 1891(f) of the Act—

(1) Requires the Secretary to develop a range of such remedies; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on HHAs.

[52 FR 22446, June 12, 1987, as amended at 59 FR 56251, Nov. 10, 1994; 61 FR 32349, June 24, 1996]

§ 498.2 Definitions.

As used in this part—

Affected party means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and ''party'' means the affected party or CMS (or the OIG), as appropriate.

ALJ stands for Administrative Law Judge.

Departmental Appeals Board or *Board* means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

OHA stands for the Social Security Administration's Office of Hearings and Appeals.

OIG stands for the Department's Office of the Inspector General.

Provider means a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), hospice, or religious nonmedical health care institution (RNHCI) that has in effect an agreement to participate in Medicare, that has in effect an agreement to participate in Medicaid, or a clinic, rehabilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and prospective provider means any of the listed entities that seeks to participate in Medicare as a provider or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

Supplier means an independent laboratory, supplier of portable X-ray services, rural health clinic (RHC), Federally qualified health center (FQHC), ambulatory surgical center (ASC), an entity approved by CMS to furnish outpatient diabetes self-management training, or end-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services, and *prospective supplier* means any of the listed entities that seeks to be approved for coverage of its services under Medicare. (However, for purposes of the sanctions and penalties that may be imposed by the OIG, the term *supplier* has the meaning specified in § 1001.2 of this title.)

[52 FR 22446, June 12, 1987, as amended at 53 FR 6551, March 1, 1988; 57 FR 24984, June 12, 1992; 58 FR 30677, May 26, 1993; 59 FR 6579, Feb. 11, 1994; 59 FR 56251, Nov. 10, 1994; 61 FR 32350, June 24, 1996; 62 FR 46037, Aug. 29, 1997; 65 FR 18549, Apr. 7, 2000; 65 FR 83154, Dec. 29, 2000; 68 FR 66721, Nov. 28, 2003; 71 FR 31054, May 31, 2006]

§ 498.3 Scope and applicability.

(a) *Scope.* (1) This part sets forth procedures for reviewing initial determinations that CMS makes with respect to the matters specified in paragraph (b) of this section, and that the OIG makes with respect to the matters

specified in paragraph (c) of this section. It also specifies, in paragraph (d) of this section, administrative actions that are not subject to appeal under this part.

(2) The determinations listed in this section affect participation in the Medicare program. Many of the procedures of this part also apply to other determinations that do not affect participation in Medicare. Some examples follow:

(i) CMS's determination to terminate an NF's Medicaid provider agreement.

(ii) CMS's determination to cancel the approval of an ICF/MR under section 1910(b) of the Act.

(iii) CMS's determination, under the Clinical Laboratory Improvement Act (CLIA), to impose alternative sanctions or to suspend, limit, or revoke the certificate of a laboratory even though it does not participate in Medicare.

(3) The following parts of this chapter specify the applicability of the provisions of this part 498 to sanctions or remedies imposed on the indicated entities:

(i) Part 431, subpart D—for nursing facilities (NFs).

(ii) Part 488, subpart E (§ 488.330(e))—for SNFs and NFs.

(iii) Part 493, subpart R (§ 493.1844)—for laboratories.

(b) *Initial determinations by CMS.* CMS makes initial determinations with respect to the following matters:

(1) Whether a prospective provider qualifies as a provider.

(2) Whether a prospective department of a provider, remote location of a hospital, satellite facility, or provider-based entity qualifies for provider-based status under § 413.65 of this chapter, or whether such a facility or entity currently treated as a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity no longer qualifies for that status under § 413.65 of this chapter.

(3) Whether an institution is a hospital qualified to elect to claim payment for all emergency hospital services furnished in a calendar year.

(4) Whether an institution continues to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished in a calendar year.

(5) Whether a prospective supplier meets the conditions for coverage of its services as those conditions are set forth elsewhere in this chapter.

(6) Whether the services of a supplier continue to meet the conditions for coverage.

(7) Whether a physical therapist in independent practice or a chiropractor meets the requirements for coverage of his or her services as set forth in subpart D of part 486 of this chapter and § 410.22 of this chapter, respectively.

(8) The termination of a provider agreement in accordance with § 489.53 of this chapter, or the termination of a rural health clinic agreement in accordance with § 405.2404 of this chapter, or the termination of a Federally qualified health center agreement in accordance with § 405.2436 of this chapter.

(9) CMS's cancellation, under section 1910(b) of the Act, of an ICF/MR's approval to participate in Medicaid.

(10) Whether, for purposes of rate setting and reimbursement, an ESRD treatment facility is considered to be hospital-based or independent.

(11) [Reserved]

(12) Whether a hospital, skilled nursing facility, home health agency, or hospice program meets or contimues to meet the advance directives requirements specified in subpart I of part 489 of this chapter.

(13) With respect to an SNF or NF, a finding of noncompliance that results in the imposition of a remedy specified in § 488.406 of this chapter, except the State monitoring remedy.

(14) The level of noncompliance found by CMS in a SNF or NF but only if a successful challenge on this issue would affect—

(i) The range of civil money penalty amounts that CMS could collect (The scope of review during a hearing on imposition of a civil money penalty is set forth in § 488.438(e) of this chapter); or

(ii) A finding of substandard quality of care that results in the loss of approval for a SNF or NF of its nurse aide training program.

(15) The effective date of a Medicare provider agreement or supplier approval.

(16) The finding of substandard quality of care that leads to the loss by a

SNF or NF of the approval of its nurse aide training program.

(17) Whether to deny or revoke a provider or supplier's Medicare enrollment in accordance with § 424.530 or § 424.535 of this chapter.

(c) *Initial determinations by the OIG.* The OIG makes initial determinations with respect to the following matters:

(1) The termination of a provider agreement in accordance with part 1001, subpart C of this title.

(2) The suspension, or exclusion from coverage and the denial of reimbursement for services furnished by a provider, practitioner, or supplier, because of fraud or abuse, or conviction of crimes related to participation in the program, in accordance with part 1001, subpart B of this title.

(3) The imposition of sanctions in accordance with part 1004 of this title.

(d) *Administrative actions that are not initial determinations.* Administrative actions that are not initial determination (and therefore not subject to appeal under this part) include but are not limited to the following:

(1) The finding that a provider or supplier determined to be in compliance with the conditions or requirements for participation or for coverage has deficiencies.

(2) The finding that a prospective provider does not meet the conditions of participation set forth elsewhere in this chapter, if the prospective provider is, nevertheless, approved for participation in Medicare on the basis of special access certification, as provided in subpart B of part 488 of this chapter.

(3) The refusal to enter into a provider agreement because the prospective provider is unable to give satisfactory assurance of compliance with the requirements of title XVIII of the Act.

(4) The finding that an entity that had its provider agreement terminated may not file another agreement because the reasons for terminating the previous agreement have not been removed or there is insufficient assurance that the reasons for the exclusion will not recur.

(5) The determination not to reinstate a suspended or excluded practitioner, provider, or supplier because the reason for the suspension or exclusion has not been removed, or there is insufficient assurance that the reason will not recur.

(6) The finding that the services of a laboratory are covered as hospital services or as physician's services, rather than as services of an independent laboratory, because the laboratory is not independent of the hospital or of the physician's office.

(7) The refusal to accept for filing an election to claim payment for all emergency hospital services furnished in a calendar year because the institution—

(i) Had previously charged an individual or other person for services furnished during that calendar year;

(ii) Submitted the election after the close of that calendar year; or

(iii) Had previously been notified of its failure to continue to comply.

(8) The finding that the reason for the revocation of a supplier's right to accept assignment has not been removed or there is insufficient assurance that the reason will not recur.

(9) The finding that a hospital accredited by the Joint Commission on Accreditation of Hospitals or the American Osteopathic Association is not in compliance with a condition of participation, and a finding that that hospital is no longer deemed to meet the conditions of participation.

(10) With respect to an SNF or NF–(i) The finding that the SNF's or NF's deficiencies pose immediate jeopardy to the health or safety of its residents;

(ii) Except as provided in paragraph (b)(13) of this section, a determination by CMS as to the facility's level of noncompliance; and

(iii) The imposition of State monitoring.

(11) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(12) The determination that the accreditation requirements of a national accreditation organization do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements.

(13) The determination that requirements imposed on a State's laboratories under the laws of that State do not provide (or do not continue to provide) reasonable assurance that laboratories licensed or approved by the State meet applicable CLIA requirements.

(14) The choice of alternative sanction or remedy to be imposed on a provider or supplier.

(15) A decision by the State survey agency as to when to conduct an initial survey of a prospective provider or supplier.

(e) *Exclusion of civil rights issues.* The procedures in this subpart do not apply to the adjudication of issues relating to a provider's compliance with civil rights requirements that are set forth in part 489 of this chapter. Those issues are handled through the Department's Office of Civil Rights.

[52 FR 22446, June 12, 1987, as amended at 52 FR 27765, July 23, 1987; 53 FR 6551, March 1, 1988; 53 FR 6649, March 2, 1988; 54 FR 5373, Feb. 2, 1989; 56 FR 8854, Mar. 1, 1991; 56 FR 48879, Sept. 26, 1991; 57 FR 8204, Mar. 6, 1992; 57 FR 34021, July 31, 1992; 57 FR 43925, Sept. 23, 1992; 59 FR 56251, Nov. 10, 1994; 60 FR 2330, Jan. 9, 1995; 60 FR 50120, Sept. 28, 1995; 61 FR 32350, June 24, 1996; 62 FR 43937, Aug. 18, 1997; 64 FR 24957, May 10, 1999; 64 FR 39937, July 23, 1999; 64 FR 43295, Aug. 10, 1999; 65 FR 18549, Apr. 7, 2000; 65 FR 62646, Oct. 19, 2000; 71 FR 20781, Apr. 21, 2006; 71 FR 37505, June 30, 2006]

§ 498.4 NFs subject to appeals process in part 498.

A NF is considered a provider for purposes of this part when it has in effect an agreement to participate in Medicaid, including an agreement to participate in both Medicaid and Medicare and it is a—

(a) State-operated NF; or

(b) Non State-operated NF that is subject to compliance action as a result of—

(1) A validation survey by CMS; or

(2) CMS's review of the State's survey findings.

[59 FR 56252, Nov. 10, 1994]

§ 498.5 Appeal rights.

(a) *Appeal rights of prospective providers.* (1) Any prospective provider dissatisfied with an initial determination or revised initial determination that it does not qualify as a provider may request reconsideration in accordance with § 498.22(a).

(2) Any prospective provider dissatisfied with a reconsidered determination under paragraph (a)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(b) *Appeal rights of providers.* Any provider dissatisfied with an initial determination to terminate its provider agreement is entitled to a hearing before an ALJ.

(c) *Appeal rights of providers and prospective providers.* Any provider or prospective provider dissatisfied with a hearing decision may request Departmental Appeals Board review, and has a right to seek judicial review of the Board's decision.

(d) *Appeal rights of prospective suppliers.* (1) Any prospective supplier dissatisfied with an initial determination or a revised initial determination that its services do not meet the conditions for coverage may request reconsideration in accordance with § 498.22(a).

(2) Any prospective supplier dissatisfied with a reconsidered determination under paragraph (d)(1) of this section, or a revised reconsidered determination under § 498.30, is entitled to a hearing before an ALJ.

(e) *Appeal rights of suppliers.* Any supplier dissatisfied with an initial determination that the services subject to the determination no longer meet the conditions for coverage, is entitled to a hearing before an ALJ.

(f) *Appeal rights of suppliers and prospective suppliers.* (1) Any supplier or prospective supplier dissatisfied with the hearing decision may request Departmental Appeals Board review of the ALJ's decision.

(2) Suppliers and prospective suppliers do not have a right to judicial review except as provided in paragraph (i) of this section.

(g) *Appeal rights for certain practitioners.* A physical therapist in independent practice or a chiropractor dissatisfied with a determination that he or she does not meet the requirements for coverage of his or her services has the same appeal rights as suppliers have under paragraphs (d), (e) and (f) of this section.

(h) *Appeal rights for nonparticipating hospitals that furnish emergency services.* A nonparticipating hospital dissatisfied with a determination or decision that it does not qualify to elect to claim payment for all emergency services furnished during a calendar year has the same appeal rights that providers have under paragraph (a), (b), and (c) of this section.

(i) *Appeal rights for suspended or excluded practitioners, providers, or suppliers.* (1) Any practitioner, provider, or supplier who has been suspended, or whose services have been excluded from coverage in accordance with § 498.3(c)(2), or has been sanctioned in accordance with § 498.3(c)(3), is entitled to a hearing before an ALJ.

(2) Any suspended or excluded practitioner, provider, or supplier dissatisfied with a hearing decision may request Departmental Appeals Board review and has a right to seek judicial review of the Board's decision by filing an action in Federal district court.

(j) *Appeal rights for Medicaid ICFs/MR terminated by CMS.* (1) Any Medicaid ICF/MR that has had its approval cancelled by CMS in accordance with § 498.3(b)(8) has a right to a hearing before an ALJ, to request Departmental Appeals Board review of the hearing decision, and to seek judicial review of the Board's decision.

(2) The Medicaid agreement remains in effect until the period for requesting a hearing has expired or, if the facility requests a hearing, until a hearing decision is issued, unless CMS—

(i) Makes a written determination that continuation of provider status for the SNF or ICF constitutes an immediate and serious threat to the health and safety of patients and specifies the reasons for that determination; and

(ii) Certifies that the facility has been notified of its deficiencies and has failed to correct them.

(k) *Appeal rights of NFs.* Under the circumstances specified in § 431.153 (g) and (h) of this chapter, an NF has a right to a hearing before an ALJ, to request Board review of the hearing decision, and to seek judicial review of the Board's decision.

[52 FR 22446, June 12, 1987, as amended at 57 FR 43925, Sept. 23, 1992; 59 FR 56252, Nov. 10, 1994; 61 FR 32350, June 24, 1996]

§ 498.10 Appointment of representatives.

(a) An affected party may appoint as its representative anyone not disqualified or suspended from acting as a representative in proceedings before the Secretary or otherwise prohibited by law.

(b) If the representative appointed is not an attorney, the party must file written notice of the appointment with CMS, the ALJ, or the Departmental Appeals Board.

(c) If the representative appointed is an attorney, the attorney's statement that he or she has the authority to represent the party is sufficient.

§ 498.11 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 498.10 may, on behalf of the represented party—

(1) Give and accept any notice or request pertinent to the proceedings set forth in this part;

(2) Present evidence and allegations as to facts and law in any proceedings affecting that party to the same extent as the party; and

(3) Obtain information to the same extent as the party.

(b) A notice or request may be sent to the affected party, to the party's representative, or to both. A notice or request sent to the representative has the same force and effect as if it had been sent to the party.

§ 498.13 Fees for services of representatives.

Fees for any services performed on behalf of an affected party by an attorney appointed and qualified in accordance with § 498.10 are not subject to the provisions of section 206 of Title II of the Act, which authorizes the Secretary to specify or limit those fees.

§ 498.15 Charge for transcripts.

A party that requests a transcript of prehearing or hearing proceedings or Board review must pay the actual or

estimated cost of preparing the transcript unless, for good cause shown by that party, the payment is waived by the ALJ or the Departmental Appeals Board, as appropriate.

[52 FR 22446, June 12, 1987, as amended at 61 FR 51021, Sept. 30, 1996]

§ 498.17 Filing of briefs with the ALJ or Departmental Appeals Board, and opportunity for rebuttal.

(a) *Filing of briefs and related documents.* If a party files a brief or related document such as a written argument, contention, suggested finding of fact, conclusion of law, or any other written statement, it must submit an original and one copy to the ALJ or the Departmental Appeals Board, as appropriate. The material may be filed by mail or in person and must include a statement certifying that a copy has been furnished to the other party.

(b) *Opportunity for rebuttal.* (1) The other party will have 20 days from the date of mailing or personal service to submit any rebuttal statement or additional evidence. If a party submits a rebuttal statement or additional evidence, it must file an original and one copy with the ALJ or the Board and furnish a copy to the other party.

(2) The ALJ or the Board will grant an opportunity to reply to the rebuttal statement only if the party shows good cause.

Subpart B—Initial, Reconsidered, and Revised Determinations

§ 498.20 Notice and effect of initial determinations.

(a) *Notice of initial determination*—(1) *General rule.* CMS or the OIG, as appropriate, mails notice of an initial determination to the affected party, setting forth the basis or reasons for the determination, the effect of the determination, and the party's right to reconsideration, if applicable, or to a hearing.

(2) *Special rules: Independent laboratories and suppliers of portable x-ray services.* If CMS determines that an independent laboratory or a supplier of portable x-ray services no longer meets the conditions for coverage of some or all of its services, the notice—

(i) Specifies an effective date of termination of coverage that is at least 15 days after the date of the notice;

(ii) Is also sent to physicians, hospitals, and other parties that might use the services of the laboratory or supplier; and

(iii) In the case of laboratories, specifies the categories of laboratory tests that are no longer covered.

(3) *Special rules: Nonparticipating hospitals that elect to claim payment for emergency services.* If CMS determines that a nonparticipating hospital no longer qualifies to elect to claim payment for all emergency services furnished in a calendar year, the notice—

(i) States the calendar year to which the determination applies;

(ii) Specifies an effective date that is at least 5 days after the date of the notice; and

(iii) Specifies that the determination applies to services furnished, in the specified calendar year, to patients accepted (as inpatients or outpatients) on or after the effective date of the determination.

(4) *Other special rules.* Additional rules pertaining, for example, to content and timing of notice, notice to the public and to other entities, and time allowed for submittal of additional information, are set forth elsewhere in this chapter, as follows:

Part 405 Subpart X—for rural health clinics.
Part 416—for ambulatory surgical centers.
Part 489—for providers, when their provider agreements have been terminated.
Part 1001, Subpart B—for excluded or suspended providers, suppliers, physicians, or practitioners.
Part 1001, Subpart C—for providers, when their provider agreements are terminated by the OIG.
Part 1004—for sanctioned providers and practitioners.

(b) *Effect of initial determination.* An initial determination is binding unless it is—

(1) Reconsidered in accordance with § 498.24;

(2) Reversed or modified by a hearing decision in accordance with § 498.78; or

(3) Revised in accordance with § 498.32 or § 498.100.

§ 498.22 Reconsideration.

(a) *Right to reconsideration.* CMS reconsiders any initial determination

that affects a prospective provider or supplier, or a hospital seeking to qualify to claim payment for all emergency hospital services furnished in a calendar year, if the affected party files a written request in accordance with paragraphs (b) and (c) of this section. (None of the determinations made by the OIG are subject to reconsideration.)

(b) *Request for reconsideration: Manner and timing.* The affected party specified in paragraph (a) of this section, if dissatisfied with the initial determination may request reconsideration by filing the request—

(1) With CMS or with the State survey agency;

(2) Directly or through its legal representative or other authorized official; and

(3) Within 60 days from receipt of the notice of initial determination, unless the time is extended in accordance with paragraph (d) of this section. The date of receipt will be presumed to be 5 days after the date on the notice unless there is a showing that it was, in fact, received earlier or later.

(c) *Content of request.* The request for reconsideration must state the issues, or the findings of fact with which the affected party disagrees, and the reasons for disagreement.

(d) *Extension of time to file a request for reconsideration.* (1) If the affected party is unable to file the request within the 60 days specified in paragraph (b) of this section, it may file a written request with CMS, stating the reasons why the request was not filed timely.

(2) CMS will extend the time for filing a request for reconsideration if the affected party shows good cause for missing the deadline.

§ 498.23 Withdrawal of request for reconsideration.

A request for reconsideration is considered withdrawn if the requestor files a written withdrawal request before CMS mails the notice of reconsidered determination, and CMS approves the withdrawal request.

§ 498.24 Reconsidered determination.

When a request for reconsideration has been properly filed in accordance with § 498.22, CMS—

(a) Receives written evidence and statements that are relevant and material to the matters at issue and are submitted within a reasonable time after the request for reconsideration;

(b) Considers the initial determination, the findings on which the initial determination was based, the evidence considered in making the initial determination, and any other written evidence submitted under paragraph (a) of this section, taking into account facts relating to the status of the prospective provider or supplier subsequent to the initial determination; and

(c) Makes a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based.

§ 498.25 Notice and effect of reconsidered determination.

(a) *Notice.* (1) CMS mails notice of a reconsidered determination to the affected party.

(2) The notice gives the reasons for the determination.

(3) If the determination is adverse, the notice specifies the conditions or requirements of law or regulations that the affected party fails to meet, and informs the party of its right to a hearing.

(b) *Effect.* A reconsidered determination is binding unless—

(1) CMS or the OIG, as appropriate, further revises the revised determination; or

(2) The revised determination is reversed or modified by a hearing decision.

Subpart C—Reopening of Initial or Reconsidered Determinations

§ 498.30 Limitation on reopening.

An initial or reconsidered determination that a prospective provider is a provider or that a hospital qualifies to elect to claim payment for all emergency services furnished in a calendar year may not be reopened. CMS or the OIG, as appropriate, may on its own initiative, reopen any other initial or reconsidered determination, within 12 months after the date of notice of the initial determination.

§ 498.32 Notice and effect of reopening and revision.

(a) *Notice.* (1) CMS or the OIG, as appropriate, gives the affected party notice of reopening and of any revision of the reopened determination.

(2) The notice of revised determination states the basis or reason for the revised determination.

(3) If the determination is that a supplier or prospective supplier does not meet the conditions for coverage of its services, the notice specifies the conditions with respect to which the affected party fails to meet the requirements of law and regulations, and informs the party of its right to a hearing.

(b) *Effect.* A revised determination is binding unless

(1) The affected party requests a hearing before an ALJ; or

(2) CMS or the OIG further revises the revised determination.

Subpart D—Hearings

§ 498.40 Request for hearing.

(a) *Manner and timing of request.* (1) An affected party entitled to a hearing under § 498.5 may file a request for a hearing with CMS or the OIG, as appropriate, or with OHA.

(2) The affected party or its legal representative or other authorized official must file the request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended in accordance with paragraph (c) of this section. (Presumed date of receipt is determined in accordance with § 498.22(b)(3)).

(b) *Content of request for hearing.* The request for hearing must—

(1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and

(2) Specify the basis for contending that the findings and conclusions are incorrect.

(c) *Extension of time for filing a request for hearing.* If the request was not filed within 60 days—

(1) The affected party or its legal representative or other authorized official may file with the ALJ a written request for extension of time stating the reasons why the request was not filed timely.

(2) For good cause shown, the ALJ may extend the time for filing the request for hearing.

§ 498.42 Parties to the hearing.

The parties to the hearing are the affected party and CMS or the OIG, as appropriate.

§ 498.44 Designation of hearing official.

(a) The Associate Commissioner for Hearings and Appeals, or his or her delegate designates an ALJ or a member or members of the Departmental Appeals Board to conduct the hearing.

(b) If appropriate, the Associate Commissioner or the delegate may substitute another ALJ or another member or other members of the Departmental Appeals Board to conduct the hearing.

(c) As used in this part, ''ALJ'' includes a member or members of the Departmental Appeals Board who are designated to conduct a hearing.

§ 498.45 Disqualification of Administrative Law Judge.

(a) An ALJ may not conduct a hearing in a case in which he or she is prejudiced or partial to the affected party or has any interest in the matter pending for decision.

(b) A party that objects to the ALJ designated to conduct the hearing must give notice of its objections at the earliest opportunity.

(c) The ALJ will consider the objections and decide whether to withdraw or proceed with the hearing.

(1) If the ALJ withdraws, another will be designated to conduct the hearing.

(2) If the ALJ does not withdraw, the objecting party may, after the hearing, present its objections to the Departmental Appeals Board as reasons for changing, modifying, or reversing the ALJ's decision or providing a new hearing before another ALJ.

§ 498.47 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying

the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

(b) On the request of either party or on his or her own motion, the ALJ may adjourn the prehearing conference and reconvene at a later date.

§ 498.48 Notice of prehearing conference.

(a) *Timing of notice.* The ALJ will fix a time and place for the prehearing conference and mail written notice to the parties at least 10 days before the scheduled date.

(b) *Content of notice.* The notice will inform the parties of the purpose of the conference and specify what issues are sought to be resolved, agreed to, or excluded.

(c) *Additional issues.* Issues other than those set forth in the notice of determination or the request for hearing may be considered at the prehearing conference if—

(1) Either party gives timely notice to that effect to the ALJ and the other party; or

(2) The ALJ raises the issues in the notice of prehearing conference or at the conference.

§ 498.49 Conduct of prehearing conference.

(a) The prehearing conference is open to the affected party or its representative, to the CMS or OIG representatives and their technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) The ALJ may accept the agreement of the parties as to the following:

(1) Facts that are not in controversy.

(2) Questions that have been resolved favorably to the affected party after the determination in dispute.

(3) Remaining issues to be resolved.

(c) The ALJ may request the parties to indicate the following:

(1) The witnesses that will be present to testify at the hearing.

(2) The qualifications of those witnesses.

(3) The nature of other evidence to be submitted.

§ 498.50 Record, order, and effect of prehearing conference.

(a) *Record of prehearing conference.* (1) A record is made of all agreements and stipulations entered into at the prehearing conference.

(2) The record may be transcribed at the request of either party or the ALJ.

(b) *Order and opportunity to object.* (1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 days to file objections to the order.

(3) After the 10 days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference.* The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 498.52 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 498.53 Change in time and place of hearing.

(a) The ALJ may change the time and place for the hearing either on his or her own initiative or at the request of a party for good cause shown, or may adjourn or postpone the hearing.

(b) The ALJ may reopen the hearing for receipt of new evidence at any time before mailing the notice of hearing decision.

(c) The ALJ gives the parties reasonable notice of any change in time or place or any adjournment or reopening of the hearing.

§ 498.54 Joint hearings.

When two or more affected parties have requested hearings and the same or substantially similar matters are at issue, the ALJ may, if all parties agree,

fix a single time and place for the prehearing conference or hearing and conduct all proceedings jointly. If joint hearings are held, a single record of the preceedings is made and a separate decision issued with respect to each affected party.

§ 498.56 Hearing on new issues.

(a) *Basic rules.* (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

(2) The ALJ may consider new issues even if CMS or the OIG has not made initial or reconsidered determinations on them, and even if they arose after the request for hearing was filed or after a prehearing conference.

(3) The ALJ may give notice of hearing on new issues at any time after the hearing request is filed and before the hearing record is closed.

(b) *Time limits.* The ALJ will not consider any issue that arose on or after any of the following dates:

(1) The effective date of the termination of a provider agreement.

(2) The date on which it is determined that a supplier no longer meets the conditions for coverage of its services.

(3) The effective date of the notice to a hospital of its failure to remain in compliance with the qualifications for claiming reimbursement for all emergency services furnished to Medicare beneficiaries during the calendar year.

(4) The effective date of the suspension, or of the exclusion from coverage of services furnished by a suspended or excluded practitioner, provider, or supplier.

(5) With respect to Medicaid SNFs or ICFs surveyed under section 1910(c) of the Act—

(i) The completion date of the survey or resurvey that is the basis for a proposed cancellation of approval; or

(ii) If approval was cancelled before the hearings, because of immediate and serious threat to patient health and safety, the effective date of cancellation.

(c) *Notice and conduct of hearing on new issues.* (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 498.52.

(2) After giving notice, the ALJ will, except as provided in paragraph (d) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

(d) *Remand to CMS or the OIG.* At the request of either party, or on his or her own motion, in lieu of a hearing under paragraph (c) of this section, the ALJ may remand the case to CMS or the OIG for consideration of the new issue and, if appropriate, a determination. If necessary, the ALJ may direct CMS or the OIG to return the case to the ALJ for further proceedings.

[52 FR 22446, June 12, 1987, as amended at 53 FR 31335, Aug. 18, 1988]

§ 498.58 Subpoenas.

(a) *Basis for issuance.* The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas if they are reasonably necessary for the full presentation of a case.

(b) *Timing of request by a party.* The party must file a written request for a subpoena with the ALJ at least 5 days before the date set for the hearing.

(c) *Content of request.* The request must:

(1) Identify the witnesses or documents to be produced;

(2) Describe their addresses or location with sufficient particularity to permit them to be found; and

(3) Specify the pertinent facts the party expects to establish by the witnesses or documents, and indicate why those facts could not be established without use of a subpoena.

(d) *Method of issuance.* Subpoenas are issued in the name of the Secretary, who pays the cost of issuance and the fees and mileage of any subpoenaed witnesses.

§ 498.60 Conduct of hearing.

(a) *Participants in the hearing.* The hearing is open to the parties and their representatives and technical advisors, and to any other persons whose presence the ALJ considers necessary or proper.

(b) *Hearing procedures.* (1) The ALJ inquires fully into all of the matters at issue, and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(2) If the ALJ believes that there is relevant and material evidence available which has not been presented at the hearing, he may, at any time before mailing of notice of the decision, reopen the hearing to receive that evidence.

(3) The ALJ decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

(c) *Scope of review: Civil money penalty.* In civil money penalty cases—

(1) The scope of review is as specified in § 488.438(e) of this chapter; and

(2) CMS's determination as to the level of noncompliance of an SNF or NF must be upheld unless it is clearly erroneous.

[52 FR 22446, June 12, 1987, as amended at 61 FR 32350, June 24, 1996]

§ 498.61 Evidence.

Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence.

[59 FR 56252, Nov. 10, 1994, as amended at 61 FR 32350, June 24, 1996]

§ 498.62 Witnesses.

Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

§ 498.63 Oral and written summation.

The parties to a hearing are allowed a reasonable time to present oral summation and to file briefs or other written statements of proposed findings of fact and conclusions of law. Copies of any briefs or other written statements must be sent in accordance with § 498.17.

§ 498.64 Record of hearing.

A complete record of the proceedings at the hearing is made and transcribed in all cases.

§ 498.66 Waiver of right to appear and present evidence.

(a) *Waiver procedures.* (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

(2) If the affected party wishes to withdraw a waiver, it may do so, for good cause, at any time before the ALJ mails notice of the hearing decision.

(b) *Effect of waiver.* If the affected party waives the right to appear and present evidence, the ALJ need not conduct an oral hearing except in one of the following circumstances:

(1) The ALJ believes that the testimony of the affected party or its representatives or other witnesses is necessary to clarify the facts at issue.

(2) CMS or the OIG shows good cause for requiring the presentation of oral evidence.

(c) *Dismissal for failure to appear.* If, despite the waiver, the ALJ sends notice of hearing and the affected party fails to appear, or to show good cause for the failure, the ALJ will dismiss the appeal in accordance with § 498.69.

(d) *Hearing without oral testimony.* When there is no oral testimony, the ALJ will—

(1) Make a record of the relevant written evidence that was considered in making the determination being appealed, and of any additional evidence submitted by the parties;

(2) Furnish to each party copies of the additional evidence submitted by the other party; and

(3) Give both parties a reasonable opportunity for rebuttal.

(e) *Handling of briefs and related statements.* If the parties submit briefs or other written statements of evidence or proposed findings of facts or conclusions of law, those documents will be handled in accordance with § 498.17.

§ 498.68 Dismissal of request for hearing.

(a) The ALJ may, at any time before mailing the notice of the decision, dismiss a hearing request if a party withdraws its request for a hearing or the affected party asks that its request be dismissed.

(b) An affected party may request a dismissal by filing a written notice with the ALJ.

§ 498.69 Dismissal for abandonment.

(a) The ALJ may dismiss a request for hearing if it is abandoned by the party that requested it.

(b) The ALJ may consider a request for hearing to be abandoned if the party or its representative—

(1) Fails to appear at the prehearing conference or hearing without having previously shown good cause for not appearing; and

(2) Fails to respond, within 10 days after the ALJ sends a ''show cause'' notice, with a showing of good cause.

§ 498.70 Dismissal for cause.

On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:

(a) *Res judicata.* There has been a previous determination or decision with respect to the rights of the same affected party on the same facts and law pertinent to the same issue or issues which has become final either by judicial affirmance or, without judicial consideration, because the affected party did not timely request reconsideration, hearing, or review, or commence a civil action with respect to that determination or decision.

(b) *No right to hearing.* The party requesting a hearing is not a proper party or does not otherwise have a right to a hearing.

(c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

§ 498.71 Notice and effect of dismissal and right to request review.

(a) Notice of the ALJ's dismissal action is mailed to the parties. The notice advises the affected party of its right to request that the dismissal be vacated as provided in § 498.72.

(b) The dismissal of a request for hearing is binding unless it is vacated by the ALJ or the Departmental Appeals Board.

§ 498.72 Vacating a dismissal of request for hearing.

An ALJ may vacate any dismissal of a request for hearing if a party files a request to that effect within 60 days from receipt of the notice of dismissal and shows good cause for vacating the dismissal. (Date of receipt is determined in accordance with § 498.22(b)(3).)

§ 498.74 Administrative Law Judge's decision.

(a) *Timing, basis and content.* As soon as practical after the close of the hearing, the ALJ issues a written decision in the case. The decision is based on the evidence of record and contains separate numbered findings of fact and conclusions of law.

(b) *Notice and effect.* A copy of the decision is mailed to the parties and is binding on them unless—

(1) A party requests review by the Departmental Appeals Board within the time period specified in § 498.82, and the Board reviews the case;

(2) The Departmental Appeals Board denies the request for review and the party seeks judicial review by filing an action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals;

(3) The decision is revised by an ALJ or the Departmental Appeals Board; or

(4) The decision is a recommended decision directed to the Board.

[52 FR 22446, June 12, 1987, as amended at 61 FR 32351, June 24, 1996]

§ 498.76 Removal of hearing to Departmental Appeals Board.

(a) At any time before the ALJ receives oral testimony, the Board may remove to itself any pending request for a hearing.

(b) Notice of removal is mailed to each party.

(c) The Board conducts the hearing in accordance with the rules that apply to ALJ hearings under this subpart.

§ 498.78 Remand by the Administrative Law Judge.

(a) If CMS or the OIG requests remand, and the affected party concurs in writing or on the record, the ALJ may remand any case properly before him or her to CMS or the OIG for a determination satisfactory to the affected party.

(b) The ALJ may remand at any time before notice of hearing decision is mailed.

Subpart E—Departmental Appeals Board Review

§ 498.80 Right to request Departmental Appeals Board review of Administrative Law Judge's decision or dismissal.

Either of the parties has a right to request Departmental Appeals Board review of the ALJ's decision or dismissal order, and the parties are so informed in the notice of the ALJ's action.

§ 498.82 Request for Departmental Appeals Board review.

(a) *Manner and time of filing.* (1) Any party that is dissatisfied with an ALJ's decision or dismissal of a hearing request, may file a written request for review by the Departmental Appeals Board.

(2) The requesting party or its representative or other authorized official must file the request with the OHA within 60 days from receipt of the notice of decision or dismissal, unless the Board, for good cause shown by the requesting party, extends the time for filing. The rules set forth in § 498.40(c) apply to extension of time for requesting Departmental Appeals Board review. (The date of receipt of notice is determined in accordance with § 498.22(c)(3).)

(b) *Content of request for review.* A request for review of an ALJ decision or dismissal must specify the issues, the findings of fact or conclusions of law with which the party disagrees, and the basis for contending that the findings and conclusions are incorrect.

§ 498.83 Departmental Appeals Board action on request for review.

(a) *Request by CMS or the OIG.* The Departmental Appeals Board may dismiss, deny, or grant a request made by CMS or the OIG for review of an ALJ decision or dismissal.

(b) *Request by the affected party.* The Board will grant the affected party's request for review unless it dismisses the request for one of the following reasons:

(1) The affected party requests dismissal of its request for review.

(2) The affected party did not file timely or show good cause for late filing.

(3) The affected party does not have a right to review.

(4) A previous determination or decision, based on the same facts and law, and regarding the same issue, has become final through judicial affirmance or because the affected party failed to timely request reconsideration, hearing, Board review, or judicial review, as appropriate.

(c) *Effect of dismissal.* The dismissal of a request for Departmental Appeals Board review is binding and not subject to further review.

(d) *Review panel.* If the Board grants a request for review of the ALJ's decision, the review will be conducted by a panel of at least two members of the Board, designated by the Chairperson or Deputy Chairperson, and one individual designated by the Secretary from the U.S Public Health Service.

§ 498.85 Procedures before the Departmental Appeals Board on review.

The parties are given, upon request, a reasonable opportunity to file briefs or other written statements as to fact and law, and to appear before the Departmental Appeals Board to present evidence or oral arguments. Copies of any brief or other written statement must be sent in accordance with § 498.17.

§ 498.86 Evidence admissible on review.

(a) The Departmental Appeals Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing, (or the documents considered by the ALJ if the hearing was waived), if the Board considers

that the additional evidence is relevant and material to an issue before it.

(b) If it appears to the Board that additional relevant evidence is available, the Board will require that it be produced.

(c) Before additional evidence is admitted into the record—

(1) Notice is mailed to the parties (unless they have waived notice) stating that evidence will be received regarding specified issues; and

(2) The parties are given a reasonable time to comment and to present other evidence pertinent to the specified issues.

(d) If additional evidence is presented orally to the Board, a transcript is prepared and made available to any party upon request.

§ 498.88 Decision or remand by the Departmental Appeals Board.

(a) When the Departmental Appeals Board reviews an ALJ's decision or order of dismissal, or receives a case remanded by a court, the Board may either issue a decision or remand the case to an ALJ for a hearing and decision or a recommended decision for final decision by the Board.

(b) In a remanded case, the ALJ initiates additional proceedings and takes other actions as directed by the Board in its order of remand, and may take other action not inconsistent with that order.

(c) Upon completion of all action called for by the remand order and any other consistent action, the ALJ promptly makes a decision or, as specified by the Board, certifies the case to the Board with a recommended decision.

(d) The parties have 20 days from the date of a notice of a recommended decision to submit to the Board any exception, objection, or comment on the findings of fact, conclusions of law, and recommended decision.

(e) After the 20-day period, the Board issues its decision adopting, modifying or rejecting the ALJ's recommended decision.

(f) If the Board does not remand the case to an ALJ, the following rules apply:

(1) The Board's decision—

(i) Is based upon the evidence in the hearing record and any further evidence that the Board receives during its review;

(ii) Is in writing and contains separate numbered findings of fact and conclusions of law; and

(iii) May modify, affirm, or reverse the ALJ's decision.

(2) A copy of the Board's decision is mailed to each party.

§ 498.90 Effect of Departmental Appeals Board decision.

(a) *General rule.* The Board's decision is binding unless—

(1) The affected party has a right to judicial review and timely files a civil action in a United States District Court or, in the case of a civil money penalty, in a United States Court of Appeals; or

(2) The Board reopens and revises its decision in accordance with § 498.102.

(b) *Right to judicial review.* Section 498.5 specifies the circumstances under which an affected party has a right to seek judicial review.

(c) *Special rules: Civil money penalty*—(1) *Finality of Board's decision.* When CMS imposes a civil money penalty, notice of the Board's decision (or denial of review) is the final administrative action that initiates the 60-day period for seeking judicial review.

(2) *Timing for collection of civil money penalty.* For SNFs and NFs, the rules that apply are those set forth in subpart F of part 488 of this chapter.

[61 FR 32351, June 24, 1996]

§ 498.95 Extension of time for seeking judicial review.

(a) Any affected party that is dissatisfied with an Departmental Appeals Board decision and is entitled to judicial review must commence civil action within 60 days from receipt of the notice of the Board's decision (as determined under § 498.22(c)(3)), unless the Board extends the time in accordance with paragraph (c) of this section.

(b) The request for extension must be filed in writing with the Board before the 60-day period ends.

(c) For good cause shown, the Board may extend the time for commencing civil action.

Subpart F—Reopening of Decisions Made by Administrative Law Judges or the Departmental Appeals Board

§ 498.100 Basis, timing, and authority for reopening an ALJ or Board decision.

(a) *Basis and timing for reopening.* An ALJ of Departmental Appeals Board decision may be reopened, within 60 days from the date of the notice of decision, upon the motion of the ALJ or the Board or upon the petition of either party to the hearing.

(b) *Authority to reopen.* (1) A decision of the Departmental Appeals Board may be reopened only by the Departmental Appeals Board.

(2) A decision of an ALJ may be reopened by that ALJ, by another ALJ if that one is not available, or by the Departmental Appeals Board. For purposes of this paragraph, an ALJ is considered to be unavailable if the ALJ has died, terminated employment, or been transferred to another duty station, is on leave of absence, or is unable to conduct a hearing because of illness.

§ 498.102 Revision of reopened decision.

(a) *Revision based on new evidence.* If a reopened decision is to be revised on the basis of new evidence that was not included in the record of that decision, the ALJ or the Departmental Appeals Board—

(1) Notifies the parties of the proposed revision; and

(2) Unless the parties waive their right to hearing or appearance—

(i) Grants a hearing in the case of an ALJ revision; and

(ii) Grants opportunity to appear in the case of a Board revision.

(b) *Basis for revised decision and right to review.* (1) If a revised decision is necessary, the ALJ or the Departmental Appeals Board, as appropriate, renders it on the basis of the entire record.

(2) If the decision is revised by an ALJ, the Departmental Appeals Board may review that revised decision at the request of either party or on its own motion.

§ 498.103 Notice and effect of revised decision.

(a) *Notice.* The notice mailed to the parties states the basis or reason for the revised decision and informs them of their right to Departmental Appeals Board review of an ALJ revised decision, or to judicial review of a Board reviewed decision.

(b) *Effect*—(1) *ALJ revised decision.* An ALJ revised decision is binding unless it is reviewed by the Departmental Appeals Board.

(2) *Departmental Appeals Board revised decision.* A Board revised decision is binding unless a party files a civil action in a district court of the United States within the time frames specified in § 498.95.

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

PART 505—ESTABLISHMENT OF THE HEALTH CARE INFRASTRUCTURE IMPROVEMENT PROGRAM

Subpart A—Loan Criteria

Secs.

505.1 Basis and scope.
505.3 Definitions.
505.5 Loan criteria.
505.7 Terms of the loan.
505.9 State and local permits.
505.11 Loan application requirements and procedures.

Subpart B—Forgiveness of Indebtedness

505.13 Conditions for loan forgiveness.
505.15 Plan criteria for meeting the conditions for loan forgiveness.
505.17 Reporting requirements for meeting the conditions for loan forgiveness.
505.19 Approval or denial of loan forgiveness.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C 1302 and 1395hh).

SOURCE: 70 FR 57374, Sept. 30, 2005, unless otherwise noted.

Subpart A—Loan Criteria

§ 505.1 Basis and scope.

This part implements section 1016 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) which amends section 1897 of the Act. Section 1897 of the Act as amended by section 6045 of the Tsunami Relief Act of 2005 authorizes the Secretary to establish a loan program by which qualifying hospitals may apply for a loan for the capital costs of the health care infrastructure improvement projects. Section 1897 of the Act appropriates $142,000,000 for the loan program including program administration. The funds are available beginning July 1, 2004 through September 30, 2008. This part sets forth the criteria that CMS uses to select among qualifying hospitals.

§ 505.3 Definitions.

For purposes of this subpart, the following definitions apply:

Eligible project means the project of a qualifying hospital that is designed to improve the health care infrastructure of the hospital, including construction, renovation, or other capital improvements.

Entity is an entity described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of the code. An entity must also have at least one existing memorandum of understanding or affiliation agreement with a hospital located in the State in which the entity is located and retains clinical outpatient treatment for cancer on site as well as laboratory research, education, and outreach for cancer in the same facility.

*Outreach program*s mean formal cancer programs for teaching, diagnostic screening, therapy or treatment, prevention, or interventions to enhance the health and knowledge of their designated population(s).

Qualifying hospital means a hospital as defined at section 1861(e) of the Act (42 U.S,C. 1395x(e)) or an entity (as defined in this section) that is engaged in research in the causes, prevention, and treatment of cancer; and is either designated as a cancer center for the National Cancer Institute; or designated by the State legislature as the official cancer institute of the State before December 8, 2003.

Unique research resources means resources that are used for the purpose of discovering or testing options related to the causes, prevention, and treatment of cancer.

[70 FR 57374, Sept. 30, 2005, as amended at 71 FR 48143, Aug. 18, 2006]

§ 505.5 Loan criteria.

(a) *Qualifying criteria.* To qualify for the loan program, the applicant must meet the following conditions:

(1) Meet the definition of a ''qualifying hospital'' as set forth in § 505.3 of this part.

(2) Request a loan for the capital costs of an ''eligible project'' as defined in § 505.3 of this part. The capital costs

for which a qualifying hospital may obtain a loan are limited to the reasonable costs incurred by the hospital, and capitalized on the Medicare cost report, for any facility or item of equipment that it has acquired the possession or use of at the time the loan funding is awarded.

(b) *Selection criteria.* In selecting loan recipients, CMS prioritizes qualifying hospitals that meet the following criteria:

(1) The hospital is located in a State that, based on population density, is defined as a rural State. A rural State is one of ten States with the lowest population density. An applicant entity is required to be located in one of these ten States. The ten States are prioritized beginning with the State with the lowest population density. Population density is determined based on the most recent available U.S. Census Bureau data.

(2) The hospital is located in a State with multiple Indian tribes in the State. After prioritizing based on paragraph (b)(1) of this section, States are further prioritized based on the States with the most Indian tribes. The number of Indian tribes in a State is based on the most recent data available published in ''Indian Entities Recognized and Eligible to Receive Services from the United State Bureau of Indian Affairs.'' (68 FR 68180) published on December 5, 2003.

(c) CMS will send written notice to qualifying hospitals that have been selected to participate in the loan program under this part.

§ 505.7 Terms of the loan.

All loan recipients must agree to the following loan terms:

(a) *Loan obligation.* An authorized official of a qualifying hospital must execute a promissory note, loan agreement, or a form approved by CMS and accompanied by any other documents CMS may designate. The loan recipient must provide required documentation in a timely manner.

(b) *Schedule of loan.* A loan recipient receives a lump sum distribution for which payment of principal and interest is deferred for 60 months beginning with the day of award notification from CMS. The loan repayment period is 20 years.

(c) *Bankruptcy protection.* In the event a loan recipient files for bankruptcy protection in a court of competent jurisdiction or otherwise proves to be insolvent, CMS may terminate the deferment period described in paragraph (b) of this section and require immediate payment of the loan. If a loan recipient should file for bankruptcy protection in a court of competent jurisdiction or should otherwise evidence insolvency after the deferment period we will require immediate repayment of the outstanding principal and interest due. Those payments may be deducted from any Medicare payments otherwise due that hospital.

(d) *Loan forgiveness.* CMS does not require a loan recipient to begin making payments of principal or interest at the end of the 60-month deferment period if it determines that the loan recipient meets the criteria for loan forgiveness under section 1897 of the Act, as determined by the Secretary.

(e) *Default.* If a loan recipient fails to make any payment in repayment of a loan under this subpart within 10 days of its due date, the loan recipient may be considered to have defaulted on the loan. Upon default, all principal and accrued interest become due immediately, and CMS may require immediate payment of any outstanding principal and interest due. Those payments may be deducted from any Medicare payments otherwise due that hospital.

(f) *Loan repayment.* The loan recipient must meet the following conditions:

(1) Make payments every month for 20 years until the loan, including interest payments, are paid in full.

(2) Pay interest on the unpaid principal until the full amount of principal has been paid.

(3) Pay interest at a yearly rate based upon the rate as fixed by the Secretary of the Treasury and set forth at 45 CFR 30.13(a).

(4) If a loan recipient fails to make any payment in repayment of a loan under this subpart within 10 days of its due date, that payment may be deducted from any Medicare payments otherwise due to the recipient.

(g) *Interest rate and monthly payment charges.* CMS calculates interest charges and payments consistent with § 405.378 of this chapter.

(h) *Loan recipient's right to prepay.* A loan recipient has the right to make payments of principal at any time before they are due. A loan recipient may make full prepayment or partial prepayment without paying any prepayment charge. If a prepayment is made, the loan recipient must provide written notice to CMS at CMS, Division of Accounting Operations, P.O. Box 75120, Baltimore, MD 21207–0520.

§ 505.9 State and local permits.

With respect to an eligible project, the provision of a loan under this part shall not—

(a) Relieve the recipient of the loan or any obligation to obtain any required State or local permit or approval with respect to the project.

(b) Limit the right of any unit of State or local government to approve or regulate any rate of return on private equity invested in the project.

(c) Supersede any State or local law (including any regulation) applicable to the construction or operation of the project.

§ 505.11 Loan application requirements and procedures.

(a) The loan application must be received by CMS no later than 5 p.m. e.d.t. on December 29, 2005.

(b) The requested information must be typed or clearly printed in ink and the loan recipient must mail or deliver an original copy of the loan to CMS. The loan application must contain the following information:

(1) Qualifying hospital's name and street address.

(2) Qualifying hospital's Medicare provider number.

(3) Name, title, and telephone number of a contact person submitting the application.

(4) Provide all appropriate supporting documentation for each answer made on the loan application.

Subpart B—Forgiveness of Indebtedness

SOURCE: 71 FR 48144, Aug. 18, 2006, unless otherwise noted.

§ 505.13 Conditions for loan forgiveness.

The Secretary may forgive a loan provided under this part if the qualifying hospital—

(a) Has been selected to participate in the loan program specified in § 505.5(c).

(b) Has established the following in accordance with a plan that meets the criteria specified in § 505.15:

(1) An outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas;

(2) An outreach program for cancer prevention, early diagnosis, and treatment that provides services to multiple Indian tribes; and

(3) Unique research resources (such as population databases) or an affiliation with an entity that has unique research resources.

(c) Submits to CMS, within the timeframe specified by the Secretary, a—

(1) Written request for loan forgiveness; and

(2) Loan forgiveness plan that meets the criteria specified in § 505.15 of this subpart.

§ 505.15 Plan criteria for meeting the conditions for loan forgiveness.

The qualifying hospital requesting loan forgiveness must submit to CMS a plan specifying how it will develop, implement, or maintain an existing outreach program for cancer prevention, early diagnosis, and treatment for a substantial majority of the residents of a State or region, including residents of rural areas and for multiple Indian tribes and specifying how the qualifying hospital will establish or maintain existing unique research resources or an affiliation with an entity that has unique research resources.

(a) *Outreach programs.* The initial plan must specify how the hospital will establish or develop, implement, or

maintain existing outreach programs. The plan must—

(1) Address cancer prevention for cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for decreasing the targeted cancer rates during the loan deferment program; and

(2) Address early diagnosis of cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for improving early diagnosis rates for the targeted cancer(s) during the loan deferment period;

(3) Address cancer treatment for cancers that are prevalent in the designated populations or cancers that are targeted by the qualifying hospital, interventions, and goals for improving cancer treatment rates for the targeted cancer(s) during the loan deferment; and

(4) Identify the measures that will be used to determine the qualifying hospital's annual progress in meeting the initial goals specified in paragraphs (a)(1) through (a)(3) of this section.

(b) *Unique research resources.* The plan must specify how the qualifying hospital will establish or maintain existing unique research resources or an affiliation with an entity that has unique research resources.

§ 505.17 Reporting requirements for meeting the conditions for loan forgiveness.

(a) *Annual reporting requirements.* On an annual basis, beginning one year from the date that CMS notified the qualifying hospital of the loan award, the qualifying hospital must submit a report to CMS that updates the plan specified in § 505.15 by—

(1) Describing the qualifying hospital's progress in meeting its initial plan goals;

(2) Describing any changes to the qualifying hospital's initial plan goals; and

(3) Including at least one measure used to track the qualifying hospital's progress in meeting its plan goals.

(b) *Review of annual reports.* CMS will review each qualifying hospital's annual report to provide the hospital with feedback regarding its loan forgiveness status. If CMS determines that the annual report shows that the qualifying hospital has fulfilled the conditions, plan criteria, and reporting requirements for loan forgiveness specified in §§ 505.13, 505.15, and § 505.17, CMS will notify the qualifying hospital in writing that the loan is forgiven.

(c) *Final annual reporting requirements.* A qualifying hospital must submit its final report to CMS at least 6 months before the end of the loan deferment period specified in § 505.7(b).

§ 505.19 Approval or denial of loan forgiveness.

(a) *Approval of loan forgiveness.* If CMS determines that a qualifying hospital has met the conditions, plan criteria, and reporting requirements for loan forgiveness specified in § 505.13, § 505.15, and § 505.17, CMS will send a written notification of approval for loan forgiveness to the qualifying hospital by the earlier of—

(1) 30 days from the date of receipt of the annual report that shows the qualifying hospital has satisfied the requirements for loan forgiveness; or

(2) 90 days before the end of the loan deferment period defined in § 505.7(b).

(b) *Denial of loan forgiveness.* If CMS determines that a qualifying hospital has not met the conditions, plan criteria, or reporting requirements for loan forgiveness specified in § 505.13, § 505.15, or § 505.17 of this part, CMS will send a written notification of denial of loan forgiveness to the qualifying hospital at least 30 days before the end of the loan deferment period defined in § 505.7(b).

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

EDITORIAL NOTE: Nomenclature changes to chapter V appear at 66 FR 39452, July 31, 2001, and 67 FR 36540, May 24, 2002.

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SUBCHAPTER A—GENERAL PROVISIONS

PART 1000—INTRODUCTION; GENERAL DEFINITIONS

Subpart A [Reserved]

Subpart B—Definitions

Sec.

1000.10 General definitions.
1000.20 Definitions specific to Medicare.
1000.30 Definitions specific to Medicaid.

AUTHORITY: 42 U.S.C. 1320 and 1395hh.

SOURCE: 51 FR 34766, Sept. 30, 1986, unless otherwise noted.

Subpart A [Reserved]

Subpart B—Definitions

§ 1000.10 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

Beneficiary means any individual eligible to have benefits paid to him or her, or on his or her behalf, under Medicare or any State health care program.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

Directly, as used in the definition of ''furnished'' in this section, means the provision of items and services by individuals or entities (including items and services provided by them, but manufactured, ordered or prescribed by another individual or entity) who submit claims to Medicare, Medicaid or other Federal health care programs.

ESRD stands for end-stage renal disease.

FR stands for FEDERAL REGISTER.

Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity. This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

Indirectly, as used in the definition of ''furnished'' in this section, means the provision of items and services manufactured, distributed or otherwise supplied by individuals or entities who do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that provide items and services to providers, practitioners or suppliers who submit claims to these programs for such items and services. This term does not include individuals and entities that submit claims directly to these programs for items and services ordered or prescribed by another individual or entity.

Inspector General means the Inspector General for Health and Human Services.

Medicaid means medical assistance provided under a State plan approved under Title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under Title XVIII of the Act.

OIG means the Office of Inspector General within HHS.

QIO stands for Utilization and Quality Control Quality Improvement Organization.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

[51 FR 34766, Sept. 30, 1986 as amended at 57 FR 3329, Jan. 29, 1992; 63 FR 46685, Sept. 2, 1998; 66 FR 39452, July 31, 2001]

§ 1000.20 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Carrier means an entity that has a contract with CMS to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Entitled means that an individual meets all the requirements for Medicare benefits.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of Title XVIII of the Act.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

Medicare Part A means the hospital insurance program authorized under Part A of Title XVIII of the Act.

Medicare Part B means the supplementary medical insurance program authorized under Part B of Title XVIII of the Act.

Provider means a hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or effective November 1, 1983 through September 30, 1986, a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has a similar agreement but only to furnish outpatient physical therapy or speech pathology services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services covered under Part B of Title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

[51 FR 34766, Sept. 30, 1986, as amended at 57 FR 3329, Jan. 29, 1992]

§ 1000.30 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Medicaid agency or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

Provider means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

Recipient means an individual who has been determined eligible for Medicaid.

Services means the types of medical assistance specified in sections 1905(a)(1) through (18) of the Act.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State plan or *the plan* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

SUBCHAPTER B—OIG AUTHORITIES

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

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APPENDIX A TO SUBPART C OF PART 1001

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1001.1801 Waivers of exclusions.
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Subpart E—Notice and Appeals

1001.2001 Notice of intent to exclude.
1001.2002 Notice of exclusion.
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Subpart F—Reinstatement into the Programs

1001.3001 Timing and method of request for reinstatement.
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1001.3003 Approval of request for reinstatement.
1001.3004 Denial of request for reinstatement.
1001.3005 Reversed or vacated decisions.

AUTHORITY: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395y(d), 1395y(e), 1395cc(b)(2) (D), (E) and (F), and 1395hh; and sec. 2455, Pub.L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

EFFECTIVE DATE NOTE: At 71 FR 45136, Aug. 8, 2006, the authority for part 1001 was revised, effective Oct. 10, 2006. For the convenience of the user, the revised text is set forth as follows:

AUTHORITY: 42 U.S.C. 1302, 1320a–7, 1320a–7b, 1395u(j), 1395u(k), 1395w–104(e)(6), 1395y(d), 1395y(e), 1395cc(b)(2)(D), (E) and (F), and 1395hh; and sec. 2455, Pub. L. 103–355, 108 Stat. 3327 (31 U.S.C. 6101 note).

SOURCE: 57 FR 3330, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 1001.1 Scope and purpose.

(a) The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in Medicare, Medicaid and all other Federal health care programs. They also state the effect of exclusion, the factors that will be considered in determining the length of any exclusion, the provisions governing notices of exclusions, and the process by which an excluded individual or entity may seek reinstatement into the programs.

(b) The regulations in this part are applicable to and binding on the Office of Inspector General (OIG) in imposing

and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and, where applicable, in imposing exclusions proposed by the OIG).

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993; 64 FR 39426, July 22, 1999]

§ 1001.2 Definitions.

Controlled substance means a drug or other substance, or immediate precursor:

(a) Included in schedules I, II, III, IV or V of part B of subchapter I in 21 U.S.C. chapter 13, or

(b) That is deemed a controlled substance by the law of any State.

Convicted means that—

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending, or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(b) A Federal, State or local court has made a finding of guilt against an individual or entity;

(c) A Federal, State or local court has accepted a plea of guilty or *nolo contendere* by an individual or entity; or

(d) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

Exclusion means that items and services furnished, ordered or prescribed by a specified individual or entity will not be reimbursed under Medicare, Medicaid and all other Federal health care programs until the individual or entity is reinstated by the OIG.

Federal health care program means any plan or program providing health care benefits, whether directly through insurance or otherwise, that is funded directly, in whole or part, by the United States Government (other than the Federal Employees Health Benefits Program), or any State health care program as defined in this section.

HHS means Department of Health and Human Services.

Incarceration means imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest and home detention.

OIG means Office of Inspector General of the Department of Health and Human Services.

Patient means any individual who is receiving health care items or services, including any item or service provided to meet his or her physical, mental or emotional needs or well-being (including a resident receiving care in a facility as described in part 483 of this chapter), whether or not reimbursed under Medicare, Medicaid and any other Federal health care program and regardless of the location in which such item or service is provided.

QIO means Utilization and Quality Control Quality Improvement Organization as created by the Tax Equity and Fiscal Responsibility Act of 1982 (42 U.S.C. 1320c–3).

Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. When the Department has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care. This definition will not be construed to mean that all other treatments meet professionally recognized standards.

Sole community physician means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

Sole source of essential specialized services in the community means that an individual or entity—

(1) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Health Resources Services Administration as a health professional shortage

area for that medical specialty, as listed in 42 part 5, appendices B–F;

(2) Is a sole community hospital, as defined in §412.92 of this title; or

(3) Is the only source of specialized services in a reasonably defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

State health care program means:

(a) A State plan approved under title XIX of the Act (Medicaid),

(b) Any program receiving funds under title V of the Act or from an allotment to a State under such title (Maternal and Child Health Services Block Grant program), or

(c) Any program receiving funds under title XX of the Act or from any allotment to a State under such title (Block Grants to States for Social Services).

State Medicaid Fraud Control Unit means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and §1002.305 of this chapter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46686, Sept. 2, 1998; 64 FR 39426, July 22, 1999]

Subpart B—Mandatory Exclusions

§1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program;

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients (the delivery of a health care item or service includes the provision of any item or service to an individual to meet his or her physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare, Medicaid or any Federal health care program);

(c) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996, relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(1) In connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(2) With respect to any act or omission in a health care program (other than Medicare and a State health care program) operated by, or financed in whole or in part, by any Federal, State or local government agency; or

(d) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider or supplier;

(2) Holds, or has held, a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in an entity that is a health care provider or supplier, or is, or has ever been, an officer, director, agent or managing employee (as defined in section 1126(b) of the Act) of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

[63 FR 46686, Sept. 2, 1998, as amended at 67 FR 11932, Mar. 18, 2002]

§1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with §1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, that caused, or were intended to cause, a financial loss to a Government program or to one or more entities of $5,000 or more. (The entire amount of financial loss to such programs or entities, including any amounts resulting from similar acts

not adjudicated, will be considered regardless of whether full or partial restitution has been made);

(2) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(3) The acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals;

(4) In convictions involving patient abuse or neglect, the action that resulted in the conviction was premeditated, was part of a continuing pattern of behavior, or consisted of non-consensual sexual acts;

(5) The sentence imposed by the court included incarceration;

(6) The convicted individual or entity has a prior criminal, civil or administrative sanction record;

(7) The individual or entity has at any time been overpaid a total of $1,500 or more by Medicare, Medicaid or any other Federal health care programs as a result of *intentional* improper billings;

(8) The individual or entity has previously been convicted of a criminal offense involving the same or similar circumstances; or

(9) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for imposition of the exclusion.

(c) Only if any of the aggravating factors set forth in paragraph (b) of this section justifies an exclusion longer than 5 years, may mitigating factors be considered as a basis for reducing the period of exclusion to no less than 5 years. Only the following factors may be considered mitigating—

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss (both actual loss and intended loss) to Medicare or any other Federal, State or local governmental health care program due to the acts that resulted in the conviction, and similar acts, is less than $1,500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

(3) The individual's or entity's cooperation with Federal or State officials resulted in—

(i) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(iii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

(d) In the case of an exclusion under this subpart, based on a conviction occurring on or after August 5, 1997, an exclusion will be—

(1) For not less than 10 years if the individual has been convicted on one other occasion of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act (The aggravating and mitigating factors in paragraphs (b) and (c) of this section can be used to impose a period of time in excess of the 10-year mandatory exclusion); or

(2) Permanent if the individual has been convicted on two or more other occasions of one or more offenses for which an exclusion may be effected under section 1128(a) of the Act.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46686, Sept. 2, 1998; 63 FR 57918, Oct. 29, 1998; 64 FR 39426, July 22, 1999; 67 FR 11932, Mar. 18, 2002]

Subpart C—Permissive Exclusions

§ 1001.201 Conviction relating to program or health care fraud.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of—

(1) A misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) In connection with the delivery of any health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(ii) With respect to any act or omission in a health care program, other than Medicare and a State health care program, operated by, or financed in whole or in part by, any Federal, State or local government agency; or

(2) Fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program, other than a health care program, operated by or financed in whole or in part by any Federal, State or local government agency.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts resulting in the conviction, or similar acts that caused, or reasonably could have been expected to cause, a financial loss of $5,000 or more to a Government program or to one or more other entities, or had a significant financial impact on program beneficiaries or other individuals. (The total amount of financial loss will be considered, including any amounts resulting from similar acts not adjudicated, regardless of whether full or partial restitution has been made);

(ii) The acts that resulted in the conviction, or similar acts, were committed over a period of one year or more;

(iii) The acts that resulted in the conviction, or similar acts, had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals;

(iv) The sentence imposed by the court included incarceration;

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The individual or entity was convicted of 3 or fewer offenses, and the entire amount of financial loss (both actual loss and reasonably expected loss) to a Government program or to other individuals or entities due to the acts that resulted in the conviction and similar acts is less than $1,500;

(ii) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(iii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid or any of the other Federal health care programs, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iv) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999; 67 FR 11932, Mar. 18, 2002; 67 FR 21579, May 1, 2002]

§ 1001.301 Conviction relating to obstruction of an investigation.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation into any criminal offense described in §§ 1001.101 or 1001.201.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form the basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The interference with, or obstruction of, the investigation caused the expenditure of significant additional time or resources;

(ii) The interference or obstruction had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or on the Medicare, Medicaid or other Federal health care programs;

(iii) The interference or obstruction also affected a civil or administrative investigation;

(iv) The sentence imposed by the court included incarceration;

(v) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(vi) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) The record of the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition, before or during the commission of the offense, that reduced the individual's culpability;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992; 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999]

§ 1001.401 Conviction relating to controlled substances.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a misdemeanor relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This section applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider or supplier;

(2) Holds or has held a direct or indirect ownership or control interest, as defined in section 1124(a)(3) of the Act, in an entity that is a health care provider or supplier, or is or has been an officer, director, agent or managing employee, as defined in section 1126(b) of the Act, of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

(b) For purposes of this section, the definition of *controlled substance* will be the definition that applies to the law forming the basis for the conviction.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (b)(2) and (b)(3) of this section form a basis for lengthening or shortening that period.

(2) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;

(ii) The acts that resulted in the conviction or similar acts had a significant adverse mental, physical or financial impact on program beneficiaries or

other individuals or the Medicare, Medicaid or other Federal health care programs;

(iii) The sentence imposed by the court included incarceration;

(iv) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(v) Whether the individual or entity was convicted of other offenses besides those which formed the basis for the exclusion, or has been the subject of any other adverse action by any other Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for shortening the period of exclusion—

(i) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(C) The imposition of a civil money penalty against others; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999]

§ 1001.501 License revocation or suspension.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license (including the right to apply for or renew such a license), for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual's or entity's professional competence, professional performance or financial integrity was pending before a State licensing authority.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which an individual's or entity's license is revoked, suspended or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the revocation, suspension or loss of the individual's or entity's license to provide health care had or could have had a significant adverse physical, emotional or financial impact on one or more program beneficiaries or other individuals;

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(iii) The acts, or similar acts, had or could have had a significant adverse impact on the financial integrity of the programs; or

(iv) The individual or entity has been the subject of any other adverse action by any other Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with a State licensing authority resulted in—

(A) The sanctioning of other individuals or entities, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

(ii) Alternative sources of the type of health care items or services furnished

by the individual or entity are not available.

(4) When an individual or entity has been excluded under this section, the OIG will consider a request for reinstatement in accordance with § 1001.3001 if the individual or entity obtains a valid license in the State where the license was originally revoked, suspended, surrendered or otherwise lost.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998]

§ 1001.601 Exclusion or suspension under a Federal or State health care program.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care, or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity.

(2) The term ''or otherwise sanctioned'' in paragraph (a)(1) of this section is intended to cover all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which the individual or entity is excluded or suspended from a Federal or State health care program.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The acts that resulted in the exclusion, suspension or other sanction under Medicare, Medicaid and all other Federal health care programs had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

(ii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(iii) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only if any of the aggravating factors set forth in paragraph (b)(2) of this section justifies a longer exclusion may mitigating factors be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factors may be considered mitigating—

(i) The individual's or entity's cooperation with Federal or State officials resulted in—

(A) The sanctioning of other individuals or entities, or

(B) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

(ii) Alternative sources of the types of health care items or services furnished by the individual or entity are not available.

(4) If the individual or entity is eligible to apply for reinstatement in accordance with § 1001.3001 of this part, and the sole reason for the State denying reinstatement is the existing Medicare exclusion imposed by the OIG as a result of the original State action, the OIG will consider a request for reinstatement.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998]

§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.

(a) Circumstance for exclusion. The OIG may exclude an individual or entity that has—

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's

usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) The OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by the OIG.

(c) Exceptions. An individual or entity will not be excluded for—

(1) Submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

(d) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (d)(2) and (d)(3) of this section form a basis for lengthening or shortening the period. In no case may the period be shorter than 1 year for any exclusion taken in accordance with paragraph (a)(2) of this section.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The violations were serious in nature, and occurred over a period of one year or more;

(ii) The violations had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals;

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing;

(iv) The violation resulted in financial loss to Medicare, Medicaid and all other Federal health care programs of $1,500 or more; or

(v) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998]

§ 1001.801 Failure of HMOs and CMPs to furnish medically necessary items and services.

(a) Circumstances for exclusion. The OIG may exclude an entity—

(1) That is a—

(i) Health maintenance organization (HMO), as defined in section 1903(m) of the Act, providing items or services under a State Medicaid Plan;

(ii) Primary care case management system providing services, in accordance with a waiver approved under section 1915(b)(1) of the Act; or

(iii) HMO or competitive medical plan providing items or services in accordance with a risk-sharing contract under section 1876 of the Act;

(2) That has failed substantially to provide medically necessary items and services that are required under a plan, waiver or contract described in paragraph (a)(1) of this section to be provided to individuals covered by such plan, waiver or contract; and

(3) Where such failure has adversely affected or has a substantial likelihood of adversely affecting covered individuals.

(b) The OIG's determination under paragraph (a)(2) of this section—that the medically necessary items and services required under law or contract were not provided—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO or other quality assurance organization under contract with a State Medicaid plan for the area served by the HMO or competitive medical plan;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies;

(5) CMS's HMO compliance office; or

(6) Any other sources deemed appropriate by the OIG.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors set forth in paragraphs (c)(2) and (c)(3) of this section form a basis for lengthening or shortening the period.

(2) Any of the following factors may be considered aggravating and a basis for lengthening the period of exclusion—

(i) The entity failed to provide a large number or a variety of items or services;

(ii) The failures occurred over a lengthy period of time;

(iii) The entity's failure to provide a necessary item or service that had or could have had a serious adverse effect;

(iv) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing; or

(v) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factors may be considered as mitigating and a basis for reducing the period of exclusion—

(i) There were few violations and they occurred over a short period of time; or

(ii) Alternative sources of the type of health care items or services furnished by the entity are not available.

(iii) The entity took corrective action upon learning of impermissible activities by an employee or contractor.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998]

§ 1001.901 False or improper claims.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that it determines has committed an act described in section 1128A of the Act. The imposition of a civil money penalty or assessment is not a prerequisite for an exclusion under this section.

(b) *Length of exclusion.* In determining the length of an exclusion imposed in accordance with this section, the OIG will consider the following factors—

(1) The nature and circumstances surrounding the actions that are the basis for liability, including the period of time over which the acts occurred, the number of acts, whether there is evidence of a pattern and the amount claimed;

(2) The degree of culpability;

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(4) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

(5) Other matters as justice may require.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§ 1001.951 Fraud and kickbacks and other prohibited activities.

(a) *Circumstance for exclusion.* (1) Except as provided for in paragraph (a)(2)(ii) of this section, the OIG may exclude any individual or entity that it determines has committed an act described in section 1128B(b) of the Act.

(2) With respect to acts described in section 1128B of the Act, the OIG—

(i) May exclude any individual or entity that it determines has knowingly and willfully solicited, received, offered or paid any remuneration in the manner and for the purposes described therein, irrespective of whether the individual or entity may be able to prove that the remuneration was also intended for some other purpose; and

(ii) Will not exclude any individual or entity if that individual or entity can prove that the remuneration that is the subject of the exclusion is exempted from serving as the basis for an exclusion.

(b) *Length of exclusion.* (1) The following factors will be considered in determining the length of exclusion in accordance with this section—

(i) The nature and circumstances of the acts and other similar acts;

(ii) The nature and extent of any adverse physical, mental, financial or other impact the conduct had on program beneficiaries or other individuals or the Medicare, Medicaid and all other Federal health care programs;

(iii) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(iv) The individual or entity has been the subject of any other adverse action by any Federal, State or local government agency or board, if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion; or

(v) Any other facts bearing on the nature and seriousness of the individual's or entity's misconduct.

(2) It will be considered a mitigating factor if—

(i) The individual had a documented mental, emotional, or physical condition before or during the commission of the prohibited act(s) that reduced the individual's culpability for the acts in question;

(ii) The individual's or entity's cooperation with Federal or State officials resulted in the—

(A) Sanctioning of other individuals or entities, or

(B) Imposition of a civil money penalty against others; or

(iii) Alternative sources of the type of health care items or services provided by the individual or entity are not available.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 67 FR 11933, Mar. 18, 2002]

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

(a) *Investment interests.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor as long as all of the applicable standards are met within one of the following three categories of entities:

(1) If, within the previous fiscal year or previous 12 month period, the entity possesses more than $50,000,000 in undepreciated net tangible assets (based on the net acquisition cost of purchasing such assets from an unrelated entity) related to the furnishing of health care items and services, all of the following five standards must be met—

(i) With respect to an investment interest that is an equity security, the equity security must be registered with the Securities and Exchange Commission under 15 U.S.C. 781 (b) or (g).

(ii) The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms (including any direct or indirect transferability restrictions) and at a price equally available to the public when trading on a registered securities exchange, such as the New York Stock

Exchange or the American Stock Exchange, or in accordance with the National Association of Securities Dealers Automated Quotation System.

(iii) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

(2) If the entity possesses investment interests that are held by either active or passive investors, all of the following eight applicable standards must be met—

(i) No more than 40 percent of the value of the investment interests of each class of investment interests may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity. (For purposes of paragraph (a)(2)(i) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

(ii) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(v) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors.

(vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors.

(vii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(viii) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(3)(i) If the entity possesses investment interests that are held by either active or passive investors and is located in an underserved area, all of the following eight standards must be met—

(A) No more than 50 percent of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity. (For purposes of paragraph (a)(3)(i)(A) of this section, equivalent classes of equity investments may be combined, and equivalent classes of debt instruments may be combined.)

(B) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors.

(C) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.

(D) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.

(E) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors.

(F) At least 75 percent of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period must be derived from the service of persons who reside in an underserved area or are members of medically underserved populations.

(G) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor in the entity) must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

(H) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(ii) If an entity that otherwise meets all of the above standards is located in an area that was an underserved area at the time of the initial investment, but subsequently ceases to be an underserved area, the entity will be deemed to comply with paragraph (a)(3)(i) of this section for a period equal to the lesser of:

(A) The current term of the investment remaining after the date upon which the area ceased to be an underserved area or

(B) Three years from the date the area ceased to be an underserved area.

(4) For purposes of paragraph (a) of this section, the following terms apply. *Active investor* means an investor either who is responsible for the day-to-day management of the entity and is a bona fide general partner in a partnership under the Uniform Partnership Act or who agrees in writing to undertake liability for the actions of the entity's agents acting within the scope of their agency. *Investment interest* means a security issued by an entity, and may include the following classes of investments: shares in a corporation, interests or units in a partnership or limited liability company, bonds, debentures, notes, or other debt instruments. *Investor* means an individual or entity either who directly holds an investment interest in an entity, or who holds such investment interest indirectly by, including but not limited to, such means as having a family member hold such investment interest or holding a legal or beneficial interest in another entity (such as a trust or holding company) that holds such investment interest. *Passive investor* means an investor who is not an active investor, such as a limited partner in a partnership under the Uniform Partnership Act, a shareholder in a corporation, or a holder of a debt security. *Underserved area* means any defined geographic area that is designated as a Medically Underserved Area (MUA) in accordance with regulations issued by the Department. *Medically underserved population* means a Medically Underserved Population (MUP) in accordance with regulations issued by the Department.

(b) *Space rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following six standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the premises leased between the parties for the term of the lease and specifies the premises covered by the lease.

(3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (b) of this section, the term *fair market value* means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid and all other Federal health care programs.

(c) *Equipment rental.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following six standards are met—

(1) The lease agreement is set out in writing and signed by the parties.

(2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.

(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

(4) The term of the lease is for not less than one year.

(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal health care programs.

(6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. Note that for purposes of paragraph (c) of this section, the term *fair market value* means that the value of the equipment when obtained from a manufacturer or professional distributor, but shall not be adjusted to reflect the additional value one party (either the prospective lessee or lessor) would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(d) *Personal services and management contracts.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—

(1) The agency agreement is set out in writing and signed by the parties.

(2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.

(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their

precise length, and the exact charge for such intervals.

(4) The term of the agreement is for not less than one year.

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.

(6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.

(7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

(e) *Sale of practice.* (1) As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by another practitioner where the former practitioner is selling his or her practice to the latter practitioner, as long as both of the following two standards are met—

(i) The period from the date of the first agreement pertaining to the sale to the completion of the sale is not more than one year.

(ii) The practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs after 1 year from the date of the first agreement pertaining to the sale.

(2) As used in section 1128B of the Act, ''remuneration'' does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following four standards are met:

(i) The period from the date of the first agreement pertaining to the sale to the completion date of the sale is not more than three years.

(ii) The practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise generate business for, the purchasing hospital or entity for which payment may be made under Medicare, Medicaid or other Federal health care programs.

(iii) The practice being acquired must be located in a Health Professional Shortage Area (HPSA), as defined in Departmental regulations, for the practitioner's specialty area.

(iv) Commencing at the time of the first agreement pertaining to the sale, the purchasing hospital or entity must diligently and in good faith engage in commercially reasonable recruitment activities that:

(A) May reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a one year period and

(B) Will satisfy the conditions of the practitioner recruitment safe harbor in accordance with paragraph (n) of this section.

(f) *Referral services.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value between an individual or entity (''participant'') and another entity serving as a referral service (''referral service''), as long as all of the following four standards are met—

(1) The referral service does not exclude as a participant in the referral service any individual or entity who meets the qualifications for participation.

(2) Any payment the participant makes to the referral service is assessed equally against and collected equally from all participants, and is only based on the cost of operating the referral service, and not on the volume or value of any referrals to or business otherwise generated by either party for the referral service for which payment may be made in whole or in part under

Medicare, Medicaid or other Federal health care programs.

(3) The referral service imposes no requirements on the manner in which the participant provides services to a referred person, except that the referral service may require that the participant charge the person referred at the same rate as it charges other persons not referred by the referral service, or that these services be furnished free of charge or at reduced charge.

(4) The referral service makes the following five disclosures to each person seeking a referral, with each such disclosure maintained by the referral service in a written record certifying such disclosure and signed by either such person seeking a referral or by the individual making the disclosure on behalf of the referral service—

(i) The manner in which it selects the group of participants in the referral service to which it could make a referral;

(ii) Whether the participant has paid a fee to the referral service;

(iii) The manner in which it selects a particular participant from this group for that person;

(iv) The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and

(v) The nature of any restrictions that would exclude such an individual or entity from continuing as a participant.

(g) *Warranties.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value under a warranty provided by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) of the item, as long as the buyer complies with all of the following standards in paragraphs (g)(1) and (g)(2) of this section and the manufacturer or supplier complies with all of the following standards in paragraphs (g)(3) and (g)(4) of this section—

(1) The buyer must fully and accurately report any price reduction of the item (including a free item), which was obtained as part of the warranty, in the applicable cost reporting mechanism or claim for payment filed with the Department or a State agency.

(2) The buyer must provide, upon request by the Secretary or a State agency, information provided by the manufacturer or supplier as specified in paragraph (g)(3) of this section.

(3) The manufacturer or supplier must comply with either of the following two standards—

(i) The manufacturer or supplier must fully and accurately report the price reduction of the item (including a free item), which was obtained as part of the warranty, on the invoice or statement submitted to the buyer, and inform the buyer of its obligations under paragraphs (a)(1) and (a)(2) of this section.

(ii) Where the amount of the price reduction is not known at the time of sale, the manufacturer or supplier must fully and accurately report the existence of a warranty on the invoice or statement, inform the buyer of its obligations under paragraphs (g)(1) and (g)(2) of this section, and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty.

(4) The manufacturer or supplier must not pay any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself.

For purposes of paragraph (g) of this section, the term *warranty* means either an agreement made in accordance with the provisions of 15 U.S.C. 2301(6), or a manufacturer's or supplier's agreement to replace another manufacturer's or supplier's defective item (which is covered by an agreement made in accordance with this statutory provision), on terms equal to the agreement that it replaces.

(h) *Discounts.* As used in section 1128B of the Act, ''remuneration'' does not include a discount, as defined in paragraph (h)(5) of this section, on an item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs for a buyer as long as the buyer complies with the applicable standards of paragraph (h)(1) of this section; a seller as long as the seller complies with the applicable standards

of paragraph (h)(2) of this section; and an offeror of a discount who is not a seller under paragraph (h)(2) of this section so long as such offeror complies with the applicable standards of paragraph (h)(3) of this section.

(1) With respect to the following three categories of buyers, the buyer must comply with all of the applicable standards within one of the three following categories—

(i) If the buyer is an entity which is a health maintenance organization (HMO) or a competitive medical plan (CMP) acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, it need not report the discount except as otherwise may be required under the risk contract.

(ii) If the buyer is an entity which reports its costs on a cost report required by the Department or a State health care program, it must comply with all of the following four standards—

(A) The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;

(B) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(C) The buyer must fully and accurately report the discount in the applicable cost report; and

(D) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii) of this section, or information provided by the offeror as specified in paragraph (h)(3)(ii) of this section.

(iii) If the buyer is an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the buyer must comply with both of the following standards—

(A) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and

(B) the buyer (if submitting the claim) must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section, or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section.

(2) The seller is an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs to the buyer and who permits a discount to be taken off the buyer's purchase price. The seller must comply with all of the applicable standards within one of the following three categories—

(i) If the buyer is an entity which is an HMO a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the seller need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the seller must comply with either of the following two standards—

(A) Where a discount is required to be reported to Medicare or a State health care program under paragraph (h)(1) of this section, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph; or

(B) Where the value of the discount is not known at the time of sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request

under paragraph (h)(1) of this section; when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which would impede the buyer from meeting its obligations under this paragraph.

(iii) If the buyer is an individual or entity not included in paragraph (h)(2)(i) or (h)(2)(ii) of this section, the seller must comply with either of the following two standards—

(A) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary or a State agency, information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section; or

(B) Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.

(3) The offeror of a discount is an individual or entity who is not a seller under paragraph (h)(2) of this section, but promotes the purchase of an item or service by a buyer under paragraph (h)(1) of this section at a reduced price for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs. The offeror must comply with all of the applicable standards within the following three categories—

(i) If the buyer is an entity which is an HMO or a CMP acting in accordance with a risk contract under section 1876(g) or 1903(m) of the Act, or under another State health care program, the offeror need not report the discount to the buyer for purposes of this provision.

(ii) If the buyer is an entity that reports its costs on a cost report required by the Department or a State agency, the offeror must comply with the following two standards—

(A) The offeror must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request under paragraph (h)(1) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's ability to meet its obligations under this paragraph.

(iii) If the buyer is an individual or entity in whose name a request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs (not including individuals or entities defined as buyers in paragraph (h)(1)(i) or (h)(1)(ii) of this section), the offeror must comply with the following two standards—

(A) The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section; and

(B) The offeror of the discount must refrain from doing anything that would impede the buyer's or seller's ability to meet its obligations under this paragraph.

(4) For purposes of this paragraph, a *rebate* is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale.

(5) For purposes of this paragraph, the term *discount* means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction. The term *discount* does not include—

(i) Cash payment or cash equivalents (except that rebates as defined in paragraph (h)(4) of this section may be in the form of a check);

(ii) Supplying one good or service without charge or at a reduced charge

to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(iii) A reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs;

(iv) A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;

(v) Warranties;

(vi) Services provided in accordance with a personal or management services contract; or

(vii) Other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section.

(i) *Employees.* As used in section 1128B of the Act, ''remuneration'' does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs. For purposes of paragraph (i) of this section, the term *employee* has the same meaning as it does for purposes of 26 U.S.C. 3121(d)(2).

(j) *Group purchasing organizations.* As used in section 1128B of the Act, ''remuneration'' does not include any payment by a vendor of goods or services to a group purchasing organization (GPO), as part of an agreement to furnish such goods or services to an individual or entity as long as both of the following two standards are met—

(1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following—

(i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.

(ii) In the event the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods or services, the agreement specifies the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO).

(2) Where the entity which receives the goods or service from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity. Note that for purposes of paragraph (j) of this section, the term *group purchasing organization* (GPO) means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).

(k) *Waiver of beneficiary coinsurance and deductible amounts.* As used in section 1128B of the Act, ''remuneration'' does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to pay coinsurance or deductible amounts as long as all of the standards are met within either of the following two categories of health care providers:

(1) If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the following three standards—

(i) The hospital must not later claim the amount reduced or waived as a bad debt for payment purposes under Medicare or otherwise shift the burden of the reduction or waiver onto Medicare, a State health care program, other payers, or individuals.

(ii) The hospital must offer to reduce or waive the coinsurance or deductible amounts without regard to the reason for admission, the length of stay of the beneficiary, or the diagnostic related group for which the claim for Medicare reimbursement is filed.

(iii) The hospital's offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

(2) If the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under titles V or XIX of the Act to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under title V of the Act, the health care center or facility may reduce or waive the coinsurance or deductible amounts for items or services for which payment may be made in whole or in part under part B of Medicare or a State health care program.

(l) *Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans.* (1) As used in section 1128B of the Act, ''remuneration'' does not include the additional coverage of any item or service offered by a health plan to an enrollee or the reduction of some or all of the enrollee's obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts attributable to items or services covered by the health plan, the Medicare program, or a State health care program, as long as the health plan complies with all of the standards within one of the following two categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, prepaid health plan, or other health plan under contract with CMS or a State health care program and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, it must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract unless otherwise approved by CMS or by a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan or other health plan that has executed a contract or agreement with CMS or with a State health care program to receive payment for enrollees on a reasonable cost or similar basis, it must comply with both of the following two standards—

(A) The health plan must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract or agreement unless otherwise approved by CMS or by a State health care program; and

(B) The health plan must not claim the costs of the increased coverage or the reduced cost-sharing or premium amounts as a bad debt for payment purposes under Medicare or a State health care program or otherwise shift the burden of the increased coverage or reduced cost-sharing or premium amounts to the extent that increased payments are claimed from Medicare or a State health care program.

(2) For purposes of paragraph (l) of this section, the terms—

Contract health care provider means an individual or entity under contract with a health plan to furnish items or services to enrollees who are covered by the health plan, Medicare, or a State health care program.

Enrollee means an individual who has entered into a contractual relationship with a health plan (or on whose behalf an employer, or other private or governmental entity has entered into such a relationship) under which the individual is entitled to receive specified health care items and services, or insurance coverage for such items and

services, in return for payment of a premium or a fee.

Health plan means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity:

(i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by CMS or a State health care program;

(ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations;

(iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or

(iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this definition, and is paid a fee for the administration of the plan which reflects the fair market value of those services.

(m) *Price reductions offered to health plans.* (1) As used in section 1128B of the Act, ''remuneration'' does not include a reduction in price a contract health care provider offers to a health plan in accordance with the terms of a written agreement between the contract health care provider and the health plan for the sole purpose of furnishing to enrollees items or services that are covered by the health plan, Medicare, or a State health care program, as long as both the health plan and contract health care provider comply with all of the applicable standards within one of the following four categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, or prepaid health plan under contract with CMS or a State agency and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, the contract health care provider must not claim payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by CMS or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with CMS or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, and the methodology for computing the payment to the contract health care provider;

(C) The health plan must fully and accurately report, on the applicable cost report or other claim form filed with the Department or the State health care program, the amount it has paid the contract health care provider under the agreement for the covered items and services furnished to enrollees; and

(D) The contract health care provider must not claim payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement except as approved by CMS or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iii) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section and the contract health care provider is not paid on an at-risk, capitated basis, both the

health plan and contract health care provider must comply with all of the following six standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, which party is to file claims or requests for payment with Medicare or the State health care program for such items and services, and the schedule of fees the contract health care provider will charge for furnishing such items and services to enrollees;

(C) The fee schedule contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement, unless a fee increase results directly from a payment update authorized by Medicare or the State health care program;

(D) The party submitting claims or requests for payment from Medicare or the State health care program for items and services furnished in accordance with the agreement must not claim or request payment for amounts in excess of the fee schedule;

(E) The contract health care provider and the health plan must fully and accurately report on any cost report filed with Medicare or a State health care program the fee schedule amounts charged in accordance with the agreement and, upon request, will report to the Medicare or a State health care program the terms of the agreement and the amounts paid in accordance with the agreement; and

(F) The party to the agreement, which does not have the responsibility under the agreement for filing claims or requests for payment, must not claim or request payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iv) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section, and the contract health care provider is paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following five standards—

(A) The term of the agreement between the health plan and the contract health provider must be for not less than one year;

(B) The agreement between the health plan and the contract health provider must specify in advance the covered items and services to be furnished to enrollees and the total amount per enrollee (which may be expressed in a per month or other time period basis) the contract health care provider will be paid by the health plan for furnishing such items and services to enrollees and must set forth any copayments, if any, to be paid by enrollees to the contract health care provider for covered services;

(C) The payment amount contained in the agreement between the health care plan and the contract health care provider must remain in effect throughout the term of the agreement;

(D) The contract health care provider and the health plan must fully and accurately report to the Medicare and State health care program upon request, the terms of the agreement and the amounts paid in accordance with the agreement; and

(E) The contract health care provider must not claim or request payment in any form from the Department, a State health care program or an enrollee (other than copayment amounts described in paragraph (m)(2)(iv)(B) of this section) and the health plan must not pay the contract care provider in excess of the amounts described in paragraph (m)(2)(iv)(B) of this section for items and services covered by the agreement.

(2) For purposes of this paragraph, the terms *contract health care provider*, *enrollee*, and *health plan* have the same meaning as in paragraph (l)(2) of this section.

(n) *Practitioner recruitment.* As used in section 1128B of the Act, ''remuneration'' does not include any payment or exchange of anything of value by an

entity in order to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA for his or her specialty area, as defined in Departmental regulations, that is served by the entity, as long as all of the following nine standards are met—

(1) The arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party.

(2) If a practitioner is leaving an established practice, at least 75 percent of the revenues of the new practice must be generated from new patients not previously seen by the practitioner at his or her former practice.

(3) The benefits are provided by the entity for a period not in excess of 3 years, and the terms of the agreement are not renegotiated during this 3-year period in any substantial aspect; provided, however, that if the HPSA to which the practitioner was recruited ceases to be a HPSA during the term of the written agreement, the payments made under the written agreement will continue to satisfy this paragraph for the duration of the written agreement (not to exceed 3 years).

(4) There is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for the entity as a condition for receiving the benefits; provided, however, that for purposes of this paragraph, the entity may require as a condition for receiving benefits that the practitioner maintain staff privileges at the entity.

(5) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(6) The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

(7) The practitioner agrees to treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(8) At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA or a Medically Underserved Area (MUA) or who are part of a Medically Underserved Population (MUP), all as defined in paragraph (a) of this section.

(9) The payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments or benefits of items or services payable by a Federal health care program.

(o) *Obstetrical malpractice insurance subsidies.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made by a hospital or other entity to another entity that is providing malpractice insurance (including a self-funded entity), where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner (including a certified nurse-midwife as defined in section 1861(gg) of the Act) who engages in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA, as long as all of the following seven standards are met—

(1) The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner, which sets out the payments to be made by the entity, and the terms under which the payments are to be provided.

(2)(i) The practitioner must certify that for the initial coverage period (not to exceed one year) the practitioner has a reasonable basis for believing that at least 75 percent of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance will either—

(A) Reside in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Be part of a MUP, as defined in paragraph (a) of this section.

(ii) Thereafter, for each additional coverage period (not to exceed one year), at least 75 percent of the practitioner's obstetrical patients treated under the prior coverage period (not to exceed one year) must have—

(A) Resided in a HPSA or MUA, as defined in paragraph (a) of this section; or

(B) Been part of a MUP, as defined in paragraph (a) of this section.

(3) There is no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits.

(4) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(5) The amount of payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

(6) The practitioner must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(7) The insurance is a bona fide malpractice insurance policy or program, and the premium, if any, is calculated based on a bona fide assessment of the liability risk covered under the insurance. For purposes of paragraph (o) of this section, *costs of malpractice insurance premiums* means:

(i) For practitioners who engage in obstetrical practice full-time, any costs attributable to malpractice insurance; or

(ii) For practitioners who engage in obstetrical practice on a part-time or sporadic basis, the costs:

(A) Attributable exclusively to the obstetrical portion of the practitioner's malpractice insurance and

(B) Related exclusively to obstetrical services provided in a primary care HPSA.

(p) *Investments in group practices.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to a solo or group practitioner investing in his or her own practice or group practice if the following four standards are met—

(1) The equity interests in the practice or group must be held by licensed health care professionals who practice in the practice or group.

(2) The equity interests must be in the practice or group itself, and not some subdivision of the practice or group.

(3) In the case of group practices, the practice must:

(i) Meet the definition of ''group practice'' in section 1877(h)(4) of the Social Security Act and implementing regulations; and

(ii) Be a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.

(4) Revenues from ancillary services, if any, must be derived from ''in-office ancillary services'' that meet the definition of such term in section 1877(b)(2) of the Act and implementing regulations.

(q) *Cooperative hospital service organizations.* As used in section 1128B of the Act, ''remuneration'' does not include any payment made between a cooperative hospital service organization (CHSO) and its patron-hospital, both of which are described in section 501(e) of the Internal Revenue Code of 1986 and are tax-exempt under section 501(c)(3) of the Internal Revenue Code, where the CHSO is wholly owned by two or more patron-hospitals, as long as the following standards are met—

(1) If the patron-hospital makes a payment to the CHSO, the payment must be for the purpose of paying for the bona fide operating expenses of the CHSO, or

(2) If the CHSO makes a payment to the patron-hospital, the payment must be for the purpose of paying a distribution of net earnings required to be made under section 501(e)(2) of the Internal Revenue Code of 1986.

(r) *Ambulatory surgical centers.* As used in section 1128B of the Act, ''remuneration'' does not include any payment that is a return on an investment interest, such as a dividend or interest income, made to an investor, as long as the investment entity is a certified ambulatory surgical center (ASC) under part 416 of this title, whose operating and recovery room space is dedicated exclusively to the ASC, patients referred to the investment entity by an investor are fully informed of the investor's investment interest, and all of the applicable standards are met within one of the following four categories—

(1) *Surgeon-owned ASCs*—If all of the investors are general surgeons or surgeons engaged in the same surgical specialty, who are in a position to refer patients directly to the entity and perform surgery on such referred patients; surgical group practices (as defined in this paragraph) composed exclusively of such surgeons; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each surgeon investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any surgeon investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(2) *Single-Specialty ASCs*—If all of the investors are physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices (as defined in this paragraph) composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following six standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures (as defined in this paragraph).

(iii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any

pre-operational services rendered) of that investor.

(v) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vi) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(3) *Multi-Specialty ASCs*—If all of the investors are physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients; group practices, as defined in this paragraph, composed exclusively of such physicians; or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to make or influence referrals directly or indirectly to the entity or any of its investors, all of the following seven standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) At least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the physician's performance of procedures (as defined in this paragraph).

(iii) At least one-third of the procedures (as defined in this paragraph) performed by each physician investor for the previous fiscal year or previous 12-month period must be performed at the investment entity.

(iv) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(v) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(4) *Hospital/Physician ASCs*—If at least one investor is a hospital, and all of the remaining investors are physicians who meet the requirements of paragraphs (r)(1), (r)(2) or (r)(3) of this section; group practices (as defined in this paragraph) composed of such physicians; surgical group practices (as defined in this paragraph); or investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors, and are not in a position to refer patients directly or indirectly to the entity or any of its investors, all of the following eight standards must be met—

(i) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity.

(ii) The entity or any investor (or other individual or entity acting on behalf of the entity or any investor) must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest.

(iii) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(iv) The entity and any hospital or physician investor must treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(v) The entity may not use space, including, but not limited to, operating and recovery room space, located in or owned by any hospital investor, unless such space is leased from the hospital in accordance with a lease that complies with all the standards of the space rental safe harbor set forth in paragraph (b) of this section; nor may it use equipment owned by or services provided by the hospital unless such equipment is leased in accordance with a lease that complies with the equipment rental safe harbor set forth in paragraph (c) of this section, and such services are provided in accordance with a contract that complies with the personal services and management contracts safe harbor set forth in paragraph (d) of this section.

(vi) All ancillary services for Federal health care program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal health care programs.

(vii) The hospital may not include on its cost report or any claim for payment from a Federal health care program any costs associated with the ASC (unless such costs are required to be included by a Federal health care program).

(viii) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity.

(5) For purposes of paragraph (r) of this section, *procedures* means any procedure or procedures on the list of Medicare-covered procedures for ambulatory surgical centers in accordance with regulations issued by the Department and *group practice* means a group practice that meets all of the standards of paragraph (p) of this section. *Surgical group practice* means a group practice that meets all of the standards of paragraph (p) of this section and is composed exclusively of surgeons who meet the requirements of paragraph (r)(1) of this section.

(s) *Referral arrangements for specialty services.* As used in section 1128B of the Act, ''remuneration'' does not include any exchange of value among individuals and entities where one party agrees to refer a patient to the other party for the provision of a specialty service payable in whole or in part under Medicare, Medicaid or any other Federal health care programs in return for an agreement on the part of the other party to refer that patient back at a mutually agreed upon time or circumstance as long as the following four standards are met—

(1) The mutually agreed upon time or circumstance for referring the patient back to the originating individual or entity is clinically appropriate.

(2) The service for which the referral is made is not within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral.

(3) The parties receive no payment from each other for the referral and do not share or split a global fee from any Federal health care program in connection with the referred patient.

(4) Unless both parties belong to the same group practice as defined in paragraph (p) of this section, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payors or the patient compensating the parties for the services they each have furnished to the patient.

(t) *Price reductions offered to eligible managed care organizations.* (1) As used in section 1128(B) of the Act, ''remuneration'' does not include any payment between:

(i) An eligible managed care organization and any first tier contractor for providing or arranging for items or services, as long as the following three standards are met—

(A) The eligible managed care organization and the first tier contractor have an agreement that:

(*1*) Is set out in writing and signed by both parties;

(*2*) Specifies the items and services covered by the agreement;

(*3*) Is for a period of at least one year; and

(*4*) Specifies that the first tier contractor cannot claim payment in any form directly or indirectly from a Federal health care program for items or services covered under the agreement, except for:

(*i*) HMOs and competitive medical plans with cost-based contracts under section 1876 of the Act where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program;

(*ii*) Federally qualified HMOs without a contract under sections 1854 or 1876 of the Act, where the agreement with the eligible managed care organization sets out the arrangements in accordance with which the first tier contractor is billing the Federal health care program; or

(*iii*) First tier contractors that are Federally qualified health centers that claim supplemental payments from a Federal health care program.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis.

(C) Neither party to the agreement shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor or between two downstream contractors to provide or arrange for items or services, as long as the following four standards are met—

(A) The parties have an agreement that:

(*1*) Is set out in writing and signed by both parties;

(*2*) Specifies the items and services covered by the agreement;

(*3*) Is for a period of at least one year; and

(*4*) Specifies that the party providing the items or services cannot claim payment in any form from a Federal health care program for items or services covered under the agreement.

(B) In establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the agreement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis.

(C) Neither party shifts the financial burden of the agreement to the extent that increased payments are claimed from a Federal health care program.

(D) The agreement between the eligible managed care organization and first tier contractor covering the items or services that are covered by the agreement between the parties does not involve:

(*1*) A Federally qualified health center receiving supplemental payments;

(*2*) A HMO or CMP with a cost-based contract under section 1876 of the Act; or

(*3*) A Federally qualified HMO, unless the items or services are covered by a risk based contract under sections 1854 or 1876 of the Act.

(2) For purposes of this paragraph, the following terms are defined as follows:

(i) *Downstream contractor* means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between an eligible managed care organization and the first tier contractor.

(ii) *Eligible managed care organization*[1] means—

(A) A HMO or CMP with a risk or cost based contract in accordance with section 1876 of the Act;

(B) Any Medicare Part C health plan that receives a capitated payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by CMS under section 1854 of the Act;

(C) Medicaid managed care organizations as defined in section 1903(m)(1)(A)

[1] The eligible managed care organizations in paragraphs (u)(2)(ii)(A)–(F) of this section are only eligible with respect to items or services covered by the contracts specified in those paragraphs.

that provide or arrange for items or services for Medicaid enrollees under a contract in accordance with section 1903(m) of the Act (except for fee-for-service plans or medical savings accounts);

(D) Any other health plans that provide or arrange for items and services for Medicaid enrollees in accordance with a risk-based contract with a State agency subject to the upper payment limits in §447.361 of this title or an equivalent payment cap approved by the Secretary;

(E) Programs For All Inclusive Care For The Elderly (PACE) under sections 1894 and 1934 of the Act, except for for-profit demonstrations under sections 4801(h) and 4802(h) of Pub. L. 105–33; or

(F) A Federally qualified HMO.

(iii) *First tier contractor* means an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services.

(iv) *Items and services* means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (*e.g.,* case management), utilization review and quality assurance. Marketing and other pre-enrollment activities are not ''items or services'' for purposes of this section.

(u) *Price reductions offered by contractors with substantial financial risk to managed care organizations.* (1) As used in section 1128(B) of the Act, ''remuneration'' does not include any payment between:

(i) A qualified managed care plan and a first tier contractor for providing or arranging for items or services, where the following five standards are met—

(A) The agreement between the qualified managed care plan and first tier contractor must:

(*1*) Be in writing and signed by the parties;

(*2*) Specify the items and services covered by the agreement;

(*3*) Be for a period of a least one year;

(*4*) Require participation in a quality assurance program that promotes the coordination of care, protects against underutilization and specifies patient goals, including measurable outcomes where appropriate; and

(*5*) Specify a methodology for determining payment that is commercially reasonable and consistent with fair market value established in an arms-length transaction and includes the intervals at which payments will be made and the formula for calculating incentives and penalties, if any.

(B) If a first tier contractor has an investment interest in a qualified managed care plan, the investment interest must meet the criteria of paragraph (a)(1) of this section.

(C) The first tier contractor must have substantial financial risk for the cost or utilization of services it is obligated to provide through one of the following four payment methodologies:

(*1*) A periodic fixed payment per patient that does not take into account the dates services are provided, the frequency of services, or the extent or kind of services provided;

(*2*) Percentage of premium;

(*3*) Inpatient Federal health care program diagnosis-related groups (DRGs) (other than those for psychiatric services);

(*4*) Bonus and withhold arrangements, provided—

(*i*) The target payment for first tier contractors that are individuals or non-institutional providers is at least 20 percent greater than the minimum payment, and for first tier contractors that are institutional providers, i.e., hospitals and nursing homes, is at least 10 percent greater than the minimum payment;

(*ii*) The amount at risk, *i.e.,* the bonus or withhold, is earned by a first tier contractor in direct proportion to the ratio of the contractor's actual utilization to its target utilization;

(*iii*) In calculating the percentage in accordance with paragraph (u)(1)(i)(C)(*4*)(*i*) of this section, both the target payment amount and the minimum payment amount include any performance bonus, *e.g.,* payments for timely submission of paperwork, continuing medical education, meeting attendance, etc., at a level achieved by 75 percent of the first tier contractors who are eligible for such payments;

(*iv*) Payment amounts, including any bonus or withhold amounts, are reasonable given the historical utilization patterns and costs for the same or comparable populations in similar managed care arrangements; and

(*v*) Alternatively, for a first tier contractor that is a physician, the qualified managed care plan has placed the physician at risk for referral services in an amount that exceeds the substantial financial risk threshold set forth in 42 CFR 417.479(f) and the arrangement is in compliance with the stop-loss and beneficiary survey requirements of 42 CFR 417.479(g).

(D) Payments for items and services reimbursable by Federal health care program must comply with the following two standards—

(*1*) The qualified managed care plan (or in the case of a self-funded employer plan that contracts with a qualified managed care plan to provide administrative services, the self-funded employer plan) must submit the claims directly to the Federal health care program, in accordance with a valid reassignment agreement, for items or services reimbursed by the Federal health care program. (Notwithstanding the foregoing, inpatient hospital services, other than psychiatric services, will be deemed to comply if the hospital is reimbursed by a Federal health care program under a DRG methodology.)

(*2*) Payments to first tier contractors and any downstream contractors for providing or arranging for items or services reimbursed by a Federal health care program must be identical to payment arrangements to or between such parties for the same items or services provided to other beneficiaries with similar health status, provided that such payments may be adjusted where the adjustments are related to utilization patterns or costs of providing items or services to the relevant population.

(E) In establishing the terms of an arrangement—

(*1*) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(*2*) Neither party to the arrangement shifts the financial burden of such arrangement to the extent that increased payments are claimed from a Federal health care program.

(ii) A first tier contractor and a downstream contractor, or between downstream contractors, to provide or arrange for items or services, as long as the following three standards are met—

(A) Both parties are being paid for the provision or arrangement of items or services in accordance with one of the payment methodologies set out in paragraph (u)(1)(i)(C) of this section;

(B) Payment arrangements for items and services reimbursable by a Federal health care program comply with paragraph (u)(1)(i)(D) of this section; and

(C) In establishing the terms of an arrangement—

(*1*) Neither party gives or receives remuneration in return for or to induce the provision or acceptance of business (other than business covered by the arrangement) for which payment may be made in whole or in part by a Federal health care program on a fee-for-service or cost basis; and

(*2*) Neither party to the arrangement shifts the financial burden of the arrangement to the extent that increased payments are claimed from a Federal health care program.

(2) For purposes of this paragraph, the following terms are defined as follows:

(i) *Downstream contractor* means an individual or entity that has a subcontract directly or indirectly with a first tier contractor for the provision or arrangement of items or services that are covered by an agreement between a qualified managed care plan and the first tier contractor.

(ii) *First tier contractor* means an individual or entity that has a contract directly with a qualified managed care plan to provide or arrange for items or services.

(iii) *Is obligated to provide* for a contractor refers to items or services:

(A) Provided directly by an individual or entity and its employees;

(B) For which an individual or entity is financially responsible, but which

are provided by downstream contractors;

(C) For which an individual or entity makes referrals or arrangements; or

(D) For which an individual or entity receives financial incentives based on its own, its provider group's, or its qualified managed care plan's performance (or combination thereof).

(iv) *Items and services* means health care items, devices, supplies or services or those services reasonably related to the provision of health care items, devices, supplies or services including, but not limited to, non-emergency transportation, patient education, attendant services, social services (e.g., case management), utilization review and quality assurance. Marketing or other pre-enrollment activities are not ''items or services'' for purposes of this definition in this paragraph.

(v) *Minimum payment* is the guaranteed amount that a provider is entitled to receive under an agreement with a first tier or downstream contractor or a qualified managed care plan.

(vi) *Qualified managed care plan* means a health plan as defined in paragraph (l)(2) of this section that:

(A) Provides a comprehensive range of health services;

(B) Provides or arranges for—

(*1*) Reasonable utilization goals to avoid inappropriate utilization;

(*2*) An operational utilization review program;

(*3*) A quality assurance program that promotes the coordination of care, protects against underutilization, and specifies patient goals, including measurable outcomes where appropriate;

(*4*) Grievance and hearing procedures;

(*5*) Protection of enrollees from incurring financial liability other than copayments and deductibles; and

(*6*) Treatment for Federal health care program beneficiaries that is not different than treatment for other enrollees because of their status as Federal health care program beneficiaries; and

(C) Covers a beneficiary population of which either—

(*1*) No more than 10 percent are Medicare beneficiaries, not including persons for whom a Federal health care program is the secondary payer; or

(*2*) No more than 50 percent are Medicare beneficiaries (not including persons for whom a Federal health care program is the secondary payer), provided that payment of premiums is on a periodic basis that does not take into account the dates services are rendered, the frequency of services, or the extent or kind of services rendered, and provided further that such periodic payments for the non-Federal health care program beneficiaries do not take into account the number of Federal health care program fee-for-service beneficiaries covered by the agreement or the amount of services generated by such beneficiaries.

(vii) *Target payment* means the fair market value payment established through arms length negotiations that will be earned by an individual or entity that:

(A) Is dependent on the individual or entity's meeting a utilization target or range of utilization targets that are set consistent with historical utilization rates for the same or comparable populations in similar managed care arrangements, whether based on its own, its provider group's or the qualified managed care plan's utilization (or a combination thereof); and

(B) Does not include any bonus or fees that the individual or entity may earn from exceeding the utilization target.

(v) *Ambulance replenishing.* (1) As used in section 1128B of the Act, ''remuneration'' does not include any gift or transfer of drugs or medical supplies (including linens) by a hospital or other receiving facility to an ambulance provider for the purpose of replenishing comparable drugs or medical supplies (including linens) used by the ambulance provider (or a first responder) in connection with the transport of a patient by ambulance to the hospital or other receiving facility if all of the standards in paragraph (v)(2) of this section are satisfied *and* all of the applicable standards in *either* paragraph (v)(3)(i), (v)(3)(ii) or (v)(3)(iii) of this section are satisfied. However, to qualify under paragraph (v), the ambulance that is replenished must be used to provide emergency ambulance services an average of three times per week, as measured over a reasonable period of time. Drugs and medical supplies (including linens) initially used

by a first responder and replenished at the scene of the illness or injury by the ambulance provider that transports the patient to the hospital or other receiving facility will be deemed to have been used by the ambulance provider.

(2) To qualify under paragraph (v) of this section, the ambulance replenishing arrangement must satisfy *all* of the following four conditions—

(i)(A) Under no circumstances may the ambulance provider (or first responder) and the receiving facility both bill for the same replenished drug or supply. Replenished drugs or supplies may only be billed (including claiming bad debt) to a Federal health care program by either the ambulance provider (or first responder) or the receiving facility.

(B) All billing or claims submission by the receiving facility, ambulance provider or first responder for replenished drugs and medical supplies used in connection with the transport of a Federal health care program beneficiary must comply with all applicable Federal health care program payment and coverage rules and regulations.

(C) Compliance with paragraph (v)(2)(i)(B) of this section will be determined separately for the receiving facility and the ambulance provider (and first responder, if any), so long as the receiving facility, ambulance provider (or first responder) refrains from doing anything that would impede the other party or parties from meeting their obligations under paragraph (v)(2)(i)(B).

(ii)(A) The receiving facility or ambulance provider, or both, must

(*1*) Maintain records of the replenished drugs and medical supplies and the patient transport to which the replenished drugs and medical supplies related;

(*2*) Provide a copy of such records to the other party within a reasonable time (unless the other party is separately maintaining records of the replenished drugs and medical supplies); and

(*3*) Make those records available to the Secretary promptly upon request.

(B) A pre-hospital care report (including, but not limited to, a trip sheet, patient care report or patient encounter report) prepared by the ambulance provider and filed with the receiving facility will meet the requirements of paragraph (v)(2)(ii)(A) of this section, provided that it documents the specific type and amount of medical supplies and drugs used on the patient and subsequently replenished.

(C) For purposes of paragraph (v)(2)(ii) of this section, documentation may be maintained and, if required, filed with the other party in hard copy or electronically. If a replenishing arrangement includes linens, documentation need not be maintained for their exchange. If documentation is not maintained for the exchange of linens, the receiving facility will be presumed to have provided an exchange of comparable clean linens for soiled linens for each ambulance transport of a patient to the receiving facility. Records required under paragraph (v)(2)(ii)(A) of this section must be maintained for 5 years.

(iii) The replenishing arrangement must not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program (other than the referral of the particular patient to whom the replenished drugs and medical supplies were furnished).

(iv) The receiving facility and the ambulance provider otherwise comply with all Federal, State, and local laws regulating ambulance services, including, but not limited to, emergency services, and the provision of drugs and medical supplies, including, but not limited to, laws relating to the handling of controlled substances.

(3) To qualify under paragraph (v) of this section, the arrangement must satisfy *all* of the standards in *one* of the following three categories:

(i) *General replenishing.* (A) The receiving facility must replenish medical supplies or drugs on an equal basis for all ambulance providers that bring patients to the receiving facility in any one of the categories described in paragraph (v)(3)(i)(A)(*1*), (*2*), or (*3*) of this section. A receiving facility may offer replenishing to one or more of the categories and may offer different replenishing arrangements to different categories, so long as the replenishing is

conducted uniformly within each category. For example, a receiving facility may offer to replenish a broader array of drugs or supplies for ambulance providers that do no not charge for their services than for ambulance providers that charge for their services. Within each category, the receiving facility may limit its replenishing arrangements to the replenishing of emergency ambulance transports only. A receiving facility may offer replenishing to one or more of the categories—

(*1*) All ambulance providers that do not bill any patient or insurer (including Federal health care programs) for ambulance services, regardless of the payor or the patient's ability to pay (i.e., ambulance providers, such as volunteer companies, that provide ambulance services without charge to any person or entity);

(*2*) All not-for-profit and State or local government ambulance service providers (including, but not limited to, municipal and volunteer ambulance services providers); or

(*3*) All ambulance service providers.

(B)(*1*) The replenishing arrangement must be conducted in an open and public manner. A replenishing arrangement will be considered to be conducted in an open and public manner if one of the following two conditions are satisfied:

(*i*) A written disclosure of the replenishing program is posted conspicuously in the receiving facility's emergency room or other location where the ambulance providers deliver patients and copies are made available upon request to ambulance providers, Government representatives, and members of the public (subject to reasonable photocopying charges). The written disclosure can take any reasonable form and should include the category of ambulance service providers that qualifies for replenishment; the drugs or medical supplies included in the replenishment program; and the procedures for documenting the replenishment. A sample disclosure form is included in Appendix A to subpart C of this part for illustrative purposes only. No written contracts between the parties are required for purposes of paragraph (v)(3)(i)(B)(*1*)(*i*) of this section; or

(*ii*) The replenishment arrangement operates in accordance with a plan or protocol of general application promulgated by an Emergency Medical Services (EMS) Council or comparable entity, agency or organization, provided a copy of the plan or protocol is available upon request to ambulance providers, Government representatives and members of the public (subject to reasonable photocopying charges). While parties are encouraged to participate in collaborative, comprehensive, community-wide EMS systems to improve the delivery of EMS in their local communities, nothing in this paragraph shall be construed as requiring the involvement of such organizations or the development or implementation of ambulance replenishment plans or protocols by such organizations.

(*2*) Nothing in this paragraph (v)(3)(i) shall be construed as requiring disclosure of confidential proprietary or financial information related to the replenishing arrangement (including, but not limited to, information about cost, pricing or the volume of replenished drugs or supplies) to ambulance providers or members of the general public.

(ii) *Fair market value replenishing.* (A) Except as otherwise provided in paragraph (v)(3)(ii)(B) of this section, the ambulance provider must pay the receiving facility fair market value, based on an arms-length transaction, for replenished medical supplies; and

(B) If payment is not made at the same time as the replenishing of the medical supplies, the receiving facility and the ambulance provider must make commercially reasonable payment arrangements in advance.

(iii) *Government mandated replenishing.* The replenishing arrangement is undertaken in accordance with a State or local statute, ordinance, regulation or binding protocol that requires hospitals or receiving facilities in the area subject to such requirement to replenish ambulances that deliver patients to the hospital with drugs or medical supplies (including linens) that are used during the transport of that patient.

(4) For purposes of paragraph (v) of this section—

(i) A *receiving facility* is a hospital or other facility that provides emergency medical services.

(ii) An *ambulance provider* is a provider or supplier of ambulance transport services that provides emergency ambulance services. The term does not include a provider of ambulance transport services that provides only non-emergency transport services.

(iii) A *first responder* includes, but is not limited to, a fire department, paramedic service or search and rescue squad that responds to an emergency call (through 9–1–1 or other emergency access number) and treats the patient, but does not transport the patient to the hospital or other receiving facility.

(iv) An *emergency ambulance service* is a transport by ambulance initiated as a result of a call through 9–1–1 or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient and available at the receiving facility.

(v) *Medical supplies* includes linens, unless otherwise provided.

[57 FR 3330, Jan. 29, 1992, as amended at 57 FR 52729, Nov. 5, 1992; 61 FR 2135, Jan. 25, 1996; 64 FR 63513, Nov. 19, 1999; 64 FR 63551, Nov. 19, 1999; 64 FR 71317, Dec. 21, 1999; 66 FR 62989, Dec. 4, 2001; 66 FR 63749, Dec. 10, 2001; 67 FR 11933, Mar. 18, 2002]

EFFECTIVE DATE NOTE: At 71 FR 45136, Aug. 8, 2006, §1001.952 was amended by republishing the introductory text, by adding and reserving paragraph (w), and by adding new paragraphs (x) and (y), effective Oct. 10, 2006. For the convenience of the user, the added text is set forth as follows:

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

* * * * *

(x) *Electronic prescribing items and services.* As used in section 1128B of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice to a prescribing health care professional who is a member of the group practice; and

(iii) A PDP sponsor or MA organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.

(4) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.

(5) Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(6) Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor's cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor (or affiliated parties). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

NOTE TO PARAGRAPH (X): For purposes of paragraph (x) of this section, *group practice* shall have the meaning set forth at 42 CFR 411.352; *member of the group practice* shall mean all persons covered by the definition of

''member of the group or member of a group practice'' at 42 CFR 411.351, as well as other prescribing health care professionals who are owners or employees of the group practice; *prescribing health care professional* shall mean a physician or other health care professional licensed to prescribe drugs in the State in which the drugs are dispensed; *PDP sponsor* or *MA organization* shall have the meanings set forth at 42 CFR 423.4 and 422.2, respectively; *prescription information* shall mean information about prescriptions for drugs or for any other item or service normally accomplished through a written prescription; and *electronic health record* shall mean a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

(y) *Electronic health records items and services.* As used in section 1128B of the Act, ''remuneration'' does not include nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:

(1) The items and services are provided to an individual or entity engaged in the delivery of health care by—

(i) An individual or entity that provides services covered by a Federal health care program and submits claims or requests for payment, either directly or through reassignment, to the Federal health care program; or

(ii) A health plan.

(2) The software is interoperable at the time it is provided to the recipient. For purposes of this subparagraph, software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to the date it is provided to the recipient.

(3) The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems.

(4) Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

(5) Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For the purposes of this paragraph (y)(5), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:

(i) The determination is based on the total number of prescriptions written by the recipient (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a Federal health care program);

(ii) The determination is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or total relative value units);

(iii) The determination is based on the total number of hours that the recipient practices medicine;

(iv) The determination is based on the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);

(v) The determination is based on whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff;

(vi) The determination is based on the level of uncompensated care provided by the recipient; or

(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

(6) The arrangement is set forth in a written agreement that —

(i) Is signed by the parties;

(ii) Specifies the items and services being provided, the donor's cost of those items and services, and the amount of the recipient's contribution; and

(iii) Covers all of the electronic health records items and services to be provided by the donor (or any affiliate). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.

(7) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

(8) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.

(9) The items and services do not include staffing of the recipient's office and are not used primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations.

(10) The electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(11) Before receipt of the items and services, the recipient pays 15 percent of the donor's cost for the items and services. The donor (or any affiliated individual or entity) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services.

(12) The donor does not shift the costs of the items or services to any Federal health care program.

(13) The transfer of the items and services occurs, and all conditions in this paragraph (y) have been satisfied, on or before December 31, 2013.

NOTE TO PARAGRAPH (Y): For purposes of paragraph (y) of this section, *health plan* shall have the meaning set forth at § 1001.952(1)(2); *interoperable* shall mean able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered; and *electronic health record* shall mean a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

§ 1001.1001 Exclusion of entities owned or controlled by a sanctioned person.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an entity if:

(i) A person with a relationship with such entity—

(A) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b) (1), (2) or (3) of the Act;

(B) Has had civil money penalties or assessments imposed under section 1128A of the Act; or

(C) Has been excluded from participation in Medicare or any of the State health care programs, and

(ii) Such a person—

(A)(*1*) Has a direct or indirect ownership interest (or any combination thereof) of 5 percent or more in the entity;

(*2*) Is the owner of a whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, in which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(*3*) Is an officer or director of the entity, if the entity is organized as a corporation;

(*4*) Is partner in the entity, if the entity is organized as a partnership;

(*5*) Is an agent of the entity; or

(*6*) Is a managing employee, that is, an individual (including a general manager, business manager, administrator or director) who exercises operational or managerial control over the entity or part thereof, or directly or indirectly conducts the day-to-day operations of the entity or part thereof, or

(B) Was formerly described in paragraph (a)(1)(ii)(A) of this section, but is no longer so described because of a transfer of ownership or control interest to an immediate family member or a member of the person's household as defined in paragraph (a)(2) of this section, in anticipation of or following a conviction, assessment of a CMP, or imposition of an exclusion.

(2) For purposes of this section, the term:

Agent means any person who has express or implied authority to obligate or act on behalf of an entity.

Immediate family member means, a person's husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild.

Indirect ownership interest includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue. (For example, an individual has a 10 percent ownership interest in the entity at issue if he or she has a 20 percent ownership interest in a corporation that wholly owns a subsidiary that is a 50 percent owner of the entity in issue.)

Member of household means, with respect to a person, any individual with

whom they are sharing a common abode as part of a single family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of household.

Ownership interest means an interest in:

(i) The capital, the stock or the profits of the entity, or

(ii) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

(b) *Length of exclusion.* (1) Except as provided in §1001.3002(c), exclusions under this section will be for the same period as that of the individual whose relationship with the entity is the basis for this exclusion, if the individual has been or is being excluded.

(2) If the individual was not excluded, the length of the entity's exclusion will be determined by considering the factors that would have been considered if the individual had been excluded.

(3) An entity excluded under this section may apply for reinstatement at any time in accordance with the procedures set forth in §1001.3001(a)(2).

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39427, July 22, 1999]

§1001.1051 Exclusion of individuals with ownership or control interest in sanctioned entities.

(a) *Circumstance for exclusion.* The OIG may exclude any individual who—

(1) Has a direct or indirect ownership or control interest in a sanctioned entity, and who knows or should know (as defined in section 1128A(i)(6) of the Act) of the action constituting the basis for the conviction or exclusion set forth in paragraph (b) of this section; or

(2) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such an entity.

(b) For purposes of paragraph (a) of this section, the term ''sanctioned entity'' means an entity that—

(1) Has been convicted of any offense described in §§1001.101 through 1001.401 of this part; or

(2) Has been terminated or excluded from participation in Medicare, Medicaid and all other Federal health care programs.

(c) *Length of exclusion.* (1) If the entity has been excluded, the length of the individual's exclusion will be for the same period as that of the sanctioned entity with which the individual has the prohibited relationship.

(2) If the entity was not excluded, the length of the individual's exclusion will be determined by considering the factors that would have been considered if the entity had been excluded.

(3) An individual excluded under this section may apply for reinstatement in accordance with the procedures set forth in §1001.3001.

[63 FR 46689, Sept. 2, 1998]

§1001.1101 Failure to disclose certain information.

(a) *Circumstance for exclusion.* The OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by section 1124, 1124A or 1126 of the Act, and by part 455, subpart B and part 420, subpart C of this title.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where full and accurate, or complete, disclosure was not made;

(2) The significance of the undisclosed information;

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(4) Any other facts that bear on the nature or seriousness of the conduct;

(5) The availability of alternative sources of the type of health care services provided by the entity; and

(6) The extent to which the entity knew that the disclosures made were not full or accurate.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§1001.1201 Failure to provide payment information.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that furnishes items or services for which payment may be made under Medicare or any of the State health care programs and that:

(1) Fails to provide such information as is necessary to determine whether such payments are or were due and the amounts thereof, or

(2) Has refused to permit such examination and duplication of its records as may be necessary to verify such information.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where information was not provided;

(2) The circumstances under which such information was not provided;

(3) The amount of the payments at issue;

(4) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(5) The availability of alternative sources of the type of health care items or services provided by the individual or entity.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§ 1001.1301 Failure to grant immediate access.

(a) *Circumstance for exclusion.* (1) The OIG may exclude any individual or entity that fails to grant immediate access upon reasonable request to—

(i) The Secretary, a State survey agency or other authorized entity for the purpose of determining, in accordance with section 1864(a) of the Act, whether—

(A) An institution is a hospital or skilled nursing facility;

(B) An agency is a home health agency;

(C) An agency is a hospice program;

(D) A facility is a rural health clinic as defined in section 1861(aa)(2) of the Act, or a comprehensive outpatient rehabilitation facility as defined in section 1861(cc)(2) of the Act;

(E) A laboratory is meeting the requirements of section 1861(s) (15) and (16) of the Act, and section 353(f) of the Public Health Service Act;

(F) A clinic, rehabilitation agency or public health agency is meeting the requirements of section 1861(p)(4) (A) or (B) of the Act;

(G) An ambulatory surgical center is meeting the standards specified under section 1832(a)(2)(F)(i) of the Act;

(H) A portable x-ray unit is meeting the requirements of section 1861(s)(3) of the Act;

(I) A screening mammography service is meeting the requirements of section 1834(c)(3) of the Act;

(J) An end-stage renal disease facility is meeting the requirements of section 1881(b) of the Act;

(K) A physical therapist in independent practice is meeting the requirements of section 1861(p) of the Act;

(L) An occupational therapist in independent practice is meeting the requirements of section 1861(g) of the Act;

(M) An organ procurement organization meets the requirements of section 1138(b) of the Act; or.

(N) A rural primary care hospital meets the requirements of section 1820(i)(2) of the Act;

(ii) The Secretary, a State survey agency or other authorized entity to perform the reviews and surveys required under State plans in accordance with sections 1902(a)(26) (relating to inpatient mental hospital services), 1902(a)(31) (relating to intermediate care facilities for the mentally retarded), 1919(g) (relating to nursing facilities), 1929(i) (relating to providers of home and community care and community care settings), 1902(a)(33) and 1903(g) of the Act;

(iii) The OIG for the purposes of reviewing records, documents and other data necessary to the performance of the Inspector General's statutory functions; or

(iv) A State Medicaid fraud control unit for the purpose of conducting its activities.

(2) For purposes of paragraphs (a)(1)(i) and (a)(1)(ii) of this section, the term—

Failure to grant immediate access means the failure to grant access at the time of a reasonable request or to provide a compelling reason why access may not be granted.

Reasonable request means a written request made by a properly identified agent of the Secretary, of a State survey agency or of another authorized

entity, during hours that the facility, agency or institution is open for business.

The request will include a statement of the authority for the request, the rights of the entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the penalties for failure to comply, including when the exclusion will take effect.

(3) For purposes of paragraphs (a)(1)(iii) and (a)(1)(iv) of this section, the term—

Failure to grant immediate access means:

(i) Except where the OIG or State Medicaid fraud control unit reasonably believes that requested documents are about to be altered or destroyed, the failure to produce or make available for inspection and copying requested records upon reasonable request, or to provide a compelling reason why they cannot be produced, within 24 hours of such request;

(ii) Where the OIG or State Medicaid fraud control unit has reason to believe that requested documents are about to be altered or destroyed, the failure to provide access to requested records at the time the request is made.

Reasonable request means a written request for documents, signed by a designated representative of the OIG or the State Medicaid fraud control unit, and made by a properly identified agent of the OIG or a State Medicaid fraud control unit during reasonable business hours, where there is information to suggest that the individual or entity has violated statutory or regulatory requirements under titles V, XI, XVIII, XIX or XX of the Act. The request will include a statement of the authority for the request, the rights of the individual or entity in responding to the request, the definition of *reasonable request* and *immediate access*, and the effective date, length, and scope and effect of the exclusion that would be imposed for failure to comply with the request, and the earliest date that a request for reinstatement would be considered.

(4) Nothing in this section shall in any way limit access otherwise authorized under State or Federal law.

(b) *Length of exclusion.* (1) An exclusion of an individual under this section may be for a period equal to the sum of:

(i) The length of the period during which the immediate access was not granted, and

(ii) An additional period of up to 90 days.

(2) The exclusion of an entity may be for a longer period than the period in which immediate access was not granted based on consideration of the following factors—

(i) The impact of the failure to grant the requested immediate access on Medicare or any of the State health care programs, beneficiaries or the public;

(ii) The circumstances under which such access was refused;

(iii) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

(iv) Whether the entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral).

(3) For purposes of paragraphs (b)(1) and (b)(2) of this section, the length of the period in which immediate access was not granted will be measured from the time the request is made, or from the time by which access was required to be granted, whichever is later.

(c) The exclusion will be effective as of the date immediate access was not granted.

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 40753, July 30, 1993; 63 FR 46689, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

§ 1001.1401 Violations of PPS corrective action.

(a) *Circumstance for exclusion.* The OIG may exclude any hospital that CMS determines has failed substantially to comply with a corrective action plan required by CMS under section 1886(f)(2)(B) of the Act.

(b) *Length of exclusion.* The following factors will be considered in determining the length of exclusion under this section—

(1) The impact of the hospital's failure to comply on Medicare, Medicaid or any of the other Federal health care programs, program beneficiaries or other individuals;

(2) The circumstances under which the failure occurred;

(3) The nature of the failure to comply;

(4) The impact of the exclusion on Medicare, Medicaid or any of the other Federal health care programs, beneficiaries or the public; and

(5) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral).

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

§ 1001.1501 Default of health education loan or scholarship obligations.

(a) *Circumstance for exclusion.* (1) Except as provided in paragraph (a)(4) of this section, the OIG may exclude any individual that the Public Health Service (PHS) determines is in default on repayments of scholarship obligations or loans in connection with health professions education made or secured in whole or in part by the Secretary.

(2) Before imposing an exclusion in accordance with paragraph (a)(1) of this section, the OIG must determine that PHS has taken all reasonable administrative steps to secure repayment of the loans or obligations. If PHS has offered a Medicare offset arrangement as required by section 1892 of the Act, the OIG will find that all reasonable steps have been taken.

(3) The OIG will take into account access of beneficiaries to physicians' services for which payment may be made under Medicare, Medicaid or other Federal health care programs in determining whether to impose an exclusion.

(4) The OIG will not exclude a physician who is the sole community physician or the sole source of essential specialized services in a community if a State requests that the physician not be excluded.

(b) *Length of exclusion.* The individual will be excluded until such time as PHS notifies the OIG that the default has been cured or that there is no longer an outstanding debt. Upon such notice, the OIG will inform the individual of his or her right to apply for reinstatement.

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39427, July 22, 1999; 67 FR 11935, Mar. 18, 2002]

§ 1001.1601 Violations of the limitations on physician charges.

(a) *Circumstance for exclusion.* (1) The OIG may exclude a physician whom it determines—

(i) Is a non-participating physician under section 1842(j) of the Act;

(ii) Furnished services to a beneficiary;

(iii) Knowingly and willfully billed—

(A) On a repeated basis for such services actual charges in excess of the maximum allowable actual charge determined in accordance with section 1842(j)(1)(C) of the Act for the period January 1, 1987 through December 31, 1990, or

(B) Individuals enrolled under part B of title XVIII of the Act during the statutory freeze for actual charges in excess of such physician's actual charges determined in accordance with section 1842(j)(1)(A) of the Act for the period July 1, 1984 to December 31, 1986; and''

(iv) Is not the sole community physician or sole source of essential specialized services in the community.

(2) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(b) *Length of exclusion.* (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of services for which the physician billed in excess of the maximum allowable charges;

(ii) The number of beneficiaries for whom services were billed in excess of the maximum allowable charges;

(iii) The amount of the charges that were in excess of the maximum allowable charges;

(iv) Whether the physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(v) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§ 1001.1701 Billing for services of assistant at surgery during cataract operations.

(a) Circumstance for exclusion. The OIG may exclude a physician whom it determines—

(1) Has knowingly and willfully presented or caused to be presented a claim, or billed an individual enrolled under Part B of the Medicare program (or his or her representative) for:

(i) Services of an assistant at surgery during a cataract operation, or

(ii) Charges that include a charge for an assistant at surgery during a cataract operation;

(2) Has not obtained prior approval for the use of such assistant from the appropriate Utilization and Quality Control Quality Improvement Organization (QIO) or Medicare carrier; and

(3) Is not the sole community physician or sole source of essential specialized services in the community.

(b) The OIG will take into account access of beneficiaries to physicians' services for which Medicare payment may be made in determining whether to impose an exclusion.

(c) Length of exclusion. (1) In determining the length of an exclusion in accordance with this section, the OIG will consider the following factors—

(i) The number of instances for which claims were submitted or beneficiaries were billed for unapproved use of assistants during cataract operations;

(ii) The amount of the claims or bills presented;

(iii) The circumstances under which the claims or bills were made, including whether the services were medically necessary;

(iv) Whether approval for the use of an assistant was requested from the QIO or carrier;

(v) Whether the physician has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral); and

(vi) The availability of alternative sources of the type of health care items or services furnished by the physician.

(2) The period of exclusion may not exceed 5 years.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

APPENDIX A TO SUBPART C OF PART 1001

The following is a sample written disclosure for purposes of satisfying the requirements of §1001.952(v)(3)(i)(B)(*1*)(*i*) of this part. This form is for illustrative purposes only; parties may, but are not required to, adapt this sample written disclosure form.

NOTICE OF AMBULANCE RESTOCKING PROGRAM

Hospital X offers the following ambulance restocking program:

1. We will restock all ambulance providers (other than ambulance providers that do not provide emergency services) that bring patients to Hospital X [or to a subpart of Hospital X, such as the emergency room] in the following category or categories: [insert description of category of ambulances to be restocked, i.e., all ambulance providers, all ambulance providers that do not charge patients or insurers for their services, or all nonprofit and Government ambulance providers]. [Optional: We only offer restocking of emergency transports.]

2. The restocking will include the following drugs and medical supplies, and linens, used for patient prior to delivery of the patient to Hospital X: [insert description of drugs and medical supplies, and linens to be restocked].

3. The ambulance providers [will/will not] be required to pay for the restocked drugs and medical supplies, and linens.

4. The restocked drugs and medical supplies, and linens, must be documented as follows: [insert description consistent with the documentation requirements described in §1001.952(v). By way of example only, documentation may be by a patient care report filed with the receiving facility within 24 hours of delivery of the patient that records the name of the patient, the date of the transport, and the relevant drugs and medical supplies.]

5. This restocking program does not apply to the restocking of ambulances that only provide non-emergency services or to the general stocking of an ambulance provider's inventory.

6. To ensure that Hospital X does not bill any Federal health care program for restocked drugs or supplies for which a participating ambulance provider bills or is eligible to bill, all participating ambulance providers must notify Hospital X if they intend to submit claims for restocked drugs or supplies to any Federal health care program. Participating ambulance providers must agree to

work with Hospital X to ensure that only one party bills for a particular restocked drug or supply.

7. All participants in this ambulance restocking arrangement that bill Federal health care programs for restocked drugs or supplies must comply with all applicable Federal program billing and claims filing rules and regulations.

8. For further information about our restocking program or to obtain a copy of this notice, please contact [name] at [telephone number].

Dated:_____

/s/_____
Appropriate officer or official

[66 FR 62991, Dec. 4, 2001]

Subpart D—Waivers and Effect of Exclusion

§ 1001.1801 Waivers of exclusions.

(a) The OIG has the authority to grant or deny a request from a State health care program that an exclusion from that program be waived with respect to an individual or entity, except that no waiver may be granted with respect to an exclusion under § 1001.101(b). The request must be in writing and from an individual directly responsible for administering the State health care program.

(b) With respect to exclusions under § 1001.101(a), a request from a State health care program for a waiver of the exclusion will only be considered if the individual or entity is the sole community physician or the sole source of essential specialized services in a community.

(c) With respect to exclusions imposed under subpart C of this part, a request for waiver will only be granted if the OIG determines that imposition of the exclusion would not be in the public interest.

(d) If the basis for the waiver ceases to exist, the waiver will be rescinded, and the individual or entity will be excluded for the period remaining on the exclusion, measured from the time the exclusion would have been imposed if the waiver had not been granted.

(e) In the event a waiver is granted, it is applicable only to the program(s) for which waiver is requested.

(f) The decision to grant, deny or rescind a request for a waiver is not subject to administrative or judicial review.

(g) The Inspector General may waive the exclusion of an individual or entity from participation in the Medicare program in conjunction with granting a waiver requested by a State health care program. If a State program waiver is rescinded, the derivative waiver of the exclusion from Medicare is automatically rescinded.

§ 1001.1901 Scope and effect of exclusion.

(a) *Scope of exclusion.* Exclusions of individuals and entities under this title will be from Medicare, Medicaid and any of the other Federal health care programs, as defined in § 1001.2.

(b) *Effect of exclusion on excluded individuals and entities.* (1) Unless and until an individual or entity is reinstated into the Medicare, Medicaid and other Federal health care programs in accordance with subpart F of this part, no payment will be made by Medicare, Medicaid or any of the other Federal health care programs for any item or service furnished, on or after the effective date specified in the notice period, by an excluded individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(2) An excluded individual or entity may not take assignment of an enrollee's claim on or after the effective date of exclusion.

(3) An excluded individual or entity that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act and other provisions. In addition, submitting claims, or causing claims to be submitted or payments to be made for items or services furnished, ordered or prescribed,

including administrative and management services or salary, may serve as the basis for denying reinstatement to the programs.

(c) *Exceptions to paragraph (b)(1) of this section.* (1) If an enrollee of Part B of Medicare submits an otherwise payable claim for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual after the effective date of exclusion, CMS will pay the first claim submitted by the enrollee and immediately notify the enrollee of the exclusion.

(2) CMS will not pay an enrollee for items or services furnished by an excluded individual or entity, or under the medical direction or on the prescription of an excluded physician or other authorized individual more than 15 days after the date on the notice to the enrollee, or after the effective date of the exclusion, whichever is later.

(3) Unless the Secretary determines that the health and safety of beneficiaries receiving services under Medicare, Medicaid or any of the other Federal health care programs warrants the exclusion taking effect earlier, payment may be made under such program for up to 30 days after the effective date of the exclusion for—

(i) Inpatient institutional services furnished to an individual who was admitted to an excluded institution before the date of the exclusion,

(ii) Home health services and hospice care furnished to an individual under a plan of care established before the effective date of the exclusion, and

(iii) Any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of the exclusion and delivered within 30 days of the effective date of such exclusion. (For the period October 2, 1998, to October 4, 1999, payment may be made under Medicare or a State health care program for up to 60 days after the effective date of the exclusion for any health care items that are ordered by a practitioner, provider or supplier from an excluded manufacturer before the effective date of such exclusion and delivered within 60 days of the effect of the exclusion.)

(4) CMS will not pay any claims submitted by, or for items or services ordered or prescribed by, an excluded provider for dates of service 15 days or more after the notice of the provider's exclusion was mailed to the supplier.

(5)(i) Notwithstanding the other provisions of this section, payment may be made under Medicare, Medicaid or other Federal health care programs for certain emergency items or services furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of exclusion. To be payable, a claim for such emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services specifying the nature of the emergency and why the items or services could not have been furnished by an individual or entity eligible to furnish or order such items or services.

(ii) Notwithstanding paragraph (c)(5)(i) of this section, no claim for emergency items or services will be payable if such items or services were provided by an excluded individual who, through an employment, contractual or any other arrangement, routinely provides emergency health care items or services.

[57 FR 3330, Jan. 29, 1992, as amended at 60 FR 32917, June 26, 1995; 63 FR 46690, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

Subpart E—Notice and Appeals

§ 1001.2001 Notice of intent to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with subpart C of this part, or in accordance with subpart B of this part where the exclusion is for a period exceeding 5 years, it will send written notice of its intent, the basis for the proposed exclusion and the potential effect of an exclusion. Within 30 days of receipt of notice, which will be deemed to be 5 days after the date on the notice, the individual or entity may submit documentary evidence and written argument concerning whether the exclusion is warranted and any related issues.

(b) If the OIG proposes to exclude an individual or entity under the provisions of §1001.701 or §1001.801 of this part, in conjunction with the submission of documentary evidence and written argument, an individual or entity may request an opportunity to present oral argument to an OIG official.

(c) *Exception.* If the OIG proposes to exclude an individual or entity under the provisions of §§1001.1301, 1001.1401 or 1001.1501 of this part, paragraph (a) of this section will not apply.

(d) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraph (a) of this section will so state.

[63 FR 46690, Sept. 2, 1998, as amended at 63 FR 57918, Oct. 29, 1998]

§1001.2002 Notice of exclusion.

(a) Except as provided in §1001.2003, if the OIG determines that exclusion is warranted, it will send a written notice of this decision to the affected individual or entity.

(b) The exclusion will be effective 20 days from the date of the notice.

(c) The written notice will state—

(1) The basis for the exclusion;

(2) The length of the exclusion and, where applicable, the factors considered in setting the length;

(3) The effect of the exclusion;

(4) The earliest date on which the OIG will consider a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

(6) The appeal rights available to the excluded individual or entity.

(d) Paragraph (b) of this section does not apply to exclusions imposed in accordance with §1001.1301.

(e) No later than 15 days prior to the final exhibit exchanges required under §1005.8 of this chapter, the OIG may amend its notice letter if information comes to light that justifies the imposition of a different period of exclusion other than the one proposed in the original notice letter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

§1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §§1001.901, 1001.951, 1001.1601 or 1001.1701, it will send written notice of this decision to the affected individual or entity. The written notice will provide the same information set forth in §1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the receipt of the notice (as defined in §1005.2 of this chapter) unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth—

(1) The specific issues or statements in the notice with which the individual or entity disagrees;

(2) The basis for that disagreement;

(3) The defenses on which reliance is intended;

(4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an administrative law judge (ALJ) proceeding in accordance with part 1005 of this chapter.

(b)(1) If the individual or entity does not make a written request for a hearing as provided for in paragraph (a) of this section, the OIG will send a notice of exclusion as described in §1001.2002.

(2) If the individual or entity makes a timely written request for a hearing and the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant immediate exclusion, an exclusion will only go into effect, with the date of the ALJ's decision, if the ALJ upholds the decision to exclude.

(c) If, prior to issuing a notice of proposal to exclude under paragraph (a) of this section, the OIG determines that

the health or safety of individuals receiving services under Medicare or any of the State health care programs warrants the exclusion taking place prior to the completion of an ALJ proceeding in accordance with part 1005 of this chapter, the OIG will proceed under §§1001.2001 and 1001.2002.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998; 65 FR 24414, Apr. 26, 2000]

§ 1001.2004 Notice to State agencies.

HHS will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion, and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) HHS will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation of the facts and circumstances of the exclusion.

(b) HHS will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and the OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) HHS will give notice of the exclusion and the effective date to the public, to beneficiaries (in accordance with §1001.1901(c)), and, as appropriate, to—

(1) Any entity in which the excluded individual is known to be serving as an employee, administrator, operator, or in which the individual is serving in any other capacity and is receiving payment for providing services (The lack of this notice will not affect CMS's ability to deny payment for services);

(2) State Medicaid Fraud Control Units;

(3) Utilization and Quality Control Quality Improvement Organizations;

(4) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations;

(5) Medical societies and other professional organizations;

(6) Contractors, health care prepayment plans, private insurance companies and other affected agencies and organizations;

(7) The State and Area Agencies on Aging established under title III of the Older Americans Act;

(8) The National Practitioner Data Bank.

(9) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

(b) In the case of an exclusion under §1001.101 of this chapter, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, HHS will give notice to the Attorney General of the United States of the facts and circumstances of the exclusion and the length of the exclusion.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

§ 1001.2007 Appeal of exclusions.

(a)(1) Except as provided in §1001.2003, an individual or entity excluded under this Part may file a request for a hearing before an ALJ only on the issues of whether:

(i) The basis for the imposition of the sanction exists, and

(ii) The length of exclusion is unreasonable.

(2) When the OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.

(3) The request for a hearing should contain the information set forth in §1005.2(d) of this chapter.

(b) The excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in §1001.2002 to file a request for such a hearing.

(c) The standard of proof at a hearing is preponderance of the evidence.

(d) When the exclusion is based on the existence of a criminal conviction or a civil judgment imposing liability

by Federal, State or local court, a determination by another Government agency, or any other prior determination where the facts were adjudicated and a final decision was made, the basis for the underlying conviction, civil judgment or determination is not reviewable and the individual or entity may not collaterally attack it either on substantive or procedural grounds in this appeal.

(e) The procedures in part 1005 of this chapter will apply to the appeal.

[57 FR 3330, Jan. 29, 1992, as amended at 67 FR 11935, Mar. 18, 2002]

Subpart F—Reinstatement into the Programs

§ 1001.3001 Timing and method of request for reinstatement.

(a)(1) Except as provided in paragraphs (a)(2) and (a)(3) of this section or in § 1001.501(b)(4) of this part, an excluded individual or entity (other than those excluded in accordance with §§ 1001.1001 and 1001.1501) may submit a written request for reinstatement to the OIG only after the date specified in the notice of exclusion. Obtaining a program provider number or equivalent does not reinstate eligibility.

(2) An entity under § 1001.1001 may apply for reinstatement prior to the date specified in the notice of exclusion by submitting a written request for reinstatement that includes documentation demonstrating that the standards set forth in § 1001.3002(c) have been met.

(3) Upon receipt of a written request, the OIG will require the requestor to furnish specific information and authorization to obtain information from private health insurers, peer review bodies, probation officers, professional associates, investigative agencies and such others as may be necessary to determine whether reinstatement should be granted.

(4) Failure to furnish the required information or authorization will result in the continuation of the exclusion.

(b) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the individual or entity may request reinstatement once the reduced exclusion period expires.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

§ 1001.3002 Basis for reinstatement.

(a)(1) The OIG will authorize reinstatement if it determines that—

(i) The period of exclusion has expired;

(ii) There are reasonable assurances that the types of actions that formed the basis for the original exclusion have not recurred and will not recur; and

(iii) There is no additional basis under sections 1128(a) or (b) or 1128A of the Act for continuation of the exclusion.

(2) Submitting claims or causing claims to be submitted or payments to be made by the programs for items or services furnished, ordered or prescribed, including administrative and management services or salary, may serve as the basis for denying reinstatement. This section applies regardless of whether an individual or entity has obtained a program provider number or equivalent, either as an individual or as a member of a group, prior to being reinstated.

(b) In making the reinstatement determination, the OIG will consider—

(1) Conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the OIG at the time of the exclusion;

(2) Conduct of the individual or entity after the date of the notice of exclusion;

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare, Medicaid and all other Federal health care programs, have been paid or satisfactory arrangements have been made to fulfill obligations;

(4) Whether CMS has determined that the individual or entity complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or supplier conditions for coverage under the statutes and regulations; and

(5) [Reserved]

(6) Whether the individual or entity has, during the period of exclusion,

submitted claims, or caused claims to be submitted or payment to be made by any Federal health care program, for items or services the excluded party furnished, ordered or prescribed, including health care administrative services.

(c) If the OIG determines that the criteria in paragraphs (a)(1)(ii) and (iii) of this section have been met, an entity excluded in accordance with §1001.1001 will be reinstated upon a determination by the OIG that the individual whose conviction, exclusion or civil money penalty was the basis for the entity's exclusion—

(1) Has properly reduced his or her ownership or control interest in the entity below 5 percent;

(2) Is no longer an officer, director, agent or managing employee of the entity; or

(3) Has been reinstated in accordance with paragraph (a) of this section or §1001.3005.

(d) Reinstatement will not be effective until the OIG grants the request and provides notice under §1001.3003(a) of this part. Reinstatement will be effective as provided in the notice.

(e) A determination with respect to reinstatement is not appealable or reviewable except as provided in §1001.3004.

(f) An ALJ may not require reinstatement of an individual or entity in accordance with this chapter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 64 FR 39427, July 22, 1999]

§1001.3003 Approval of request for reinstatement.

(a) If the OIG grants a request for reinstatement, the OIG will—

(1) Give written notice to the excluded individual or entity specifying the date of reinstatement;

(2) Notify CMS of the date of the individual's or entity's reinstatement;

(3) Notify appropriate Federal and State agencies that administer health care programs that the individual or entity has been reinstated into all Federal health care programs; and

(4) To the extent applicable, give notice to others that were originally notified of the exclusion.

(b) A determination by the OIG to reinstate an individual or entity has no effect if a Federal health care program has imposed a longer period of exclusion under its own authorities.

[64 FR 39428, July 22, 1999]

§1001.3004 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, OIG will give written notice to the requesting individual or entity. Within 30 days of the date on the notice, the excluded individual or entity may submit:

(1) Documentary evidence and written argument against the continued exclusion,

(2) A written request to present written evidence and oral argument to an OIG official, or

(3) Both documentary evidence and a written request.

(b) After evaluating any additional evidence submitted by the excluded individual or entity (or at the end of the 30-day period, if none is submitted), the OIG will send written notice either confirming the denial, and indicating that a subsequent request for reinstatement will not be considered until at least one year after the date of denial, or approving the request consistent with the procedures set forth in §1001.3003(a).

(c) The decision to deny reinstatement will not be subject to administrative or judicial review.

§1001.3005 Reversed or vacated decisions.

(a) An individual or entity will be reinstated into Medicare, Medicaid and other Federal health care programs retroactive to the effective date of the exclusion when such exclusion is based on—

(1) A conviction that is reversed or vacated on appeal;

(2) An action by another agency, such as a State agency or licensing board, that is reversed or vacated on appeal; or

(3) An OIG exclusion action that is reversed or vacated at any stage of an individual's or entity's administrative appeal process.

(b) If an individual or entity is reinstated in accordance with paragraph

(a) of this section, CMS and other Federal health care programs will make payment for services covered under such program that were furnished or performed during the period of exclusion.

(c) The OIG will give notice of a reinstatement under this section in accordance with §1001.3003(a).

(d) An action taken by the OIG under this section will not require any other Federal health care program to reinstate the individual or entity if such program has imposed an exclusion under its own authority.

(e) If an action which results in the retroactive reinstatement of an individual or entity is subsequently overturned, the OIG may reimpose the exclusion for the initial period of time, less the period of time that was served prior to the reinstatement of the individual or entity.

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39428, July 22, 1999; 67 FR 11935, Mar. 18, 2002]

PART 1002—PROGRAM INTEGRITY—STATE-INITIATED EXCLUSIONS FROM MEDICAID

Subpart A—General Provisions

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Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

1002.230 Notification of State or local convictions of crimes against Medicaid.

AUTHORITY: 42 U.S.C. 1302, 1320a–3, 1320a–5, 1320a–7, 1396(a)(4)(A), 1396(p)(1), 1396a(30), 1396a(39), 1396b(a)(6), 1396b(b)(3), 1396b(i)(2) and 1396b(q).

SOURCE: 57 FR 3343, Jan. 29, 1992, unless otherwise noted.

Subpart A—General Provisions

§1002.1 Scope and purpose.

The regulations in this part specify certain bases upon which individuals and entities may, or in some cases must, be excluded from participation in the Medicaid program. These regulations specifically address the authority of State agencies to exclude on their own initiative, regardless of whether the OIG has excluded an individual or entity under part 1001 of this chapter. These regulations also delineate the States' obligation to inform the OIG of certain Medicaid-related convictions.

§1002.2 General authority.

(a) In addition to any other authority it may have, a State may exclude an individual or entity from participation in the Medicaid program for any reason for which the Secretary could exclude that individual or entity from participation in the Medicare, Medicaid and other Federal health care programs under sections 1128, 1128A or 1866(b)(2) of the Social Security Act.

(b) Nothing contained in this part should be construed to limit a State's own authority to exclude an individual or entity from Medicaid for any reason or period authorized by State law.

[57 FR 3343, Jan. 29, 1992, as amended at 64 FR 39428, July 22, 1999]

§1002.3 Disclosure by providers and State Medicaid agencies.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person described in §1001.1001(a)(1) of this chapter.

(b) *Notification to Inspector General.* (1) The Medicaid agency must notify the Inspector General of any disclosures made under paragraph (a) of this section within 20 working days from the date it receives the information.

(2) The agency must promptly notify the Inspector General of any action it takes on the provider's application for participation in the program.

(3) The agency must also promptly notify the Inspector General of any action it takes to limit the ability of an individual or entity to participate in its program, regardless of what such an action is called. This includes, but is not limited to, suspension actions, settlement agreements and situations where an individual or entity voluntarily withdraws from the program to avoid a formal sanction.

(c) *Denial or termination of provider participation.* (1) The Medicaid agency may refuse to enter into or renew an agreement with a provider if any person who has ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid or the title XX Services program.

(2) The Medicaid agency may refuse to enter into, or terminate, a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under paragraph (a) of this section.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

§ 1002.100 State plan requirement.

The plan must provide that the requirements of this subpart are met. However, the provisions of these regulations are minimum requirements. The agency may impose broader sanctions if it has the authority to do so under State law.

Subpart B—Mandatory Exclusion

§ 1002.203 Mandatory exclusion.

(a) The State agency, in order to receive Federal financial participation (FFP), must provide that it will exclude from participation any HMO, or entity furnishing services under a waiver approved under section 1915(b)(1) of the Act, if such organization or entity—

(1) Could be excluded under § 1001.1001 or § 1001.1051 of this chapter, or

(2) Has, directly or indirectly, a substantial contractual relationship with an individual or entity that could be excluded under § 1001.1001 or § 1001.1051 of this chapter.

(b) As used in this section, the term—

Exclude includes the refusal to enter into or renew a participation agreement or the termination of such an agreement.

Substantial contractual relationship is one in which the sanctioned individual described in § 1001.1001 of this chapter has direct or indirect business transactions with the organization or entity that, in any fiscal year, amount to more than $25,000 or 5 percent of the organization's or entity's total operating expenses, whichever is less. Business transactions include, but are not limited to, contracts, agreements, purchase orders, or leases to obtain services, supplies, equipment, space or salaried employment.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

Subpart C—Permissive Exclusions

§ 1002.210 Permissive exclusions; general authority.

The State agency must have administrative procedures in place that enable it to exclude an individual or entity for any reason for which the Secretary could exclude such individual or entity under parts 1001 or 1003 of this chapter. The period of such exclusion is at the discretion of the State agency.

§ 1002.211 Effect of exclusion.

(a) *Denial of payment.* Except as provided for in § 1001.1901(c)(3), (c)(4) and (c)(5)(i) of this chapter, no payment may be made by the State agency for any item or service furnished on or after the effective date specified in the notice by an excluded individual or entity, or at the medical direction or on the prescription of a physician who is excluded when a person furnishing such item or service knew, or had reason to know, of the exclusion.

(b) *Denial of FFP.* FFP is not available where the State agency is required to deny payment under paragraph (a) of this section. FFP will be reinstated at such time as the excluded individual

or entity is reinstated in the Medicaid program.

[57 FR 3343, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998]

§ 1002.212 State agency notifications.

When the State agency initiates an exclusion under § 1002.210, it must provide to the individual or entity subject to the exclusion notification consistent with that required in subpart E of part 1001 of this chapter, and must notify other State agencies, the State medical licensing board (where applicable), the public, beneficiaries, and others as provided in §§ 1001.2005 and 1001.2006 of this chapter.

§ 1002.213 Appeals of exclusions.

Before imposing an exclusion under § 1002.210, the State agency must give the individual or entity the opportunity to submit documents and written argument against the exclusion. The individual or entity must also be given any additional appeals rights that would otherwise be available under procedures established by the State.

§ 1002.214 Basis for reinstatement after State agency-initiated exclusion.

(a) The provisions of this section and § 1002.215 apply to the reinstatement in the Medicaid program of all individuals or entities excluded in accordance with § 1002.210, if a State affords reinstatement opportunity to those excluded parties.

(b) An individual or entity who has been excluded from Medicaid may be reinstated only by the Medicaid agency that imposed the exclusion.

(c) An individual or entity may submit to the State agency a request for reinstatement at any time after the date specified in the notice of exclusion.

§ 1002.215 Action on request for reinstatement.

(a) The State agency may grant reinstatement only if it is reasonably certain that the types of actions that formed the basis for the original exclusion have not recurred and will not recur. In making this determination, the agency will consider, in addition to any factors set forth in State law—

(1) The conduct of the individual or entity occurring prior to the date of the notice of exclusion, if not known to the agency at the time of the exclusion;

(2) The conduct of the individual or entity after the date of the notice of exclusion; and

(3) Whether all fines, and all debts due and owing (including overpayments) to any Federal, State or local government that relate to Medicare or any of the State health care programs, have been paid, or satisfactory arrangements have been made, that fulfill these obligations.

(b) Notice of action on request for reinstatement. (1) If the State agency approves the request for reinstatement, it must give written notice to the excluded party, and to all others who were informed of the exclusion in accordance with § 1002.212, specifying the date on which Medicaid program participation may resume.

(2) If the State agency does not approve the request for reinstatement, it will notify the excluded party of its decision. Any appeal of a denial of reinstatement will be in accordance with State procedures and need not be subject to administrative or judicial review, unless required by State law.

Subpart D—Notification to OIG of State or Local Convictions of Crimes Against Medicaid

§ 1002.230 Notification of State or local convictions of crimes against Medicaid.

(a) The State agency must notify the OIG whenever a State or local court has convicted an individual who is receiving reimbursement under Medicaid of a criminal offense related to participation in the delivery of health care items or services under the Medicaid program, except where the State Medicaid Fraud Control Unit (MFCU) has so notified the OIG.

(b) If the State agency was involved in the investigation or prosecution of the case, it must send notice within 15 days after the conviction.

(c) If the State agency was not so involved, it must give notice within 15 days after it learns of the conviction.

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

Sec.

1003.100 Basis and purpose.
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1003.105 Exclusion from participation in Medicare, Medicaid and all Federal health care programs.
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1003.132 Limitations.
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1003.135 Reinstatement.

AUTHORITY: 42 U.S.C. 262a, 1302, 1320–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395cc(j), 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395nn(g), 1395ss(d), 1396b(m), 11131(c), and 11137(b)(2).

SOURCE: 51 FR 34777, Sept. 30, 1986, unless otherwise noted.

§ 1003.100 Basis and purpose.

(a)*Basis.* This part implements sections 1128(c), 1128A, 1140, 1860D–31(i)(3), 1876(i)(6), 1877(g), 1882(d) and 1903(m)(5) of the Social Security Act; sections 421(c) and 427(b)(2) of Pub. L. 99–660; and section 201(i) of Pub. L. 107–188 (42 U.S.C. 1320–7(c), 1320a–7a, 1320b–10, 1395w–141(i)(3), 1395dd(d)(1), 1395mm, 1395ss(d), 1396b(m), 11131(c), 11137(b)(2) and 262).

(b) *Purpose.* This part—

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

(i) Have knowingly submitted certain prohibited claims under Federal health care programs;

(ii) Seek payment in violation of the terms of an agreement or a limitation on charges or payments under the Medicare program, or a requirement not to charge in excess of the amount permitted under the Medicaid program;

(iii) Give false or misleading information that might affect the decision to discharge a Medicare patient from the hospital;

(iv)(A) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99–660, and regulations specified in 45 CFR part 60, or

(B) Are health plans and fail to report information concerning sanctions or other adverse actions imposed on providers as required to be reported to the Healthcare Integrity and Protection Data Bank (HIPDB) in accordance with section 1128E of the Act;

(v) Misuse certain Departmental and Medicare and Medicaid program words, letters symbols or emblems;

(vi) Violate a requirement of section 1867 of the Act or § 489.24 of this title;

(vii) Substantially fail to provide an enrollee with required medically necessary items and services; engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses; or do not meet the requirements for physician incentive plans for Medicare specified in §§ 417.479(d) through (f) of this title;

(viii) Present or cause to be presented a bill or claim for designated health services (as defined in § 411.351 of this title) that they know, or should know, were furnished in accordance with a referral prohibited under § 411.353 of this title;

(ix) Have collected amounts that they know or should know were billed in violation of § 411.353 of this title and have not refunded the amounts collected on a timely basis;

(x) Are physicians or entities that enter into an arrangement or scheme that they know or should know has as a principal purpose the assuring of referrals by the physician to a particular entity which, if made directly, would violate the provisions of § 411.353 of this title;

(xi) Are excluded, and who retain an ownership or control interest of five percent or more in an entity participating in Medicare or a State health care program, or who are officers or managing employees of such an entity (as defined in section 1126(b) of the Act);

(xii) Offer inducements that they know or should know are likely to influence Medicare or State health care program beneficiaries to order or receive particular items or services;

(xiii) Are physicians who knowingly misrepresent that a Medicare beneficiary requires home health services;

(xiv) Have submitted, or caused to be submitted, certain prohibited claims, including claims for services rendered by excluded individuals employed by or otherwise under contract with such person, under one or more Federal health care programs;

(xv) Violate the Federal health care programs' anti-kickback statute as set forth in section 1128B of the Act;

(xvi) Violate the provisions of part 73 of this title, implementing section 351A(b) and (c) of the Public Health Service Act, with respect to the possession and use within the United States, receipt from outside the United States, and transfer within the United States, of select agents and toxins in use, or transfer of listed biological agents and toxins; or

(xvii) Violate the provisions of part 403, subpart H of this title, implementing the Medicare prescription drug discount card and transitional assistance program, by misleading or defrauding program beneficiaries, by overcharging a discount program enrollee, or by misusing transitional assistance funds.

(2) Provides for the exclusion of persons from the Medicare or State health care programs against whom a civil money penalty or assessment has been imposed, and the basis for reinstatement of persons who have been excluded; and

(3) Sets forth the appeal rights of persons subject to a penalty, assessment and exclusion.

[65 FR 24414, Apr. 26, 2000, as amended at 67 FR 11935, Mar. 18, 2002; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§ 1003.101 Definitions.

For purposes of this part:

Act means the Social Security Act.

Adverse effect means medical care has not been provided and the failure to provide such necessary medical care has presented an imminent danger to the health, safety, or well-being of the patient or has placed the patient unnecessarily in a high-risk situation.

ALJ means an Administrative Law Judge.

Assessment means the amount described in § 1003.104, and includes the plural of that term.

Claim means an application for payment for an item or service to a Federal health care program (as defined in section 1128B(f) of the Act).

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

Contracting organization means a public or private entity, including of a health maintenance organization (HMO), competitive medical plan, or health insuring organization (HIO) which meets the requirements of section 1876(b) of the Act or is subject to the requirements in section 1903(m)(2)(A) of the Act and which has contracted with the Department or a State to furnish services to Medicare beneficiaries or Medicaid recipients.

Department means the Department of Health and Human Services.

Enrollee means an individual who is eligible for Medicare or Medicaid and who enters into an agreement to receive services from a contracting organization that contracts with the Department under title XVIII or title XIX of the Act.

Exclusion means the temporary or permanent barring of a person from participation in a Federal health care program (as defined in section 1128B(f) of the Act).

Inspector General means the Inspector General of the Department or his or her designees.

Item or service includes—

(a) Any item, device, medical supply or service provided to a patient (i) which is listed in an itemized claim for program payment or a request for payment, or (ii) for which payment is included in other Federal or State health

care reimbursement methods, such as a prospective payment system; and

(b) In the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

Maternal and Child Health Services Block Grant program means the program authorized under Title V of the Act.

Medicaid means the program of grants to the States for medical assistance authorized under title XIX of the Act.

Medical malpractice claim or action means a written complaint or claim demanding payment based on a physician's, dentist's or other health care practitioner's provision of, or failure to provide health care services, and includes the filing of a cause of action based on the law of tort brought in any State or Federal court or other adjudicative body.

Medicare means the program of health insurance for the aged and disabled authorized under Title XVIII of the Act.

Participating hospital means (1) a hospital or (2) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Penalty means the amount described in §1003.103 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physician incentive plan means any compensation arrangement between a contracting organization and a physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

Preventive care, for purposes of the definition of the term Remuneration as set forth in this section and the preventive care exception to section 231(h) of HIPAA, means any service that—

(1) Is a prenatal service or a postnatal well-baby visit or is a specific clinical service described in the current U.S. Preventive Services Task Force's *Guide to Clinical Preventive Services,* and

(2) Is reimbursable in whole or in part by Medicare or an applicable State health care program.

Remuneration, as set forth in §1003.102(b)(13) of this part, is consistent with the definition contained in section 1128A(i)(6) of the Act, and includes the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value. The term ''remuneration'' does not include—

(1) The waiver of coinsurance and deductible amounts by a person, if the waiver is not offered as part of any advertisement or solicitation; the person does not routinely waive coinsurance or deductible amounts; and the person waives coinsurance and deductible amounts after determining in good faith that the individual is in financial need or failure by the person to collect coinsurance or deductible amounts after making reasonable collection efforts;

(2) Any permissible practice as specified in section 1128B(b)(3) of the Act or in regulations issued by the Secretary;

(3) Differentials in coinsurance and deductible amounts as part of a benefit plan design (as long as the differentials have been disclosed in writing to all beneficiaries, third party payers and providers), to whom claims are presented; or

(4) Incentives given to individuals to promote the delivery of preventive care services where the delivery of such services is not tied (directly or indirectly) to the provision of other services reimbursed in whole or in part by Medicare or an applicable State health care program. Such incentives may include the provision of preventive care, but may not include—

(i) Cash or instruments convertible to cash; or

(ii) An incentive the value of which is disproportionally large in relationship to the value of the preventive care service (*i.e.,* either the value of the service itself or the future health care costs reasonably expected to be avoided as a result of the preventive care).

Request for payment means an application submitted by a person to any person for payment for an item or service.

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department seeking assistance and includes a physician on call for the care of such individual.

Secretary means the Secretary of the Department or his or her designees.

Select agents and toxins means agents and toxins that are listed by the HHS Secretary as having the potential to pose a severe threat to public health and safety, in accordance with section 351A(a)(1) of the Public Health Service Act.

Should know or *should have known* means that a person, with respect to information—

(1) Acts in deliberate ignorance of the truth or falsity of the information; or

(2) Acts in reckless disregard of the truth or falsity of the information. For purposes of this definition, no proof of specific intent to defraud is required.

Social Services Block Grant program means the program authorized under title XX of the Social Security Act.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

State health care program means a State plan approved under title XIX of the Act, any program receiving funds under title V of the Act or from an allotment to a State under such title, or any program receiving funds under title XX of the Act or from an allotment to a State under such title.

Timely basis means, in accordance with §1003.102(b)(9) of this part, the 60-day period from the time the prohibited amounts are collected by the individual or the entity.

Transitional assistance means the subsidy funds that Medicare beneficiaries enrolled in the prescription drug discount card and transitional assistance program may apply toward the cost of covered discount card drugs in the manner described in §403.808(d) of this title.

[51 FR 34777, Sept. 30, 1986, as amended at 56 FR 28492, June 21, 1991; 57 FR 3345, Jan. 29, 1992; 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 61 FR 13449, Mar. 27, 1996; 65 FR 24415, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 66 FR 39452, July 31, 2001; 67 FR 11935, Mar. 18, 2002; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§1003.102 Basis for civil money penalties and assessments.

(a) The OIG may impose a penalty and assessment against any person whom it determines in accordance with this part has knowingly presented, or caused to be presented, a claim which is for—

(1) An item or service that the person knew, or should have known, was not provided as claimed, including a claim that is part of a pattern or practice of claims based on codes that the person knows or should know will result in greater payment to the person than the code applicable to the item or service actually provided;

(2) An item or service for which the person knew, or should have known, that the claim was false or fraudulent, including a claim for any item or service furnished by an excluded individual employed by or otherwise under contract with that person;

(3) An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was made;

(4) A physician's services (or an item or service) for which the person knew, or should have known, that the individual who furnished (or supervised the furnishing of) the service—

(i) Was not licensed as a physician;

(ii) Was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing); or

(iii) Represented to the patient at the time the service was furnished that the physician was certified in a medical specialty board when he or she was not so certified;

(5) A payment that such person knows, or should know, may not be made under §411.353 of this title; or

(6) An item or service that a person knows or should know is medically unnecessary, and which is part of a pattern of such claims.

(b) The OIG may impose a penalty, and where authorized, an assessment against any person (including an insurance company in the case of paragraphs (b)(5) and (b)(6) of this section) whom it determines in accordance with this part—

(1) Has knowingly presented or caused to be presented a request for payment in violation of the terms of—

(i) An agreement to accept payments on the basis of an assignment under section 1842(b)(3)(B)(ii) of the Act;

(ii) An agreement with a State agency or other requirement of a State Medicaid plan not to charge a person for an item or service in excess of the amount permitted to be charged;

(iii) An agreement to be a participating physician or supplier under section 1842(h)(1); or

(iv) An agreement in accordance with section 1866(a)(1)(G) of the Act not to charge any person for inpatient hospital services for which payment had been denied or reduced under section 1886(f)(2) of the Act.

(2)–(3) [Reserved]

(4) Has knowingly given or caused to be given to any person, in the case of inpatient hospital services subject to the provisions of section 1886 of the Act, information that he or she knew, or should have known, was false or misleading and that could reasonably have been expected to influence the decision when to discharge such person or another person from the hospital.

(5) Fails to report information concerning—

(i) A payment made under an insurance policy, self-insurance or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement of, or in satisfaction in whole or in part of, a medical malpractice claim or action or a judgment against such a physician, dentist or other practitioner in accordance with section 421 of Public Law 99–660 (42 U.S.C. 11131) and as required by regulations at 45 CFR part 60; or

(ii) An adverse action required to be reported to the Healthcare Integrity and Protection Data Bank as established by section 221 of Public Law 104–191 and set forth in section 1128E of the Act.

(6) Improperly discloses, uses or permits access to information reported in accordance with part B of title IV of Pub. L. 99–660, in violation of section 427 of Pub. L. 99–660 (42 U.S.C. 11137) or regulations at 45 CFR part 60. (The disclosure of information reported in accordance with part B of title IV in response to a subpoena or a discovery request is considered to be an improper disclosure in violation of section 427 of Pub. L. 99–660. However, disclosure or release by an entity of original documents or underlying records from which the reported information is obtained or derived is not considered to be an improper disclosure in violation of section 427 of Pub. L. 99–660.)

(7) Has made use of the words, letters, symbols or emblems as defined in paragraph (b)(7)(i) of this section in such a manner that such person knew or should have known would convey, or in a manner which reasonably could be interpreted or construed as conveying, the false impression that an advertisement, solicitation or other item was authorized, approved or endorsed by the Department or CMS, or that such person or organization has some connection with or authorization from the Department or CMS. Civil money penalties—

(i) May be imposed, regardless of the use of a disclaimer of affiliation with the United States Government, the Department or its programs, for misuse of—

(A) The words ''Department of Health and Human Services,'' ''Health and Human Services,'' ''Centers for Medicare & Medicaid Services,'' ''Medicare,'' or ''Medicaid,'' or any other combination or variation of such words;

(B) The letters ''DHHS,'' ''HHS,'' or ''CMS,'' or any other combination or variation of such letters; or

(C) A symbol or emblem of the Department or CMS (including the design of, or a reasonable facsimile of the design of, the Medicare card, the check used for payment of benefits under title II, or envelopes or other stationery used by the Department or

CMS) or any other combination or variation of such symbols or emblems; and

(ii) Will not be imposed against any agency or instrumentality of a State, or political subdivision of the State, that makes use of any symbol or emblem, or any words or letters which specifically identifies that agency or instrumentality of the State or political subdivision.

(8) Is a contracting organization that CMS determines has committed an act or failed to comply with the requirements set forth in §417.500(a) or §434.67(a) of this title or failed to comply with the requirement set forth in §434.80(c) of this title.

(9) Has not refunded on a timely basis, as defined in §1003.101 of this part, amounts collected as the result of billing an individual, third party payer or other entity for a designated health service that was provided in accordance with a prohibited referral as described in §411.353 of this title.

(10) Is a physician or entity that enters into—

(i) A cross referral arrangement, for example, whereby the physician owners of entity ''X'' refer to entity ''Y,'' and the physician owners of entity ''Y'' refer to entity ''X'' in violation of §411.353 of this title, or

(ii) Any other arrangement or scheme that the physician or entity knows, or should know, has a principal purpose of circumventing the prohibitions of §411.353 of this title.

(11) Has violated section 1128B of the Act by unlawfully offering, paying, soliciting or receiving remuneration in return for the referral of business paid for by Medicare, Medicaid or other Federal health care programs.

(12) Who is not an organization, agency or other entity, and who is excluded from participating in Medicare or a State health care program in accordance with sections 1128 or 1128A of the Act, and who—

(i) Knows or should know of the action constituting the basis for the exclusion, and retains a direct or indirect ownership or control interest of five percent or more in an entity that participates in Medicare or a State health care program; or

(ii) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such entity.

(13) Offers or transfers remuneration (as defined in §1003.101 of this part) to any individual eligible for benefits under Medicare or a State health care program, that such person knows or should know is likely to influence such individual to order or to receive from a particular provider, practitioner or supplier any item or service for which payment may be made, in whole or in part, under Medicare or a State health care program.

(14) Is a physician and who executes a document falsely by certifying that a Medicare beneficiary requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements set forth in sections 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(15) Has knowingly and willfully presented, or caused to be presented, a bill or request for payment for items and services furnished to a hospital patient for which payment may be made under the Medicare or another Federal health care program, if that bill or request is inconsistent with an arrangement under section 1866(a)(1)(H) of the Act, or violates the requirements for such an arrangement.

(16) Is involved in the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins in violation of part 73 of this chapter as determined by the HHS Secretary, in accordance with sections 351A(b) and (c) of the Public Health Service Act.

(17) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly misrepresented or falsified information in outreach material or comparable material provided to a program enrollee or other person.

(18) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly charged a program enrollee in violation of the terms of the endorsement contract.

(19) Is an endorsed sponsor under the Medicare prescription drug discount card program who knowingly used transitional assistance funds of any

program enrollee in any manner that is inconsistent with the purpose of the transitional assistance program.

(c)(1) The Office of the Inspector General (OIG) may impose a penalty for violations of section 1867 of the Act or §489.24 of this title against—

(i) Any participating hospital with an emergency department that—

(A) Knowingly violates the statute on or after August 1, 1986 or;

(B) Negligently violates the statute on or after May 1, 1991; and

(ii) Any responsible physician who—

(A) Knowingly violates the statute on or after August 1, 1986;

(B) Negligently violates the statute on or after May 1, 1991;

(C) Signs a certification under section 1867(c)(1)(A) of the Act if the physician knew or should have known that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(D) Misrepresents an individual's condition or other information, including a hospital's obligations under this section.

(2) For purposes of this section, a responsible physician or hospital ''knowingly'' violates section 1867 of the Act if the responsible physician or hospital recklessly disregards, or deliberately ignores a material fact.

(d)(1) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a claim as described in paragraph (a) of this section, each such person may be held liable for the penalty prescribed by this part, and an assessment may be imposed against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(2) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a request for payment or for giving false or misleading information as described in paragraph (b) of this section, each such person may be held liable for the penalty prescribed by this part.

(3) In any case in which it is determined that more than one person was responsible for failing to report information that is required to be reported on a medical malpractice payment, or for improperly disclosing, using, or permitting access to information, as described in paragraphs (b)(5) and (b)(6) of this section, each such person may be held liable for the penalty prescribed by this part.

(4) In any case in which it is determined that more than one responsible physician violated the provisions of section 1867 of the Act or of §489.24 of this title, a penalty may be imposed against each responsible physician.

(5) Under this section, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

(e) For purposes of this section, the term ''knowingly'' is defined consistent with the definition set forth in the Civil False Claims Act (31 U.S.C. 3729(b)), that is, a person, with respect to information, has actual knowledge of information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and that no proof of specific intent to defraud is required.

[57 FR 3345, Jan. 29, 1992; 57 FR 9670, Mar. 20, 1992, as amended at 59 FR 32124, June 22, 1994; 59 FR 36086, July 15, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 64 FR 39428, July 22, 1999; 65 FR 18550, Apr. 7, 2000; 65 FR 24415, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b) through (k) of this section, the OIG may impose a penalty of not more than—

(1) $2,000 for each wrongful act occurring before January 1, 1997 that is subject to a determination under §1003.102; and

(2) $10,000 for each wrongful act occurring on or after January 1, 1997 that is subject to a determination under §1003.102.

(b) The OIG may impose a penalty of not more than $15,000 for each person with respect to whom a determination was made that false or misleading information was given under §1003.102(b)(4), or for each item and

service that is subject to a determination under §1003.102(a)(5) or §1003.102(b)(9) of this part. The OIG may impose a penalty of not more than $100,000 for each arrangement or scheme that is subject to a determination under §1003.102(b)(10) of this part.

(c) The OIG may impose a penalty of not more than $11,000[1] for each payment for which there was a failure to report required information in accordance with §1003.102(b)(5), or for each improper disclosure, use or access to information that is subject to a determination under §1003.102(b)(6).

(d)(1) The OIG may impose a penalty of not more than $5,000 for each violation resulting from the misuse of Departmental, CMS, Medicare or Medicaid program words, letters, symbols or emblems as described in §1003.102(b)(7) relating to printed media, and a penalty of not more than $25,000 in the case of such misuse related to a broadcast or telecast, that is related to a determination under §1003.102(b)(7).

(2) For purposes of this paragraph, a violation is defined as—

(i) In the case of a direct mailing solicitation or advertisement, each separate piece of mail which contains one or more words, letters, symbols or emblems related to a determination under §1003.102(b)(7);

(ii) In the case of a printed solicitation or advertisement, each reproduction, reprinting or distribution of such item related to a determination under §1003.102(b)(7); and

(iii) In the case of a broadcast or telecast, each airing of a single commercial or solicitation related to a determination under §1003.102(b)(7).

(e) For violations of section 1867 of the Act or §489.24 of this title, the OIG may impose—

(1) Against each participating hospital with an emergency department, a penalty of not more than $50,000 for each negligent violation occurring on or after May 1, 1991, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed $25,000; and

(2) Against each responsible physician, a penalty of not more than $50,000 for each negligent violation occurring on or after May 1, 1991.

(f)(1) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by CMS that a contracting organization has—

(i) Failed substantially to provide an enrollee with required medically necessary items and services and the failure adversely affects (or has the likelihood of adversely affecting) the enrollee;

(ii) Imposed premiums on enrollees in excess of amounts permitted under section 1876 or title XIX of the Act;

(iii) Acted to expel or to refuse to reenroll a Medicare beneficiary in violation of the provisions of section 1876 of the Act and for reasons other than the beneficiary's health status or requirements for health care services;

(iv) Misrepresented or falsified information furnished to an individual or any other entity under section 1876 or section 1903(m) of the Act;

(v) Failed to comply with the requirements of section 1876(g)(6)(A) of the Act, regarding prompt payment of claims; or

(vi) Failed to comply with the requirements of §§417.479 (d) through (i) of this title for Medicare, and §§417.479 (d) through (g) and (i) of this title for Medicaid, regarding certain prohibited incentive payments to physicians.

(2) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by CMS that a contracting organization with a contract under section 1876 of the Act—

(i) Employs or contracts with individuals or entities excluded, under section 1128 or section 1128A of the Act, from participation in Medicare for the provision of health care, utilization review, medical social work, or administrative services; or

(ii) Employs or contracts with any entity for the provision of services (directly or indirectly) through an excluded individual or entity.

[1] As adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–134).

(3) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $100,000 for each determination that a contracting organization has—

(i) Misrepresented or falsified information to the Secretary under section 1876 of the Act or to the State under section 1903(m) of the Act; or

(ii) Acted to expel or to refuse to reenroll a Medicaid recipient because of the individual's health status or requirements for health care services, or engaged in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1876 or section 1903(m) of the Act) with the contracting organization by Medicare beneficiaries and Medicaid recipients whose medical condition or history indicates a need for substantial future medical services.

(4) If enrolles are charged more than the allowable premium, the OIG will impose an additional penalty equal to double the amount of excess premium charged by the contracting organization. The excess premium amount will be deducted from the penalty and returned to the enrollee.

(5) The OIG will impose an additional $15,000 penalty for each individual not enrolled when CMS determines that a contracting organization has committed a violation described in paragraph (f)(3)(ii) of this section.

(6) For purposes of paragraph (f) of this section, a violation is each incident where a person has committed an act listed in §417.500(a) or §434.67(a) of this title, or failed to comply with a requirement set forth in §434.80(c) of this title.

(g) The OIG may impose a penalty of not more than $25,000 against a health plan for failing to report information on an adverse action required to be reported to the Healthcare Integrity and Protection Data Bank in accordance with section 1128E of the Act and §1003.102(b)(5)(ii).

(h) For each violation of §1003.102(b)(11), the OIG may impose—

(1) A penalty of not more than $50,000, and

(2) An assessment of up to three times the total amount of remuneration offered, paid, solicited or received, as specified in §1003.104(b).

(i) For violations of §1003.102(b)(14) of this part, the OIG may impose a penalty of not more than the greater of—

(1) $5,000, or

(2) Three times the amount of Medicare payments for home health services that are made with regard to the false certification of eligibility by a physician in accordance with sections 1814(a)(2)(C) or 1835(a)(2)(A) of the Act.

(j) The OIG may impose a penalty of not more than $10,000 per day for each day that the prohibited relationship described in §1001.102(b)(12) of this part occurs.

(k) For violations of section 1862(a)(14) of the Act and §1003.102(b)(15), the OIG may impose a penalty of not more than $2,000 for each bill or request for payment for items and services furnished to a hospital patient.

(l) For violations of section 351A(b) or (c) of the Public Health Service Act and 42 CFR part 73, the OIG may impose a penalty of not more than $250,000 in the case of an individual, and not more than $500,000 in the case of any other person.

(m) For violations of section 1860D–31 of the Act and 42 CFR part 403, subpart H, regarding the misleading or defrauding of program beneficiaries, or the misuse of transitional assistance funds, the OIG may impose a penalty of not more than $10,000 for each individual violation.

[57 FR 3346, Jan. 29, 1992, as amended at 59 FR 32125, June 22, 1994; 59 FR 48566, Sept. 22, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996; 61 FR 52301, Oct. 7, 1996; 64 FR 39429, July 22, 1999; 65 FR 18550, Apr. 7, 2000; 65 FR 24416, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 67 FR 76905, Dec. 13, 2002; 69 FR 28845, May 19, 2004]

§1003.104 Amount of assessment.

(a) The OIG may impose an assessment, where authorized, in accordance with §1003.102, of not more than—

(1) Two times the amount for each item or service wrongfully claimed prior to January 1, 1997; and

(2) Three times the amount for each item or service wrongfully claimed on or after January 1, 1997.

(b) The assessment is in lieu of damages sustained by the Department or a State agency because of that claim.

[65 FR 24416, Apr. 26, 2000]

§ 1003.105 Exclusion from participation in Medicare, Medicaid and all Federal health care programs.

(a)(1) Except as set forth in paragraph (b) of this section, the following persons may be subject, in lieu of or in addition to any penalty or assessment, to an exclusion from participation in Medicare for a period of time determined under § 1003.107. There will be exclusions from Federal health care programs for the same period as the Medicare exclusion for any person who—

(i) Is subject to a penalty or assessment under § 1003.102(a), (b)(1), (b)(4), (b)(12), (b)(13) or (b)(15); or

(ii) Commits a gross and flagrant, or repeated, violation of section 1867 of the Act or § 489.24 of this title on or after May 1, 1991. For purposes of this section, a gross and flagrant violation is one that presents an imminent danger to the health, safety or well-being of the individual who seeks emergency examination and treatment or places that individual unnecessarily in a high-risk situation.

(b)(1)(i) With respect to any exclusion based on liability for a penalty or assessment under § 1003.102 (a), (b)(1), or (b)(4), the OIG will consider an application from a State agency for a waiver if the person is the sole community physician or the sole source of essential specialized services in a community. With respect to any exclusion imposed under § 1003.105(a)(1)(ii), the OIG will consider an application from a State agency for a waiver if the physician's exclusion from the State health care program would deny beneficiaries access to medical care or would otherwise cause hardship to beneficiaries.

(ii) If a waiver is granted, it is applicable only to the State health care program for which the State requested the waiver.

(iii) If the OIG subsequently obtains information that the basis for a waiver no longer exists, or the State agency submits evidence that the basis for the waiver no longer exists, the waiver will cease and the person will be excluded from the State health care program for the remainder of the period that the person is excluded from Medicare.

(iv) The OIG notifies the State agency whether its request for a waiver has been granted or denied.

(v) The decision to deny a waiver is not subject to administrative or judicial review.

(2) For purposes of this section, the definitions contained in § 1001.2 of this chapter for ''sole community physician'' and ''sole source of essential specialized services in a community'' apply.

(c) When the Inspector General proposes to exclude a nursing facility from the Medicare and Medicaid programs, he or she will, at the same time he or she notifies the respondent, notify the appropriate State licensing authority, the State Office of Aging, the long-term care ombudsman, and the State Medicaid agency of the Inspector General's intention to exclude the facility.

[59 FR 32125, June 22, 1994, as amended at 64 FR 39429, July 22, 1999; 65 FR 24416, Apr. 26, 2000; 65 FR 35584, June 5, 2000]

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) *Amount of penalty.* (1) In determining the amount of any penalty or assessment in accordance with § 1003.102(a), (b)(1), (b)(4), and (b)(9) through (b)(16) of this part, the Department will take into account—

(i) The nature of the claim, referral arrangement or other wrongdoing;

(ii) The degree of culpability of the person against whom a civil money penalty is proposed;

(iii) The history of prior offenses of the person against whom a civil money penalty is proposed;

(iv) The financial condition of the person against whom a civil money penalty is proposed;

(v) The completeness and timeliness of the refund with respect to § 1003.102(b)(9);

(vi) The amount of financial interest involved with respect to § 1003.102(b)(12);

(vii) The amount of remuneration offered or transferred with respect to § 1003.102(b)(13); and

(viii) Such other matters as justice may require.

(2) In determining the amount of any penalty in accordance with §§ 1003.102 (b)(5) and (b)(6), the Department will take into account—

(i) The nature and circumstances of the failure to properly report information, or the improper disclosure of information, as required;

(ii) The degree of culpability of the person in failing to provide timely and complete data or in improperly disclosing, using or permitting access to information, as appropriate;

(iii) The materiality, or significance of omission, of the information to be reported, or the materiality of the improper disclosure of, or use of, or access to information, as appropriate;

(iv) Any prior history of the person with respect to violations of these provisions; and

(v) Such other matters as justice may require.

(3)(i) In determining the amount of any penalty in accordance with § 1003.102(b)(7), the OIG will take into account—

(A) The nature and objective of the advertisement, solicitation or other communication, and the degree to which it has the capacity to deceive members of the public;

(B) The degree of culpability of the individual, organization or entity in the use of the prohibited words, letters, symbols or emblems;

(C) The frequency and scope of the violation, and whether a specific segment of the population was targeted;

(D) The prior history of the individual, organization or entity in its willingness or refusal to comply with informal requests to correct violations;

(E) The history of prior offenses of the individual, organization or entity in its misuse of Departmental and program words, letters, symbols and emblems;

(F) The financial condition of the individual, organization or entity involved with the violation; and

(G) Such other matters as justice may require.

(ii) The use of a disclaimer of affiliation with the United States Government, the Department or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with § 1003.102(b)(7).

(4) In determining the amount of any penalty in accordance with § 1003.102(c), the OIG takes into account—

(i) The degree of culpability of the respondent;

(ii) The seriousness of the condition of the individual seeking emergency medical treatment;

(iii) Any other instances where the respondent failed to provide appropriate emergency medical screening, stabilization and treatment of individuals coming to a hospital's emergency department or to effect an appropriate transfer;

(iv) The respondent's financial condition;

(v) The nature and circumstances of the violation; and

(vi) Such other matters as justice may require.

(5) In determining the appropriate amount of any penalty in accordance with § 1003.103(f), the OIG will consider as appropriate—

(i) The nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided;

(ii) The degree of culpability of the contracting organization;

(iii) The seriousness of the adverse effect that resulted or could have resulted from the failure to provide required medically necessary care;

(iv) The harm which resulted or could have resulted from the provision of care by a person that the contracting organization is expressly prohibited, under section 1876(i)(6) or section 1903(p)(2) of the Act, from contracting with or employing;

(v) The harm which resulted or could have resulted from the contracting organization's expulsion or refusal to reenroll a Medicare beneficiary or Medicaid recipient;

(vi) The nature of the misrepresentation or fallacious information furnished by the contracting organization to the Secretary, State, enrollee or other entity under section 1876 or section 1903(m) of the Act;

(vii) The extent to which the failure to provide medically necessary services

could be attributed to a prohibited inducement to reduce or limit services under a physician incentive plan and the harm to the enrollee which resulted or could have resulted from such failure. It would be considered an aggravating factor if the contracting organization knowingly or routinely engaged in any prohibited practice which acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization;

(viii) The history of prior offenses by the contracting organization or principals of the contracting organization, including whether, at any time prior to determination of the current violation or violations, the contracting organization or any of its principals were convicted of a criminal charge or were held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services; and

(ix) Such other matters as justice may require.

(b) *Determining the amount of the penalty or assessment.* As guidelines for taking into account the factors listed in paragraph (a)(1) of this section, the following circumstances are to be considered—

(1) *Nature and circumstances of the incident.* It should be considered a mitigating circumstance if all the items or services or incidents subject to a determination under §1003.102 included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or incidents, and the total amount claimed or requested for such items or services was less than $1,000. It should be considered an aggravating circumstance if—

(i) Such items or services or incidents were of several types, occurred over a lengthy period of time;

(ii) There were many such items or services or incidents (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of incidents);

(iii) The amount claimed or requested for such items or services was substantial; or

(iv) The false or misleading information given resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission.

(2) Degree of culpability. It should be considered a mitigating circumstance if corrective steps were taken promptly after the error was discovered. It should be considered an aggravating circumstance if—

(i) The respondent knew the item or service was not provided as claimed or if the respondent knew that the claim was false or fraudulent;

(ii) The respondent knew that the items or services were furnished during a period that he or she had been excluded from participation and that no payment could be made as specified in §§1003.102(a)(3) and 1003.102(b)(12), or because payment would violate the terms of an assignment or an agreement with a State agency or other agreement or limitation on payment under §1003.102(b);

(iii) The respondent knew that the information could reasonably be expected to influence the decision of when to discharge a patient from a hospital; or

(iv) The respondent knew that the offer or transfer of remuneration described in §1003.102(b)(13) of this part would influence a beneficiary to order or receive from a particular provider, practitioner or supplier items or services reimbursable under Medicare or a State health care program.

(3) *Prior offenses.* It should be considered an aggravating circumstance if at any time prior to the incident or presentation of any claim or request for payment which included an item or service subject to a determination under §1003.102, the respondent was held liable for criminal, civil or administrative sanctions in connection with a program covered by this part or any other public or private program of reimbursement for medical services.

(4) *Other wrongful conduct.* It should be considered an aggravating circumstance if there is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon

which liability is based, relating to government programs or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings will not apply to proof of other wrongful conduct as an aggravating circumstance.

(5) *Financial condition.* In all cases, the resources available to the respondent will be considered when determining the amount of the penalty and assessment.

(6) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature should be taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to assure the achievement of the purposes of this part.

(c) In determining the amount of the penalty and assessment to be imposed for every item or service or incident subject to a determination under §§ 1003.102(a), (b)(1) and (b)(4)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximium permitted by §§ 1003.103(a) and 1003.104, to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close or at the maximum permitted by §§ 1003.103(a) and 1003.104, to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should never be less than double the approximate amount of damages and costs (as defined in paragraph (f) of this section) sustained by the United States, or any State, as a result of claims or incidents subject to a determination under §§ 1003.102(a), (b)(1) and (b)(4).

(d) In considering the factors listed in paragraph (a)(4) of this section for violations subject to a determination under § 1003.103(e), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(1) *Degree of culpability.* It would be a mitigating circumstance if the respondent hospital had appropriate policies and procedures in place, and had effectively trained all of its personnel in the requirements of section 1867 of the Act and § 489.24 of this title, but an employee or responsible physician acted contrary to the respondent hospital's policies and procedures.

(2) *Seriousness of individual's condition.* It would be an aggravating circumstance if the respondent's violation(s) occurred with regard to an individual who presented to the hospital a request for treatment of a medical condition that was clearly an emergency, as defined by § 489.24(b) of this title.

(3) *Prior offenses.* It would be an aggravating circumstance if there is evidence that at any time prior to the current violation(s) the respondent was found to have violated any provision of section 1867 of the Act or § 489.24 of this title.

(4) *Financial condition.* In all cases, the resources available to the respondent would be considered when determining the amount of the penalty. A respondent's audited financial statements, tax returns or financial disclosure statements, as appropriate, will be reviewed by OIG in making a determination with respect to the respondent's financial condition.

(5) *Nature and circumstances of the incident.* It would be considered a mitigating circumstance if an individual presented a request for treatment, but subsequently exhibited conduct that demonstrated a clear intent to leave the respondent hospital voluntarily. In reviewing such circumstances, the OIG would evaluate the respondent's efforts to—

(i) Provide the services required by section 1867 of the Act and § 489.24 of this title, despite the individual's withdrawal of the request for examination or treatment; and

(ii) Document any attempts to inform the individual (or his or her representative) of the risks of leaving the respondent hospital without receiving an appropriate medical screening examination or treatment, and obtain written acknowledgment from the individual (or his or her representative) prior to the individual's departure from

the respondent hospital that he or she is leaving contrary to medical advice.

(6) *Other matters as justice may require.* (i) It would be considered a mitigating circumstance if the respondent hospital—

(A) Developed and implemented a corrective action plan;

(B) Took immediate appropriate action against any hospital personnel or responsible physician who violated section 1867 of the Act or §489.24 of this title prior to any investigation of the respondent hospital by CMS; or

(C) Is a rural or publicly-owned facility that is faced with severe physician staffing and financial deficiencies.

(ii) It would be considered an aggravating circumstance if an individual was severely harmed or died as a result, directly or indirectly, of the respondent's violation of section 1867 of the Act or §489.24 of this title.

(iii) Other circumstances of an aggravating or mitigating nature will be taken into account if, in the interests of justice, they require either a reduction of the penalty or an increase in order to assure the achievement of the purposes of this part.

(e) In considering the factors listed in paragraph (a)(5) of this section for violations subject to a determination under §1003.103(f), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(f)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution and administrative review of the case.

(3) Nothing in this section will limit the authority of the Department to settle any issue or case as provided by §1003.126, or to compromise any penalty and assessment as provided by §1003.128.

[57 FR 3347, Jan. 29, 1992, as amended at 59 FR 32125, June 22, 1994; 59 FR 36086, July 15, 1994; 59 FR 48567, Sept. 22, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996; 64 FR 39429, July 22, 1999; 65 FR 24416, Apr. 26, 2000; 67 FR 11935, Mar. 18, 2002; 70 FR 13325, Mar. 18, 2005]

§ 1003.107 Determinations regarding exclusion.

(a) In determining whether to exclude a person under this part and the duration of any exclusion, the Department considers the circumstances described in §1003.106(a).

(b) With respect to determinations to exclude a person under §§1003.102(a), (b)(1), (b)(4), (b)(12) or (b)(13) of this part, the Department considers those circumstances described in §1003.106(b). Where there are aggravating circumstances with respect to such determinations, the person should be excluded.

(c) The guidelines set forth in this section are not binding. Nothing in this section limits the authority of the Department to settle any issue or case as provided by §1003.126 of this part.

[59 FR 32126, June 22, 1994, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1003.108 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

[59 FR 32126, June 22, 1994]

§ 1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, assessment, or proposes to exclude a respondent from participation in a Federal health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—

(1) Reference to the statutory basis for the penalty, assessment and exclusion;

(2) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment and exclusion are proposed (except in cases where the Inspector General is relying upon statistical sampling in accordance with §1003.133 in which case the notice shall describe those claims and requests for payment comprising the sample upon which the Inspector General is relying and will also briefly describe the statistical sampling technique utilized by the Inspector General);

(3) The reason why such claims, requests for payments or incidents subject the respondent to a penalty, assessment and exclusion;

(4) The amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(5) Any circumstances described in §1003.106 that were considered when determining the amount of the proposed penalty and assessment and the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of respondent's right to a hearing, and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

(b) Any person upon whom the Inspector General has proposed the imposition of a penalty, assessment or exclusion may appeal such proposed penalty, assessment or exclusion to the DAB in accordance with §1005.2 of this chapter. The provisions of part 1005 of this chapter govern such appeals.

(c) If the respondent fails, within the time permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

[57 FR 3348, Jan. 29, 1992, as amended at 59 FR 32126, June 22, 1994; 64 FR 39429, July 22, 1999; 65 FR 24418, Apr. 26, 2000]

§1003.110 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by §1003.109(a), the Inspector General may impose the proposed penalty, assessment, and exclusion, or any less severe penalty, assessment, and suspension. The Inspector General shall notify the respondent by certified mail, return receipt requested, of any penalty, assessment, and exclusion that has been imposed and of the means by which the respondent may satisfy the judgment. The respondent has no right to appeal a penalty, assessment, and exclusion, with respect to which he or she has not requested a hearing.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3348, Jan. 29, 1992]

§1003.114 Collateral estoppel.

(a) Where a final determination pertaining to the respondent's liability under §1003.102 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent shall be bound by such determination in any proceeding under this part.

(b) In a proceeding under this part that—

(1) Is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(2) Involves the same transactions as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

[57 FR 3348, Jan. 29, 1992, as amended at 64 FR 39429, July 22, 1999]

§1003.126 Settlement.

The Inspector General has exclusive authority to settle any issues or case, without consent of the ALJ.

[65 FR 24418, Apr. 26, 2000]

§1003.127 Judicial review.

Section 1128A(e) of the Act authorizes judicial review of a penalty, assessment or exclusion that has become final. Judicial review may be sought by a respondent only with respect to a penalty, assessment or exclusion with

respect to which the respondent filed an exception under §1005.21(c) of this chapter unless the failure or neglect to urge such exception will be excused by the court in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

[57 FR 3348, Jan. 29, 1992]

§ 1003.128 Collection of penalty and assessment.

(a) Once a determination by the Secretary has become final, collection of any penalty and assessment will be the responsibility of CMS, except in the case of the Maternal and Child Health Services Block Grant program, where the collection will be the responsibility of the PHS, and in the case of the Social Services Block Grant program, where the collection will be the responsibility of the Office of Human Development Services.

(b) A penalty or assessment imposed under this part may be compromised by the Inspector General, and may be recovered in a civil action brought in the United States district court for the district where the claim was presented, or where the respondent resides.

(c) The amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3349, Jan. 29, 1992; 65 FR 24418, Apr. 26, 2000]

§ 1003.129 Notice to other agencies.

Whenever a penalty, assessment or exclusion become final, the following organizations and entities will be notified about such action and the reasons for it—the appropriate State or local medical or professional association; the appropriate Quality Improvement Organization; as appropriate, the State agency responsible or the administration of each State health care program; the appropriate Medicare carrier or intermediary; the appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies); and the long-term care ombudsman. In cases involving exclusions, notice will also be given to the public of the exclusion and its effective date.

[57 FR 3349, Jan. 29, 1992]

§ 1003.132 Limitations.

No action under this part will be entertained unless commenced, in accordance with §1003.109(a) of this part, within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[57 FR 3349, Jan. 29, 1992]

§ 1003.133 Statistical sampling.

(a) In meeting the burden of proof set forth in §1005.15, the Inspector General may introduce the results of a statistical sampling study as evidence of the number and amount of claims and/or requests for payment as described in §1003.102 that were presented or caused to be presented by respondent. Such a statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, shall constitute prima facie evidence of the number and amount of claims or requests for payment as described in §1003.102.

(b) Once the Inspector General has made a prima facie case as described in paragraph (a) of this section, the burden of production shall shift to respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Inspector General will then be given the opportunity to rebut this evidence.

[51 FR 34777, Sept. 30, 1986, as amended at 57 FR 3349, Jan. 29, 1992]

§ 1003.134 Effect of exclusion.

The effect of an exclusion will be as set forth in §1001.1901 of this chapter.

[57 FR 3349, Jan. 29, 1992]

§ 1003.135 Reinstatement.

A person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with the provisions of §§ 1001.3001 through 1001.3004 of this chapter.

[57 FR 3349, Jan. 29, 1992]

PART 1004—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES BY A QUALITY IMPROVEMENT ORGANIZATION

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Subpart F—Appeals

1004.140 Appeal rights.

AUTHORITY: 42 U.S.C. 1302 and 1320c–5.

SOURCE: 60 FR 63640, Dec. 12, 1995, unless otherwise noted.

Subpart A—General Provisions

§ 1004.1 Scope and definitions.

(a) *Scope.* This part implements section 1156 of the Act by—

(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;

(2) Establishing criteria and procedures for the reports required from quality improvement organizations (QIOs) when there is failure to meet those obligations;

(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and

(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions.* As used in this part, unless the context indicates otherwise—

Dentist is limited to licensed doctors of dental surgery or dental medicine.

Economically means the services are provided at the least expensive, medically appropriate type of setting or level of care available.

Exclusion means that items and services furnished or ordered (or at the medical direction or on the prescription of a physician) by a specified health care practitioner, provider or other person during a specified period are not reimbursed under titles V, XVIII, XIX, or XX of the Social Security Act and all other Federal non-procurement programs.

Gross and flagrant violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.

Health care service or services means services or items for which payment may be made (in whole or in part) under the Medicare or State health care programs.

Health professional shortage area (HPSA) means an area designated by the Secretary and defined in 42 CFR 5.2.

Metropolitan Statistical Area means an area as defined by the Executive Office of Management and Budget.

Obligation means any of the obligations specified at section 1156(a) of the Act.

Other person means a hospital or other health care facility, an organization or an agency that provides health care services or which payment may be made (in whole or in part) under the Medicare or State health care programs.

Pattern or care means that the care under question has been demonstrated in more than three instances, each of which involved different admissions.

Pharmacy professional is a term limited to individuals who are licensed or registered to provide pharmaceutical services.

Podiatric professional is a term limited to licensed doctors of podiatric medicine.

Practice area means the location where over 50 percent of the practitioner's or other person's patients are seen.

Practitioner means a physician or other health care professional licensed under State law to practice his or her profession.

Primary medical care professional is a term limited to:

(i) Licensed doctors of medicine and doctors of osteopathy providing direct patient care who practice in the fields of general or family practice, general internal medicine, pediatrics, obstetrics and gynecology, surgery, and any other specialty that is not accommodated by the remaining specialty HPSA designator, or

(ii) Those facilities where care and treatment is provided to patients with health problems other than mental disorders.

Pro area means the geographic area subject to review by a particular QIO.

Provider means a hospital or other health care facility, agency, or organization.

Psychiatric professional is a term limited to licensed doctors of medicine who limit their practice to psychiatry or to those facilities where care and treatment is limited to patients with mental disorders.

Rural means any area outside an urban area.

Rural health professional shortage area means any health professional shortage area located outside a Metropolitan Statistical Area.

Sanction means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a QIO.

Serious risk includes situations that may involve the risk of unnecessary treatment, prolonged treatment, lack of treatment, incorrect treatment, medical complication, premature discharge, physiological or anatomical impairment, disability, or death.

State health care program means a State plan approved under title XIX, any program receiving funds under title V or from an allotment to a State under such title, or any program receiving funds under title XX or from an allotment to a State under such title.

Substantial violation in a substantial number of cases means a pattern of providing care, as defined in this section, that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the QIO.

Urban means a Metropolitan Statistical Area as defined by the Executive Office of Management and Budget.

Vision care professional is a term limited to licensed doctors of medicine who limit their practice to ophthalmology and to doctors of optometry.

Subpart B—Sanctions Under the QIO Program; General Provisions

§ 1004.10 Statutory obligations of practitioners and other persons.

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under the Medicare or State health care programs to ensure, to the extent of his or her or its authority, that those services are—

(a) Provided economically and only when, and to the extent, medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of medical necessity and quality in the form and

fashion and at such time that the reviewing QIO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements) to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 1004.20 Sanctions.

In addition to any other sanction provided under the law, a practitioner or other person may be—

(a) Excluded from participating in programs under titles V, XVIII, XIX, and XX of the Social Security Act for a period of no less than 1 year; or

(b) In lieu of exclusion and as a condition for continued participation in titles V, XVIII, XIX, and XX of the Act, if the violation involved the provision or ordering of health care services (or services furnished at the medical direction or on the prescription of a physician) that were medically improper or unnecessary, required to pay an amount of up to $10,000 for each instance in which improper or unnecessary services were furnished or ordered (or prescribed, if appropriate). The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.

[62 FR 23143, Apr. 29, 1997]

Subpart C—QIO Responsibilities

§ 1004.30 Basic responsibilities.

(a) The QIO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 1004.10.

(b) When the QIO identifies situations where an obligation specified in § 1004.10 is violated, it will afford the practitioner or other person reasonable notice and opportunity for discussion and, if appropriate, a suggested method for correcting the situation and a time period for a corrective action in accordance with §§ 1004.40 and 1004.60.

(c) The QIO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this section and, if appropriate, the opportunity to enter into and complete a corrective action plan (CAP) if the QIO finds that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of admissions; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The QIO report to the OIG must comply with the provisions of § 1004.80.

(e) If a practitioner or other person relocates to another QIO area prior to a finding of a violation or sanction recommendation, and the originating QIO—

(1) Is able to make a finding, the originating QIO must, as appropriate, close the case or forward a sanction recommendation to the OIG; or

(2) Cannot make a finding, the originating QIO must forward all documentation regarding the case to the QIO with jurisdiction, and notify the practitioner or other person of this action.

(f) The QIO must deny payment for services or items furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by an excluded practitioner or other person when the QIO identifies the services or items. It must report the findings to the Centers for Medicare & Medicaid Services.

§ 1004.40 Action on identification of a violation.

When a QIO identifies a violation, it must—

(a) Indicate whether the violation is a gross and flagrant violation or is a substantial violation in a substantial number of cases; and

(b) Send the practitioner or other person written notice of the identification of a violation containing the following information—

(1) The obligation(s) involved;

(2) The situation, circumstances or activity that resulted in a violation;

(3) The authority and responsibility of the QIO to report violations of any

obligation under section 1156(a) of the Act;

(4) A suggested method for correcting the situation and a time period for corrective action, if appropriate;

(5) The sanction that the QIO could recomment to the OIG;

(6) The right of the practitioner or other person to submit to the QIO within 30 days of receipt of the notice additional information or a written request for a meeting with the QIO to review and discuss the finding, or both. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary. The notice will also state that if a meeting is requested—

(i) It will be held within 30 days of receipt by the QIO of the request, but may be extended for good cause;

(ii) The practitioner or other person may have an attorney present; and

(iii) The attorney, if present, will be permitted to make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person's behalf; and

(7) A copy of the material used by the QIO in arriving at its finding except for QIO deliberations, as set forth in §476.139 of this part.

§ 1004.50 Meeting with a practitioner or other person.

If the practitioner or other person requests a meeting with the QIO—

(a) The QIO panel that meets with the practitioner or other person must consist of a minimum of 3 physicians;

(b) No physician member of the QIO panel may be in direct economic competition with the practitioner or other person being considered for sanction;

(c) The QIO must ensure that no physician member of the QIO panel has a substantial bias for or against the practitioner or other person being considered for sanction;

(d) At least one member of the QIO panel meeting with the practitioner or other person should practice in a similar area, e.g., urban or rural, and at least one member of the panel must be in the same specialty (both requirements could be met by a single individual);

(e) If the practitioner or other person has an attorney present, that attorney will be permitted to make opening and closing remarks, ask clarifying questions and assist the practitioner or other person in presenting the testimony of expert witnesses who may appear on the practitioner's or other person behalf;

(f) The physician who recommends to the QIO that a practitioner or other person be sanctioned may not vote on that recommendation at the meeting;

(g) The QIO may allow the practitioner or other person 5 working days after the meeting to provide the QIO additional relevant information that may affect its finding; and

(h) A verbatim record must be made of the meeting and must be made available to the practitioner or other person promptly.

§ 1004.60 QIO finding of a violation.

(a) On the basis of any additional information received, the QIO will affirm or modify its finding. If the QIO affirms its finding, it may suggest in writing a method for correcting the situation and a time period for corrective action. This CAP could correspond with, or be a continuation of, a prior CAP or be a new proposal based on additional information received by the QIO. If the finding has been resolved to the QIO's satisfaction, the QIO may modify its initial finding or recommendation or close the case.

(b) The QIO must give written notice to the practitioner or other person of any action it takes as a result of the additional information received, as specified in §1004.70.

(c) At least one member of the QIO participating in the process which resulted in a recommendation to the OIG that a practitioner or other person be sanctioned should practice in a similar geographic area, e.g. urban or rural, and at least one member of the panel must be in the same medical specialty. Both requirements can be met by a single individual. In addition, no one at the QIO who is a participant in such a finding may be in direct economic competition with, or have a substantial bias for or against, that practitioner or

other person being recommended for sanction.

§ 1004.70 QIO action on final finding of a violation.

If the finding is not resolved to the QIO's satisfaction as specified in § 1004.60(a), the QIO must—

(a) Submit its report and recommendation to the OIG;

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of all the material that is being forwarded to the OIG, advising that—

(1) The QIO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional written material or documentary evidence to the OIG at its headquarters location. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified in § 1004.100(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered; and

(c) Provide notice to the State medical board or to other appropriate licensing boards for other practitioner types when it submits a report and recommendations to the OIG with respect to a physician or other person whom the board is responsible for licensing.

§ 1004.80 QIO report to the OIG.

(a) *Manner of reporting.* If the violation(s) identified by the QIO have not been resolved, it must submit a report and recommendation to the OIG at the field office with jurisdiction.

(b) *Content of report.* The QIO report must include the following information—

(1) Identification of the practitioner or other person and, when applicable, the name of the director, administrator or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including specific dates, places, circumstances and other relevant facts;

(4) Pertinent documentary evidence;

(5) Copies of written correspondence, including reports of conversations with the practitioner or other person regarding the violation and, if applicable, a copy of the verbatim transcript of the meeting with the practitioner or other person;

(6) The QIO's finding that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in a substantial number of cases or is gross and flagrant;

(7) A case-by-case analysis and evaluation of any additional information provided by the practitioner or other person in response to the QIO's initial finding;

(8) A copy of the CAP that was developed and documentation of the results of such plan;

(9) The number of admissions by the practitioner or other person reviewed by the QIO during the period in which the violation(s) were identified;

(10) The professional qualifications of the QIO's reviewers; and

(11) The QIO's sanction recommendation.

(c) *QIO recommendation.* The QIO must specify in its report—

(1) The sanction recommended;

(2) The amount of the monetary penalty recommended, if applicable;

(3) The period of exclusion recommended, if applicable;

(4) The availability of alternative sources of services in the community, with supporting information; and

(5) The county or counties in which the practitioner or other person furnishes services.

[60 FR 63640, Dec. 12, 1995, as amended at 62 FR 23143, Apr. 29, 1997]

§ 1004.90 Basis for recommended sanction.

The QIO's specific recommendation must be based on documentation provided to the OIG showing its consideration of—

(a) The type of offense involved;

(b) The severity of the offense;

(c) The deterrent value;

(d) The practitioner's or other person's previous sanction record;

(e) The availability of alternative sources of services in the community; and

(f) Any other factors that the QIO considers relevant, such as the duration of the problem.

Subpart D—OIG Responsibilities

§ 1004.100 Acknowledgement and review of report.

(a) *Acknowledgement.* The OIG will inform the QIO of the date it received the QIO's report and recommendation.

(b) *Review.* The OIG will review the QIO report and recommendation to determine whether—

(1) The QIO has followed the regulatory requirements of this part; and

(2) A violation has occurred.

(c) *Rejection of the QIO recommendation.* If the OIG decides that a sanction is not warranted, it will notify the QIO that recommended the sanction, the affected practitioner or other person, and the licensing board informed by the QIO of the sanction recommendation that the recommendation is rejected.

(d) *Decision to sanction.* If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

(1) The recommendation of the QIO;

(2) The type of offense;

(3) The severity of the offense;

(4) The previous sanction record of the practitioner or other person;

(5) The availability of alternative sources of services in the community;

(6) Any prior problems the Medicare or State health care programs have had with the practitioner or other person; and

(7) Any other matters relevant to the particular case.

(e) *Exclusion sanction.* If the QIO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 1004.110(f).

(f) *Monetary penalty.* If the QIO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 1004.110 (a)–(e).

[60 FR 63640, Dec. 12, 1995, as amended at 62 FR 23143, Apr. 29, 1997]

§ 1004.110 Notice of sanction.

(a) The OIG must notify the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 20 days from the date of the notice. Receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice must specify—

(1) The legal and factual basis for the determination;

(2) The sanction to be imposed;

(3) The effective date and, if appropriate, the duration of the exclusion;

(4) The appeal rights of the practitioner or other person;

(5) The opportunity and the process necessary to provide alternative notification as set forth in paragraphs (d) and (e) of this section; and

(6) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) *Patient notification.* (1)(i) The OIG will provide a sanctioned practitioner or other person an opportunity to elect to inform each of their patients of the sanction action. In order to elect this option, the sanctioned practitioner or other person must, within 30 calendar days from receipt of the OIG notice, inform both new and existing patients through written notice—based on a suggested (non-mandatory) model provided to the sanctioned individual by the OIG—of the sanction and, in the case of an exclusion, its effective date. Receipt of the OIG notice is presumed to be 5 days after the date of the notice, unless there is a reasonable showing to the contrary. Within this same period, the practitioner or other person must also sign and return the certification that the OIG will provide with the notice. For purposes of this section, the term ''all existing patients'' includes all patients currently under active treatment with the practitioner or other person, as well as all patients who have been treated by the practitioner or other person within the last 3 years. In addition, the practitioner or

other person must notify all prospective patients orally at the time such persons request an appointment. If the sanctioned party is a hospital, it must notify all physicians who have privileges at the hospital, and must post a notice in its emergency room, business office and in all affiliated entities regarding the exclusion. In addition, for purposes of this section, the term ''in all affiliated entities'' encompasses all entities and properties in which the hospital has a direct or indirect ownership interest of 5 percent or more and any management, partnership or control of the entity.

(ii) The certification will provide that the practitioner or other person—

(A) Has informed each of his, her or its patients in writing that the practitioner or other person has been sanctioned, or if a hospital, has informed all physicians having privileges at the hospital that it has been sanctioned;

(B) If excluded from Medicare and the State health care programs, has informed his, her or its existing patients in writing that the programs will not pay for items and services furnished or ordered (or at the medical direction or on the prescription of an excluded physician) by the practitioner or other person until they are reinstated, or if a hospital, has provided this information to all physicians having privileges at that hospital;

(C) If excluded from Medicare and State health care programs, will provide prospective patients—or if a hospital, physicians requesting privileges at that hospital prior to furnishing or ordering (or in the case of an excluded physician, medically directing or prescribing) services—oral information of both the sanction and that the programs will not pay for services provided and written notification of the same at the time of the provision of services;

(D) If excluded from Medicare and State health care programs and is an entity such as a hospital, has posted a notice in its emergency room, business office and in all affiliated entities that the programs will not pay for services provided; and

(E) Certifies to the truthfulness and accuracy of the notification and the statements in the certification.

(2) If the sanctioned practitioner or other person does not inform his, her or its patients *and* does not return the required certification within the 30-day period, or if the sanctioned practitioner or other person returns the certification within the 30-day period but the OIG obtains reliable evidence that such person nevertheless has not adequately informed new and existing patients of the sanction, the OIG—

(i) Will see that the public is notified directly of the identity of the sanctioned practitioner or other person, the finding that the obligation has been violated, and the effective date of any exclusion; and

(ii) May consider this failure to adhere to the certification obligation as an adverse factor at the time the sanctioned practitioner or other person requests reinstatement.

(3) If the sanctioned practitioner or other person is entitled to a preliminary hearing in accordance with §1004.140(a) and requests such a preliminary hearing, and if the administrative law judge (ALJ) decides that he, she or it poses a risk to program beneficiaries, the sanctioned practitioner or other person would have 30 days from the date of receipt of the ALJ's decision to provide certification to the OIG in accordance with §1004.110(d)(1). The date of receipt is presumed to be 5 days after the date of the ALJ's decision, unless there is a reasonable showing to the contrary.

(e) Notice of the sanction is also provided to the following entities as appropriate—

(1) The QIO that originated the sanction report;

(2) QIOs in adjacent areas;

(3) State Medicaid fraud control units and State licensing and accreditation bodies;

(4) Appropriate program contractors and State agencies;

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations and Federally-funded community health centers where the practitioner or other person works;

(6) Medical societies and other professional organizations; and

(7) Medicare carriers and fiscal intermediaries, health care prepayment plans and other affected agencies and organizations.

(f) If an exclusion sanction is effectuated because a decision was not made within 120 days after receipt of the QIO recommendation, notification is as follows—

(1) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person, in compliance with the requirements of paragraph (c) of this section, affirming the QIO recommendation based on the OIG's review of the case, and that the exclusion is effective 20 days from the date of the notice; and

(2) Notice of sanction is also provided as specified in paragraph (e) of this section.

[60 FR 63640, Dec. 12, 1995; 61 FR 1841, Jan. 24, 1996, as amended at 62 FR 23143, Apr. 29, 1997]

Subpart E—Effect and Duration of Exclusion

§ 1004.120 Effect of an exclusion on program payments and services.

The effect of an exclusion is set forth in § 1001.1901 of this chapter.

§ 1004.130 Reinstatement after exclusion.

(a) A practitioner or other person who has been excluded in accordance with this part may apply for reinstatement at the end of the period of exclusion. The OIG will consider any request for reinstatement in accordance with provisions of §§ 1001.3001 through 1001.3005 of this chapter.

(b) The OIG may also consider a practitioner's or other person's compliance with the certification obligation in § 1004.110(d) at the time of reinstatement.

Subpart F—Appeals

§ 1004.140 Appeal rights.

(a) *Right to preliminary hearing.* (1)(i) A practitioner or other person excluded from participation in Medicare and any State health care programs under section 1156 of the Act may request a preliminary hearing if the location where services are rendered to over 50 percent of the practitioner's or other person's patients at the time of the exclusion notice is in a rural HPSA or in a county with a population of less than 70,000.

(ii) Unless the practitioner's or other person's practice meets the definition for psychiatric professional, vision care professional, dental professional, podiatric professional or pharmacy professional, the HPSA used by the OIG for determination of entitlement to a preliminary hearing will be the HPSA list for primary medical care professional.

(iii) Information on the population size of a county in order to determine entitlement to a preliminary hearing will be obtained by the OIG from the responsible officials of that county.

(2)(i) A request for a preliminary hearing must be made in writing and received by the Departmental Appeals Board (DAB) no later than the 15th day after the notice of exclusion is received by a practitioner or other person. The date of receipt of the notice of exclusion by the practitioner or other person is presumed to be 5 days after the date appearing on the notice, unless there is a reasonable showing to the contrary.

(ii) A request for a preliminary hearing will stay the effective date of the exclusion pending a decision of the ALJ at the preliminary hearing, and all the parties informed by the OIG of the exclusion will be notified of the stay.

(iii) A request for a preliminary hearing received after the 15-day period has expired will be treated as a request for a hearing before an ALJ in accordance with paragraph (b) of this section.

(iv) If the practitioner or other person exercises his, her or its right to a preliminary hearing, such a hearing must be held by the ALJ in accordance with paragraph (a)(3)(i) of this section unless the OIG waives it in accordance with paragraph (a)(6)(i) of this section.

(v) The ALJ cannot consolidate the preliminary hearing with a full hearing without the approval of all parties to the hearing.

(3)(i) The preliminary hearing will be conducted by an ALJ of the DAB in a city that the ALJ deems equitable to

all parties. The ALJ will conduct the preliminary hearing and render a decision no later than 45 days after receipt of the request for such a hearing by the DAB. Unless there is a reasonable showing to the contrary, date of receipt by the DAB is presumed to be 5 days after the date on the request for a preliminary hearing or, if undated, the date of receipt will be the date the DAB actually received the request. A reasonable extension to the 45-day period of up to 15 days may be requested by any party to the preliminary hearing and such a request may be granted upon concurrence by all parties to the preliminary hearing. Such request must be received no later than 15 days prior to the scheduled date of the preliminary hearing.

(ii) The only issue to be heard and decided on by the ALJ at the preliminary hearing, based on the preponderance of the evidence, is whether the practitioner's or other person's continued participation in the Medicare and State health care programs during the appeal of the exclusion before an ALJ would place program beneficiaries at serious risk. The ALJ's decision is to be based on the preponderance of the evidence.

(iii) In the interest of time, the ALJ may issue an oral decision to be followed by a written decision.

(iv) In those cases where the ALJ has stayed an exclusion after a preliminary hearing, a full hearing must be held and a decision rendered by the ALJ within 6 months. If, for any reason, the request for a full hearing before the ALJ is withdrawn or dismissed, the practitioner or other person will be excluded effective 5 days after the notice of the withdrawal or dismissal is received in the OIG headquarters.

(4) The preliminary hearing decision is not appealable or subject to further administrative or judicial review.

(5) A practitioner or other person found at the preliminary hearing not to place program beneficiaries at serious risk, but later determined to have been properly excluded from program participation after a full hearing before an ALJ, is not entitled to have the exclusion stayed further during an appeal to the DAB. Exclusions in such instances will be effective 5 days after receipt of the ALJ decision in the OIG headquarters.

(6)(i) After notice of a timely request for a preliminary hearing, the OIG may determine that the practitioner's or other person's continued program participation during the appeal before the ALJ will not place program beneficiaries at serious risk and waive the preliminary hearing. Under these circumstances, the exclusion will be stayed pending the decision of the ALJ after a full hearing. the hearing must be held, and a decision reached, within 6 months.

(ii) If the OIG decides to waive the preliminary hearing, the request for the preliminary hearing will be considered a request for a hearing before the ALJ in accordance with paragraph (b) of this section.

(b) *Right to administrative review.* (1) A practitioner or other person dissatisfied with an OIG determination, or an exclusion that results from a determination not being made within 120 days, is entitled to appeal such sanction in accordance with part 1005 of this chapter.

(2) Due to the 120-day statutory requirement specified in §1004.100(e), the following limitations apply—

(i) The period of time for submitting additional information will not be extended.

(ii) Any material received by the OIG after the 30-day period allowed will not be considered by the ALJ or the DAB.

(3) The OIG's determination continues in effect unless reversed by a hearing.

(c) *Rights to judicial review.* Any practitioner or other person dissatisfied with a final decision of the Secretary may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 1005—APPEALS OF EXCLUSIONS, CIVIL MONEY PENALTIES AND ASSESSMENTS

Sec.

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AUTHORITY: 42 U.S.C. 405(a), 405(b), 1302, 1320a–7, 1320a–7a and 1320c–5.

SOURCE: 57 FR 3350, Jan. 29, 1992, unless otherwise noted.

§ 1005.1 Definitions.

Civil money penalty cases refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose civil money penalties under Medicare or the State health care programs.

DAB refers to the Departmental Appeals Board or its delegatee.

Exclusion cases refer to all proceedings arising under any of the statutory bases for which the OIG has been delegated authority to impose exclusions under Medicare or the State health care programs.

Inspector General (IG) means the Inspector General of the Department of Health and Human Services or his or her designees.

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1005.2 Hearing before an administrative law judge.

(a) A party sanctioned under any criteria specified in parts 1001, 1003 and 1004 of this chapter may request a hearing before an ALJ.

(b) In exclusion cases, the parties to the proceeding will consist of the petitioner and the IG. In civil money penalty cases, the parties to the proceeding will consist of the respondent and the IG.

(c) The request for a hearing will be made in writing to the DAB; signed by the petitioner or respondent, or by his or her attorney; and sent by certified mail. The request must be filed within 60 days after the notice, provided in accordance with §§ 1001.2002, 1001.203 or 1003.109, is received by the petitioner or respondent. For purposes of this section, the date of receipt of the notice letter will be presumed to be 5 days after the date of such notice unless there is a reasonable showing to the contrary.

(d) The request for a hearing will contain a statement as to the specific issues or findings of fact and conclusions of law in the notice letter with which the petitioner or respondent disagrees, and the basis for his or her contention that the specific issues or findings and conclusions were incorrect.

(e) The ALJ will dismiss a hearing request where—

(1) The petitioner's or the respondent's hearing request is not filed in a timely manner;

(2) The petitioner or respondent withdraws his or her request for a hearing;

(3) The petitioner or respondent abandons his or her request for a hearing; or

(4) The petitioner's or respondent's hearing request fails to raise any issue which may properly be addressed in a hearing.

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1005.3 Rights of parties.

(a) Except as otherwise limited by this part, all parties may—

(1) Be accompanied, represented and advised by an attorney;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery of documents as permitted by this part;

(4) Agree to stipulations of fact or law which will be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

(8) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

(b) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of section

206 of title II of the Act, which authorizes the Secretary to specify or limit these fees.

§ 1005.4 Authority of the ALJ.

(a) The ALJ will conduct a fair and impartial hearing, avoid delay, maintain order and assure that a record of the proceeding is made.

(b) The ALJ has the authority to—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of documentary discovery as permitted by this part;

(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(9) Examine witnesses;

(10) Receive, rule on, exclude or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact; and

(13) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone.

(c) The ALJ does not have the authority to—

(1) Find invalid or refuse to follow Federal statutes or regulations or secretarial delegations of authority;

(2) Enter an order in the nature of a directed verdict;

(3) Compel settlement negotiations;

(4) Enjoin any act of the Secretary;

(5) Review the exercise of discretion by the OIG to exclude an individual or entity under section 1128(b) of the Act, or determine the scope or effect of the exclusion,

(6) Set a period of exclusion at zero, or reduce a period of exclusion to zero, in any case where the ALJ finds that an individual or entity committed an act described in section 1128(b) of the Act, or

(7) Review the exercise of discretion by the OIG to impose a CMP, assessment or exclusion under part 1003 of this chapter.

[57 FR 3350, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993]

§ 1005.5 Ex parte contacts.

No party or person (except employees of the ALJ's office) will communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 1005.6 Prehearing conferences.

(a) The ALJ will schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this part;

(9) The time and place for the hearing;

(10) Such other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings; and

(11) Potential settlement of the case.

(c) The ALJ will issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 1005.7 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying which are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term documents includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section will be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system will be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section will not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request will either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part will be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. (The party receiving a request for production may also file a motion for protective order any time prior to the date the production is due.)

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

(i) Is irrelevant,

(ii) Is unduly costly or burdensome,

(iii) Will unduly delay the proceeding, or

(iv) Seeks privileged information.

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

[57 FR 3350, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993; 65 FR 24418, Apr. 26, 2000; 65 FR 35584, June 5, 2000; 67 FR 11936, Mar. 18, 2002]

§ 1005.8 Exchange of witness lists, witness statements and exhibits.

(a) At least 15 days before the hearing, the ALJ will order the parties to exchange witness lists, copies of prior written statements of proposed witnesses and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 1005.16.

(b) (1) If at any time a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ will determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of such evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure to timely exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief:

(i) The testimony of any witness whose name does not appear on the witness list, and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of such evidence would cause substantial prejudice to the objecting

party. If the ALJ finds that there is no substantial prejudice, the evidence may be admitted. If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or at his or her discretion, may postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence.

(c) Unless another party objects within a reasonable period of time prior to the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 1005.9 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of an individual in accordance with paragraph (a) of this section may also require the individual (whether or not the individual is a party) to produce evidence authorized under § 1005.7 of this part at or prior to the hearing.

(c) When a subpoena is served by a respondent or petitioner on a particular individual or particular office of the OIG, the OIG may comply by designating any of its representatives to appear and testify.

(d) A party seeking a subpoena will file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. Such request will:

(1) Specify any evidence to be produced,

(2) Designate the witnesses, and

(3) Describe the address and location with sufficient particularity to permit such witnesses to be found.

(e) The subpoena will specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena will serve it by delivery to the individual named, or by certified mail addressed to such individual at his or her last dwelling place or principal place of business.

(h) The individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in section 205(e) of the Social Security Act (42 U.S.C. 405(e)).

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§ 1005.10 Fees.

The party requesting a subpoena will pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage will accompany the subpoena when served, except that when a subpoena is issued on behalf of the IG, a check for witness fees and mileage need not accompany the subpoena.

§ 1005.11 Form, filing and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ will include an original and two copies.

(2) Every pleading and paper filed in the proceeding will contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper will be signed by, and will contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Secretary will, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document will be made by delivering a copy, or

placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service will be made upon such attorney in lieu of the party.

(c) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, will be proof of service.

§ 1005.12 Computation of time.

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays and legal holidays observed by the Federal Government will be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 1005.2.

§ 1005.13 Motions.

(a) An application to the ALJ for an order or ruling will be by motion. Motions will state the relief sought, the authority relied upon and the facts alleged, and will be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions will be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ will make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 1005.14 Sanctions.

(a) The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. Such sanctions will reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(1) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established;

(2) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(3) Striking pleadings, in whole or in part;

(4) Staying the proceedings;

(5) Dismissal of the action;

(6) Entering a decision by default; and

(7) Refusing to consider any motion or other action that is not filed in a timely manner.

(b) In civil money penalty cases commenced under section 1128A of the Act or under any provision which incorporates section 1128A(c)(4) of the Act, the ALJ may also order the party or attorney who has engaged in any of the acts described in paragraph (a) of this section to pay attorney's fees and other costs caused by the failure or misconduct.

§ 1005.15 The hearing and burden of proof.

(a) The ALJ will conduct a hearing on the record in order to determine whether the petitioner or respondent should be found liable under this part.

(b) With regard to the burden of proof in civil money penalty cases under part 1003, in Quality Improvement Organization exclusion cases under part 1004, and in exclusion cases under §§ 1001.701, 1001.901 and 1001.951 of this chapter—

(1) The respondent or petitioner, as applicable, bears the burden of going forward and the burden of persuasion with respect to affirmative defenses and any mitigating circumstances; and

(2) The IG bears the burden of going forward and the burden of persuasion with respect to all other issues.

(c) Burden of proof in all other exclusion cases. In all exclusion cases except those governed by paragraph (b) of this section, the ALJ will allocate the burden of proof as the ALJ deems appropriate.

(d) The burden of persuasion will be judged by a preponderance of the evidence.

(e) The hearing will be open to the public unless otherwise ordered by the ALJ for good cause shown.

(f)(1) A hearing under this part is not limited to specific items and information set forth in the notice letter to the petitioner or respondent. Subject to the 15-day requirement under §1005.8, additional items and information, including aggravating or mitigating circumstances that arose or became known subsequent to the issuance of the notice letter, may be introduced by either party during its case-in-chief unless such information or items are—

(i) Privileged;

(ii) Disqualified from consideration due to untimeliness in accordance with §1004.130(a)(2)(ii); or

(iii) Deemed otherwise inadmissible under §1005.17.

(2) After both parties have presented their cases, evidence may be admitted on rebuttal even if not previously exchanged in accordance with §1005.8.

[57 FR 3350, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 65 FR 24418, Apr. 26, 2000]

§1005.16 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing will be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony (other than expert testimony) may be admitted in the form of a written statement. The ALJ may, at his or her discretion, admit prior sworn testimony of experts which has been subject to adverse examination, such as a deposition or trial testimony. Any such written statement must be provided to all other parties along with the last known address of such witnesses, in a manner that allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing will be exchanged as provided in §1005.8.

(c) The ALJ will exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth,

(2) Avoid repetition or needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ will permit the parties to conduct such cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses. This does not authorize exclusion of—

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual engaged in assisting the attorney for the IG.

[57 FR 3350, Jan. 29, 1992, as amended at 67 FR 11936, Mar. 18, 2002]

§1005.17 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue

delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. Such evidence is admissible regardless of whether the crimes, wrongs or acts occurred during the statute of limitations period applicable to the acts which constitute the basis for liability in the case, and regardless of whether they were referenced in the IG's notice sent in accordance with §§ 1001.2002, 1001.2003 or 1003.109.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless otherwise ordered by the ALJ for good cause shown.

(j) The ALJ may not consider evidence regarding the issue of willingness and ability to enter into and successfully complete a corrective action plan when such evidence pertains to matters occurring after the submittal of the case to the Secretary. The determination regarding the appropriateness of any corrective action plan is not reviewable.

§ 1005.18 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§ 1005.19 Post-hearing briefs.

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ will fix the time for filing such briefs which are not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 1005.20 Initial decision.

(a) The ALJ will issue an initial decision, based only on the record, which will contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase or reduce the penalties, assessment or exclusion proposed or imposed by the IG, or reverse the imposition of the exclusion. In exclusion cases where the period of exclusion commenced prior to the hearing, any period of exclusion imposed by the ALJ will be deemed to commence on the date such exclusion originally went into effect.

(c) The ALJ will issue the initial decision to all parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. The decision will be accompanied by a statement describing the right of any party to file a notice of appeal with the DAB and instructions for how to file such appeal. If the ALJ fails to meet the deadline contained in this paragraph, he or she will notify the parties of the reason for the delay and will set a new deadline.

(d) Except for exclusion actions taken in accordance with § 1001.2003 of this chapter and as provided in paragraph (e) of this section, unless the initial decision is appealed to the DAB, it will be final and binding on the parties 30 days after the ALJ serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(e) If an extension of time within which to appeal the initial decision is

granted under §1005.21(a), except as provided in §1005.22(a), the initial decision will become final and binding on the day following the end of the extension period.

[57 FR 3350, Jan. 29, 1992, as amended at 65 FR 24418, Apr. 26, 2000]

§1005.21 Appeal to DAB.

(a) Any party may appeal the initial decision of the ALJ to the DAB by filing a notice of appeal with the DAB within 30 days of the date of service of the initial decision. The DAB may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the DAB a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the DAB, the ALJ will forward the record of the proceeding to the DAB.

(c) A notice of appeal will be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and accompanying brief. The DAB may permit the parties to file reply briefs.

(d) There is no right to appear personally before the DAB or to appeal to the DAB any interlocutory ruling by the ALJ, except on the timeliness of a filing of the hearing request.

(e) The DAB will not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the DAB that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at such hearing, the DAB may remand the matter to the ALJ for consideration of such additional evidence.

(g) The DAB may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty, assessment or exclusion determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the initial decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the DAB will issue to each party to the appeal a copy of the DAB's decision and a statement describing the right of any petitioner or respondent who is found liable to seek judicial review.

(j) Except with respect to any penalty, assessment or exclusion remanded by the ALJ, the DAB's decision, including a decision to decline review of the initial decision, becomes final and binding 60 days after the date on which the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k) (1) Any petition for judicial review must be filed within 60 days after the DAB serves the parties with a copy of the decision. If service is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging a final action of the DAB will be sent by certified mail, return receipt requested, to the Chief Counsel to the IG. The petition copy will be time-stamped by the clerk of the court when the original is filed with the court.

(3) If the Chief Counsel to the IG receives two or more petitions within 10 days after the DAB issues its decision, the Chief Counsel to the IG will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10-day period.

[57 FR 3350, Jan. 29, 1992, as amended at 63 FR 46691, Sept. 2, 1998; 65 FR 24419, Apr. 26, 2000]

§1005.22 Stay of initial decision.

(a) In a CMP case under section 1128A of the Act, the filing of a respondent's request for review by the DAB will automatically stay the effective date of the ALJ's decision.

(b) (1) After the DAB renders a decision in a CMP case, pending judicial review, the respondent may file a request for stay of the effective date of any penalty or assessment with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of such a request will automatically act to stay the effective date of the penalty or assessment until such time as the ALJ rules upon the request.

(2) The ALJ may not grant a respondent's request for stay of any penalty or assessment unless the respondent posts a bond or provides other adequate security.

(3) The ALJ will rule upon a respondent's request for stay within 10 days of receipt.

§ 1005.23 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties, including Federal representatives such as Medicare carriers and intermediaries and Quality Improvement Organizations, is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the DAB inconsistent with substantial justice. The ALJ and the DAB at every stage of the proceeding will disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

PART 1006—INVESTIGATIONAL INQUIRIES

Sec.
1006.1 Scope.
1006.2 Contents of subpoena.
1006.3 Service and fees.
1006.4 Procedures for investigational inquiries.
1006.5 Enforcement of a subpoena.

AUTHORITY: 42 U.S.C. 405(d), 405(e), 1302 and 1320a–7a.

SOURCE: 57 FR 3354, Jan. 29, 1992, unless otherwise noted.

§ 1006.1 Scope.

(a) The provisions in this part govern subpoenas issued by the Inspector General, or his or her delegates, in accordance with sections 205(d) and 1128A(j) of the Act, and require the attendance and testimony of witnesses and the production of any other evidence at an investigational inquiry.

(b) Such subpoenas may be issued in investigations under section 1128A of the Act or under any other section of the Act that incorporates the provisions of section 1128A(j).

(c) Nothing in this part is intended to apply to or limit the authority of the Inspector General, or his or her delegates, to issue subpoenas for the production of documents in accordance with 5 U.S.C. 6(a)(4), App. 3.

§ 1006.2 Contents of subpoena.

A subpoena issued under this part will—

(a) State the name of the individual or entity to whom the subpoena is addressed;

(b) State the statutory authority for the subpoena;

(c) Indicate the date, time and place that the investigational inquiry at which the witness is to testify will take place;

(d) Include a reasonably specific description of any documents or items required to be produced; and

(e) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In such event, the named entity will designate one or more individuals who will testify on its behalf, and will state as to each individual so designated that individual's name and address and the matters on which he or she will testify. The individual so designated will testify as to matters known or reasonably available to the entity.

§ 1006.3 Service and fees.

(a) A subpoena under this part will be served by—

(1) Delivering a copy to the individual named in the subpoena;

(2) Delivering a copy to the entity named in the subpoena at its last principal place of business; or

(3) Registered or certified mail addressed to such individual or entity at its last known dwelling place or principal place of business.

(b) A verified return by the individual serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, will be proof of service.

(c) Witnesses will be entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Such fees need not be paid at the time the subpoena is served.

§ 1006.4 Procedures for investigational inquiries.

(a) Testimony at investigational inquiries will be taken under oath or affirmation.

(b) Investigational inquiries are nonpublic investigatory proceedings. Attendance of non-witnesses is within the discretion of the OIG, except that—

(1) A witness is entitled to be accompanied, represented and advised by an attorney; and

(2) Representatives of the OIG are entitled to attend and ask questions.

(c) A witness will have an opportunity to clarify his or her answers on the record following the questions by the OIG.

(d) Any claim of privilege must be asserted by the witness on the record.

(e) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to the objection.

(f) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the OIG may seek enforcement of the subpoena under § 1006.5.

(g)(1) The proceedings will be recorded and transcribed.

(2) The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(3)(i) The transcript will be submitted to the witness for signature.

(ii) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the OIG written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(iii) Where, as provided in paragraph (g)(2) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(iv) The OIG's proposed corrections the record of transcript will be attached to the transcript.

(h) Testimony and other evidence obtained in an investigational inquiry may be used by the OIG or DHHS in any of its activities, and may be used or offered into evidence in any administrative or judicial proceeding.

[57 FR 3354, Jan. 29, 1992, as amended at 65 FR 24419, Apr. 26, 2000]

§ 1006.5 Enforcement of a subpoena.

A subpoena to appear at an investigational inquiry is enforceable through the District Court of the United States and the district where the subpoenaed person is found, resides or transacts business.

PART 1007—STATE MEDICAID FRAUD CONTROL UNITS

Sec.

1007.1 Definitions.
1007.3 Scope and purpose.
1007.5 Basic requirement.

1007.7 Organization and location requirements.
1007.9 Relationship to, and agreement with, the Medicaid agency.
1007.11 Duties and responsibilities of the unit.
1007.13 Staffing requirements.
1007.15 Applications, certification and recertification.
1007.17 Annual report.
1007.19 Federal financial participation (FFP).
1007.21 Other applicable HHS regulations.

AUTHORITY: 42 U.S.C. 1396b(a)(6), 1396b(b)(3) and 1396b(q).

SOURCE: 57 FR 3355, Jan. 29, 1992, unless otherwise noted.

§ 1007.1 Definitions.

As used in this part, unless otherwise indicated by the context:

Employ or *employee*, as the context requires, means full-time duty intended to last at least a year. It includes an arrangement whereby an individual is on full-time detail or assignment to the unit from another government agency, if the detail or assignment is for a period of at least 1 year and involves supervision by the unit.

Provider means an individual or entity that furnishes items or services for which payment is claimed under Medicaid.

Unit means the State Medicaid fraud control unit.

§ 1007.3 Scope and purpose.

This part implements sections 1903(a)(6), 1903(b)(3), and 1903(q) of the Social Security Act, as amended by the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95–142). The statute authorizes the Secretary to pay a State 90 percent of the costs of establishing and operating a State Medicaid fraud control unit, as defined by the statute, for the purpose of eliminating fraud in the State Medicaid program.

§ 1007.5 Basic requirement.

A State Medicaid fraud control unit must be a single identifiable entity of the State government certified by the Secretary as meeting the requirements of §§ 1007.7 through 1007.13 of this part.

§ 1007.7 Organization and location requirements.

Any of the following three alternatives is acceptable:

(a) The unit is located in the office of the State Attorney General or another department of State government which has Statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the provision or administration of medical assistance under a State plan implementing title XIX of the Act;

(b) If there is no State agency with Statewide authority and capability for criminal fraud prosecutions, the unit has established formal procedures that assure that the unit refers suspected cases of criminal fraud in the State Medicaid program to the appropriate State prosecuting authority or authorities, and provides assistance and coordination to such authority or authorities in the prosecution of such cases; or

(c) The unit has a formal working relationship with the office of the State Attorney General and has formal procedures for referring to the Attorney General suspected criminal violations occurring in the State Medicaid program and for effective coordination of the activities of both entities relating to the detection, investigation and prosecution of those violations. Under this requirement, the office of the State Attorney General must agree to assume responsibility for prosecuting alleged criminal violations referred to it by the unit. However, if the Attorney General finds that another prosecuting authority has the demonstrated capacity, experience and willingness to prosecute an alleged violation, he or she may refer a case to that prosecuting authority, as long as the Attorney General's Office maintains oversight responsibility for the prosecution and for coordination between the unit and the prosecuting authority.

§ 1007.9 Relationship to, and agreement with, the Medicaid agency.

(a) The unit must be separate and distinct from the Medicaid agency.

(b) No official of the Medicaid agency will have authority to review the activities of the unit or to review or overrule the referral of a suspected criminal violation to an appropriate prosecuting authority.

(c) The unit will not receive funds paid under this part either from or through the Medicaid agency.

(d) The unit will enter into an agreement with the Medicaid agency under which the Medicaid agency will agree to comply with all requirements of §455.21(a)(2) of this title.

§1007.11 Duties and responsibilities of the unit.

(a) The unit will conduct a Statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws pertaining to fraud in the administration of the Medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State Medicaid plan.

(b) (1) The unit will also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State Medicaid plan and may review complaints of the misappropriation of patient's private funds in such facilities.

(2) If the initial review indicates substantial potential for criminal prosecution, the unit will investigate the complaint or refer it to an appropriate criminal investigative or prosecutive authority.

(3) If the initial review does not indicate a substantial potential for criminal prosecution, the unit will refer the complaint to an appropriate State agency.

(c) If the unit, in carrying out its duties and responsibilities under paragraphs (a) and (b) of this section, discovers that overpayments have been made to a health care facility or other provider of medical assistance under the State Medicaid plan, the unit will either attempt to collect such overpayment or refer the matter to an appropriate State agency for collection.

(d) Where a prosecuting authority other than the unit is to assume responsibility for the prosecution of a case investigated by the unit, the unit will insure that those responsible for the prosecutive decision and the preparation of the case for trial have the fullest possible opportunity to participate in the investigation from its inception and will provide all necessary assistance to the prosecuting authority throughout all resulting prosecutions.

(e) The unit will make available to Federal investigators or prosecutors all information in its possession concerning fraud in the provision or administration of medical assistance under the State plan and will cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations.

(f) The unit will safeguard the privacy rights of all individuals and will provide safeguards to prevent the misuse of information under the unit's control.

§1007.13 Staffing requirements.

(a) The unit will employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficient manner. The staff must include:

(1) One or more attorneys experienced in the investigation or prosecution of civil fraud or criminal cases, who are capable of giving informed advice on applicable law and procedures and providing effective prosecution or liaison with other prosecutors;

(2) One or more experienced auditors capable of supervising the review of financial records and advising or assisting in the investigation of alleged fraud; and

(3) A senior investigator with substantial experience in commercial or financial investigations who is capable of supervising and directing the investigative activities of the unit.

(b) The unit will employ, or have available to it, professional staff who are knowledgeable about the provision of medical assistance under title XIX and about the operation of health care providers.

§1007.15 Applications, certification and recertification.

(a) *Initial application.* In order to receive FFP under this part, the unit must submit to the Secretary, an application approved by the Governor,

containing the following information and documentation—

(1) A description of the applicant's organization, structure, and location within State government, and an indication of whether it seeks certification under § 1007.7 (a), (b), or (c);

(2) A statement from the State Attorney General that the applicant has authority to carry out the functions and responsibilities set forth in this part. If the applicant seeks certification under § 1007.7(b), the statement must also specify either that—

(i) There is no State agency with the authority to exercise Statewide prosecuting authority for the violations with which the unit is concerned, or

(ii) Although the State Attorney General may have common law authority for Statewide criminal prosecutions, he or she has not exercised that authority;

(3) A copy of whatever memorandum of agreement, regulation, or other document sets forth the formal procedures required under § 1007.7(b), or the formal working relationship and procedures required under § 1007.7(c);

(4) A copy of the agreement with the Medicaid agency required under § 1007.9;

(5) A statement of the procedures to be followed in carrying out the functions and responsibilities of this part;

(6) A projection of the caseload and a proposed budget for the 12-month period for which certification is sought; and

(7) Current and projected staffing, including the names, education, and experience of all senior professional staff already employed and job descriptions, with minimum qualifications, for all professional positions.

(b) *Conditions for, and notification of certification.* (1) The Secretary will approve an application only if he or she has specifically approved the applicant's formal procedures under § 1007.7 (b) or (c), if either of those provisions is applicable, and has specifically certified that the applicant meets the requirements of § 1007.7;

(2) The Secretary will promptly notify the applicant whether the application meets the requirements of this part and is approved. If the application is not approved, the applicant may submit an amended application at any time. Approval and certification will be for a period of 1 year.

(c) *Conditions for recertification.* In order to continue receiving payments under this part, a unit must submit a reapplication to the Secretary at least 60 days prior to the expiration of the 12-month certification period. A reapplication must—

(1) Advise the Secretary of any changes in the information or documentation required under paragraphs (a) (1) through (5) of this section;

(2) Provide projected caseload and proposed budget for the recertification period; and

(3) Include or reference the annual report required under § 1007.17.

(d) *Basis for recertification.* (1) The Secretary will consider the unit's reapplication, the reports required under § 1007.17, and any other reviews or information he or she deems necessary or warranted, and will promptly notify the unit whether he or she has approved the reapplication and recertified the unit.

(2) In reviewing the reapplication, the Secretary will give special attention to whether the unit has used its resources effectively in investigating cases of possible fraud, in preparing cases for prosecution, and in prosecuting cases or cooperating with the prosecuting authorities.

(Approved by the Office of Management and Budget under control number 0990–0162)

§ 1007.17 Annual report.

At least 60 days prior to the expiration of the certification period, the unit will submit to the Secretary a report covering the last 12 months (the first 9 months of the certification period for the first annual report), and containing the following information—

(a) The number of investigations initiated and the number completed or closed, categorized by type of provider;

(b) The number of cases prosecuted or referred for prosecution; the number of cases finally resolved and their outcomes; and the number of cases investigated but not prosecuted or referred for prosecution because of insufficient evidence;

(c) The number of complaints received regarding abuse and neglect of patients in health care facilities; the

number of such complaints investigated by the unit; and the number referred to other identified State agencies;

(d) The number of recovery actions initiated by the unit; the number of recovery actions referred to another agency; the total amount of overpayments identified by the unit; and the total amount of overpayments actually collected by the unit;

(e) The number of recovery actions initiated by the Medicaid agency under its agreement with the unit, and the total amount of overpayments actually collected by the Medicaid agency under this agreement;

(f) Projections for the succeeding 12 months for items listed in paragraphs (a) through (e) of this section;

(g) The costs incurred by the unit; and

(h) A narrative that evaluates the unit's performance; describes any specific problems it has had in connection with the procedures and agreements required under this part; and discusses any other matters that have impaired its effectiveness.

(Approved by the Office of Management and Budget under control number 0990–0162)

§ 1007.19 Federal financial participation (FFP).

(a) *Rate of FFP.* Subject to the limitation of this section, the Secretary will reimburse each State by an amount equal to 90 percent of the costs incurred by a certified unit which are attributable to carrying out its functions and responsibilities under this part.

(b) *Retroactive certification.* The Secretary may grant certification retroactive to the date on which the unit first met all the requirements of the statute and of this part. For any quarter with respect to which the unit is certified, the Secretary will provide reimbursement for the entire quarter.

(c) *Amount of FFP.* FFP for any quarter will not exceed the higher of $125,000 or one-quarter of 1 percent of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State Medicaid program.

(d) *Costs subject to FFP.* (1) FFP is available under this part for the expenditures attributable to the establishment and operation of the unit, including the cost of training personnel employed by the unit. Reimbursement will be limited to costs attributable to the specific responsibilities and functions set forth in this part in connection with the investigation and prosecution of suspected fraudulent activities and the review of complaints of alleged abuse or neglect of patients in health care facilities.

(2) (i) Establishment costs are limited to clearly identifiable costs of personnel that—

(A) Devote full time to the establishment of the unit which does achieve certification; and

(B) Continue as full-time employees after the unit is certified.

(ii) All establishment costs will be deemed made in the first quarter of certification.

(e) *Costs not subject to FFP.* FFP is not available under this part for expenditures attributable to—

(1) The investigation of cases involving program abuse or other failures to comply with applicable laws and regulations, if these cases do not involve substantial allegations or other indications of fraud;

(2) Efforts to identify situations in which a question of fraud may exist, including the screening of claims, analysis of patterns of practice, or routine verification with recipients of whether services billed by providers were actually received;

(3) The routine notification of providers that fraudulent claims may be punished under Federal or State law;

(4) The performance by a person other than a full-time employee of the unit of any management function for the unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers;

(5) The investigation or prosecution of cases of suspected recipient fraud not involving suspected conspiracy with a provider; or

(6) Any payment, direct or indirect, from the unit to the Medicaid agency, other than payments for the salaries of employees on detail to the unit.

§ 1007.21 Other applicable HHS regulations.

Except as otherwise provided in this part, the following regulations from 45 CFR subtitle A apply to grants under this part:

Part 16, subpart C—Department Grant Appeals Process—Special Provisions Applicable to Reconsideration of Disallowances [Note that this applies only to disallowance determinations and not to any other determinations, e.g., over certification or recertification];

Part 74—Administration of Grants;

Part 75—Informal Grant Appeals Procedures;

Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services, Effectuation of title VI of the Civil Rights Act of 1964;

Part 81—Practice and Procedure for Hearings Under 45 CFR part 80;

Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance;

Part 91—Nondiscrimination on the Basis of Age in HHS Programs or Activities Receiving Federal Financial Assistance.

PART 1008—ADVISORY OPINIONS BY THE OIG

Subpart A—General Provisions

Sec.

1008.1 Basis and purpose.
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1008.5 Matters subject to advisory opinions.

Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

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Subpart C—Advisory Opinion Fees

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Subpart F—Scope and Effect of OIG Advisory Opinions

1008.51 Exclusivity of OIG advisory opinions.
1008.53 Affected parties.
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1008.59 Range of the advisory opinion.

AUTHORITY: 42 U.S.C. 1320a-7d(b).

SOURCE: 62 FR 7357, Feb. 19, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 1008.1 Basis and purpose.

(a) This part contains the specific procedures for the submission of requests by an individual or entity for advisory opinions to, and the issuance of advisory opinions by, the OIG, in consultation with the Department of Justice (DoJ), in accordance with section 1128D(b) of the Social Security Act (Act), 42 U.S.C. 1320a–7d(b). The OIG will issue such advisory opinions based on actual or proposed factual circumstances submitted by the requesting individual or entity, or by counsel on behalf of the requesting individual or entity, provided all other requirements of this part are satisfied (including the requirement that the requesting individual or entity provide the certifications required in accordance with § 1008.38 of this part).

(b) An individual or entity may request an advisory opinion from the OIG regarding any of five specific subject matters described in § 1008.5 of this part.

(c) The requesting party must provide a complete description of the facts as set forth in subpart B of this part, and pay the costs to the OIG of processing the request for an advisory opinion as set forth in subpart C of this part.

(d) Nothing in this part limits the investigatory or prosecutorial authority of the OIG, DoJ or any other agency of the Government.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

§ 1008.3 Effective period.

The provisions in this part are applicable to requests for advisory opinions submitted on or after February 21, 1997, and before August 21, 2000, and to any requests submitted during any other time period for which the OIG is required by law to issue advisory opinions.

§ 1008.5 Matters subject to advisory opinions.

(a) An individual or entity may request an advisory opinion from the OIG regarding—

(1) What constitutes prohibited remuneration within the meaning of section 1128B(b) of the Act;

(2) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in section 1128B(b)(3) of the Act for activities that do not result in prohibited remuneration;

(3) Whether an arrangement, or proposed arrangement, satisfies the criteria set forth in §1001.952 of this chapter for activities that do not result in prohibited remuneration;

(4) What constitutes an inducement to reduce or limit services under section 1128A(b) of the Act to Medicare or Medicaid program beneficiaries; and

(5) Whether any activity, or proposed activity, constitutes grounds for the imposition of a sanction under sections 1128, 1128A or 1128B of the Act.

(b) *Exceptions.* The OIG will not address through the advisory opinion process—

(1) What the fair market value will be, or whether fair market value was paid or received, for any goods, services or property; or

(2) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

Subpart B—Preliminary Obligations and Responsibilities of the Requesting Party

§ 1008.11 Who may submit a request.

Any individual or entity may submit a request to the OIG for an advisory opinion regarding an existing arrangement or one which the requestor in good faith specifically plans to undertake. The requestor must be a party to the arrangement, or proposed arrangement, that is the subject of the request.

§ 1008.15 Facts subject to advisory opinions.

(a) The OIG will consider requests from a requesting party for advisory opinions regarding the application of specific facts to the subject matters set forth in §1008.5(a) of this part. The facts must relate to an existing arrangement, or one which the requestor in good faith plans to undertake. The plans may be contingent upon receiving a favorable advisory opinion. The advisory opinion request should contain a complete description of the arrangement that the requestor is undertaking, or plans to undertake.

(b) Requests presenting a general question of interpretation, posing a hypothetical situation, or regarding the activities of third parties do not qualify as advisory opinion requests.

(c) Advisory opinion request will not be accepted, and/or opinions will not be issued when—

(1) The request is not related to a named individual or entity;

(2) The same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency; or

(3) An informed opinion cannot be made, or could be made only after extensive investigation, clinical study, testing, or collateral inquiry.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

§ 1008.18 Preliminary questions suggested for the requesting party.

(a) The OIG may establish and maintain a set of questions corresponding to the categories of opinion subject matter as set forth in § 1008.5(a) of this part as appropriate. The questions will be designed to elicit specific information relevant to the advisory opinion being sought; however, answering the questions is voluntary.

(b) Questions the OIG suggests that the requestor address may be obtained from the OIG. Requests should be made in writing, specify the subject matter, and be sent to the headquarter offices of the OIG.

(c) When submitting a request for an advisory opinion, a requestor may answer the questions corresponding to the subject matter for which the opinion is requested. The extent to which any of the questions is not fully answered may effect the content of the advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

Subpart C—Advisory Opinion Fees

§ 1008.31 OIG fees for the cost of advisory opinions.

(a) *Responsibility for fees.* The requestor is responsible for paying a fee equal to the costs incurred by the Department in responding to the request for an advisory opinion.

(b) *Initial payment.* A request for an advisory opinion must be accompanied by a check or money order payable to the Treasury of the United States for $250. This initial payment is non-refundable.

(c) *Calculation of costs:* Prior to the issuance of the advisory opinion, the OIG will calculate the costs incurred by the Department in responding to the request. The calculation will include the costs of salaries and benefits payable to attorneys and others who have worked on the request in question, as well as administrative and supervisory support for such person. The OIG has the exclusive authority to determine the cost of responding to a request for an advisory opinion and such determination is not reviewable or waiveable.

(d) *Agreement to pay all costs.* (1) By submitting the request for an advisory opinion, the requestor agrees, except as indicated in paragraph (d)(4) of this section, to pay all costs incurred by the OIG in responding to the request for an advisory opinion.

(2) In its request for an advisory opinion, the requestor may request a written estimate of the cost involved in processing the advisory opinion. Within 10 business days of receipt of the request, the OIG will notify in writing of such estimate. Such estimate will not be binding on the Department, and the actual cost to be paid may be higher or lower than estimated. The time period for issuing the advisory opinion will be tolled from the time the OIG notifies the requestor of the estimate until the OIG receives written confirmation from the requestor that the requestor wants the OIG to continue processing the request. Such notice may include a new or revised triggering dollar amount, as set forth in paragraph (d)(3) of this section.

(3) In its request for an advisory opinion, the requestor may designate a triggering dollar amount. If the OIG estimates that the costs of processing the advisory opinion request have reached, or are likely to exceed, the designated triggering dollar amount, the OIG will notify the requestor. The requestor may revise its designated triggering dollar amount in writing in its response to notification of a cost estimate in accordance with paragraph (d)(2) of this section.

(4) If the OIG notifies the requestor that the estimated cost of processing the request has reached or is likely to exceed the triggering dollar amount, the OIG will stop processing the request until such time as the requestor makes a written request for the OIG to continue processing the request. Any delay in the processing of the request for an advisory opinion attributable to these procedures will toll the time for issuance of an advisory opinion until the requestor asks the OIG to continue working on the request.

(5) If the requestor chooses not to pay for completion of an advisory opinion, or withdraws the request, the requestor is still obligated to pay for all costs incurred and identified by the

OIG attributable to processing the request for an advisory opinion up to that point.

(6) If the costs incurred by the OIG in responding to the request are greater than the amount paid by the requestor, the OIG will, prior to the issuance of the advisory opinion, notify the requestor of any additional amount due. The OIG will not issue an advisory opinion until the full amount owed by the requestor has been paid. Once the requestor has paid the OIG the total amount due for the costs of processing the request, the OIG will issue the advisory opinion. The time period for issuing advisory opinions will be tolled from the time the OIG notifies the requestor of the amount owed until the time full payment is received.

(e) *Fees for outside experts.* (1) In addition to the fees identified in this section, the requestor also must pay any required fees for expert opinions, if any, from outside sources, as described in §1008.33.

(2) If the OIG determines that it is necessary to obtain expert advice to issue a requested advisory opinion, the OIG will notify the requestor of that fact and provide the identity of the appropriate expert and an estimate of the costs of the expert advice.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38324, July 16, 1998]

§1008.33 Expert opinions from outside sources.

(a) The OIG may request expert advice from qualified sources on nonlegal issues if necessary to respond to the advisory opinion request. For example, the OIG may require the use of appropriate medical reviewers, such as quality improvement organizations, to obtain medical opinions on specific issues.

(b) The time period for issuing an advisory opinion will be tolled from the time that the OIG notifies the requestor of the need for an outside expert opinion until the time the OIG receives the necessary expert opinion.

(c) Once payment is made for the cost of the expert opinion, as set forth in §1008.31(e) of this part, either directly to the expert or otherwise, the OIG will arrange for a prompt expert review of the issue or issues in question. Regardless of the manner of payment, the expert's work and opinion will be subject to the sole direction of the OIG.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

Subpart D—Submission of a Formal Request for an Advisory Opinion

§1008.36 Submission of a request.

(a) A request for a formal advisory opinion must be submitted in writing. An original and 2 copies of the request should be addressed to the headquarter offices of the OIG.

(b) Each request for an advisory opinion must include—

(1) To the extent known to the requestor, the identities, including the names and addresses, of the requestor and of all other actual and potential parties to the arrangement, that are the subject of the request for an advisory opinion;

(2) The name, title, address, and daytime telephone number of a contact person who will be available to discuss the request for an advisory opinion with the OIG on behalf of the requestor;

(3) A declaration of the subject category or categories as described in §1008.5 of this part for which the advisory opinion is requested. To the extent an individual or entity requests an advisory opinion in accordance with §§1008.5(a)(3) or (a)(5) of this part, the requesting individual or entity should identify the specific subsections of sections 1128, 1128A or 1128B of the Act or the specific provision of §1001.952 of this chapter about which an advisory opinion is sought:

(4) A complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct,[1] including—

(i) Background information,

(ii) For existing arrangements, complete copies of all operative documents,

[1] The requestor is under an affirmative obligation to make full and true disclosure with respect to the facts regarding the advisory opinion being requested.

(iii) For proposed arrangements, complete copies of all operative documents, if possible, and otherwise descriptions of proposed terms, drafts, or models of documents sufficient to permit the OIG to render an informed opinion,

(iv) Detailed statements of all collateral or oral understandings, if any, and

(v) If applicable, a designation of trade secrets or confidential commercial or financial information in the manner described in 45 CFR 5.65;

(5) Signed certifications by the requestor(s), as described in §1008.37 of this part;

(6) A check or money order payable to the Treasury of the United States in the amount of $250, as discussed in §1008.31(b) of this part;

(7) A declaration regarding whether an advisory opinion in accordance with part 411 of this title has been or will be requested from CMS about the arrangement that is the subject of the advisory opinion request; and

(8) Each requesting party's Taxpayer Identification Number.

(Approved by the Office of Management and Budget under control number 0990–0213)

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

§1008.37 Disclosure of ownership and related information.

Each individual or entity requesting an advisory opinion must supply full and complete information as to the identity of each entity owned or controlled by the individual or entity, and of each person with an ownership or control interest in the entity, as defined in section 1124(a)(1) of the Social Security Act (42 U.S.C. 1320a–3(a)(1)) and part 420 of this chapter.

(Approved by the Office of Management and Budget under control number 0990–0213)

[67 FR 11936, Mar. 18, 2002]

§1008.38 Signed certifications by the requestor.

(a) Every request must include the following signed certification from all requestors: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided is true and correct, and constitutes a complete description of the facts regarding which an advisory opinion is sought, to the best of my knowledge and belief.''

(b) If the advisory opinion relates to a proposed arrangement, the request must also include the following signed certification from all requestors: ''The arrangement described in this request for an advisory opinion is one that [the requestor(s)] in good faith plan(s) to undertake.'' This statement may be made contingent on a favorable OIG advisory opinion, in which case, the phrase ''if the OIG issues a favorable advisory opinion'' should be added to the certification.

(c) The certification(s) must be signed by—

(1) The requestor, if the requestor is an individual;

(2) The chief executive officer, or comparable officer, of the requestor, if the requestor is a corporation;

(3) The managing partner of the requestor, if the requestor is a partnership; or

(4) The managing member, or comparable person, if the requestor is a limited liability company.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

§1008.39 Additional information.

(a) If the request for an advisory opinion does not contain all of the information required by §1008.36 of this part, or the OIG believes it needs more information prior to rendering an advisory opinion, the OIG may, at any time, request whatever additional information or documents it deems necessary. The time period for the issuance of an advisory opinion will be tolled from the time the OIG requests the additional information from the requestor until such time as the OIG determines that it has received the requested information.

(b) The OIG may request additional information before or after the request for an advisory opinion has been accepted.

(c) Additional information should be provided in writing and certified to be a true, correct and complete disclosure

of the requested information in a manner equivalent to that described in §1008.38 of this part.

(d) In connection with any request for an advisory opinion, the OIG or DoJ may conduct whatever independent investigation they believe appropriate.

(e) Requesting parties are required to notify the OIG if they request an advisory opinion in accordance with part 411 of this title from CMS about the arrangement that is the subject of their advisory opinion request.

(f) Where appropriate, after receipt of an advisory opinion request, the OIG may consult with the requesting parties to the extent the OIG deems necessary.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38325, July 16, 1998]

§1008.40 Withdrawal.

The requestor of an advisory opinion may withdraw the request prior to the issuance of a formal advisory opinion by the OIG. The withdrawal must be written and must be submitted to the same address as the submitted request, as indicated in §§1008.18(b) and 1008.36(a) of this part. Regardless of whether the request is withdrawn, the requestor must pay the costs expended by the OIG in processing the opinion, as discussed in §1008.31(d) of this part. The OIG reserves the right to retain any request for an advisory opinion, documents and information submitted to it under these procedures, and to use them for any governmental purposes.

Subpart E—Obligations and Responsibilities of the OIG

§1008.41 OIG acceptance of the request.

(a) Upon receipt of a request for an advisory opinion, the OIG will promptly make an initial determination whether the submission includes all of the information the OIG will require to process the request.

(b) Within 10 working days of receipt of the request, the OIG will—

(1) Formally accept the request for an advisory opinion,

(2) Notify the requestor of what additional information is needed, or

(3) Formally decline to accept the request.

(c) If the requestor provides the additional information requested, or otherwise resubmits the request, the OIG will process the resubmission in accordance with paragraphs (a) and (b) of this section as if it was an initial request for an advisory opinion.

(d) Upon acceptance of the request, the OIG will notify the requestor by regular U.S. mail of the date that the request for the advisory opinion was formally accepted.

(e) The 60-day period for issuance of an advisory opinion set forth in §1008.43(c) of this part will not commence until the OIG has formally accepted the request for an advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

§1008.43 Issuance of a formal advisory opinion.

(a) An advisory opinion will be considered issued once payment is received and it is dated, numbered, and signed by an authorized official of the OIG.

(b) An advisory opinion will contain a description of the material facts provided to the OIG with regard to the arrangement for which an advisory opinion has been requested. The advisory opinion will state the OIG's opinion regarding the subject matter of the request based on the facts provided to the OIG. If necessary, to fully describe the arrangement, the OIG is authorized to include in the advisory opinion the material facts of the arrangement, notwithstanding that some of these facts could be considered confidential information or trade secrets within the meaning of 18 U.S.C. 1905.

(c)(1) The OIG will issue an advisory opinion, in accordance with the provisions of this part, within 60 days after the request for an advisory opinion has been formally accepted;

(2) If the 60th day falls on a Saturday, Sunday, or Federal holiday, the time period will end at the close of the next business day following the weekend or holiday;

(3) The 60 day period will be tolled from the time the OIG—

(i) Notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount until the time when the OIG receives written notice from the requestor to continue processing the request;

(ii) Requests additional information from the requestor until the time the OIG receives the requested information;

(iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and

(iv) Notifies the requestor of the need for expert advice until the time the OIG receives the expert advice.

(d) After the OIG has notified the requestor of the full amount owed and the OIG has received full payment of that amount, the OIG will issue the advisory opinion and promptly mail it to the requestor by regular first class U.S. mail.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

§ 1008.45 Rescission, termination or modification.

(a) Any advisory opinion given by the OIG is without prejudice to the right of the OIG to reconsider the questions involved and, where the public interest requires, to rescind, terminate or modify the advisory opinion. Requestors will be given a preliminary notice of the OIG's intent to rescind, terminate or modify the opinion, and will be provided a reasonable opportunity to respond. A final notice of rescission, termination or modification will be given to the requestor so that the individual or entity may discontinue or modify, as the case may be, the course of action taken in accordance with the OIG advisory opinion.

(b) For purposes of this part—

(1) To *rescind* an advisory opinion means that the advisory opinion is revoked retroactively to the original date of issuance with the result that the advisory opinion will be deemed to have been without force and effect from the original date of issuance. Recission may occur only where relevant and material facts were not fully, completely and accurately disclosed to the OIG.

(2) To *terminate* an advisory opinion means that the advisory opinion is revoked as of the termination date and is no longer in force and effect after the termination date. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith discontinued in accordance with reasonable time frames established by the OIG after consultation with the requestor.

(3) To *modify* an advisory opinion means that the advisory opinion is amended, altered, or limited, and that the advisory opinion continues in full force and effect in modified form thereafter. The OIG will not proceed against the requestor under this part if such action was promptly, diligently, and in good faith modified in accordance with reasonable time frames established by the OIG after consultation with the requestor.

[63 FR 38326, July 16, 1998]

§ 1008.47 Disclosure.

(a) Advisory opinions issued and released in accordance with the provisions set forth in this part will be available to the public.

(b) Promptly after the issuance and release of an advisory opinion to the requestor, a copy of the advisory opinion will be available for public inspection between the hours of 10:00 a.m. and 3:00 p.m. on normal business days at the headquarter offices of the OIG and on the DHHS/OIG web site.

(c) Any pre-decisional document, or part of such pre-decisional document, that is prepared by the OIG, DoJ, or any other Department or agency of the United States in connection with an advisory opinion request under the procedures set forth in this part generally will be exempt from disclosure under 5 U.S.C. 552, and will not be made publicly available.

(d) Documents submitted by the requestor to the OIG in connection with a request for an advisory opinion may be available to the public in accordance with 5 U.S.C. 552 through procedures set forth in 45 CFR part 5.

(e) Nothing in this section will limit the OIG's right, in its discretion, to

issue a press release or otherwise publicly disclose the identity of the requesting party or parties, and the nature of the action taken by the OIG upon the request.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

Subpart F—Scope and Effect of OIG Advisory Opinions

§ 1008.51 Exclusivity of OIG advisory opinions.

The only method for obtaining a binding advisory opinion regarding any of the subject matters set forth in §1008.5(a) is through the procedures described in this part. No binding advisory opinion, oral or written, has or may be issued by the OIG regarding the specific matters set forth in §1008.5(a) except through written opinions issued in accordance with this part.

§ 1008.53 Affected parties.

An advisory opinion issued by the OIG will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion.

§ 1008.55 Admissibility of evidence.

(a) The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections 1128, 1128A or 1128B of the Act.

(b) An advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate the provisions of sections 1128, 1128A or 1128B of the Act or any other law.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

§ 1008.59 Range of the advisory opinion.

(a) An advisory opinion will state only the OIG's opinion regarding the subject matter of the request. If the arrangement for which an advisory opinion is requested is subject to approval or regulation by any other Federal, State or local government agency, such advisory opinion may not be taken to indicate the OIG's views on the legal or factual issues that may be raised before that agency. The OIG will not provide any legal opinion on questions or issues regarding an authority which is vested in other Federal, State or local government agencies.

(b) An advisory opinion issued under this part will not bind or obligate any agency other than the Department. It will not affect the requestor's, or anyone else's, obligations to any other agency, or under any statutory or regulatory provision other than that which is the specific subject matter of the advisory opinion.

[62 FR 7357, Feb. 19, 1997, as amended at 63 FR 38326, July 16, 1998]

FINDING AIDS

A list of CFR titles, subtitles, chapters, subchapters and parts and an alphabetical list of agencies publishing in the CFR are included in the CFR Index and Finding Aids volume to the Code of Federal Regulations which is published separately and revised annually.

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Material Approved for Incorporation by Reference

(Revised as of October 1, 2006)

The Director of the Federal Register has approved under 5 U.S.C. 552(a) and 1 CFR part 51 the incorporation by reference of the following publications. This list contains only those incorporations by reference effective as of the revision date of this volume. Incorporations by reference found within a regulation are effective upon the effective date of that regulation. For more information on incorporation by reference, see the preliminary pages of this volume.

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CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

	42 CFR
American Association on Mental Retardation 1719 Kalorama Road NW., Washington, DC 20009	
Classification in Mental Retardation, 1983	483.102(b)
American National Standards Institute 25 West 43rd Street, Fourth floor, New York, NY 10036 Telephone: (212) 642-4900	
ANSI A117.1–1971 Specifications for Making Buildings and Facilities Accessible to and Usable by Physically Handicapped People.	442.330(a)(2) and (b)
American Psychiatric Association Division of Publications and Marketing, 1400 K St., N.W., Washington, DC 20005	
Diagnostic and Statistical Manual of Mental Disorders, Third Edition, Revised, 1987.	483.102(b)
National Academy of Sciences Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418	
Recommended Dietary Allowances Current Edition, 1980 (9th Ed.)	442.332(a)(1)
National Fire Protection Association 1 Batterymarch Park, Quincy, MA 02269–9101, Telephone: (800) 344-3555	
NFPA 101, Life Safety Code (2000 Edition)	460.72; 482.41; 483.70; 483.470; 485.623
NFPA Standard No. 220, Standard on Type of Building Construction (1979 Ed.).	442.323

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VIII Office of Special Counsel (Parts 1800—1899)

IX Appalachian Regional Commission (Parts 1900—1999)

XI Armed Forces Retirement Home (Part 2100)

XIV Federal Labor Relations Authority, General Counsel of the Federal Labor Relations Authority and Federal Service Impasses Panel (Parts 2400—2499)

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Table of OMB Control Numbers

The OMB control numbers for chapter IV of title 42 appear in §400.310. Sections 400.300 and 400.310 are reprinted below for the convenience of the user.

Subpart C—OMB Control Numbers for Approved Collections of Information

SOURCE: 49 FR 4477, Feb. 7, 1984, unless therwise noted.

§400.300 Scope.

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in CMS regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR part 1320. CMS intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35 which requires that agencies shall not engage in a ''collection of information'' without obtaining a control number from OMB.

§400.310 Display of currently valid OMB control numbers.

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[60 FR 50445, Sept. 29, 1995, as amended at 60 FR 63188, Dec. 8, 1995]

List of CFR Sections Affected

All changes in this volume of the Code of Federal Regulations that were made by documents published in the FEDERAL REGISTER since January 1, 2001, are enumerated in the following list. Entries indicate the nature of the changes effected. Page numbers refer to FEDERAL REGISTER pages. The user should consult the entries for chapters and parts as well as sections for revisions.

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431.51 (a) introductory text, (b)(1) introductory text and (2) amended; (a)(4) and (5) revised; (a)(6) added 6403
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431.220 (a) introductory text revised; (a)(1), (2) and (3) amended; (a)(5) added 6403
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431.636 Added 2666
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431.865 (b) amended 2666
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433 Authority citation revised 2666
433.10 (c)(4) added 2666
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435.212 Amended; heading and introductory text revised 6404
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435.229 Added 2667
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435.326 Revised 6404
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435.910 (h) added 2667
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435.1001 (a) revised 2667
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435.1002 (c) added 2667
(a) amended 6404
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Regulation at 66 FR 2667 eff. date delayed 11547, 31178
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435.1007 (b) and (e) revised; (f) added 2321
(a) amended 2667
Regulation at 66 FR 2667 eff. date delayed 11547, 31178
Regulation at 66 FR 2321 eff. date delayed 14343
435.1100—435.1102 (Subpart L) Added 2667
Regulation at 66 FR 2667 eff. date delayed 11547, 31178
435.1101 Amended 33822
436.3 Amended 2668
Regulation at 66 FR 2668 eff. date delayed 11547, 31178
436.229 Added 2668
Regulation at 66 FR 2668 eff. date delayed 11547, 31178
436.1001 (a) revised 2668
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436.1002 (c) added 2669
Regulation at 66 FR 2669 eff. date delayed 11547, 31178
436.1100—436.1102 (Subpart L) Added 2669
Regulation at 66 FR 2669 eff. date delayed 11547, 31178
436.1101 Amended 33822
438 Added 6404
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440.168 Added 6426
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441 Clarification 28116
441.151 Revised; interim 7160
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447.46 Added 6426
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447.53 (b) introductory text amended; (b)(6) removed; (e) added 6426
Regulation at 66 FR 6426 eff. date delayed 11546, 32776
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447.58 Amended 6426
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447.60 Added 6426
Regulation at 66 FR 6426 eff. date delayed 11546, 32776
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447.272 Revised 3175
(e)(2)(ii)(A) revised; (e)(2)(ii)(D) added; eff. 11–5–01 46399
447.304 (c) and note revised 3176
447.321 Revised 3176
(e)(2)(ii)(A) revised; (e)(2)(ii)(D) added; eff. 11–5–01 46399
447.361 Removed 6426
Regulation at 66 FR 6426 eff. date delayed 11546, 32776
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457.1—457.170 (Subpart A) Added 2670
Regulation at 66 FR 2670 eff. date delayed 11547, 31178
457.60 Regulation at 66 FR 2671 delayed; (b)(2) revised; (b)(7) and (8) amended; interim 33822
457.203 Added 2674
Regulation at 66 FR 2674 eff. date delayed 11547, 31178
457.204 (d)(2) revised 2674

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457.208 (a) revised 2674
Regulation at 66 FR 2674 eff. date delayed 11547, 31178
457.234 Removed 2674
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457.300—457.380 (Subpart C) Added 2674
Regulation at 66 FR 2674 eff. date delayed 11547, 31178
457.301 Regulation at 66 FR 2675 delayed; amended; interim 33823
457.320 Regulation at 66 FR 2676 delayed; (b)(4) revised; interim 33823
457.340 Regulation at 66 FR 2676 delayed; (b) through (e) redesignated as (c) through (f); new (b) added; interim 33823
457.350 Regulation at 66 FR 2677 delayed; (e)(4) and (g)(3) added; (f)(5)(iii) removed 33823
457.355 Regulation at 66 FR 2678 delayed; introductory text and (a) redesignated as (a) and (b); new (a) heading added; new (b) revised; interim 33823
457.401—457.495 (Subpart D) Added 2674
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457.450 Regulation at 66 FR 2680 delayed; revised; interim 33823
457.495 Regulation at 66 FR 2680 delayed; (d) revised; interim 33824
457.500—457.570 (Subpart E) Added 2674
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457.505 Regulation at 66 FR 2681 delayed; (d)(1), (3) and (e) revised; interim 33824
457.540 Regulation at 66 FR 2682 delayed; (f) amended; interim 33824
457.560 Regulation at 66 FR 2682 delayed; (a) and (b) removed; amended 33824
457.624 Removed 2683
Regulation at 66 FR 2683 eff. date delayed 11547, 31178
457.700—457.750 (Subpart G) Added 2683

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457.750 Regulation at 66 FR 2684 delayed; (b)(7) removed; new (b)(8) redesignated as new (b)(7); interim 33824
457.800—457.810 (Subpart H) Added 2683
Regulation at 66 FR 2683 eff. date delayed 11547, 31178
457.900—457.985 (Subpart I) Added 2683
Regulation at 66 FR 2683 eff. date delayed 11547, 31178
457.940 Regulation at 66 FR 2685 delayed; (b)(1) and (d) amended; interim 33824
457.980 Regulation at 66 FR 2686 delayed; (a) and (b) designation removed; interim 33824
457.1000—457.1015 (Subpart J) Added 2683
Regulation at 66 FR 2683 eff. date delayed 11547, 31178
457.1000 Regulation at 66 FR 2686 delayed; (a)(1) and (2) amended; interim 33824
457.1005 Regulation at 66 FR 2687 delayed; heading amended; interim 33824
457.1010 Regulation at 66 FR 2687 delayed; heading amended; interim 33824
457.1100—457.1190 (Subpart K) Added 2683
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457.1120 Regulation at 66 FR 2687 delayed; revised; interim 33824
457.1130 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1140 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1150 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1160 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1170 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1180 Regulation at 66 FR 2688 delayed; amended; interim 33824
457.1190 Regulation at 66 FR 2688 delayed; amended; interim 33824
480.111 Regulation at 65 FR 83154 confirmed 14861
482.52 (a) revised 4686

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(a) revised; (c) added 56769
483.350—483.376 (Subpart G) Added; interim 7161
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483.352 Amended; interim 28116
483.358 (a), (c), (d), (f) introductory text, (g)(1), (3) and (j) revised; (b) amended; interim 28116
483.360 Introductory text revised; interim 28117
483.362 (b) and (c) revised; interim 28117
483.364 (c) and (d) revised; interim 28117
483.374 (c) added; interim 28117
484.14 (g) amended 32778
484.36 (d)(3) amended 32778
484.52 (b) amended 32778
485 Technical correction 13020, 13021
485.610 (a)(2)(ii) and (b) revised; (c) added 39938
485.612 Revised; interim 32196
485.639 (c) revised 4687
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(b) revised 39938
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(c) revised; (e) added 56769
485.643 (f) revised 39938
486.301 (b)(4) added 67111
486.302 Amended 39938
486.309 Added 67111
489 Technical correction 3497
489.20 (s) introductory text revised 39601
489.21 (h) revised 39601
489.24 (i) corrected 1599
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498.2 Regulation at 65 FR 83154 confirmed 14861
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1000.10 Amended 39452
1001.952 (v) added 62989

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(v)(4)(iii) corrected 63749
1001.101—1001.1701 (Subpart C) Appendix A added 62991
1003.101 Amended 39452

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430 Technical correction 42609
430.5 Regulation at 66 FR 6402, 11546, 32276 and 43090 withdrawn 40988
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431 Technical correction 42609
431.51 Regulation at 66 FR 6402, 11546, 32276 and 43090 withdrawn 40988
(a) introductory text, (b)(1) introductory text and (2) amended; (a)(4) and (5) revised; (a)(6) added 41094
431.55 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
(c)(1)(i) added 41094
431.200 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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431.201 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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431.220 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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431.244 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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434 Technical correction 42609
434.1 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
(a) revised 41095
434.2 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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434.6 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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434.20—434.38 (Subpart C) Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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434.42 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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434.50—434.67 (Subpart E) Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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434.70 Regulation at 66 FR 6403, 11546, 32276 and 43090 withdrawn 40988
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434.71 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
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434.72 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 41095
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434.73 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
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434.74 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
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434.75 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
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434.80 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
Removed 41095
435 Technical correction 42609
435.212 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988
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435.326 Regulation at 66 FR 6404, 11546, 32276 and 43090 withdrawn 40988

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438.10 Corrected 65505
438.52 Corrected 65505
438.100 Corrected 65505
438.102 Corrected 65505
438.114 Corrected 65505
438.116 Corrected 65505
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438.703 Corrected 65505
438.810 Corrected 65505
440 Technical correction 42609
440.168 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
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447 Technical correction 42609
447.46 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
Added 41115
447.53 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
(b) introductory text amended; (b)(6) removed; (e) added 41116
447.58 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
Amended 41116
447.60 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
Added 41116
447.272 (b), (d), (e)(1)(ii) and (f) revised; (c)(1) removed; (c)(2), (3), (e)(2)(ii)(C)(*8*) and (iii) redesignated as (c)(1), (2), (e)(2)(iii) and (iv); (e)(2)(v) added 2610
Regulation at 67 FR 2610 eff. date delayed to 4–15–02 12479
447.321 (b) through (d), (e)(1)(ii) and (f) revised; (e)(2)(ii)(C)(*8*) and (iii) redesignated as (e)(2)(iii) and (iv); (e)(2)(v) added 2611

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447.361 Regulation at 66 FR 6426, 11546, 32276 and 43090 withdrawn 40988
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457.10 Amended 61974
457.350 (b) text redesignated as (b)(1); (b)(2) added 61974
457.622 (c)(5) revised 61974
457.626 (a)(3) added 61974
460 Nomenclature change; eff. 10–31–02 61504
460.10—460.24 (Subpart B) Heading revised; eff. 10–31–02 61504
460.10 Revised; eff. 10–31–02 61504
460.12 (a)(2) removed; eff. 10–31–02 61505
460.26 Added; eff. 10–31–02 61505
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460.28 Added; eff. 10–31–02 61505
460.30 (b) revised; (c) added; eff. 10–31–02 61505
460.60 (b) and (c) revised; eff. 10–31–02 61505
460.68 (b) revised; (c) removed; eff. 10–31–02 61505
460.70 (b)(1)(i) and (e)(2) revised; (e)(5)(vi) through (ix) and (f) added; eff. 10–31–02 61505
460.71 Added; eff. 10–31–02 61505
460.102 (d)(2)(iii) revised; (d)(3) amended; (f) and (g) removed; eff. 10–31–02 61506
476.71 (c)(2) revised 56056
482.23 (c)(2) amended 61814
483.40 (b)(3) revised 61814
484.18 (c) amended 61814
485.618 (d) revised 80041
485.645 (d)(6) revised 50120
489 Technical correction 11549, 13278, 15011
489.27 Revised 16669
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1001.1501 (b) revised 11935
1001.2007 (d) revised 11935
1001.3005 (a) revised; (e) added 11935
1003 Authority citation revised 76905
1003.100 (b)(1)(iv), (xii) and (xiii) revised; (b)(1)(xiv) and (xv) added 11935
(a), (b)(1)(xiv) and (xv) revised; (b)(1)(xvi) added 76905
1003.101 Amended 11935, 76905
1003.102 (b)(16) added 76905
1003.103 (l) added 76905
1003.106 (a)(4)(iii) revised 11935
1005.7 (e)(1) revised 11936
1005.16 (b) revised 11936
1008.37 Revised 11936

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433.15 (b)(10) added 3635
438.310—438.370 (Subpart E) Added 3635
440 Technical correction 55882, 58756
440.40 (a)(1)(ii)(A) revised 46071
440.155 (c) introductory text revised 46071
447.500—447.550 (Subpart I) Added 51917
Regulation at 68 FR 51912 eff. date corrected 55527
460.72 (b)(1) revised; (b)(3) added 1386
476.78 (b) introductory text, (2), (c) introductory text and (d) revised; (c)(4) added 67960
482.12 (f)(3) added; eff. 11–10–03 53262
482.21 Revised 3454
482.41 (b)(1) introductory text, and (i) revised; (b)(7)(iv) added 1386
483 Technical correction 55882, 58756

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483.5 Revised 46071
483.10 (b)(12) added 46072
483.12 (a)(8) and (b)(4) added 46072
483.20 (k)(1) amended 46072
483.35 (h) redesignated as (i); new (h) added; eff. 10–27–03 55539
483.70 (a) introductory text revised; (a)(4) added 1387
483.75 (e)(1) amended; (q) added; eff. 10–27–03 55539
483.160 Added; eff. 10–27–03 55539
483.301—483.311 (Subpart D) Heading revised 55539
483.470 (j)(1)(i), (iii) and (2) revised; (j)(3) added 1387
484.265 Added 67960
485 Policy statement 9567
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485.623 (d)(1) and (2) revised; (d)(5) added 1387
488 Technical correction 55882, 58756
488.301 Amended; eff. 10–27–03 55539
488.438 (d)(3) added 46072
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489.2 (b)(9) added 66720
489.10 (a) and (c) revised 66720
489.20 (p) revised 16669
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(s)(12) revised 46072
489.22 (d) amended 46072
489.24 (i) removed; (c) through (h) redesignated as (d) through new (i); (a) and new (d) revised; (b), new (e)(1)(i), (ii)(C), (2)(iii), (3), (g), (h)(1), (2) introductory text, (iii)(B), (vi) and (4) amended; new (c) and (j) added; eff. 11–10–03 53262
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489.53 (a)(3) revised 66720
489.102 (a) introductory text revised 66720
491.2 Revised 74816
491.3 Revised 74816
491.5 (b) revised; (d) and (e) removed; (f) redesignated as (d) 74816
491.8 (a)(6) revised; (d) added 74817
491.11 Revised 74817
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493.3 (b)(3) amended 3702
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493.801—493.865 (Subpart H) Heading revised 3702
493.801 (a)(2)(ii) amended 3702
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493.911 (c)(1) amended 3702
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493.915 (c)(1) amended 3702
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493.1234 Corrected 50724
493.1239 Heading, (a), (b), and (c) corrected 50724
493.1249 Heading, (b) and (c) corrected 50724
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493.1253 (b)(2) corrected 50724
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493.1271 (f) corrected 50724
493.1273 (a) corrected 50724
493.1274 (d)(2)(iii) and (h) corrected 50724
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493.1407 (e)(5) amended 3713
493.1443 (b)(3) revised 3713
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460.72 (b)(1) and (3) revised; (b)(4) added 49266
480 Heading revised 49266
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480.101 (b) amended 49267
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480.105 (a), (b)(1) and (2) amended 49267
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480.120 Introductory text and (a)(5) amended 49267
480.121 Amended 49267
480.130 Amended 49267
480.132 (b)(2) and (3) amended 49267
480.133 (a)(2)(iii) revised 49266
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480.137 (a) introductory text amended 49267
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480.140 (d) and (e) redesignated as (e) and (f); new (d) added 49266

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480.141 Amended 49267
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485 Application deadline 69536
485.610 (b) introductory text and (c) revised; (b)(3) added 49271
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485.620 (a) revised 49271
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485.645 (a)(2) revised 49272
485.647 Added 49272
486.150—486.163 (Subpart D) Removed 66426
489 Authority citation revised 69268
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489.20 (m) amended; (t) added 49272
489.27 (b) revised 69268
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1003.101 Amended; interim 28845
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1003.102 (b)(17), (18) and (19) added; interim 28845
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1003.103 (m) added; interim 28845
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457.720 Revised; interim 58276
460.72 (b)(5) added; interim 15238
482.41 (b)(9) added; interim 15238
483.25 (n) added 58851
483.30 (e) added 62073
483.70 (a)(6) and (7) added; interim 15238
483.470 (j)(7) revised; interim 15238
484.20 (a) and (c) revised 76208
484.202 Amended 68142
485.610 (b)(1)(i) amended; (b)(1)(ii) removed; (b)(1)(iii) redesignated as new (b)(1)(ii); (d) added 47490
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1001 Authority citation revised 45136
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