



CODE OF FEDERAL REGULATIONS

Title 45 Public Welfare

Parts 1 to 139

Revised as of October 1, 2025

Containing a codification of documents
of general applicability and future effect

As of October 1, 2025

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Cite this Code: CFR

*To cite the regulations in
this volume use title,
part and section num-
ber. Thus, 45 CFR 2.1
refers to title 45, part 2,
section 1.*

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Each volume of the Code is revised at least once each calendar year and issued on a quarterly basis approximately as follows:

Title 1 through Title 16.....	as of January 1
Title 17 through Title 27.....	as of April 1
Title 28 through Title 41.....	as of July 1
Title 42 through Title 50.....	as of October 1

The appropriate revision date is printed on the cover of each volume.

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The term “[Reserved]” is used as a place holder within the Code of Federal Regulations. An agency may add regulatory information at a “[Reserved]” location at any time. Occasionally “[Reserved]” is used editorially to indicate that a portion of the CFR was left vacant and not dropped in error.

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An index to the text of “Title 3—The President” is carried within that volume.

The Federal Register Index is issued monthly in cumulative form. This index is based on a consolidation of the “Contents” entries in the daily Federal Register.

A List of CFR Sections Affected (LSA) is published monthly, keyed to the revision dates of the 50 CFR titles.

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OLIVER A. POTTS,
Director,
Office of the Federal Register
October 1, 2025

THIS TITLE

Title 45—PUBLIC WELFARE is composed of five volumes. The parts in these volumes are arranged in the following order: Parts 1–139, 140–199, 200–499, 500–1199, and 1200 to end. Volumes one and two (parts 1–139 and parts 140–199) contain all current regulations issued under Subtitle A—Department of Health and Human Services. Volumes three through five contain all current regulations issued under Subtitle B—Regulations Relating to Public Welfare. Volume three (parts 200–499) contains all current regulations issued under Chapter II—Office of Family Assistance (Assistance Programs), Administration for Children and Families, Department of Health and Human Services, Chapter III—Office of Child Support Services, Administration of Families and Services, Department of Health and Human Services, and Chapter IV—Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services. Volume four (parts 500–1199) contains all current regulations issued under Chapter V—Foreign Claims Settlement Commission of the United States, Department of Justice, Chapter VI—National Science Foundation, Chapter VII—Commission on Civil Rights, Chapter VIII—Office of Personnel Management, Chapter IX—Denali Commission, Chapter X—Office of Community Services, Administration for Children and Families, Department of Health and Human Services, and Chapter XI—National Foundation on the Arts and the Humanities. Volume five (part 1200 to end) contains all current regulations issued under Chapter XII—Corporation for National and Community Service, Chapter XIII—Administration for Children and Families, Department of Health and Human Services, Chapter XVI—Legal Services Corporation, Chapter XVII—National Commission on Libraries and Information Science, Chapter XVIII—Harry S. Truman Scholarship Foundation, Chapter XXI—Commission of Fine Arts, Chapter XXIII—Arctic Research Commission, Chapter XXIV—James Madison Memorial Fellowship Foundation, and Chapter XXV—Corporation for National and Community Service. The contents of these volumes represent all of the current regulations codified under this title of the CFR as of October 1, 2025.

For this volume, Ann Worley was Chief Editor, aided by Michael Chambers. The Code of Federal Regulations publication program is under the direction of John Hyrum Martinez, assisted by Stephen J. Frattini.

Title 45—Public Welfare

(This book contains parts 1 to 139)

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SUBTITLE A—Department of Health and Human Services

EDITORIAL NOTE: Nomenclature changes to subtitle A appear at 66 FR 39452, July 31, 2001.

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SUBCHAPTER A—GENERAL ADMINISTRATION

PART 1 [RESERVED]

PART 2—TESTIMONY BY EMPLOYEES AND PRODUCTION OF DOCUMENTS IN PROCEEDINGS WHERE THE UNITED STATES IS NOT A PARTY

Sec.

- 2.1 Scope, purpose, and applicability.
- 2.2 Definitions.
- 2.3 Policy on presentation of testimony and production of documents.
- 2.4 Procedures when voluntary testimony is requested or when an employee is subpoenaed.
- 2.5 Subpoenas duces tecum.
- 2.6 Certification and authentication of records.

AUTHORITY: 5 U.S.C. 301, 5 U.S.C. 552.

SOURCE: 52 FR 37146, Oct. 5, 1987, unless otherwise noted.

§ 2.1 Scope, purpose, and applicability.

(a) This part sets forth rules to be followed when an employee or former employee of the Department of Health and Human Services (“DHHS” or “Department”), other than an employee of the Food and Drug Administration, is requested or subpoenaed to provide testimony in a deposition, trial, or other similar proceeding concerning information acquired in the course of performing official duties or because of such person’s official capacity with DHHS. This part also sets forth procedures for the handling of subpoenas duces tecum and other requests for any document in the possession of DHHS, other than the Food and Drug Administration, and for the processing of requests for certification of copies of documents. Separate regulations, 21 CFR part 20, govern the Food and Drug Administration, and those regulations are not affected by this part.

(b) It is the policy of the DHHS to provide information, data, and records to non-federal litigants to the same extent and in the same manner that they are *made* available to the general public *and*, when subject to the jurisdiction of a court or other tribunal presiding over non-federal party litigation,

to follow all applicable procedural and substantive rules relating to the production of information, data, and records by a non-party. The availability of Department employees to testify in litigation not involving federal parties is governed by the Department’s policy to maintain strict impartiality with respect to private litigants and to minimize the disruption of official duties.

(c) This part applies to state, local and tribal judicial, administrative, and legislative proceedings, and to federal judicial and administrative proceedings.

(d) This part does not apply to:

(1) Any civil or criminal proceedings where the United States, the Department of Health and Human Services, and any agency thereof, or any other Federal agency is a party.

(2) Congressional requests or subpoenas for testimony or documents.

(3) Consultative services and technical assistance provided by the Department of Health and Human Services, or any agency thereof, in carrying out its normal program activities.

(4) Employees serving as expert witnesses in connection with professional and consultative services as approved outside activities in accordance with 5 CFR 2635.805 and 5 CFR 5501.106. (In cases where employees are providing such outside services, they must state for the record that the testimony represents their own views and does not necessarily represent the official position of the DHHS.)

(5) Employees making appearances in their private capacity in legal or administrative proceedings that do not relate to the Department of Health and Human Services (such as cases arising out of traffic accidents, crimes, domestic relations, etc.) and not involving professional and consultative services.

(6) Any matters covered in 21 CFR part 20, involving the Food and Drug Administration.

(7) Any civil or criminal proceedings in State court brought on behalf of the Department of Health and Human Services.

§ 2.2

Example (1): While on duty, an employee of the Department witnesses an incident in which a fellow employee trips on a loose piece of carpeting and sustains an injury. The injured employee brings a private tort action against the contractor installing the carpeting and the private landlord maintaining the building. The employee/witness is served with a subpoena to appear at a deposition to testify about the incident. The person seeking the testimony would not be required to obtain Agency head approval prior to requesting the testimony, because the subject of the testimony does not “relate to” the Department, within the meaning of § 2.1(d)(5).

Example (2): While on duty, an employee of the Department witnesses a mugging while looking out the window to check the weather, and then notifies the local police of what she observed. She is subsequently subpoenaed to testify in a criminal proceeding. The local prosecutor would not be required to obtain Agency head approval prior to requiring the employee to testify, because the subject of the testimony does not “relate to” the Department, within the meaning of § 2.1(d)(5).

Example (3): A nurse on duty at an Indian Health Service hospital emergency room treats a child who is brought in following a report of domestic violence. The nurse is subsequently served with a subpoena to testify in a criminal proceeding against one of the child’s parents concerning the injuries to the child which he observed. The local prosecutor would be required to obtain Agency head approval prior to requiring the nurse to testify, because the subject of the testimony involves “information acquired in the course of performing official duties or because of the person’s official capacity,” within the meaning of § 2.1(a).

Example (4): A personnel specialist working for the Department is subpoenaed to testify concerning the meaning of entries on time and attendance records of an employee, which the requesting party received from the employee pursuant to discovery in a personal injury action brought by the employee. The party requesting the personnel specialist to appear would be required to obtain Agency head approval prior to compelling the personnel specialist to testify, because the testimony sought involves “information acquired in the course of performing official duties or because of the person’s official capacity,” within the meaning of § 2.1(a).

Example (5): A National Institutes of Health physician is subpoenaed in a private medical malpractice action to provide expert testimony in her specialty. The party requesting her testimony would be required to obtain Agency head approval prior to her testifying in response to the subpoena, because the expert testimony sought involves “information acquired in the course of performing official duties or because of the per-

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son’s official capacity,” within the meaning of § 2.1(a).

[52 FR 37146, Oct. 5, 1987, as amended at 55 FR 4611, Feb. 9, 1990; 68 FR 25838, May 14, 2003]

§ 2.2 Definitions.

Agency head refers to the head of the relevant operating division or other major component of the DHHS, or his or her delegatee.

Agency head for the purposes of this part means the following officials for the components indicated:

- (1) Office of the Secretary—Assistant Secretary for Administration and Management;
- (2) Administration on Aging—Assistant Secretary for Aging;
- (3) Administration for Children and Families—Assistant Secretary for Children and Families;
- (4) Agency for Healthcare Research and Quality—Administrator;
- (5) Agency for Toxic Substances and Disease Registry—Administrator;
- (6) Centers for Disease Control and Prevention—Director;
- (7) Centers for Medicare and Medicaid Services—Administrator;
- (8) Health Resources and Services Administration—Administrator;
- (9) Indian Health Service—Director;
- (10) National Institutes of Health—Director;
- (11) Substance Abuse and Mental Health Services Administration—Administrator;
- (12) Office of Inspector General—Inspector General.

Employee of the Department includes current and former:

- (1) Commissioned officers in the Public Health Service Commissioned Corps, as well as regular and special DHHS employees (except employees of the Food and Drug Administration), when they are performing the duties of their regular positions, as well as when they are performing duties in a temporary assignment at DHHS or another organization.
- (2) Employees of intermediaries, carriers, Medicare Administrative Contractors, Program Safeguard Contractors, and Recovery Audit Contractors, and any successor entities, that perform one or more of the following functions described in section 1874A or 1893 of the Social Security Act relating to

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the administration of the Medicare program:

(i) Determination of payment amounts; making payments; beneficiary education and assistance; providing consultative services; communication with providers; or, provider education and technical assistance; or,

(ii) Other such functions as are necessary to carry out the Medicare program, including any of the following program integrity functions under section 1893 of the Social Security Act:

(A) Review of activities of providers or suppliers, including medical and utilization review and fraud review;

(B) Auditing of cost reports;

(C) Determinations as to whether payment should not be, or should not have been, made because Medicare is the secondary payer, and recovery of payments that should not have been made;

(D) Education of providers, beneficiaries, and other persons with respect to payment integrity and benefit quality assurance issues; or,

(E) Developing (and periodically updating) a list of items of durable medical equipment which are subject to prior authorization.

(3) Employees of a contractor, subcontractor, or state agency performing survey, certification, or enforcement functions under title XVIII of the Social Security Act or Section 353 of the Public Health Service Act but only to the extent the requested information was acquired in the course of performing those functions and regardless of whether documents are also relevant to the state's activities.

(4) Employees and qualified contractors of an entity covered under the Federally Supported Health Centers Assistance Act of 1992, as amended, 42 U.S.C. 233(g)-(n), (FSHCAA), provided that the testimony is requested in medical malpractice tort litigation and relates to the performance of medical, surgical, dental or related functions which were performed by the entity, its employees and qualified contractors at a time when the DHHS deemed the entity and its employees and qualified contractors to be covered by the FSHCAA.

Certify means to authenticate under seal, pursuant to 42 U.S.C 3505, official documents of the Department.

Testify and testimony includes both in-person, oral statements before a court, legislative or administrative body and statements made pursuant to depositions, interrogatories, declarations, affidavits, or other formal participation.

[68 FR 25839, May 14, 2003, as amended at 73 FR 53150, Sept. 15, 2008]

§2.3 Policy on Presentation of testimony and production of documents.

No employee or former employee of the DHHS may provide testimony or produce documents in any proceedings to which this part applies concerning information acquired in the course of performing official duties or because of the person's official relationship with the Department unless authorized by the Agency head pursuant to this part based on a determination by the Agency head, after consultation with the Office of the General Counsel, that compliance with the request would promote the objectives of the Department.

[68 FR 25839, May 14, 2003]

§2.4 Procedures when voluntary testimony is requested or when an employee is subpoenaed.

(a) All requests for testimony by an employee or former employee of the DHHS in his or her official capacity and not subject to the exceptions set forth in §2.1(d) of this part must be addressed to the Agency head in writing and must state the nature of the requested testimony, why the information sought is unavailable by any other means, and the reasons why the testimony would be in the interest of the DHHS or the federal government.

(b) If the Agency head denies approval to comply with a subpoena for testimony, or if the Agency head has not acted by the return date, the employee will be directed to appear at the stated time and place, unless advised by the Office of the General Counsel that responding to the subpoena would be inappropriate (in such circumstances as, for example, an instance where the subpoena was not validly issued or served, where the subpoena has been withdrawn, or where discovery has been stayed), produce a

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copy of these regulations, and respectfully decline to testify or produce any documents on the basis of these regulations.

[68 FR 25840, May 14, 2003]

§ 2.5 Subpoenas duces tecum.

(a) Whenever a subpoena duces tecum has been served upon a DHHS employee or former employee commanding the production of any record, such person shall refer the subpoena to the Office of the General Counsel (including regional chief counsels) for a determination of the legal sufficiency of the subpoena, whether the subpoena was properly served, and whether the issuing court or other tribunal has jurisdiction over the Department.) If the General Counsel or his designee determines that the subpoena is legally sufficient, the subpoena was properly served, and the tribunal has jurisdiction, the terms of the subpoena shall be complied with unless affirmative action is taken by the Department to modify or quash the subpoena in accordance with Fed. R. Civ. P. 45 (c).

(b) If a subpoena duces tecum served upon a DHHS employee or former employee commanding the production of any record is determined by the Office of the General Counsel to be legally insufficient, improperly served, or from a tribunal not having jurisdiction, such subpoena shall be deemed a request for records under the Freedom of Information Act and shall be handled pursuant to the rules governing public disclosure established in 45 CFR part 5.

[68 FR 25840, May 14, 2003]

§ 2.6 Certification and authentication of records.

Upon request, DHHS agencies will certify, pursuant to 42 U.S.C. 3505, the authenticity of copies of records that are to be disclosed. Fees for copying and certification are set forth in 45 CFR 5.43.

[68 FR 25840, May 14, 2003]

45 CFR Subtitle A (10–1–25 Edition)

PART 3—CONDUCT OF PERSONS AND TRAFFIC ON THE NATIONAL INSTITUTES OF HEALTH FEDERAL ENCLAVE

Subpart A—General

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AUTHORITY: 40 U.S.C. 318–318d. 486; Delegation of Authority, 33 FR 604.

SOURCE: 55 FR 2068, Jan. 22, 1990, unless otherwise noted.

Subpart A—General

§ 3.1 Definitions.

Director means the Director or Acting Director of the National Institutes of Health (NIH), or other officer or employee of NIH to whom the authority involved has been delegated.

Enclave means, unless the context requires a different meaning, the area, containing about 318 acres, acquired by the United States in several parcels in the years 1935 through 1983, and any further future acquisitions, comprising the National Institutes of Health located in Montgomery County, Maryland, over which the United States acquired exclusive jurisdiction under the Act of March 31, 1953, Chapter 158 (1953 Maryland Laws 311).

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Police officer means a uniformed or non-uniformed police officer appointed under a delegation of authority to the Director under Title U.S. Public Law 107-296, Homeland Security Act of 2002; any other Federal law enforcement officer; and any other person whose law enforcement services are secured by contract, or upon request or deputation from a State or local law enforcement agency.

[55 FR 2068, Jan. 22, 1990, as amended at 85 FR 72910, Nov. 16, 2020]

§3.2 Applicability.

(a) The regulations in this part apply to all areas in the enclave and to all persons on or within the enclave, except as otherwise provided.

(b) The regulations in this part do not apply to occupants, their visitors, and other authorized persons in areas used as living quarters:

(1) When specifically made inapplicable, and

(2) In the case of the following provisions: §3.24 Parking permits; §3.25 Servicing of vehicles; §3.42 Hobbies and sports; and §3.42(f) Smoking.

(c) All regulations in this part are in addition to the provisions in the United States Code, including title 18 relating to crimes and criminal procedure, and title 21 relating to food and drugs, which apply:

(1) Without regard to the place of the offense, or

(2) To areas (such as the enclave) subject to the “special maritime and territorial jurisdiction of the United States,” as defined in Title 18 United States Code section 7.

(d) In accordance with the Assimilative Crimes Act (18 U.S.C. 13), whoever is found guilty of an offense which, although not made punishable by any act of Congress, nor any provision of these regulations, would be punishable if committed within the State of Maryland, shall be guilty of a like offense and subject to a like punishment. In the event of an irreconcilable conflict between a provision of this part and a Maryland statute governing the identical subject matter, this part shall control.

(e) *Federal criminal statutes which apply.* The following Federal criminal statutes in the United States Code apply to Federal enclaves and elsewhere without regard to the place of the offense. This listing is provided solely for the information of the public and is not all-inclusive. The omission of other Federal statutes does not mean that such other statutes do not apply. In any given situation, the cited statutory provisions and any amendments in effect when the alleged offense occurred shall determine the specifics of the offense, applicability, and penalty.

Subject	U.S. Code	Provides generally	Maximum penalty
1. By force or threat of force, willful injury, intimidation or interference with, or attempts to injure, intimidate or interfere with, a person from participating in or enjoying any benefit, service, privilege, program, facility, or activity, provided by or administered by the U.S., and engaging in certain other Federal protected activities.	18 U.S.C. 245 ...	Prohibits	Not involving death or bodily injury: Imprisonment one year and/or \$1,000 fine.
2. Malicious destruction or damage, by an explosive, to a building or other property owned, possessed, used, or leased by the U.S., U.S. agency, or any organization receiving Federal financial assistance.	18 U.S.C. 844(f)	Prohibits	First offense not involving death or personal injury: Imprisonment 10 years and/or \$10,000 fine and seizure and forfeiture of explosive materials.
3. Possession of explosive in buildings owned, possessed, used, or leased by U.S. or U.S. agency.	18 U.S.C. 844(g)	Prohibits, except with written consent of the agency.	Imprisonment one year and/or \$1,000 fine and seizure and forfeiture of explosive materials.

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Subject	U.S. Code	Provides generally	Maximum penalty
4. Use of or carrying an explosive to commit, or during commission of, a felony prosecutable in a U.S. court.	18 U.S.C. 844(h)	Prohibits	First offense: Imprisonment 10 years and seizure and forfeiture of explosive materials.
5. Use of or carrying a firearm during and in relation to any crime of violence prosecutable in a U.S. court.	18 U.S.C. 924(c)	Prohibits	First offense: Imprisonment 5 years and \$5,000 fine and seizure and forfeiture of firearm and ammunition.
6. Manufacture, distribution, dispensing, or possession with intent to do these acts, of narcotics and other controlled substances and counterfeit substances.	21 U.S.C. 841, 842, 843, 845.	Prohibits, except as authorized by the Controlled Substances Act (generally 21 U.S.C. 801–904).	First offense: Imprisonment 20 years and/or \$250,000 fine depending on the amount and kind of substance (twice the above penalties for distribution by a person at least 18 years of age to one under age 21).
7. Simple possession of narcotics or other controlled substances.	21 U.S.C. 844 ...	Prohibits, unless substance obtained directly, or pursuant to prescription or order, from a practitioner, acting in the course of professional practice, or as otherwise authorized under the Controlled Substances Act.	First offense: Imprisonment 1 year and/or \$5,000 fine.

(f) *Maryland criminal statutes that apply.* The matters described in this paragraph are governed, in whole or in part, by the current version of the cited Maryland criminal statutory provisions, which are made Federal criminal offenses under the Assimilative Crimes Act (18 U.S.C. 13). This listing sets forth areas of conduct particularly relevant to the enclave and is provided solely for the information of the public. The list is not all-inclusive and omission of other Maryland criminal

statutes does not mean that such other statutes are not assimilated as Federal offenses under the Act. Generally, other Maryland criminal statutes will apply on the enclave, by force of the Act, unless superseded by Federal Law or a given provision of this part. In any given situation, the cited statutory provisions and any amendments in effect when the alleged offense occurred shall determine the specifics of the offense, applicability, and penalty.

Subject	Maryland code annotated	Provides generally	Maximum penalty
1. Pedestrian right-of-way	Transportation, Sec. 21–502.	Pedestrians have the right-of-way in crosswalks and certain other areas. Subject to certain limitations.	Imprisonment 2 months and/or \$500 fine.
	Sec. 21–511	Blind, partially blind, or hearing impaired pedestrians have the right-of-way at any crossing or intersection. Subject to certain limitations.	\$500 fine.
2. Drivers to exercise due care	Transportation, Sec. 21–504.	Drivers shall exercise due care to avoid colliding with pedestrians, children and incapacitated individuals.	\$500 fine.
3. Driving while intoxicated, under the influence of alcohol and/or a drug or controlled substance.	Transportation, Sec. 21–902.	Prohibits	Sec. 21–902(a) (driving while intoxicated, first offense): Imprisonment 1 year and/or \$1,000 fine. Sec. 21–902 (b), (c), (d) (driving under the influence): Imprisonment 2 months and/or \$500 fine.
4. Unattended motor vehicles	Transportation, Sec. 21–1101.	Prohibits leaving motor vehicles unattended unless certain precautions are taken.	\$500 fine.
5. Carrying or wearing certain concealed weapons (other than handguns) or openly with intent to injure.	Sec. 4–202	Prohibits, except for law enforcement personnel or as a reasonable precaution against apprehended danger.	Imprisonment 3 years or \$1,000 fine.

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Subject	Maryland code annotated	Provides generally	Maximum penalty
6. Unlawful wearing, carrying, or transporting a handgun, whether concealed or openly.	Sec. 4-202	Prohibits except by law enforcement personnel or with permit.	First offense and no prior related offense: Imprisonment 3 years and/or \$2,500 fine.
7. Use of handgun or concealable antique firearm in commission of felony or crime of violence.	Sec. 4-204	Prohibits	Imprisonment 20 years.
8. Disturbance of the peace	Sec. 6-409	Prohibits acting in a disorderly manner in public places.	Imprisonment 30 days and/or \$500 fine.
9. Gambling	Sec. 12-102	Prohibits betting, wagering and gambling, and certain games of chance (does not apply to vending or purchasing lottery tickets authorized under State law in accordance with approved procedures).	Sec. 240: Imprisonment one year and/or \$1,000 fine. Sec. 245: Imprisonment 2 years and/or \$100 fine.

[55 FR 2068, Jan. 22, 1990, as amended at 85 FR 72910, Nov. 16, 2020]

§ 3.3 Compliance.

A person must comply with the regulations in this part; with all official signs; and with the lawful directions or orders of a police officer or other authorized person, including traffic and parking directions.

§ 3.4 False reports and reports of injury or damage.

A person may not knowingly give any false or fictitious report concerning an accident or violation of the regulations of this part or any applicable Federal or Maryland statute to any person properly investigating an accident or alleged violation. All incidents resulting in injury to persons or willful damage to property in excess of \$100.00 (one hundred dollars) in value must be reported by the persons involved to the Police Office as soon as possible.

[55 FR 2068, Jan. 22, 1990, as amended at 88 FR 1135, Jan. 9, 2023]

§ 3.5 Lost and found, and abandoned property.

Lost articles which are found on the enclave, including money and other personal property, together with any identifying information, must be deposited at the Police Office or with an office (such as the place where found) which may likely have some knowledge of ownership. If the article is deposited with an office other than the Police Office and the owner does not claim it within 30 days, it shall be deposited at the Police Office for further disposition in accordance with General Services

Administration regulations (41 CFR 102). Abandoned, or other unclaimed property and, in the absence of specific direction by a court, forfeited property, may be so identified by the Police Office and sold and the proceeds deposited in accordance with 41 CFR part 102-41.

[57 FR 1874, Jan. 16, 1992, as amended at 85 FR 72910, Nov. 16, 2020]

§ 3.6 Nondiscrimination.

A person may not discriminate by segregation or otherwise against another person because of age, color, creed, handicap, national origin, race or sex, in furnishing or by refusing to furnish to that person the use of any facility of a public nature, including all services, privileges, accommodations, and activities provided within the enclave. (Title 18 United States Code section 245 prohibits, by use of force or threat of force, willful injury, intimidation, or interference with, a person from participating in or enjoying any benefit, service, privilege, program, facility, or activity provided by or administered by the United States, attempts to do these acts, and engaging in certain other activities.)

Subpart B—Traffic Regulations

§ 3.21 Emergency vehicles.

A person must yield the right of way to an emergency vehicle operating its siren or flashing lights.

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§ 3.22 Request for identification.

Upon request by a police officer, a person involved in any of the following situations must provide identification, for example, by exhibiting satisfactory credentials (such as an employment identification card or driver's license):

(a) A traffic accident within the enclave;

(b) The police officer reasonably believes that the individual is engaged in, or has engaged in, criminal conduct or a violation of the regulations of this part; or

(c) The enclave or a portion of the enclave is not open to the public (see § 3.41).

A driver of a motor vehicle involved in an accident within the enclave shall also exhibit, upon the request of a police officer, the owner's registration card or other satisfactory proof of ownership.

§ 3.23 Parking.

(a) A person may not stand (vehicle stopped, with or without, an occupant), or park a motor vehicle or other vehicle:

(1) In a lane, space, or area not designated by a sign for parking, and/or standing;

(2) On a sidewalk;

(3) Within an intersection or crosswalk;

(4) Within 10 feet of a fire hydrant, 5 feet of a driveway, or 20 feet of a stop sign, crosswalk, or traffic control signal;

(5) In a double-parked position;

(6) At a curb painted yellow;

(7) On the side of a street facing oncoming traffic;

(8) In a position that would obstruct traffic;

(9) For a period in excess of 24 hours, except at living quarters, or with the approval of the Police Office.

(b) A person must park bicycles, motorbikes, and similar vehicles only in designated areas, and may not bring these vehicles inside buildings.

(c) A visitor must park in an area identified for that purpose by posted signs or similar instructions, such as "visitor parking" and "reserved for visitors".

(d) A person may not drive or park an unauthorized motor vehicle on a

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grassy, or any other unpaved, area without the approval of the Police Office.

§ 3.24 Parking permits.

Except for visitor parking, a person may not park a motor vehicle without displaying a parking permit, currently valid for that location. The Director may revoke or refuse to issue or renew any parking permit for violation of this section, or any provision of this part.

§ 3.25 Servicing of vehicles.

A person may not wash, polish, change oil, lubricate, or make non-emergency repairs on a privately owned vehicle.

§ 3.26 Speed limit.

The speed limit is 25 miles per hour, unless otherwise posted. A driver of a vehicle may not exceed the speed limit.

§ 3.27 Bicycles.

A person may not operate a bicycle, motorbike, or similar vehicle without a horn or other warning device, and, if the vehicle is operated between dusk and dawn, it must be equipped with an operating headlight, and taillight or reflector.

Subpart C—Facilities and Grounds

§ 3.41 Admission to facilities or grounds.

The enclave is officially open to the public during normal working and visiting hours and for approved public events. The enclave is closed to the public at all other times, and the Director may also officially close all or part of the enclave, or any building, in emergency situations and at other times the Director deems necessary to ensure the orderly conduct of Government business. When all or part of the enclave is closed to the public, admission is restricted to employees and other authorized persons who may be required to display Government credentials or other identification when requested by a police officer and may be required to sign a register. The living quarters and adjacent areas are not open to the public but are open at all times to occupants and their visitors

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and business invitees, unless otherwise closed by the Director.

§ 3.42 Restricted activities.

(a) *Hobbies and sports.* A person may undertake hobbies and sports only in designated areas or as approved by the Director.

(b) *Pets and other animals.* A person may not bring on the enclave any cat, dog, or other animal except for authorized purposes. This prohibition does not apply to domestic pets at living quarters or to the exercise of these pets under leash or other appropriate restraints. The use of a service animal by a person with a disability to assist that person is authorized.

(c) *Photography.* A person may take photographs, films or audiovisuals, for personal or news purposes on the grounds of the enclave or in entrances, lobbies, foyers, corridors, and auditoriums in use for public meetings, except when contrary to security regulations or Department of Health and Human Services policies, or where prohibited by appropriate signs. Photographs and similar activities for advertising or commercial purposes may be taken only with the advance written approval of the Director. A person may take photographs of a patient only with the informed consent of the patient (or the natural or legal guardian) and of the Director of the Warren Grant Magnuson Clinical Center or delegate.

(d) *Intoxicating beverages, narcotics, and other controlled substances.* A person may not possess, sell, consume, or use alcohol or other intoxicating beverages, except in connection with official duties, as part of authorized research, or as otherwise authorized by the Director, or, in the case of possession, consumption or use only, in living quarters. (The sale, consumption, use, or possession of narcotics and other controlled substances is prohibited and shall be governed by the Controlled Substances Act (21 U.S.C. 841-845); driving under the influence of an alcoholic beverage, drug or controlled substance is prohibited and shall be governed by the Maryland Transportation Code Annotated section 21-902.)

(e) *Nuisances and disturbances.* The following acts by a person are prohib-

ited: Unwarranted loitering, disorderly conduct (acting in a disorderly manner to the disturbance of the public peace is prohibited and shall be governed by *Maryland Code Annotated*, Article 27, section 122); littering or disposal of rubbish in an unauthorized manner, the creation of any hazard to persons or property; the throwing of articles of any kind from or at a building; the climbing upon any part of a building for other than an authorized purpose; the loud playing of radios or other similar devices; and rollerskating, skateboarding, sledding or similar activities, except in officially designated areas.

(f) *Smoking.* Except as part of an approved medical research protocol, a person may not smoke on the enclave.

(g) *Firearms, explosive, and other weapons.* No person other than a specifically authorized police officer shall possess firearms, explosives, or other dangerous or deadly weapons or dangerous materials intended to be used as weapons either openly or concealed. Upon written request, the Director may permit possession in living quarters of antique firearms held for collection purposes, if the Director finds that the collection does not present any risk of harm.

[55 FR 2068, Jan. 22, 1990, as amended at 57 FR 1874, Jan. 16, 1992; 88 FR 1135, Jan. 9, 2023]

§ 3.43 Removal of property.

A person may not remove Federal property from the enclave or any building on the enclave without a property pass, signed by an authorized property custodian, which specifically describes the items to be removed. In an emergency, or when the property custodian is not available, a police officer may approve removal of Federal property if, after consulting with the administrative officer or other appropriate official, the police officer is authorized by the official to do so. Privately-owned property, other than that ordinarily carried on one's person, may be removed only under this property pass procedure, or upon properly establishing ownership of the property to a police officer.

Packages, briefcases, or other containers brought within the enclave are

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subject to inspection while on, or being removed from, the enclave.

§ 3.44 Solicitation.

It shall be unlawful for a person (other than an employee using authorized bulletin boards), without prior written approval of the Director, to offer or display any article or service for sale within the enclave buildings or grounds; or to display any sign, placard, or other form of advertisement; or to collect private debts; or to solicit business, alms, subscriptions or contributions, except in connection with approved national or local campaigns for funds for welfare, health and other public interest purposes, or solicitation of labor organization membership or dues as authorized under the Civil Service Reform Act of 1978 (Pub. L. 95-454).

This provision shall not apply to authorized lessees and their agents and employees with regard to space leased for commercial, cultural, educational, or recreational purposes, under the Public Buildings Cooperative Use Act of 1976 (40 U.S.C. 490(A)(16)).

Subpart D—Penalties

§ 3.61 Penalties.

(a) A person found guilty of violating any provision of the regulations in this part is subject to a fine or imprisonment of not more than thirty days or both, for each violation (Pub. L. 107-296, Homeland Security Act of 2002).

(b) Penalties for violation of offenses proscribed by Federal statutes (generally codified in title 18 of the United States Code) and Maryland criminal statutes which are made Federal offenses under the Assimilative Crimes Act and are prescribed in the applicable provisions of those statutes.

[55 FR 2068, Jan. 22, 1990, as amended at 85 FR 72910, Nov. 16, 2020; 88 FR 1135, Jan. 9, 2023]

PART 4—SERVICE OF PROCESS

Sec.

- 4.1 Suits against the Department and its employees in their official capacities.
- 4.2 Other process directed to the Department or Secretary.

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- 4.3 Process against Department officials in their individual capacities.
- 4.4 Acknowledgment of mailed process.
- 4.5 Effect of regulations.
- 4.6 Materials related to petitions under the National Vaccine Injury Compensation Program.
- 4.7 Congressional subpoenas directed to the Department or Secretary.

AUTHORITY: 5 U.S.C. 301, 42 U.S.C. 300aa-11.

SOURCE: 48 FR 24079, May 31, 1983, unless otherwise noted.

§ 4.1 Suits against the Department and its employees in their official capacities.

Summonses and complaints to be served by mail on the Department of Health and Human Services, the Secretary of Health and Human Services, or other employees of the Department in their official capacities should be sent to the General Counsel, Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, DC 20201.

§ 4.2 Other process directed to the Department or Secretary.

Subpoenas and other process (other than summonses and complaints) that are required to be served on the Department of Health and Human Services or the Secretary of Health and Human Services in his official capacity should be served as follows:

(a) If authorized by law to be served by mail, any mailed process should be sent to the General Counsel, Department of Health and Human Services, 200 Independence, S.W., Washington, DC 20201.

(b) If served by an individual, the process should be delivered to the staff in the Office of Legal Resources, Office of the General Counsel, Room 700E, 200 Independence Avenue, S.W., Washington, DC 20201, or in the absence of that staff, to any staff member of or individual assigned to the Immediate Office of the General Counsel, up to and including any Deputy General Counsel.

[48 FR 24079, May 31, 1983, as amended at 73 FR 48151, Aug. 18, 2008]

§ 4.3 Process against Department officials in their individual capacities.

Process to be served on Department officials in their individual capacities must be served in compliance with the

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requirements for service of process on individuals who are not governmental officials. The Office of the General Counsel is authorized but not required to accept process to be served on Departmental officials in their individual capacities if the suit relates to an employee's official duties.

§ 4.4 Acknowledgement of mailed process.

The Department will not provide a receipt or other acknowledgement of process received, except for a return receipt associated with certified mail and, where required, the acknowledgement specified by Rule 4(c)(2)(C) of the Federal Rules of Civil Procedure.

§ 4.5 Effect of regulations.

The regulations in this part are intended solely to identify Department officials who are authorized to accept service of process. Litigants must comply with all requirements pertaining to service of process that are established by statute and court rule even though they are not repeated in these regulations.

§ 4.6 Materials related to petitions under the National Vaccine Injury Compensation Program.

Notwithstanding the provisions of §§ 4.1, 4.2, and 4.3, service of the Secretary's copies of petitions for compensation under the VICP and of related filings, by mail, shall be served upon the Director, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration 5600 Fishers Lane, Parklawn Building, Room 16C-17, Rockville, Maryland 20857, or in person, shall be served upon the Director, Division of Vaccine Injury Compensation, Office of Special Programs, Health Resources and Services Administration, 4350 East West Highway, 10th Floor, Bethesda, Maryland 20814.

[67 FR 78990, Dec. 27, 2002]

§ 4.7 Congressional subpoenas directed to the Department or Secretary.

Notwithstanding the provisions of §§ 4.1, 4.2, and 4.3, service of Congressional subpoenas shall be delivered to the staff in the Office of the Assistant Secretary for Legislation, Department

of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201.

[73 FR 48151, Aug. 18, 2008]

PART 5—FREEDOM OF INFORMATION REGULATIONS

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AUTHORITY: 5 U.S.C. 552, 18 U.S.C. 1905, 31 U.S.C. 9701, 42 U.S.C. 1306(c), E.O. 12600, E.O.13392

SOURCE: 81 FR 74939, Oct. 28, 2016, unless otherwise noted.

Subpart A—General Information About Freedom of Information Act Requests

§ 5.1 Purpose.

This part implements the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552, as amended, for Department of Health and Human Services (HHS) records that are subject to the FOIA. This part should be read in conjunction with the text of the FOIA and the Uniform Freedom of Information Fee Schedule and Guidelines published by the Office of Management and Budget. This part contains the rules that we follow to process FOIA requests, such as the amount of time we have to make a determination regarding the release of records, who can decide to release records and who can decide not to release them, the fees we may charge, if applicable, the reasons why some records are exempt from disclosure under the FOIA, and the administrative and legal remedies available should a requester disagree with our initial disclosure determination.

(a) The FOIA provides a right of access to agency records, except to the extent that any portions of the records are protected from public disclosure by an exemption or exclusion in the statute. The FOIA does not require us to perform research for you or to answer your questions. The FOIA does not require agencies to create new records or to perform analysis of existing records; for example, by extrapolating information from existing agency records, reformatting publicly available information, preparing new electronic pro-

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grams or databases, or creating data through calculations of ratios, proportions, percentages, trends, frequency distributions, correlations, or comparisons. However, at our discretion and if it would conserve government resources, we may decide to supply requested information by consolidating information from various records.

(b) This part does not apply to data generated by an agency grant recipient under the provisions of 45 CFR part 75 to the extent the requirements of 45 CFR 75.322(e) do not apply to the data. We will not process your request under the FOIA or these regulations if that data is already available to the public through an archive or other source. In that situation, we will refer you to that other source. The procedures for requesting research data made available under the provisions of 45 CFR 75.322(e) are referenced in § 5.23(a).

§ 5.2 Presumption of openness and proactive disclosures.

(a) We will administer the FOIA with a presumption of openness. In accordance with 5 U.S.C. 552(a)(8) we will disclose records or information exempt from disclosure under the FOIA whenever disclosure would not foreseeably harm an interest protected by a FOIA exemption and disclosure is not prohibited by law. We also will consider whether partial disclosure of information is possible whenever we determine that a full disclosure of a requested record is not possible. This includes taking reasonable steps to segregate and release nonexempt information.

(b) Records that the FOIA requires agencies to make available for public inspection in an electronic format may be accessed through each OpDiv's and Staff Div's Web site. Each OpDiv and StaffDiv is responsible for determining which of its records must be made publicly available (including frequently requested records), for identifying additional records of interest to the public that are appropriate for public disclosure, and for posting and indexing such records. Each OpDiv and StaffDiv must ensure that its Web site of posted records and indices is reviewed and updated on an ongoing basis. Each OpDiv and StaffDiv has a FOIA Requester Service Center or FOIA Public Liaison

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who can assist individuals in locating records. A list of agency FOIA Public Liaisons is available at <http://www.foia.gov/report-makerequest.html>.

§ 5.3 Definitions.

The following definitions apply to this part:

Agency is defined at 5 U.S.C. 551(1). HHS is an agency. Private entities performing work under a contractual agreement with the government are not agencies for the purpose of this definition. However, information maintained on behalf of an agency under Government contract, for the purposes of records management, is considered an agency record.

Chief FOIA Officer means a senior official of HHS, at the Assistant Secretary or equivalent level, who has agency-wide responsibility for ensuring efficient and appropriate compliance with the FOIA, monitoring implementation of the FOIA throughout the agency, and making recommendations to the head of the agency to improve the agency's implementation of the FOIA. The Secretary of HHS has designated the Assistant Secretary, Office of the Assistant Secretary for Public Affairs (ASPA), as the Agency Chief FOIA Officer (ACFO); that official may be contacted at HHS.ACFO@hhs.gov.

Commercial use means a use or purpose that furthers a commercial, trade, or profit interest of the requester or the person or entity on whose behalf the request is made.

Department or HHS means the U.S. Department of Health and Human Services.

Deputy Agency Chief FOIA Officer (DACFO) means a designated official within the Office of the Assistant Secretary for Public Affairs, who has been authorized by the Chief FOIA Officer to act upon their behalf to implement compliance with the FOIA, as described above. This official is also the approving review authority for FOIA administrative appeals.

Direct costs mean those expenses that an agency incurs in searching for and duplicating (and, in the case of commercial use requests, reviewing) records in order to respond to a FOIA request. For example, direct costs include the salary of the employee per-

forming the work (*i.e.*, the basic rate of pay for the employee, plus 16 percent of that rate to cover benefits) and the cost of operating computers and other electronic equipment, such as photocopiers and scanners. Direct costs do not include overhead expenses such as the costs of space, and of heating or lighting a facility.

Duplication means the process of making a copy of a record and sending it to the requester, to the extent necessary to respond to the request. Such copies include both paper copies and electronic records. Fees for duplication are further explained within § 5.52.

Educational institution means any school that operates a program of scholarly research. A requester in this fee category must show that the request is made in connection with his or her role at the educational institution. Agencies may seek assurance from the requester that the request is in furtherance of scholarly research.

Example 1. A request from a professor of geology at a university for records relating to soil erosion, written on letterhead of the Department of Geology, would be presumed to be from an educational institution.

Example 2. A request from the same professor of geology seeking drug information from the Food and Drug Administration in furtherance of a murder mystery he is writing would not be presumed to be an institutional request, regardless of whether it was written on institutional stationery.

Example 3. A student who makes a request in furtherance of their coursework or other school-sponsored activities and provides a copy of a course syllabus or other reasonable documentation to indicate the research purpose for the request, would qualify as part of this fee category.

Expedited processing means the process set forth in the FOIA that allows requesters to request faster processing of their FOIA request, if they can demonstrate a specific compelling need.

Fee category means one of the four categories established by the FOIA to determine whether a requester will be charged fees for search, review, and duplication. The categories are: commercial use requests; non-commercial scientific or educational institutions requests; news media requests; and all other requests. Fee categories are further explained within § 5.53.

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Fee waiver means the waiver or reduction of fees if a requester is able to demonstrate that certain standards set forth in the FOIA and this part are satisfied, including that disclosure of the records is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

First-party request means a request by an individual for records pertaining to that individual, or an authorized representative acting on such an individual's behalf.

FOIA Public Liaison means an agency official who reports to the agency Chief FOIA Officer and serves as a supervisory official to whom a requester can raise concerns about the service the requester has received from the FOIA Requester Service Center. This individual is responsible for assisting in reducing delays, increasing transparency and understanding of the status of requests, and assisting in the resolution of disputes.

FOIA request means a written request that reasonably describes the records sought.

FOIA library records are records that are required to be made available to the public without a specific request under 5 U.S.C. 552(a)(2). We make FOIA library records available to the public electronically through our Web pages (<http://www.hhs.gov/foia/reading/index.html>) and at certain physical locations. A list of the physical locations is available at <http://www.hhs.gov/foia/contacts/index.html>. Other records may also be made available at our discretion through our Web pages (<http://www.hhs.gov>).

Freedom of Information Act (FOIA) means the law codified at 5 U.S.C. 552 that provides the public with the right to request agency records from Federal executive branch agencies. A link to the text of the FOIA is at <https://www.justice.gov/oip/freedom-information-act-5-usc-552>.

Freedom of Information Act (FOIA) Officer means an HHS official who has been delegated the authority to release or withhold records; to assess, waive, or reduce fees in response to FOIA requests; and to determine whether to

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grant expedited processing. In that capacity, the Freedom of Information Act (FOIA) Officer has the authority to task agency organizational components to search for records in response to a FOIA request, and to provide records located in their offices. Apart from records subject to proactive disclosure pursuant to subsection (a)(2) of the FOIA, only FOIA Officers have the authority to release or withhold records or to waive fees in response to a FOIA request. Our FOIA operations are decentralized, and each FOIA Requester Service Center has a designated official with this authority; the contact information for each FOIA Requester Service Center is available at <http://www.hhs.gov/foia/contacts/index.html>.

(1) The *HHS Freedom of Information Act (FOIA) Officer in the Office of the Secretary* means the HHS official who in addition to overseeing the daily operations of the FOIA program in that office and having the authority of a *Freedom of Information Act (FOIA) Officer*, is also responsible for the Department-wide administration and coordination of the FOIA and its implementing regulations and policies as they pertain to the programs and activities of the Department. This individual serves as the principal resource with respect to the articulation of procedures designed to implement and ensure compliance with the FOIA and its implementing regulations and policies as they pertain to the Department. This individual reports through the DACFO to the ACFO to support oversight and compliance with the OPEN Government Act.

(2) [Reserved]

Frequently requested records means records, regardless of form or format, that have been released to any person under the FOIA and that have been requested 3 or more times or because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records.

Immediate Office of the Secretary (IOS) means offices within the Office of the Secretary, responsible for operations and work of the Secretary. It includes

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the Office of the Deputy Secretary, Office of the Chief of Staff, the Secretary's Counselors, the Executive Secretariat, the Office of Health Reform, and the Office of Intergovernmental and External Affairs.

Non-commercial scientific institution means an institution that is not operated to further a commercial, trade, or profit interest and that is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry. A requester in this category must show that the request is authorized by and is made under the auspices of a qualifying institution and that the records are sought to further scientific research and are not for a commercial use.

Office of the Inspector General (OIG) means the Staff Division within the Office of the Secretary (OS), which is responsible for protecting the integrity of HHS programs and the health and welfare of the beneficiaries of those programs. OIG is responsible for processing FOIA requests for the records it maintains.

Office of the Secretary (OS) means the HHS's chief policy officer and general manager, who administers and oversees the organization, its programs and activities. The Deputy Secretary and a number of Assistant Secretaries and Staff Divisions support OS. The HHS FOIA Office within ASPA processes FOIA requests for records maintained by OS Staff Divisions other than the OIG. In certain circumstances and at the HHS FOIA Office's discretion, the HHS FOIA office may also process FOIA requests involving other HHS OpDivs, as further described in §5.28(a).

Operating Division (OpDiv) means any of the following divisions within HHS which are subject to this regulation:

Office of the Secretary (OS)
Administration for Children and Families (ACF)
Administration for Community Living (ACL)
Agency for Healthcare Research and Quality (AHRQ)
Agency for Toxic Substances and Disease Registry
(ATSDR)
Centers for Disease Control and Prevention (CDC)
Centers for Medicare & Medicaid Services (CMS)
Food and Drug Administration (FDA)

Health Resources and Services Administration (HRSA)
Indian Health Service (IHS)
National Institutes of Health (NIH)
Substance Abuse and Mental Health Services Administration (SAMHSA).

Operating Division and Staff Division Freedom of Information Act (FOIA) Officers means the officials who are responsible for overseeing the daily operations of their FOIA programs in their respective Operating Divisions or Staff Divisions, with the full authority as described in the definition of *Freedom of Information Act (FOIA) Officer*. These individuals serve as the principal resource and authority for FOIA operations and implementation within their respective Operating Divisions or Staff Divisions.

Other requester means any individual or organization whose request does not qualify as a commercial-use request, representative of the news media request (including a request made by a freelance journalist), or an educational or non-commercial scientific institution request.

Record means any information that would be an agency record when maintained by an agency in any format, including an electronic format; and any information that is maintained for an agency by an entity under Government contract, for the purposes of records management.

Redact means delete or mark over.

Representative of the news media means any person or entity that actively gathers information of potential interest to a segment of the public, uses its editorial skills to turn raw materials into a distinct work, and distributes that work to an audience. The term "news" means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations that broadcast news to the public at large and publishers of periodicals, including print and online publications that disseminate news and make their products available through a variety of means to the general public. We do not consider requests for records that support the news-dissemination function of the requester to be a commercial use. We consider "freelance" journalists who demonstrate a solid basis for

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expecting publication through a news media entity as working for that entity. A publishing contract provides the clearest evidence that a journalist expects publication; however, we also consider a requester's past publication record.

Review means examining records responsive to a request to determine whether any portions are exempt from disclosure. Review time includes processing a record for disclosure (*i.e.*, doing all that is necessary to prepare the record for disclosure), including redacting the record and marking the appropriate FOIA exemptions.

Search means the process of identifying, locating, and retrieving records to find records responsive to a request, whether in hard copy or in electronic form or format.

Staff Division (StaffDiv) means an organization component that provides leadership, direction, and policy and management guidance to the Office of the Secretary and the Department. The following StaffDivs are subject to the regulations in this part:

Immediate Office of the Secretary (IOS)
Assistant Secretary for Administration (ASA)
Assistant Secretary for Financial Resources (ASFR)
Assistant Secretary for Health (OASH)
Assistant Secretary for Legislation (ASL)
Assistant Secretary for Planning and Evaluation (ASPE)
Assistant Secretary for Public Affairs (ASPA)
Assistant Secretary for Preparedness and Response (ASPR)
Departmental Appeals Board (DAB)
Office for Civil Rights (OCR)
Office of the General Counsel (OGC)
Office of Global Affairs (OGA)
Office of the Inspector General (OIG)
Office of Medicare Hearings and Appeals (OMHA)
Office of the National Coordinator for Health Information Technology (ONC)

Submitter means any person or entity, including a corporation, State, or foreign government, but not including another Federal Government entity, that provides commercial or financial information, either directly or indirectly to the Federal Government.

Tolling means temporarily stopping the running of a time limit. We may toll a request to seek clarification or to address fee issues, as further described in § 5.24.

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§ 5.4 Regulatory scope.

The requirements in this part apply to all OpDivs and StaffDivs of HHS. Some OpDivs and StaffDivs may establish or continue to maintain additional rules because of unique program requirements, but such rules must be consistent with this part and the FOIA. If additional rules are issued, they must be published in the FEDERAL REGISTER and you may get copies online at <https://www.federalregister.gov/>, <http://www.regulations.gov/> or by contacting one of our FOIA Requester Service Centers.

§ 5.5 Interrelationship between the FOIA and the Privacy Act of 1974.

The FOIA allows any person (whether an individual or entity) to request access to records. The Privacy Act, at 5 U.S.C. 552a(d), provides an additional right of access, allowing individuals to request records about themselves, if the records are maintained in a system of records (defined in 5 U.S.C. 552a(a)(5)).

(a) *Requesting records about you.* If any part of your request includes records about yourself that are maintained within a system of records as defined by the Privacy Act at 5 U.S.C. 552a(a)(5), you should make your request in accordance with the Privacy Act and the Department's implementing regulations at 45 CFR part 5b. This includes requirements to verify your identity. We will process the request under the Privacy Act and, if it is not fully granted under the Privacy Act, we will process it under the FOIA. You may obtain, under the FOIA, information that is exempt from access under the Privacy Act, if the information is not excluded or exempt under the FOIA. If you request records about yourself that are not maintained within a system of records, we will process your request under the FOIA only.

(b) *Requesting records about another individual.* If you request records about another individual, we will process your request under the FOIA. You may receive greater access by following the procedures described in § 5.22(g).

Subpart B—How to Request Records under FOIA

§ 5.21 Who can file a FOIA request?

Any individual, partnership, corporation, association, or public or private organization other than a Federal agency, regardless of nationality, may submit a FOIA request to us. This includes state and local governments.

§ 5.22 What do I include in my FOIA request?

In your FOIA request:

(a) Provide a written description of the records you seek in sufficient detail to enable our staff to locate them with a reasonable amount of effort. The more information you provide, the better possibility we have of finding the records you are seeking. Information that will help us find the records would include:

- (1) The agencies, offices, or individuals involved;
- (2) The approximate date(s) when the records were created;
- (3) The subject, title, or description of the records sought; and
- (4) Author, recipient, case number, file designation, or other reference number, if available.

(b) Include your name, full mailing address, and phone number and if available, your email address. This information allows us to reach you faster if we have any questions about your request. It is your responsibility to keep your current mailing address up to date with the office where you have filed the FOIA request.

(c) State your willingness to pay all fees, or the maximum amount of fees you are willing to pay, and/or include a request for a fee waiver/reduction.

(d) Mark both your letter and envelope, or the subject line of your email, with the words “FOIA Request.”

(e) If you are unable to submit a written request to us due to circumstances such as disability or literacy, you may make a request orally to a FOIA Officer. FOIA Officers will put in writing an oral request made directly to them.

(f) If you are making a first-party request, you must comply with the verification of identity procedures set forth in 45 CFR part 5b.

(g) Where your request for records pertains to another individual, you may receive greater access by submitting either a notarized authorization signed by that individual or a declaration made in compliance with the requirements set forth in 28 U.S.C. 1746 by that individual authorizing disclosure of the records to the requester, or by submitting proof that the individual is deceased (e.g., a copy of a death certificate or an obituary). At our discretion, we may require you to supply additional information if necessary to verify that a particular individual has consented to disclosure of records about them.

(h) If you are requesting the medical records of an individual other than yourself from a government program that pays or provides for health care (e.g. Medicare, Indian Health Service) and you are not that individual's legally authorized representative, you should submit a Health Insurance Portability and Accountability Act (HIPAA) compliant release authorization form signed by the subject of records or the individual's legally authorized representative. The HIPAA Privacy Rule requires that an authorization form contain certain core elements and statements which are described in the Privacy Rule's requirements at 45 CFR 164.508. If you are submitting a request for Medicare records to CMS, CMS has a release authorization form at the following link: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10106.pdf>.

(i) Before filing your request, you may find it helpful to consult the HHS FOIA Requester Service Centers online at <http://www.hhs.gov/foia/contacts/index.html>, which provides additional guidance to assist in submitting a FOIA request to a specific OpDiv or StaffDiv or to regional offices or divisions within an OpDiv or StaffDiv. You may also wish to check in the agency's electronic FOIA libraries available online at <http://www.hhs.gov/foia/reading/index.html>, to see if the information you wish to obtain is already available.

§ 5.23 Where do I send my FOIA request?

We have several FOIA Requester Service Centers (FOIA offices) that

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process FOIA requests. You should send your FOIA request to the appropriate FOIA Requester Service Center that you believe would have the records you seek. An up-to-date listing is maintained online at <http://www.hhs.gov/foia/contacts/index.html>.

You also may submit your request electronically by emailing it to the appropriate FOIA Requester Service Center or by submitting it to the Department's web portal located at <https://requests.publiclink.hhs.gov/palMain.aspx>.

(a) If you are requesting research data made available under the provisions of 45 CFR 75.322(e), requests for such data should be addressed to the OpDiv that made the award under which the data were first produced. That OpDiv will process your request in accordance with established procedures consistent with the FOIA and 45 CFR 75.322(e).

(b) We officially receive your request when it reaches the FOIA Requester Service Center with responsibility for the OpDiv or StaffDiv where requested records are likely to be located, but no later than 10 working days after the request first arrives at any of our FOIA Requester Service Centers.

(c) If you have questions concerning the processing of your FOIA request, you may contact the FOIA Requester Service Center processing your request. If that initial contact does not resolve your concerns, you may wish to contact the designated FOIA Public Liaison for the OpDiv or StaffDiv processing your request. You can find a list of our FOIA Requester Service Centers and Public Liaisons at <http://www.hhs.gov/foia/contacts/index.html>.

§ 5.24 How does HHS process my FOIA request?

(a) *Acknowledgement.* We acknowledge all FOIA requests in writing within 10 working days after receipt by the appropriate office. The acknowledgement letter or email informs you of your request tracking number, provides contact information, and informs you of any complexity we are aware of in processing that may lengthen the time required to reach a final decision on the release of the records. In addition, the acknowledgement letter or email or a subsequent communication may

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also seek additional information to clarify your request.

(b) *Perfected requests.* (1) A request is considered to be perfected (*i.e.*, the 20 working day statutory response time begins to run) when—

(i) The request either has been received by the responsible FOIA office, or, in any event, not later than 10 working days after the request has been received by any HHS FOIA office;

(ii) The requested records are reasonably described; and

(iii) The request contains sufficient information to enable the FOIA office to contact you and transmit records to you.

(2) We provide at least 20 working days for you to respond to a request to perfect your request, after notification. Requests must reasonably describe the records sought and contain sufficient information to enable the FOIA office to contact you and transmit records to you. If we determine that a request does not meet these requirements, we will attempt to contact you if possible. Should you not answer any correspondence, or should the correspondence be returned as undeliverable, we reserve the right to administratively close the FOIA request.

(c) *Stops in processing time (tolling).* We may stop the processing of your request one time if we require additional information regarding the specifics of the request. The processing time resumes upon our receipt of your response. We also may stop the processing of your request if we require clarification regarding fee assessments. If additional information or clarification is required, we will attempt to contact you using the contact information you have provided. The processing time will resume upon our receipt of your response. We will provide at least 20 working days after notification for you to respond to a request for additional information or clarification regarding the specifics of your request or fee assessment. Should you not answer any correspondence, or should the correspondence be returned as undeliverable, we may administratively close the FOIA request.

(d) *Search cut-off date.* As the end or cut-off date for a records search, we use the date on which we first begin our

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search for documents responsive to your request, unless you specify an earlier cut-off date, or a specific date range for the records search. We will use the date of the first search in those cases when you request records “through the present,” “through today,” or similar language. The FOIA allows you to request existing agency records. The FOIA cannot be used to request records which the agency may create in the future in the course of carrying out its mission.

(e) *Processing queues.* We place FOIA requests in simple or complex processing queues to be processed in the order received, on a first-in, first-out basis, absent approval for expedited processing based upon a compelling need, as further explained and defined in § 5.27. We will place your request in the simple or complex processing queue based on the estimated amount of work or time needed to process the request. Among the factors we may consider are the number of records requested, the number of pages involved in processing the request, and the need for consultations or referrals. We will advise requesters of potential complicating factors in our acknowledgement letter or email, or in subsequent communications regarding your request and, when appropriate, we will offer requesters an opportunity to narrow or modify their request so that it can be placed in the simple processing track.

(f) *Unusual circumstances.* Whenever we cannot meet the statutory time limit for processing a request because of “unusual circumstances,” as defined in the FOIA, and we extend the time limit on that basis, we will notify you, before expiration of the 20-day period to respond and in writing of the unusual circumstances involved and of the date by which we estimate processing of the request will be completed. Where the extension exceeds 10 working days, we will provide you, as described by the FOIA, with an opportunity to modify the request or arrange an alternative time period for processing the original or modified request. We will make available a designated FOIA contact in the appropriate FOIA Requester Service Center or the appropriate FOIA Public Liaison for this purpose. In addition, we will

inform you of the right to seek dispute resolution services from the Office of Government Information Services (OGIS).

(g) *Aggregating requests.* For the purposes of satisfying unusual circumstances, we may aggregate requests in cases where it reasonably appears that multiple requests, submitted either by a requester or by a group of requesters acting in concert, constitute a single request, involving clearly related matters, that would otherwise involve unusual circumstances. In the event that requests are aggregated, they will be treated as one request for the purposes of calculating both response time and fees.

§ 5.25 How does HHS handle requests that involve more than one OpDiv, StaffDiv, or Federal agency?

(a) *Re-routing of misdirected requests.* When a FOIA Requester Service Center determines that a request was misdirected within HHS, the receiving FOIA Requester Service Center must route the request to the FOIA Requester Service Center of the proper OpDiv or StaffDiv within HHS.

(b) *Consultation, referral, and coordination.* When reviewing records located by an OpDiv or StaffDiv in response to a request, the OpDiv or StaffDiv will determine whether another agency of the Federal Government is better able to determine whether the record is exempt from disclosure under the FOIA. As to any such record, the OpDiv or StaffDiv must proceed in one of the following ways:

(1) *Consultation.* When records originated with an OpDiv or StaffDiv processing the request, but contain within them information of interest to another OpDiv, StaffDiv, agency or other Federal Government office, the OpDiv or StaffDiv processing the request should typically consult with that other entity prior to making a release determination.

(2) *Referral.* (i) When the OpDiv or StaffDiv processing the request believes that a different OpDiv, StaffDiv, or agency is best able to determine whether to disclose the record, the OpDiv or StaffDiv typically should refer the responsibility for responding to the request regarding that record to

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that other entity. Ordinarily, the entity that originated the record is presumed to be the best entity to make the disclosure determination. However, if the OpDiv or StaffDiv processing the request and the originating entity jointly agree that the OpDiv or StaffDiv processing the request is in the best position to respond regarding the record, then the record may be handled as a consultation.

(ii) Whenever an OpDiv or StaffDiv refers any part of the responsibility for responding to a request to another OpDiv, StaffDiv, or federal agency, it must document the referral, maintain a copy of the record that it refers, and notify the requester of the referral; informing the requester of the name(s) of the entity to which the record was referred, including that entity's FOIA contact information.

(3) *Coordination.* The standard referral procedure is not appropriate where disclosure of the identity of the OpDiv, StaffDiv, or federal agency to which the referral would be made could harm an interest protected by an applicable exemption, such as the exemptions that protect personal privacy or national security interests. In such instances, in order to avoid harm to an interest protected by an applicable exemption, the OpDiv or StaffDiv that received the request should coordinate with the originating entity to seek its views on the disclosability of the record. The release determination for the record that is the subject of the coordination should then be conveyed to the requester by the OpDiv or StaffDiv that originally received the request.

(c) *Classified information.* On receipt of any request involving classified information, the OpDiv or StaffDiv must determine whether the information is currently and properly classified in accordance with applicable classification rules. Whenever a request involves a record containing information that has been classified or may be appropriate for classification by another agency under any applicable executive order concerning the classification of records, the OpDiv or StaffDiv must refer the responsibility for responding to the request regarding that information to the agency that classified the information, or which should consider

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the information for classification. Whenever an OpDiv's or StaffDiv's record contains information that has been derivatively classified (for example, when it contains information classified by another agency), the OpDiv or StaffDiv must refer the responsibility for responding to that portion of the request to the agency that classified the underlying information.

(d) *Timing of responses to consultations and referrals.* All consultations and referrals received by the Department will be handled according to the date that the FOIA request initially was received by the first OpDiv, StaffDiv, or federal agency.

(e) *Agreements regarding consultations and referrals.* OpDivs or StaffDivs may establish agreements with other OpDivs, StaffDivs, or federal agencies to eliminate the need for consultations or referrals with respect to particular types of records.

§ 5.26 How does HHS determine estimated completion dates for FOIA requests?

(a) When we provide an estimated completion date, in accordance with § 5.24(f) and upon request, for the processing of records that do not require consultation with another agency, we estimate the completion date on the basis of our reasonable judgment as to how long it will take to complete the request. Given the uncertainty inherent in establishing any estimate, the estimated completion date is subject to change at any time.

(b) When we provide an estimated completion date, in accordance with § 5.24(f) and upon request, for records that must be reviewed by another agency, our estimate may also be based on information from the other agency.

§ 5.27 How do I request expedited processing?

(a) To request expedited processing, you must submit a statement, certified to be true and correct, explaining the basis for your need for expedited processing. You must send the request to the appropriate FOIA Officer at the address listed at <http://www.hhs.gov/foia/contacts/index.html>. You may request

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expedited processing when you first request records or at any time during our processing of your request or appeal.

(b) We process requests on an expedited basis whenever we determine that one or more of the following criteria exist:

(1) That a failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or

(2) There is an urgent need to inform the public about an actual or alleged Federal Government activity (this criterion applies only to those requests made by a person primarily engaged in disseminating information to the public).

(c) We will respond to your request for expedited processing within 10 calendar days of our receipt of your request to expedite. If we grant your request, the OpDiv or StaffDiv responsible for the review of the requested records will process your request as a priority, and it will be processed as soon as practicable. We will inform you if we deny your request for expedited processing and provide you with appeal rights. If you decide to appeal that denial, we will expedite our review of your appeal.

(d) If we must refer records to another agency, we will inform you and suggest that you seek expedited review from that agency.

§ 5.28 How does HHS respond to my request?

(a) The appropriate FOIA Officer will send you a response informing you of our release determination, including whether any responsive records were located, how much responsive material was located, whether the records are being released in full or withheld in full or in part, any fees you must pay for processing of the request, and your right to seek assistance from the appropriate FOIA Public Liaison.

(b) If we deny any part of your request, our response will explain the reasons for the denial, which FOIA exemptions apply to the withheld records, your right to appeal that determination, and your right to seek dispute resolution services from the appropriate FOIA Public Liaison or the

Office of Government Information Services (OGIS). We will advise you of the number of pages withheld or the estimated volume of withheld records, unless providing such information would harm an interest protected by an applicable FOIA exemption.

(c) Records may be withheld in full or in part if any of the nine FOIA exemptions apply. If we determine to withhold part of a record pursuant to an exemption, we will provide access to reasonably segregable non-exempt information contained in the record. On the released portion of the record, we indicate where the information has been redacted and the exemption(s) we applied, unless including that indication would harm an interest the exemption protects. In subpart C of this part, we list the exemptions to disclosure that may apply to agency records.

(d) We also may deny your request for other reasons, including that a request does not reasonably describe the records sought; the information requested is not a record subject to the FOIA; the requested records do not exist, cannot be located, or have been destroyed; or that the requested records are not readily reproducible in the form or format requested.

(e) If a request involves a voluminous amount of material or searches in multiple locations, we may provide you with interim responses if feasible and reasonably possible, releasing the records on a rolling basis.

(f) Copies of records in the format you request will be provided if the records already exist in that format or if they are reasonably and readily reproducible in the format you request.

§ 5.29 How may I request assistance with the FOIA process?

(a) If you have questions concerning the processing of your FOIA request, you should first contact the FOIA Requester Service Center processing your request. Additionally, for assistance at any point in the FOIA process, you may contact the FOIA Public Liaison at the FOIA Requester Service Center processing your request. The FOIA Public Liaison is responsible for assisting you to reduce delays, increasing transparency and understanding of the

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status of requests, and assisting to resolve any FOIA disputes. Some FOIA Requester Service Centers allow you to check the status of your request online. You can find a list of our FOIA Requester Service Centers and Public Liaisons at <http://www.hhs.gov/foia/contacts/index.html>.

(b) The Office of Government Information Services (OGIS), which is part of the National Archives and Records Administration, serves as the Federal FOIA ombudsman and assists requesters and agencies to prevent and resolve FOIA disputes through mediation. Mediation is a voluntary process. If we participate in the dispute resolution services provided by OGIS, we will actively engage as a partner to the process in an attempt to resolve the dispute and will follow the principles of confidentiality in accordance with the Administrative Dispute Resolution Act, 5 U.S.C. 571–8. You may contact OGIS at the following address: National Archives and Records Administration, Office of Government Information Services, 8601 Adelphi Road—OGIS, College Park, MD 20740–6001, or by email at ogis@nara.gov, or by telephone at 202–741–5770 or 1–877–684–6448 (toll free).

Subpart C—Exemptions to Disclosure

§5.31 What are the reasons records may be withheld?

While we are committed to providing public access to as many of our records as possible, there are instances in which information falls within one or more of the FOIA's nine exemptions and disclosure would either foreseeably harm an interest protected by a FOIA exemption or disclosure is prohibited by law. We review all records and weigh and assess all legal and policy requirements prior to making a final disclosure determination. A description of the nine FOIA exemptions is provided in paragraphs (a) through (i) of this section.

(a) *Exemption 1.* Exemption 1 protects from disclosure information specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and are in fact

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properly classified pursuant to such Executive order.

(b) *Exemption 2.* Exemption 2 authorizes our agency to withhold records that are related solely to the internal personnel rules and practices of an agency.

(c) *Exemption 3.* Exemption 3 authorizes our agency to withhold records which are specifically exempted from disclosure by statute (other than 5 U.S.C. 552(b)) provided that such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue; or establishes particular criteria for withholding or refers to particular types of matters to be withheld; and if enacted after the date of enactment of the OPEN FOIA Act of 2009, October 28, 2009, specifically cites to 5 U.S.C. 552(b)(3).

(d) *Exemption 4.* Exemption 4 authorizes our agency to withhold trade secrets and commercial or financial information obtained from a person and privileged or confidential.

(e) *Exemption 5.* Exemption 5 authorizes our agency to withhold inter-agency or intra agency memorandums or letters that would not be available by law to a party other than an agency in litigation with the agency, provided that the deliberative process privilege shall not apply to records created 25 years or more before the date on which the records were requested.

(f) *Exemption 6.* Exemption 6 authorizes our agency to protect information in personnel and medical files and similar files when the disclosure of such information would constitute a clearly unwarranted invasion of personal privacy.

(g) *Exemption 7.* Exemption 7 authorizes our agency to withhold records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information would cause the following harm(s):

(1) Could reasonably be expected to interfere with enforcement proceedings;

(2) Would deprive a person of a right to a fair trial or an impartial adjudication;

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(4) Could reasonably be expected to disclose the identity of a confidential source, including a state, local, or foreign agency or authority, or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting lawful national security intelligence investigation, information furnished by a confidential source;

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions, if such disclosure could reasonably be expected to risk circumvention of the law; or

(6) Could reasonably be expected to endanger the life or physical safety of any individual.

(h) *Exemption 8.* Exemption 8 authorizes our agency to withhold records that are contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.

(i) *Exemption 9.* Exemption 9 authorizes our agency to withhold geological and geophysical information and data, including maps, concerning wells.

§ 5.32 Records not subject to the requirements of the FOIA—law enforcement exclusions.

Under the FOIA, there is special protection for narrow categories of law enforcement and national security records. The provisions protecting those records are known as “exclusions” and are described in 5 U.S.C. 552(c). These exclusions expressly authorize Federal law enforcement agencies, under these exceptional circumstances, to treat the records as not subject to the requirements of the FOIA.

(a) Should an HHS OpDiv or StaffDiv maintain records which are subject to a FOIA exclusion, and consider employing an exclusion or have a question as

to the implementation of an exclusion, the OpDiv or StaffDiv will consult with the Office of Information Policy, U.S. Department of Justice.

(b) Because records falling within an exclusion are not subject to the requirements of the FOIA, should any HHS OpDiv or StaffDiv maintain such excluded records, the OpDiv or StaffDiv will limit its response to those records that are subject to the FOIA.

Subpart D—Confidential Commercial Information

§ 5.41 How does a submitter identify records containing confidential commercial information?

A person who submits records to the government may designate part or all of the information in such records that they may consider to be exempt from disclosure under Exemption 4 of the FOIA. The person may make this designation either at the time the records are submitted to the government or within a reasonable time thereafter. The designation must be in writing. Any such designation will expire 10 years after the records were submitted to the government.

§ 5.42 How does HHS process FOIA requests for confidential commercial information?

(a) *Predisclosure notification.* The procedures in this section apply to records on which the submitter has designated information as provided in § 5.41. They also apply to records that were submitted to the government where we have substantial reason to believe that information in the records could reasonably be considered exempt under Exemption 4. Certain exceptions to these procedures are stated in paragraph (b) of this section.

(1) When we receive a request for such records, and we determine that we may be required to disclose them, we will make reasonable efforts to notify the submitter about these facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If we must notify a large number of submitters, we may do this by posting or publishing a

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notice in a place where the submitters are reasonably likely to become aware of it.

(2) The submitter has 10 working days from the date of the notice to object to disclosure of any part of the records and to state all bases for its objections. FOIA Offices in HHS and its organizational components may extend this period as appropriate and necessary.

(3) We review and consider all objections to release that we receive within the time limit. If a submitter fails to respond within the time period specified in the notice, we will consider the submitter to have no objection to disclosure of the information. If we decide to release the records, we inform the submitter in writing, along with our reasons for the decision to release. We include with the notice a description of the information to be disclosed or copies of the records as we intend to release them. We also provide the submitter with a specific date that we intend to disclose the records, which must be at least 5 working days after the date of the notice. We do not consider any information we receive after the date of a disclosure decision.

(4) If the requester files a lawsuit under the FOIA for access to records submitted to HHS, we promptly notify the submitter.

(5) We will notify the requester in these circumstances:

(i) When we notify a submitter that we may be required to disclose information under the FOIA, we will also notify the requester that notice and opportunity to comment are being provided to the submitter;

(ii) When the agency notifies a submitter of a final disclosure decision under the FOIA,

and;

(iii) When a submitter files a lawsuit to prevent the disclosure of the information.

(b) *Exceptions to predisclosure notification.* The notice requirements in paragraph (a) of this section do not apply in the following situations:

(1) We determine that we should withhold the information under a FOIA exemption;

(2) The information has been lawfully published or made available to the public

(3) We are required by a statute (other than the FOIA), or by a regulation issued in accordance with the requirements of Executive Order 12600, to disclose the information; or

(4) The designation made by the submitter appears obviously frivolous. However, in such a case, the agency must provide the submitter with written notice of any final disclosure determination and intent to release, at least 5 working days prior to the specified disclosure date. We will notify the submitter as referenced in §5.42(a)(3).

Subpart E—Fees

§5.51 General information on fees for all FOIA requests.

(a) We generally assume that when you request records you are willing to pay the fees we charge for services associated with your request. You may specify a limit on the amount you are willing to spend. We will notify you if it appears that the fees will exceed \$25.00 or your specified limit and ask whether you nevertheless want us to proceed with the search.

(b) If you have failed to pay FOIA fees in the past, we will require you to pay your past due bill and we may also require you to pay the anticipated fee before we begin processing your current request. If we estimate that your fees may be greater than \$250.00, we also may require advance payment or a deposit before we begin processing your request. If you fail to make an advance payment within 20 working days after the date of our fee letter, we will close the request.

(c) We may charge interest on unpaid bills beginning on the 31st calendar day following the day the FOIA fee invoice was sent. We may assess interest, administrative costs, and penalties for overdue FOIA fee costs.

(d) If we determine that you (either acting alone or with a group of requesters) are breaking down a single request into a series of requests in order to avoid or reduce fees, we may aggregate all of these requests when calculating the fees. In aggregating requests, we may consider the subject matter of the

requests and whether the requests were filed close in time to one another.

(e) If, in the course of negotiating fees, you do not respond to the agency within 20 working days of our last communication, your request will be closed.

(f) We may stop the processing of your request, if necessary, to clarify fee issues with you, and to confirm your willingness to pay applicable fees. Fee related issues may arise sequentially over the course of processing a request, and the FOIA allows agencies to stop the processing time as many times as necessary in order to clarify issues regarding fee assessment and willingness to pay fees.

(g) We may charge search fees even if the records are exempt from disclosure, or if we do not find any responsive records during our search.

(h) We do not send an invoice to requesters if assessable processing fees are less than \$25.00.

§ 5.52 What is the FOIA fee schedule for obtaining records?

In responding to FOIA requests for records, we charge the following fees, where applicable, unless we have given you a reduction or waiver of fees. The fees we charge for search and review are three-tiered, and the hourly charge is determined by the classification and grade level of the employee performing the search or review. When the search or review is performed by employees at grade GS-1 through GS-8 (or equivalent), an hourly rate will be charged based on the salary of a GS-5, step 7, employee; when done by a GS-9 through GS-14 (or equivalent), an hourly rate will be charged based on the salary of a GS-12, step 4, employee; and when done by a GS-15 or above (or equivalent), an hourly rate will be charged based on the salary of a GS-15, step 7, employee. In each case, the hourly rate will be computed by taking the current hourly rate listed for the specified grade and step in the General Schedule Locality Pay Table for the Locality of Washington-Baltimore-Northern Virginia, DC-MD-VA-WV-PA, adding 16% of that rate to cover benefits, and rounding to the nearest whole dollar.

(a) *Search fees*—(1) *Manual searches*. Fees will be assessed to search agency files and records in both hardcopy and electronic format. Such fees will be at the rate or rates for the classification of the employee(s) performing the search, as established in this section.

(2) *Computer searches*. We base the fees for computer searches on the actual cost to our agency of operating the computer and the salary of the operator.

(b) *Review fees*. (1) We charge review fees for time we spend examining documents that are responsive to a request to determine whether we must apply any FOIA exemptions to withhold information. Review time includes processing any record for disclosure (*i.e.*, doing all that is necessary to prepare the record for disclosure), including redacting the record and marking the appropriate FOIA exemptions. We charge review fees even if we ultimately are unable to disclose a record.

(2) We do not charge review fees for time we spend resolving general legal or policy issues regarding the application of exemptions. However, we do charge review fees for time we spend obtaining and considering any formal objection to disclosure made by a confidential commercial information submitter.

(c) *Duplication fees*—(1) *Photocopying standard-sized pages*. The current charge for photocopying records is \$0.10 per page.

(2) *Reproduction of electronic records*. We will attempt to provide records in the format you sought, if the records are reasonably and readily reproducible in the requested format. We charge you for our direct costs for staff time and to organize, convert, and format data for release, per requester instructions, and for printouts or electronic media necessary to reproduce electronic records requested under the FOIA.

(3) *Copying other media*. We will charge you the direct cost of copying other media.

(d) *Mailing and special delivery fees*. We release records by United States Postal Service or, when appropriate, by electronic means, such as electronic mail or web portal. If a requester seeks special delivery, such as overnight

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shipping, we reserve the right to pass on the actual costs of special delivery to the requester. Requesters may provide their mailing account and billing information to the agency, so that they may pay directly for special delivery options.

(e) *Certification of records.* The FOIA does not require agencies to certify records as true copies. We may elect, as a matter of administrative discretion, to certify records upon request; however, such a request must be submitted in writing. Further, we will only certify as true copies records that have not left the agency's chain of custody. The charge for certification is \$25.00 per record certified.

(f) *Other statutes specifically providing for fees.* The fee schedule of this section does not apply to fees charged under any statute that specifically requires an OpDiv or StaffDiv to set and collect fees for particular types of records. In instances where records responsive to a request are subject to a statutorily-based fee schedule program, the OpDiv or StaffDiv must inform the requester of the contact information for that program.

§ 5.53 How does HHS calculate FOIA fees for different categories of requesters?

(a) If you are a commercial use requester, we charge you fees for searching, reviewing, and duplicating responsive records.

(b) If you are an educational or non-commercial scientific institution requester, or a member of the news media, you are entitled to search time, review time, and up to 100 pages of duplication (or the cost equivalent for other media) without charge. We charge duplication fees after the first 100 pages (or its cost equivalent).

(c) If you do not fall into either of the categories in paragraphs (a) and (b) of this section (*i.e.* you are an "other requester"), you are entitled to two hours of free search time, up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages (or its cost equivalent).

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(d)(1) If we fail to comply with the FOIA's time limits in which to respond to a request, we may not charge search fees, or, in the instances of the requester categories referenced in paragraph (b) of this section, may not charge duplication fees, except as described in (d)(2)-(4).

(2) If we have determined that unusual circumstances as defined by the FOIA apply and we provided timely written notice to the requester in accordance with the FOIA, a failure to comply with the time limit shall be excused for an additional 10 days.

(3) If we have determined that unusual circumstances, as defined by the FOIA, apply and more than 5,000 pages are necessary to respond to the request, we may charge search fees, or, in the instances of requests from requesters described in paragraph (b) of this section, may charge duplication fees if the following steps are taken: we must have provided timely written notice to the requester in accordance with the FOIA and must have discussed with the requester via written mail, email, or telephone (or made not less than three good-faith attempts to do so) how the requester could effectively limit the scope of the request in accordance with 5. U.S.C. 552(a)(6)(B)(ii). If this exception is satisfied, we may charge all applicable fees incurred in the processing of the request.

(4) If a court has determined that exceptional circumstances exist, as defined by the FOIA, a failure to comply with the time limits shall be excused for the length of time provided by the court order.

§ 5.54 How may I request a fee waiver?

(a) Requesters may seek a waiver of fees by submitting a written application demonstrating how disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.

(b) We must furnish records responsive to a request without charge or at a reduced rate when we determine, based on all available information,

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that the following three factors are satisfied:

(1) Disclosure of the requested information would shed light on the operations or activities of the government. The subject of the request must concern identifiable operations or activities of the Federal Government with a connection that is direct and clear, not remote or attenuated.

(2) Disclosure of the requested information would be likely to contribute significantly to public understanding of those operations or activities. This factor is satisfied when the following criteria are met:

(i) Disclosure of the requested records must be meaningfully informative about government operations or activities. The disclosure of information that already is in the public domain, in either the same or a substantially identical form, would not be meaningfully informative if nothing new would be added to the public's understanding.

(ii) The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area as well as the requester's ability and intention to effectively convey information to the public must be considered. We will presume that a representative of the news media will satisfy this consideration.

(3) The disclosure must not be primarily in the commercial interest of the requester. To determine whether disclosure of the requested information is primarily in the commercial interest of the requester, we will consider the following criteria:

(i) We will identify whether the requester has any commercial interest that would be furthered by the requested disclosure. A commercial interest includes any commercial, trade, or profit interest. Requesters will be given an opportunity to provide explanatory information regarding this consideration.

(ii) If there is an identified commercial interest, we will determine whether that is the primary interest furthered by the request. A waiver or reduction of fees is justified when the

requirements of paragraphs (b)(1) and (2) of this section are satisfied and any commercial interest is not the primary interest furthered by the request. We ordinarily will presume that when a news media requester has satisfied factors (b)(1) and (2) of this section, the request is not primarily in the commercial interest of the requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed to primarily serve the public interest.

(c) You should ask for waiver or reduction of fees when you first submit your request to HHS, and should address the criteria referenced in this section.

Subpart F—Appeals

§ 5.61 When may I appeal HHS's FOIA determination?

In order to fully exhaust all of your administrative remedies, you must file an appeal of an adverse agency determination in writing, and to be considered timely it must be postmarked, or in the case of electronic submissions, transmitted within 90 calendar days from the date of such determination. Any electronic transmission made after normal business hours will be considered to have been transmitted on the next calendar day. If a postmark is not legible, the timeliness of a submission will be based on the date that we receive the appeal. Adverse determinations include:

(a) Refusal to release a record, either in whole or in part;

(b) Determination that a record does not exist or cannot be found;

(c) Determination that a request does not reasonably describe the records sought;

(d) Determination that the record you sought was not subject to the FOIA;

(e) Denial of a request for expedited processing;

(f) Denial of a fee waiver request; or

(g) Fee category determination.

§ 5.62 How do I file an appeal?

(a) You have the right to appeal an adverse agency determination of your FOIA request.

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(b) You may submit your appeal via mail or electronically.

(1) Please send your appeal to the review official at the address provided in your denial letter. If you are unsure who is the appropriate review official, please contact the FOIA Requester Service Center that processed your request to obtain that information.

(2) The addresses to mail FOIA appeals for CMS and OS are, respectively: Centers for Medicare & Medicaid Services, Attn: Principal Deputy Administrator, Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244; and U.S. Department of Health and Human Services, Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, Room 729H, 200 Independence Avenue SW., Washington, DC 20201. Additionally, information, including how to submit a FOIA appeal electronically, can be found at the following online locations for CMS and OS: <https://www.cms.gov/Regulations-and-Guidance/Legislation/FOIA/filehow.html> and <https://requests.publiclink.hhs.gov/palMain.aspx>.

(3) When submitting an appeal, you should mark both your letter and envelope with the words “FOIA Appeal” or include the words “FOIA Appeal” in the subject line of your email. You should also include your FOIA request tracking number, a copy of your initial request, and a copy of our final determination letter.

(c) Your appeal should clearly identify the agency determination that is being appealed. It would be helpful if you provide specific reasons explaining why you believe the agency’s adverse determination should be reconsidered.

§ 5.63 How does HHS process appeals?

(a) We respond to your appeal within 20 working days after the appeal official designated in your appeal letter receives it. If, however, your appeal is based on a denial of a request for expedited processing, we will act on your appeal of that decision expeditiously. Before making a decision on an appeal of an adverse determination, the designated review official will consult with the Office of the General Counsel. Also, the concurrence of the Office of the Assistant Secretary for Public Affairs is required in all appeal decisions,

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including those on fees. When the review official responds to an appeal, that constitutes the Department’s final action on the request.

(b) If we reverse or modify the initial decision, we will inform you in writing and, if applicable, reprocess your request. If we do not change our initial decision, we will respond in writing to you, explain the reasons for the decision, set out any FOIA exemptions that apply, and inform you of the provisions for judicial review. If a requester files a FOIA lawsuit in reference to an appeal, we will cease processing the appeal.

§ 5.64 What avenues are available to me if I disagree with HHS’s appeal decision?

(a) In our response letter, we notify you of your right to seek judicial review of an adverse determination as set forth in the FOIA at 5 U.S.C. 552(a)(4)(B). Before seeking review by a court of an adverse determination, you generally must first submit a timely administrative appeal.

(b) We also inform you that the Office of Government Information Services (OGIS) offers mediation services to resolve disputes between FOIA requesters and Federal agencies as a non-exclusive alternative to litigation. As referenced in § 5.29(b) you may contact OGIS via mail, email, or telephone for assistance.

Subpart G—Records Retention

§ 5.71 How does HHS retain FOIA records?

We will preserve records created in administering the Department’s Freedom of Information program until disposition is authorized under an applicable General Records Schedule or other records schedule duly approved by the Archivist of the United States.

PART 5a [RESERVED]

PART 5b—PRIVACY ACT REGULATIONS

Sec.

5b.1 Definitions.

5b.2 Purpose and scope.

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- 5b.4 Maintenance of records.
- 5b.5 Notification of or access to records.
- 5b.6 Special procedures for notification of or access to medical records.
- 5b.7 Procedures for correction or amendment of records.
- 5b.8 Appeals of refusals to correct or amend records.
- 5b.9 Disclosure of records.
- 5b.10 Parents and guardians.
- 5b.11 Exempt systems.
- 5b.12 Contractors.
- 5b.13 Fees.

APPENDIX A TO PART 5b—EMPLOYEE STANDARDS OF CONDUCT

APPENDIX B TO PART 5b—ROUTINE USES APPLICABLE TO MORE THAN ONE SYSTEM OF RECORDS MAINTAINED BY HHS

APPENDIX C TO PART 5b—DELEGATIONS OF AUTHORITY [RESERVED]

AUTHORITY: 5 U.S.C. 301, 5 U.S.C. 552a.

SOURCE: 40 FR 47409, Oct. 8, 1975, unless otherwise noted.

§5b.1 Definitions.

As used in this part:

- (a) *Access* means availability of a record to a subject individual.
- (b) *Agency* means the Department of Health and Human Services.
- (c) *Department* means the Department of Health and Human Services.
- (d) *Disclosure* means the availability or release of a record to anyone other than the subject individual.
- (e) *Individual* means a living person who is a citizen of the United States or an alien lawfully admitted for permanent residence. It does not include persons such as sole proprietorships, partnerships, or corporations. A business firm which is identified by the name of one or more persons is not an individual within the meaning of this part.
- (f) *Maintain* means to maintain, collect, use, or disseminate when used in connection with the term "record"; and, to have control over or responsibility for a system of records when used in connection with the term "system of records."
- (g) *Notification* means communication to an individual whether he is a subject individual.
- (h) *Record* means any item, collection, or grouping of information about an individual that is maintained by the Department, including but not limited to the individual's education, financial transactions, medical history, and criminal or employment history and

that contains his name, or an identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph. When used in this part, record means only a record which is in a system of records.

(i) *Responsible Department official* means that officer who is listed in a notice of a system of records as the system manager for a given system of records or another individual listed in the notice of a system of records to whom requests may be made, or the designee of either such officer or individual.

(j) *Routine use* means the disclosure of a record outside the Department, without the consent of the subject individual, for a purpose which is compatible with the purpose for which the record was collected. It includes disclosures required to be made by statute other than the Freedom of Information Act, 5 U.S.C. 552. It does not include disclosures which are permitted to be made without the consent of the subject individual which are not compatible with the purpose for which it was collected such as disclosures to the Bureau of the Census, the General Accounting Office, or to Congress.

(k) *Secretary* means the Secretary of Health and Human Services, or his designee.

(l) *Statistical record* means a record maintained for statistical research or reporting purposes only and not maintained to make determinations about a particular subject individual.

(m) *Subject individual* means that individual to whom a record pertains.

(n) *System of records* means any group of records under the control of the Department from which a record is retrieved by personal identifier such as the name of the individual, number, symbol or other unique retriever assigned to the individual. Single records or groups of records which are not retrieved by a personal identifier are not part of a system of records. Papers maintained by individual employees of the Department which are prepared, maintained, or discarded at the discretion of the employee and which are not subject to the Federal Records Act, 44 U.S.C. 2901, are not part of a system of records; *Provided*, That such personal

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papers are not used by the employee or the Department to determine any rights, benefits, or privileges of individuals.

§5b.2 Purpose and scope.

(a) This part implements section 3 of the Privacy Act of 1974, 5 U.S.C. 552a (hereinafter referred to as the Act), by establishing agency policies and procedures for the maintenance of records. This part also establishes agency policies and procedures under which a subject individual may be given notification of or access to a record pertaining to him and policies and procedures under which a subject individual may have his record corrected or amended if he believes that his record is not accurate, timely, complete, or relevant or necessary to accomplish a Department function.

(b) All components of the Department are governed by the provisions of this part. Also governed by the provisions of this part are:

(1) Certain non-Federal entities which operate as agents of the Department for purposes of carrying out Federal functions, such as intermediaries and carriers performing functions under contracts and agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h and 1395u.

(2) Advisory committees and councils within the meaning of the Federal Advisory Committee Act which provide advice to (i) any official or component of the Department or (ii) the President and for which the Department has been delegated responsibility for providing services.

(c) Employees of the Department governed by this part include all regular and special government employees of the Department; members of the Public Health Service Commissioned Corps; experts and consultants whose temporary (not in excess of 1 year) or intermittent services have been procured by the Department by contract pursuant to 3109 of Title 5, United States Code; volunteers where acceptance of their services are authorized by law; those individuals performing gratuitous services as permitted under conditions prescribed by the Civil Serv-

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ice Commission; and, participants in work-study or training programs.

(d) Where other statutes mandate procedures which are inconsistent with the procedures set forth in this part, components of the Department may issue supplementary regulations containing procedures necessary to comply with such statutes. In addition, components of the Department may supplement by regulation the policies and procedures set forth in this part to meet particular needs of the programs administered by such components.

(e) This part does not:

(1) Make available to a subject individual records which are not retrieved by that individual's name or other personal identifier.

(2) Make available to the general public records which are retrieved by a subject individual's name or other personal identifier or make available to the general public records which would otherwise not be available to the general public under the Freedom of Information Act, 5 U.S.C. 552, and part 5 of this title.

(3) Govern the maintenance or disclosure of, notification of or access to, records in the possession of the Department which are subject to regulations of another agency, such as personnel records subject to the regulations of the Civil Service Commission.

(4) Apply to grantees, including State and local governments or subdivisions thereof, administering federally funded programs.

(5) Make available records compiled by the Department in reasonable anticipation of court litigation or formal administrative proceedings. The availability of such records to the general public or to any subject individual or party to such litigation or proceedings shall be governed by applicable constitutional principles, rules of discovery, and applicable regulations of the Department and any of its components.

§5b.3 Policy.

It is the policy of the Department to protect the privacy of individuals to the fullest extent possible while nonetheless permitting the exchange of records required to fulfill the administrative and program responsibilities of

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the Department, and responsibilities of the Department for disclosing records which the general public is entitled to have under the Freedom of Information Act, 5 U.S.C. 552, and part 5 of this title.

§5b.4 Maintenance of records.

(a) No record will be maintained by the Department unless:

(1) It is relevant and necessary to accomplish a Department function required to be accomplished by statute or Executive Order;

(2) It is acquired to the greatest extent practicable from the subject individual when maintenance of the record may result in a determination about the subject individual's rights, benefits or privileges under Federal programs;

(3) The individual providing the record is informed of the authority for providing the record (including whether the providing of the record is mandatory or voluntary, the principal purpose for maintaining the record, the routine uses for the record, what effect his refusal to provide the record may have on him), and if the record is not required by statute or Executive Order to be provided by the individual, he agrees to provide the record.

(b) No record will be maintained by the Department which describes how an individual exercises rights guaranteed by the First Amendment unless expressly authorized (1) by statute, or (2) by the subject individual, or (3) unless pertinent to and within the scope of an authorized law enforcement activity.

§5b.5 Notification of or access to records.

(a) *Times, places, and manner of requesting notification of or access to a record.* (1) Subject to the provisions governing medical records in §5b.6 of this part, any individual may request notification of a record. He may at the same time request access to any record pertaining to him. An individual may be accompanied by another individual of his choice when he requests access to a record in person; *Provided*, That he affirmatively authorizes the presence of such other individual during any discussion of a record to which access is requested.

(2) An individual making a request for notification of or access to a record shall address his request to the responsible Department official and shall verify his identity when required in accordance with paragraph (b)(2) of this section. At the time the request is made, the individual shall specify which systems of records he wishes to have searched and the records to which he wishes to have access. He may also request that copies be made of all or any such records. An individual shall also provide the responsible Department official with sufficient particulars to enable such official to distinguish between records on subject individuals with the same name. The necessary particulars are set forth in the notices of systems of records.

(3) An individual who makes a request in person may leave with any responsible Department official a request for notification of or access to a record under the control of another responsible Department official; *Provided*, That the request is addressed in writing to the appropriate responsible Department official.

(b) *Verification of identity*—(1) *When required.* Unless an individual, who is making a request for notification of or access to a record in person, is personally known to the responsible Department official, he shall be required to verify his identity in accordance with paragraph (b)(2) of this section if:

(i) He makes a request for notification of a record and the responsible Department official determines that the mere disclosure of the existence of the record would be a clearly unwarranted invasion of privacy if disclosed to someone other than the subject individual; or,

(ii) He makes a request for access to a record which is not required to be disclosed to the general public under the Freedom of Information Act, 5 U.S.C. 552, and part 5 of this title.

(2) *Manner of verifying identity.* (i) An individual who makes a request in person shall provide to the responsible Department official at least one piece of tangible identification such as a driver's license, passport, alien or voter registration card, or union card to verify his identity. If an individual does not have identification papers to

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verify his identity, he shall certify in writing that he is the individual who he claims to be and that he understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act subject to a \$5,000 fine.

(ii) Except as provided in paragraph (b)(2)(v) of this section, an individual who does not make a request in person shall submit a notarized request to the responsible Department official to verify his identity or shall certify in his request that he is the individual who he claims to be and that he understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act subject to a \$5,000 fine.

(iii) An individual who makes a request on behalf of a minor or legal incompetent as authorized under §5b.10 of this part shall verify his relationship to the minor or legal incompetent, in addition to verifying his own identity, by providing a copy of the minor's birth certificate, a court order, or other competent evidence of guardianship to the responsible Department official; *except that*, an individual is not required to verify his relationship to the minor or legal incompetent when he is not required to verify his own identity or when evidence of his relationship to the minor or legal incompetent has been previously given to the responsible Department official.

(iv) An individual shall further verify his identity if he is requesting notification of or access to sensitive records such as medical records. Any further verification shall parallel the record to which notification or access is being sought. Such further verification may include such particulars as the individual's years of attendance at a particular educational institution, rank attained in the uniformed services, date or place of birth, names of parents, an occupation or the specific times the individual received medical treatment.

(v) An individual who makes a request by telephone shall verify his identity by providing to the responsible Department official identifying particulars which parallel the record to

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which notification or access is being sought. If the responsible Department official determines that the particulars provided by telephone are insufficient, the requester will be required to submit the request in writing or in person. Telephone requests will not be accepted where an individual is requesting notification of or access to sensitive records such as medical records.

(c) *Granting notification of or access to a record.* (1) Subject to the provisions governing medical records in §5b.6 of this part and the provisions governing exempt systems in §5b.11 of this part, a responsible Department official, who receives a request for notification of or access to a record and, if required, verification of an individual's identity, will review the request and grant notification or access to a record, if the individual requesting access to the record is the subject individual.

(2) If the responsible Department official determines that there will be a delay in responding to a request because of the number of requests being processed, a breakdown of equipment, shortage of personnel, storage of records in other locations, etc., he will so inform the individual and indicate when notification or access will be granted.

(3) Prior to granting notification of or access to a record, the responsible Department official may at his discretion require an individual making a request in person to reduce his request to writing if the individual has not already done so at the time the request is made.

§5b.6 Special procedures for notification of or access to medical records.

(a) *General.* An individual in general has a right to notification of or access to his medical records, including psychological records, as well as to other records pertaining to him maintained by the Department. This section sets forth special procedures as permitted by the Act for notification of or access to medical records, including a special procedure for notification of or access to medical records of minors. The special procedures set forth in paragraph (b) of this section may not be suitable for use by every component of the Department. Therefore, components may

follow the paragraph (b) procedure for notification of or access to medical records, or may issue regulations establishing special procedures for such purposes. The special procedure set forth in paragraph (c) of this section relating to medical records of minors is mandatory.

(b) *Medical records procedures*—(1) *Notification of or access to medical records.*

(i) Any individual may request notification of or access to a medical record pertaining to him. Unless the individual is a parent or guardian requesting notification of or access to a minor's medical record, an individual shall make a request for a medical record in accordance with this section and the procedures in §5b.5 of this part.

(ii) An individual who requests notification of or access to a medical record shall, at the time the request is made, designate a representative in writing. The representative may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents at the representative's discretion.

(2) *Utilization of the designated representative.* A subject individual will be granted direct access to a medical record if the responsible official determines that direct access is not likely to have an adverse effect on the subject individual. If the responsible Department official believes that he is not qualified to determine, or if he does determine, that direct access to the subject individual is likely to have an adverse effect on the subject individual, the record will be sent to the designated representative. The subject individual will be informed in writing that the record has been sent.

(c) *Medical records of minors*—(1) *Requests by minors; notification of or access to medical records to minors.* A minor may request notification of or access to a medical record pertaining to him in accordance with paragraph (b) of this section.

(2) *Requests on a minor's behalf; notification of or access to medical records to an individual on a minor's behalf.* (i) In order to protect the privacy of a minor, a parent or guardian, authorized to act on a minor's behalf as provided in §5b.10 of this part, who makes a re-

quest for notification of or access to a minor's medical record will not be given direct notification of or access to such record.

(ii) A parent or guardian shall make all requests for notification of or access to a minor's medical record in accordance with this paragraph and the procedures in §5b.5 of this part. A parent or guardian shall at the time he makes a request designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent.

(iii) Where a medical record on the minor exists, it will be sent to the physician or health professional designated by the parent or guardian in all cases. If disclosure of the record would constitute an invasion of the minor's privacy, that fact will be brought to the attention of the physician or health professional to whom the record is sent. The physician or health professional will be asked to consider the effect that disclosure of the record to the parent or guardian would have on the minor in determining whether the minor's medical record should be made available to the parent or guardian. Response to the parent or guardian making the request will be made in substantially the following form:

We have completed processing your request for notification of or access to _____'s

(Name of minor)

medical records. Please be informed that if any medical record were found pertaining to that individual, they have not been sent to your designated physician or health professional.

In each case where a minor's medical record is sent to a physician or health professional, reasonable efforts will be made to so inform the minor.

§5b.7 Procedures for correction or amendment of records.

(a) Any subject individual may request that his record be corrected or amended if he believes that the record is not accurate, timely, complete, or relevant or necessary to accomplish a Department function. A subject individual making a request to amend or correct his record shall address his request to the responsible Department

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official in writing; *except that*, the request need not be in writing if the subject individual makes his request in person and the responsible Department official corrects or amends the record at that time. The subject individual shall specify in each request:

(1) The system of records from which the record is retrieved;

(2) The particular record which he is seeking to correct or amend;

(3) Whether he is seeking an addition to or a deletion or substitution of the record; and,

(4) His reasons for requesting correction or amendment of the record.

(b) A request for correction or amendment of a record will be acknowledged within 10 working days of its receipt unless the request can be processed and the subject individual informed of the responsible Department official's decision on the request within that 10 day period.

(c) If the responsible Department official agrees that the record is not accurate, timely, or complete based on a preponderance of the evidence, the record will be corrected or amended. The record will be deleted without regard to its accuracy, if the record is not relevant or necessary to accomplish the Department function for which the record was provided or is maintained. In either case, the subject individual will be informed in writing of the correction, amendment, or deletion and, if accounting was made of prior disclosures of the record, all previous recipients of the record will be informed of the corrective action taken.

(d) If the responsible Department official does not agree that the record should be corrected or amended, the subject individual will be informed in writing of the refusal to correct or amend the record. He will also be informed that he may appeal the refusal to correct or amend his record to the appropriate appeal authority listed in §5b.8 of this part. The appropriate appeal authority will be identified to the subject individual by name, title, and business address.

(e) Requests to correct or amend a record governed by the regulation of another government agency, *e.g.*, Civil Service Commission, Federal Bureau of

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Investigation, will be forwarded to such government agency for processing and the subject individual will be informed in writing of the referral.

§5b.8 Appeals of refusals to correct or amend records.

(a) *Processing the appeal.* (1) A subject individual who disagrees with a refusal to correct or amend his record may appeal the refusal in writing. All appeals shall be made to the following appeal authorities, or their designees, or successors in function:

(i) Assistant Secretary for Administration and Management for records of the Office of the Secretary, or where the initial refusal to correct or amend was made by another appeal authority. The appeal authority for an initial refusal by the Assistant Secretary for Administration and Management is the Under Secretary.

(ii) Assistant Secretary for Health for records of the Public Health Service including Office of Assistant Secretary for Health; Health Resources Administration; Health Services Administration; Alcohol, Drug Abuse, and Mental Health Administration; Center for Disease Control; National Institutes of Health; and Food and Drug Administration.

(iii) Assistant Secretary for Education for records of the Office of the Assistant Secretary for Education, National Center for Education Statistics, National Institute of Education, and Office of Education.

(iv) Assistant Secretary for Human Development for records of the Office of Human Development.

(v) Commissioner of Social Security for records of the Social Security Administration.

(vi) Administrator, Social and Rehabilitation Service for the records of the Social and Rehabilitation Service.

(2) An appeal will be completed within 30 working days from its receipt by the appeal authority; *except that*, the appeal authority may for good cause extend this period for an additional 30 days. Should the appeal period be extended, the subject individual appealing the refusal to correct or amend the record will be informed in writing of the extension and the circumstances of

the delay. The subject individual's request to amend or correct the record, the responsible Department official's refusal to correct or amend, and any other pertinent material relating to the appeal will be reviewed. No hearing will be held.

(3) If the appeal authority agrees that the record subject to the appeal should be corrected or amended, the record will be amended and the subject individual will be informed in writing of the correction or amendment. Where an accounting was made of prior disclosures of the record, all previous recipients of the record will be informed of the corrective action taken.

(4) If the appeal is denied, the subject individual will be informed in writing:

(i) Of the denial and the reasons for the denial;

(ii) That he has a right to seek judicial review of the denial; and,

(iii) That he may submit to the responsible Department official a concise statement of disagreement to be associated with the disputed record and disclosed whenever the record is disclosed.

(b) *Notation and disclosure of disputed records.* Whenever a subject individual submits a statement of disagreement to the responsible Department official in accordance with paragraph (a)(4)(iii) of this section, the record will be noted to indicate that it is disputed. In any subsequent disclosure, a copy of the subject individual's statement of disagreement will be disclosed with the record. If the responsible Department official deems it appropriate, a concise statement of the appeal authority's reasons for denying the subject individual's appeal may also be disclosed with the record. While the subject individual will have access to this statement of reasons, such statement will not be subject to correction or amendment. Where an accounting was made of prior disclosures of the record, all previous recipients of the record will be provided a copy of the subject individual's statement of disagreement, as well as the statement, if any, of the appeal authority's reasons for denying the subject individual's appeal.

§5b.9 Disclosure of records.

(a) *Consent to disclosure by a subject individual.* (1) Except as provided in

paragraph (b) of this section authorizing disclosures of records without consent, no disclosure of a record will be made without the consent of the subject individual. In each case the consent, whether obtained from the subject individual at the request of the Department or whether provided to the Department by the subject individual on his own initiative, shall be in writing. The consent shall specify the individual, organizational unit or class of individuals or organizational units to whom the record may be disclosed, which record may be disclosed and, where applicable, during which time frame the record may be disclosed (*e.g.*, during the school year, while the subject individual is out of the country, whenever the subject individual is receiving specific services). A blanket consent to disclose all of a subject individual's records to unspecified individuals or organizational units will not be honored. The subject individual's identity and, where applicable (*e.g.*, where a subject individual gives consent to disclosure of a record to a specific individual), the identity of the individual to whom the record is to be disclosed shall be verified.

(2) A parent or guardian of any minor is not authorized to give consent to a disclosure of the minor's medical record.

(b) *Disclosures without the consent of the subject individual.* The disclosures listed in this paragraph may be made without the consent of the subject individual. Such disclosures are:

(1) To those officers and employees of the Department who have a need for the record in the performance of their duties. The responsible Department official may upon request of any officer or employee, or on his own initiative, determine what constitutes legitimate need.

(2) Required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, and part 5 of this title.

(3) For a routine use as defined in paragraph (j) of §5b.1 of this part. Routine uses will be listed in any notice of a system of records. Routine uses published in appendix B are applicable to more than one system of records. Where applicable, notices of systems of records may contain references to the

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routine uses listed in appendix B. Appendix B will be published with any compendium of notices of systems of records.

(4) To the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of Title 13 U.S.C.

(5) To a recipient who has provided the agency with advance written assurance that the record will be used solely as a statistical research or reporting record; *Provided*, That, the record is transferred in a form that does not identify the subject individual.

(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value.

(7) To another government agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of such government agency or instrumentality has submitted a written request to the Department specifying the record desired and the law enforcement activity for which the record is sought.

(8) To an individual pursuant to a showing of compelling circumstances affecting the health or safety of any individual if a notice of the disclosure is transmitted to the last known address of the subject individual.

(9) To either House of Congress, or to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee.

(10) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office.

(11) Pursuant to the order of a court of competent jurisdiction.

(c) *Accounting of disclosures.* (1) An accounting of all disclosures of a record will be made and maintained by the

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Department for 5 years or for the life of the record, whichever is longer; *except that*, such an accounting will not be made:

(i) For disclosures under paragraphs (b) (1) and (2) of this section; and,

(ii) For disclosures made with the written consent of the subject individual.

(2) The accounting will include:

(i) The date, nature, and purpose of each disclosure; and

(ii) The name and address of the person or entity to whom the disclosure is made.

(3) Any subject individual may request access to an accounting of disclosures of a record. The subject individual shall make a request for access to an accounting in accordance with the procedures in §5b.5 of this part. A subject individual will be granted access to an accounting of the disclosures of a record in accordance with the procedures of this part which govern access to the related record. Access to an accounting of a disclosure of a record made under paragraph (b)(7) of this section may be granted at the discretion of the responsible Department official.

§5b.10 Parents and guardians.

For the purpose of this part, a parent or guardian of any minor or the legal guardian or any individual who has been declared incompetent due to physical or mental incapacity or age by a court of competent jurisdiction is authorized to act on behalf of an individual or a subject individual. Except as provided in paragraph (b)(2) of §5b.5, of this part governing procedures for verifying an individual's identity, and paragraph (c) (2) of §5b.6 of this part governing special procedures for notification of or access to a minor's medical records, an individual authorized to act on behalf of a minor or legal incompetent will be viewed as if he were the individual or subject individual.

§5b.11 Exempt systems.

(a) *General policy.* The Act permits certain types of specific systems of records to be exempt from some of its requirements. It is the policy of the Department to exercise authority to exempt systems of records only in compelling cases.

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(b) *Specific systems of records exempted.*

(1) Those systems of records listed in paragraph (b)(2) of this section are exempt from the following provisions of the Act and this part:

(i) 5 U.S.C. 552a(c)(3) and paragraph (c)(2) of §5b.9 of this part which require a subject individual to be granted access to an accounting of disclosures of a record.

(ii) 5 U.S.C. 552a(d) (1) through (4) and (f) and §§5b.6, 5b.7, and 5b.8 of this part relating to notification of or access to records and correction or amendment of records.

(iii) 5 U.S.C. 552a(e)(4) (G) and (H) which require inclusion of information about Department procedures for notification, access, and correction or amendment of records in the notice for the systems of records.

(iv) 5 U.S.C. 552(e)(3) and paragraph (a)(3) of §5b.4 of this part which require that an individual asked to provide a record to the Department be informed of the authority for providing the record (including whether the providing of the record is mandatory or voluntary, the principal purposes for maintaining the record, the routine uses for the record, and what effect his refusal to provide the record may have on him), and if the record is not required by statute or Executive Order to be provided by the individual, he agrees to provide the record. This exemption applies only to an investigatory record compiled by the Department for criminal law enforcement purposes in a system of records exempt under subsection (j)(2) of the Act to the extent that these requirements would prejudice the conduct of the investigation.

(2) The following systems of records are exempt from those provisions of the Act and this part listed in paragraph (b) (1) of this section.

(i) Pursuant to subsection (j)(2) of the Act:

(A) The Saint Elizabeths Hospital's Court-Ordered Forensic Investigatory Materials Files; and

(B) The Investigatory Material Compiled for Law Enforcement Purposes System, HHS.

(ii) Pursuant to subsection (k)(2) of the Act:

(A) The General Criminal Investigation Files, HHS/SSA;

(B) The Criminal Investigations File, HHS/SSA; and,

(C) The Program Integrity Case Files, HHS/SSA.

(D) Civil and Administrative Investigative Files of the Inspector General, HHS/OS/OIG.

(E) Complaint Files and Log. HHS/OS/OCR.

(F) Investigative materials compiled for law enforcement purposes for the Healthcare Integrity and Protection Data Bank (HIPDB), of the Office of Inspector General. (See §61.15 of this title for access and correction rights under the HIPDB by subjects of the Data Bank.)

(G) Investigative materials compiled for law enforcement purposes for the Program Information Management System, HHS/OS/OCR.

(H) Investigative materials compiled for law enforcement purposes from the CMS Fraud Investigation Database (FID), HHS/CMS.

(I) Investigative materials compiled for law enforcement purposes from the Automated Survey Processing Environment (ASPEN) Complaints/ Incidents Tracking System (ACTS), HHS/CMS.

(J) Investigative materials compiled for law enforcement purposes from the Health Insurance Portability and Accountability Act (HIPAA) Information Tracking System (HITS), HHS/CMS.

(K) Investigative materials compiled for law enforcement purposes from the Organ Procurement Organizations System (OPOS), HHS/CMS.

(L) Investigative materials compiled for law enforcement purposes for the National Practitioner Data Bank (NPDB). (See §60.21 of this subchapter for access and correction rights under the NPDB by subjects of the Data Bank.)

(iii) Pursuant to subsection (k)(4) of the Act:

(A) The Health and Demographic Surveys Conduct in Random Samples of the U.S. Population;

(B) The Health Manpower Inventories and Surveys;

(C) The Vital Statistics for Births, Deaths, Fetal Deaths, Marriages and Divorces Occurring in the U.S. during Each Year; and,

(D) The Maryland Psychiatric Case Register.

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(E) The Health Resources Utilization Statistics, DHHS/OASH/NCHS.

(F) National Medical Expenditure Survey Records. HHS/OASH/NCHSR.

(iv) Pursuant to subsection (k)(5) of the Act:

(A) The Investigatory Material Compiled for Security and Suitability Purposes System, HHS;

(B) The Suitability for Employment Records, HHS; and

(C) NIH Electronic Research Administration (eRA) Records, HHS/NIH/OD/OER, 09-25-0225.

(v) Pursuant to subsections (j)(2), (k)(2), and (k)(5) of the Act:

(A) The Clinical Investigatory Records, HHS/FDA;

(B) The Regulated Industry Employee Enforcement Records, HHS/FDA;

(C) The Employee Conduct Investigative Records, HHS/FDA; and,

(D) The Service Contractor Employee Investigative Records, HHS/FDA.

(vi) Pursuant to subsection (k)(6) of the Act:

(A) The Personnel Research and Merit Promotion Test Records, HHS/SSA/OMA.

(B) [Reserved]

(vii) Pursuant to subsections (k)(2) and (k)(5) of the Act:

(A) Public Health Service Records Related to Investigations of Scientific Misconduct, HHS/OASH/ORI.

(B) Administration: Investigative Records, HHS/NIH/OM/OA/OMA.

(C) FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC, 09-10-0020.

(D) NIH Records Related to Research Misconduct Proceedings, HHS/NIH, 09-25-0223.

(viii)(A) HHS Insider Threat Program Records, 09-90-1701.

(B) [Reserved]

(ix) Pursuant to subsections (j)(2) and (k)(2) of the Act:

(A) *NIH Police Records, 09-25-0224.* (All law enforcement investigatory records are exempt from subsections (c)(3), (d)(1) through (4), (e)(1), (e)(4)(G) through (I), and (f) of the Act; criminal law enforcement investigatory records are exempt from additional subsections (c)(4), (e)(2) and (3), (e)(5), (e)(8), and (g); the access exemption for non-criminal law enforcement investiga-

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tory records is limited as provided in subsection (k)(2).)

(B) [Reserved]

(3) The following systems of records are exempt from 5 U.S.C. 552a(c)(3) and §5b.9(c)(3), which require a subject individual to be granted access to an accounting of disclosures of a record; and from 5 U.S.C. 552a(d)(1) through (4) and §§5b.5, 5b.7, and 5b.8, relating to notification of or access to records and correction or amendment of records.

(i) Pursuant to subsection (k)(5) of the Privacy Act:

(A) NIH Division of Loan Repayment Record System, 09-25-0165.

(B) [Reserved]

(ii) Pursuant to subsection (k)(2) of the Privacy Act:

(A) OCSE Federal Case Registry of Child Support Orders (FCR), HHS/ACF/OCSE, 09-80-0385; only records marked with the Family Violence Indicator are exempt, based on the requirements of 42 U.S.C. 653(b)(2).

(B) [Reserved]

(4) The following systems of records are exempt from the following provisions of the Act and this part: 5 U.S.C. 552a(c)(3) and §5b.9(c)(3), which require a subject individual to be granted access to an accounting of disclosures of a record; 5 U.S.C. 552a(d)(1) through (4) and (f) and §§5b.6, 5b.7, and 5b.8, relating to notification of or access to records and correction or amendment of records; and 5 U.S.C. 552a(e)(4)(G) through (I) which require inclusion of information about Department procedures for notification, access, and correction or amendment of records and categories of record sources in the notice for the systems of records.

(i) Pursuant to subsection (k)(2) of the Privacy Act:

(A) ORR Unaccompanied Children Bureau (UCB) Child Abuse or Neglect Investigation Records and Central Registry, 09-80-0323.

(B) [Reserved]

(ii) [Reserved]

(c) *Notification of or access to records in exempt systems of records.* (1) Where a system of records is exempt as provided in paragraph (b) of this section, any individual may nonetheless request notification of or access to a record in that system. An individual shall make requests for notification of or access to a

record in an exempt system of records in accordance with the procedures of §§5b.5 and 5b.6 of this part.

(2) An individual will be granted notification of or access to a record in an exempt system but only to the extent such notification or access would not reveal the identity of a source who furnished the record to the Department under an express promise, and prior to September 27, 1975 an implied promise, that his identity would be held in confidence, if:

(i) The record is in a system of records which is exempt under subsection (k)(2) of the Act and the individual has been, as a result of the maintenance of the record, denied a right, privilege, or benefit to which he would otherwise be eligible; or,

(ii) The record is in a system of records which is exempt under subsection (k)(5) of the Act.

(3) If an individual is not granted notification of or access to a record in a system of records exempt under subsections (k) (2) and (5) of the Act in accordance with this paragraph, he will be informed that the identity of a confidential source would be revealed if notification of or access to the record were granted to him.

(d) *Discretionary actions by the responsible Department official.* Unless disclosure of a record to the general public is otherwise prohibited by law, the responsible Department official may in his discretion grant notification of or access to a record in a system of records which is exempt under paragraph (b) of this section. Discretionary notification of or access to a record in accordance with this paragraph will not be a precedent for discretionary notification of or access to a similar or related record and will not obligate the responsible Department official to exercise his discretion to grant notification of or access to any other record in a system of records which is exempt under paragraph (b) of this section.

[40 FR 47409, Oct. 8, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §5b.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§5b.12 Contractors.

(a) All contracts entered into on or after September 27, 1975 which require a contractor to maintain or on behalf of the Department to maintain, a system of records to accomplish a Department function must contain a provision requiring the contractor to comply with the Act and this part.

(b) All unexpired contracts entered into prior to September 27, 1975 which require the contractor to maintain or on behalf of the Department to maintain, a system of records to accomplish a Department function will be amended as soon as practicable to include a provision requiring the contractor to comply with the Act and this part. All such contracts must be so amended by July 1, 1976 unless for good cause the appeal authority identified in §5b.8 of this part authorizes the continuation of the contract without amendment beyond that date.

(c) A contractor and any employee of such contractor shall be considered employees of the Department only for the purposes of the criminal penalties of the Act, 5 U.S.C. 552a(i), and the employee standards of conduct listed in appendix A of this part where the contract contains a provision requiring the contractor to comply with the Act and this part.

(d) This section does not apply to systems of records maintained by a contractor as a result of his management discretion, *e.g.*, the contractor's personnel records.

§5b.13 Fees.

(a) *Policy.* Where applicable, fees for copying records will be charged in accordance with the schedule set forth in this section. Fees may only be charged where an individual requests that a copy be made of the record to which he is granted access. No fee may be charged for making a search of the system of records whether the search is manual, mechanical, or electronic. Where a copy of the record must be made in order to provide access to the record (*e.g.*, computer printout where no screen reading is available), the copy will be made available to the individual without cost. Where a medical record is made available to a representative designated by the individual or to

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a physician or health professional designated by a parent or guardian under §5b.6 of this part, no fee will be charged.

(b) *Fee schedule.* The fee schedule for the Department is as follows:

(1) Copying of records susceptible to photocopying—\$.10 per page.

(2) Copying records not susceptible to photocopying (*e.g.*, punch cards or magnetic tapes)—at actual cost to be determined on a case-by-case basis.

(3) No charge will be made if the total amount of copying does not exceed \$25.

APPENDIX A TO PART 5b—EMPLOYEE STANDARDS OF CONDUCT

(a) *General.* All employees are required to be aware of their responsibilities under the Privacy Act of 1974, 5 U.S.C. 552a. Regulations implementing the Act are set forth in 45 CFR 5b. Instruction on the requirements of the Act and regulation shall be provided to all new employees of the Department. In addition, supervisors shall be responsible for assuring that employees who are working with systems of records or who undertake new duties which require the use of systems of records are informed of their responsibilities. Supervisors shall also be responsible for assuring that all employees who work with such systems of records are periodically reminded of the requirements of the Act and are advised of any new provisions or interpretations of the Act.

(b) *Penalties.* (1) All employees must guard against improper disclosure of records which are governed by the Act. Because of the serious consequences of improper invasions of personal privacy, employees may be subject to disciplinary action and criminal prosecution for knowing and willful violations of the Act and regulation. In addition, employees may also be subject to disciplinary action for unknowing or unwillful violations, where the employee had notice of the provisions of the Act and regulations and failed to inform himself sufficiently or to conduct himself in accordance with the requirements to avoid violations.

(2) The Department may be subjected to civil liability for the following actions undertaken by its employees:

(a) Making a determination under the Act and §§5b.7 and 5b.8 of the regulation not to amend an individual's record in accordance with his request, or failing to make such review in conformity with those provisions;

(b) Refusing to comply with an individual's request for notification of or access to a record pertaining to him;

(c) Failing to maintain any record pertaining to any individual with such accu-

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racy, relevance, timeliness, and completeness as is necessary to assure fairness in any determination relating to the qualifications, character, rights, or opportunities of, or benefits to the individual that may be made on the basis of such a record, and consequently a determination is made which is adverse to the individual; or

(d) Failing to comply with any other provision of the Act or any rule promulgated thereunder, in such a way as to have an adverse effect on an individual.

(3) An employee may be personally subject to criminal liability as set forth below and in 5 U.S.C. 552a (i):

(a) Any officer or employee of an agency, who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by the Act or by rules or regulations established thereunder, and who, knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it, shall be guilty of a misdemeanor and fined not more than \$5,000.

(b) Any officer or employee of any agency who willfully maintains a system of records without meeting the notice requirements [of the Act] shall be guilty of a misdemeanor and fined not more than \$5,000.

(c) *Rules Governing Employees Not Working With Systems of Records.* Employees whose duties do not involve working with systems of records will not generally disclose to any one, without specific authorization from their supervisors, records pertaining to employees or other individuals which by reason of their official duties are available to them. Notwithstanding the above, the following records concerning Federal employees are a matter of public record and no further authorization is necessary for disclosure:

(1) Name and title of individual.

(2) Grade classification or equivalent and annual rate of salary.

(3) Position description.

(4) Location of duty station, including room number and telephone number.

In addition, employees shall disclose records which are listed in the Department's Freedom of Information Regulation as being available to the public. Requests for other records will be referred to the responsible Department official. This does not preclude employees from discussing matters which are known to them personally, and without resort to a record, to official investigators of Federal agencies for official purposes such as suitability checks, Equal Employment Opportunity investigations, adverse action proceedings, grievance proceedings, etc.

(d) *Rules governing employees whose duties require use or reference to systems of records.* Employees whose official duties require that

they refer to, maintain, service, or otherwise deal with systems of records (hereinafter referred to as "Systems Employees") are governed by the general provisions. In addition, extra precautions are required and systems employees are held to higher standards of conduct.

(1) Systems Employees shall:

(a) Be informed with respect to their responsibilities under the Act;

(b) Be alert to possible misuses of the system and report to their supervisors any potential or actual use of the system which they believe is not in compliance with the Act and regulation;

(c) Make a disclosure of records within the Department only to an employee who has a legitimate need to know the record in the course of his official duties;

(d) Maintain records as accurately as practicable.

(e) Consult with a supervisor prior to taking any action where they are in doubt whether such action is in conformance with the Act and regulation.

(2) Systems Employees shall not:

(a) Disclose in any form records from a system of records except (1) with the consent or at the request of the subject individual; or (2) where its disclosure is permitted under §5b.9 of the regulation.

(b) Permit unauthorized individuals to be present in controlled areas. Any unauthorized individuals observed in controlled areas shall be reported to a supervisor or to the guard force.

(c) Knowingly or willfully take action which might subject the Department to civil liability.

(d) Make any arrangements for the design development, or operation of any system of records without making reasonable effort to provide that the system can be maintained in accordance with the Act and regulation.

(e) *Contracting officers.* In addition to any applicable provisions set forth above, those employees whose official duties involve entering into contracts on behalf of the Department shall also be governed by the following provisions:

(1) *Contracts for design, or development of systems and equipment.* No contract for the design or development of a system of records, or for equipment to store, service or maintain a system of records shall be entered into unless the contracting officer has made reasonable effort to ensure that the product to be purchased is capable of being used without violation of the Act or regulation. Special attention shall be given to provision of physical safeguards.

(2) *Contracts for the operation of systems of records.* A review by the Contracting Officer, in conjunction with other officials whom he feels appropriate, of all proposed contracts providing for the operation of systems of records shall be made prior to execution of

the contracts to determine whether operation of the system of records is for the purpose of accomplishing a Department function. If a determination is made that the operation of the system is to accomplish a Department function, the contracting officer shall be responsible for including in the contract appropriate provisions to apply the provisions of the Act and regulation to the system, including prohibitions against improper release by the contractor, his employees, agents, or subcontractors.

(3) *Other service contracts.* Contracting officers entering into general service contracts shall be responsible for determining the appropriateness of including provisions in the contract to prevent potential misuse (inadvertent or otherwise) by employees, agents, or subcontractors of the contractor.

(f) *Rules Governing Responsible Department Officials.* In addition to the requirements for Systems Employees, responsible Department officials shall:

(1) Respond to all requests for notification of or access, disclosure, or amendment of records in a timely fashion in accordance with the Act and regulation;

(2) Make any amendment of records accurately and in a timely fashion;

(3) Inform all persons whom the accounting records show have received copies of the record prior to the amendments of the correction; and

(4) Associate any statement of disagreement with the disputed record, and

(a) Transmit a copy of the statement to all persons whom the accounting records show have received a copy of the disputed record, and

(b) Transmit that statement with any future disclosure.

APPENDIX B TO PART 5b—ROUTINE USES APPLICABLE TO MORE THAN ONE SYSTEM OF RECORDS MAINTAINED BY HHS

(1) In the event that a system of records maintained by this agency or carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

(2) Referrals may be made of assignments of research investigators and project monitors to specific research projects to the Smithsonian Institution to contribute to the

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Smithsonian Science Information Exchange, Inc.

(3) In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

(4) A record from this system of records may be disclosed as a "routine use" to a federal, state or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

(5) In the event that a system of records maintained by this agency to carry out its function indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether state or local charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

(6) Where Federal agencies having the power to subpoena other Federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.

(7) Where a contract between a component of the Department and a labor organization recognized under E.O. 11491 provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.

(8) Where the appropriate official of the Department, pursuant to the Department's Freedom of Information Regulation determines that it is in the public interest to disclose a record which is otherwise exempt from mandatory disclosure, disclosure may be made from this system of records.

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(9) The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

(10)-(99) [Reserved]

(100) To the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

(101) To individuals and organizations, deemed qualified by the Secretary to carry out specific research solely for the purpose of carrying out such research.

(102) To organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

(103) Disclosures in the course of employee discipline or competence determination proceedings.

APPENDIX C TO PART 5b—DELEGATIONS OF AUTHORITY [RESERVED]

PART 6 [RESERVED]

PART 7—EMPLOYEE INVENTIONS

Sec.

7.0 Who are employees.

7.1 Duty of employee to report inventions.

7.3 Determination as to domestic rights.

7.4 Option to acquire foreign rights.

7.7 Notice to employee of determination.

7.8 Employee's right of appeal.

AUTHORITY: Reorg. Plan No. 1 of 1953, 18 FR 2053; 3 CFR 1953 Supp. E.O. 10096, 15 FR 391; 3 CFR, 1950 Supp. and E.O. 10930, 26 FR 2583; 3 CFR 1961 Supp.

§ 7.0 Who are employees.

As used in this part, the term *Government employee* means any officer or employee, civilian or military, except such part-time employees or part-time consultants as may be excluded therefrom by a determination made in writing by the head of the employee's office or constituent organization, pursuant to an exemption approved by the Commissioner of Patents that to include him or them would be impracticable or inequitable, given the reasons therefor. A person shall not be considered to be a part-time employee or part-time consultant for this purpose unless the

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terms of his employment contemplate that he shall work for less than the minimum number of hours per day, or less than a minimum number of days per week, or less than the minimum number of weeks per year, regularly required of full-time employees of his class.

[27 FR 7986, Aug. 10, 1962]

§ 7.1 Duty of employee to report inventions.

Every Department employee is required to report to the Assistant Secretary (Health and Scientific Affairs) in accordance with the procedures established therefor, every invention made by him (whether or not jointly with others) which bears any relation to his official duties or which was made in whole or in any part during working hours, or with any contribution of Government facilities, equipment, material, funds, or information, or of time or services of other Government employees on official duty.

[31 FR 12842, Oct. 1, 1966]

§ 7.3 Determination as to domestic rights.

The determination of the ownership of the domestic right, title, and interest in and to an invention which is or may be patentable, made by a Government employee while under the administrative jurisdiction of the Department, shall be made in writing by the Assistant Secretary (Health and Scientific Affairs), in accordance with the provisions of Executive Order 10096 and Government-wide regulations issued thereunder by the Commissioner of Patents as follows:

(a) The Government as represented by the Assistant Secretary (Health and Scientific Affairs) shall obtain the entire domestic right, title and interest in and to all inventions made by any Government employee (1) during working hours, or (2) with a contribution by the Government of facilities, equipment, materials, funds, or information, or of time or services of other Government employees on official duty, or (3) which bear a direct relation to or are made in consequence of the official duties of the inventor.

(b) In any case where the contribution of the Government, as measured by any one or more of the criteria set forth in paragraph (a) of this section, to the invention is insufficient equitably to justify a requirement of assignment to the Government of the entire domestic right, title and interest in and to such invention, or in any case where the Government has insufficient interest in an invention to obtain the entire domestic right, title, and interest therein (although the Government could obtain same under paragraph (a) of this section), the Department, subject to the approval of the Commissioner, shall leave title to such invention in the employee, subject, however, to the reservation to the Government of a nonexclusive, irrevocable, royalty-free license in the invention with power to grant licenses for all governmental purposes, such reservation to appear, where practicable, in any patent, domestic or foreign, which may issue on such invention.

(c) In applying the provisions of paragraphs (a) and (b) of this section, to the facts and circumstances relating to the making of any particular invention, it shall be presumed that an invention made by an employee who is employed or assigned (1) to invent or improve or perfect any art, machine, manufacture, or composition of matter, (2) to conduct or perform research, development work, or both, (3) to supervise, direct, coordinate, or review Government financed or conducted research, development work, or both, or (4) to act in a liaison capacity among governmental or nongovernmental agencies or individuals engaged in such work, falls within the provisions of paragraph (a) of this section, and it shall be presumed that any invention made by any other employee falls within the provisions of paragraph (b) of this section. Either presumption may be rebutted by a showing of the facts and circumstances and shall not preclude a determination that these facts and circumstances justify leaving the entire right, title and interest in and to the invention in the Government employee, subject to law.

(d) In any case wherein the Government neither (1) obtains the entire domestic right, title and interest in and

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to an invention pursuant to the provisions of paragraph (a) of this section, nor (2) reserves a nonexclusive, irrevocable, royalty-free license in the invention, with power to grant licenses for all governmental purposes, pursuant to the provisions of paragraph (b) of this section, the Government shall leave the entire right, title and interest in and to the invention in the Government employee, subject to law.

[27 FR 7986, Aug. 10, 1962, as amended at 31 FR 12842, Nov. 1, 1966]

§ 7.4 Option to acquire foreign rights.

In any case where it is determined that all domestic rights should be assigned to the Government, it shall further be determined, pursuant to Executive Order 9865 and Government-wide regulations issued thereunder, that the Government shall reserve an option to require the assignment of such rights in all or in any specified foreign countries. In case where the inventor is not required to assign the patent rights in any foreign country or countries to the Government or the Government fails to exercise its option within such period of time as may be provided by regulations issued by the Commissioner of Patents, any application for a patent which may be filed in such country or countries by the inventor or his assignee shall nevertheless be subject to a nonexclusive, irrevocable, royalty-free license to the Government for all governmental purposes, including the power to issue sublicenses for use in behalf of the Government and/or in furtherance of the foreign policies of the Government.

[27 FR 7987, Aug. 10, 1962]

§ 7.7 Notice to employee of determination.

The employee-inventor shall be notified in writing of the Department's determination of the rights to his invention and of his right of appeal, if any. Notice need not be given if the employee stated in writing that he would agree to the determination of ownership which was in fact made.

[31 FR 12842, Oct. 1, 1966]

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§ 7.8 Employee's right of appeal.

An employee who is aggrieved by a determination of the Department may appeal to the Commissioner of Patents, pursuant to section 4(d) of Executive Order 10096, as amended by Executive Order 10930, and regulations issued thereunder, by filing a written appeal with the Commissioner, in duplicate, and a copy of the appeal with the Assistant Secretary (Health and Scientific Affairs), within 30 days (or such longer period as the Commissioner may, for good cause, fix in any case) after receiving written notice of such determination.

[27 FR 7986, Aug. 10, 1962, as amended at 31 FR 12842, Oct. 1, 1966]

PART 9—USE OF HHS RESEARCH FACILITIES BY ACADEMIC SCIENTISTS, ENGINEERS, AND STUDENTS

Sec.

9.1 Purpose.

9.2 Policy.

9.3 Delegations of authority.

9.4 Criteria.

9.5 Restrictions.

AUTHORITY: 27 Stat. 395, as amended; 20 U.S.C. 91.

SOURCE: 34 FR 18938, Nov. 27, 1969, unless otherwise noted.

§ 9.1 Purpose.

To enhance the availability of DHHS scientific research and study facilities to academic scientists, engineers, and qualified students.

§ 9.2 Policy.

It is the policy of the Department of Health and Human Services in accordance with the policy of the President announced on February 21, 1969, to make research and study facilities of the Department readily available to the scientific community, especially qualified academic scientists and engineers. Unique, unusual, and expensive-to-duplicate facilities at laboratories and other study and research facilities of the Department will be made available to the national scientific community, to the maximum extent practical without serious detriment to the missions of those facilities. It is also the

policy of the Department to permit qualified students and graduates of institutions of learning in the several States, and territories, as well as the District of Columbia, to use study and research facilities of the Department. When such facilities are used by academic scientists, engineers, and students, the costs incurred for the operation of the unique or unusual research facilities, as well as of the other facilities, should be funded by the operating agency responsible for the operation of that facility, except for any significant incremental costs incurred in support of research not directly related to an HHS mission.

§ 9.3 Delegations of authority.

(a) The heads of operating agencies are delegated authority for negotiations and decisions as to the use of Department facilities by qualified academic scientists, engineers, and students.

(b) The heads of operating agencies may (and are encouraged to) redelegate to the heads of their respective component organizations, with the power to further redelegate to laboratory directors, the authority for negotiations and decisions as to the use of departmental facilities. Appropriate use shall be made of advisory groups in formulating their decisions.

§ 9.4 Criteria.

(a) The official permitting use of Department facilities must determine that it would be consistent with the programs of his activity to participate. Facilities may be made available provided the use of such facilities will be of direct benefit to the objectives of the academic scientist, or engineer, or student, with the prospect of fruitful interchange of ideas and information between Department personnel and the academic scientist, or engineer, or student, and such use will not interfere with the Department program.

(b) The official permitting use of Department facilities will furnish the non-Government user with safety requirements or operating procedures to be followed. Such requirements or procedures are to include the requirement to report to the permitting official any

accident involving the non-Government user.

(c) The official delegated authority for approving the use of Department facilities will not permit the use of laboratory facilities unless he determines:

(1) That facilities are available for the period desired; and

(2) That the proposed research will not interfere with regular Department functions or needs, nor require the subsequent acquisition of additional equipment by the Department.

§ 9.5 Restrictions.

(a) Each individual authorized to use Department facilities will be expected to use the facilities and equipment with customary care and otherwise conduct himself in such manner as to complete his research or study within any time limits prescribed.

(b) Each individual authorized to use HHS facilities may not be authorized to sign requisitions for supplies and equipment.

(c) Any official approving the use of HHS facilities should seek an agreement, executed by non-Government users, absolving the Federal agency of liability in case of personal injury, death, and failure or damage to the non-Government user's experiments or equipment. The agreement must also contain a statement that the non-Government user will comply with all safety regulations and procedures while using such facilities.

PART 12—DISPOSAL AND UTILIZATION OF SURPLUS REAL PROPERTY FOR PUBLIC HEALTH PURPOSES

Sec.

- 12.1 Definitions.
- 12.2 Scope.
- 12.3 General policies.
- 12.4 Limitations.
- 12.5 Awards.
- 12.6 Notice of available property.
- 12.7 Applications for surplus real property.
- 12.8 Assignment of surplus real property.
- 12.9 General disposal terms and conditions.
- 12.10 Compliance with the National Environmental Policy Act of 1969 and other related Acts (environmental impact).
- 12.11 Special terms and conditions.
- 12.12 Utilization.
- 12.13 Form of conveyance.
- 12.14 Compliance inspections and reports.
- 12.15 Reports to Congress.

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EXHIBIT A TO PART 12—PUBLIC BENEFIT ALLOWANCE FOR TRANSFER OF REAL PROPERTY FOR HEALTH PURPOSES

AUTHORITY: Sec. 203, 63 Stat. 385, as amended; 40 U.S.C. 484; sec. 501 of Pub. L. 100-77, 101 Stat. 509-10, 42 U.S.C. 11411.

SOURCE: 45 FR 72173, Oct. 31, 1980, unless otherwise noted.

§ 12.1 Definitions.

(a) *Act* means the Federal Property and Administrative Services Act of 1949, 63 Stat. 377 (40 U.S.C. 471 *et seq.*). Terms defined in the Act and not defined in this section have the meanings given to them in the Act.

(b) *Accredited* means having the approval of a recognized accreditation board or association on a regional, State, or national level, such as a State Board of Health. *Approval* as used above describes the formal process carried out by State Agencies and institutions in determining that health organizations or programs meet minimum acceptance standards.

(c) *Administrator* means the Administrator of General Services.

(d) *Assigned property* means real and related personal property which, in the discretion of the Administrator or his designee, has been made available to the Department for transfer for public health purposes.

(e) *Department* means the U.S. Department of Health and Human Services.

(f) *Disposal agency* means the executive agency of the Government which has authority to assign property to the Department for transfer for public health purposes.

(g) *Excess* means any property under the control of any Federal agency which is not required for its needs and the discharge of its responsibilities, as determined by the head thereof.

(h) *Fair market value* means the highest price which the property will bring by sale in the open market by a willing seller to a willing buyer.

(i) *Holding agency* means the Federal agency which has control over and accountability for the property involved.

(j) *Nonprofit institution* means any institution, organization, or association, whether incorporated or unincorporated, no part of the net earnings of which inures or may lawfully inure to

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the benefit of any private shareholder or individual, and (except for institutions which lease property to assist the homeless under Title V of Pub. L. 100-77) which has been held to be tax-exempt under section 501(c)(3) of the Internal Revenue Code of 1954.

(k) *Off-site property* means surplus buildings, utilities and all other removable improvements, including related personal property, to be transferred by the Department for removal and use away from the site for public health purposes.

(l) *On-site* means surplus real property, including related personal property, to be transferred by the Department for use in place for public health purposes.

(m) *Public benefit allowance* means a discount on the sale or lease price of real property transferred for public health purposes, representing any benefit determined by the Secretary which has accrued or may accrue to the United States thereby.

(n) *Related personal property* means any personal property: (1) Which is located on and is (i) an integral part of, or (ii) useful in the operation of real property; or (2) which is determined by the Administrator to be otherwise related to the real property.

(o) *Secretary* means the Secretary of Health and Human Services.

(p) *State* means a State of the United States, and includes the District of Columbia, the Commonwealth of Puerto Rico, and the Territories and possessions of the United States.

(q) *Surplus* when used with respect to real property means any excess real property not required for the needs and the discharge of the responsibilities of all Federal agencies as determined by the Administrator.

[45 FR 72173, Oct. 31, 1980, as amended at 53 FR 7745, Mar. 10, 1988]

§ 12.2 Scope.

This part is applicable to surplus real property located within any State which is appropriate for assignment to, or which has been assigned to, the Department for transfer for public health purposes, as provided for in section 203(k) of the Act.

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§ 12.3 General policies.

(a) It is the policy of the Department to foster and assure maximum utilization of surplus real property for public health purposes, including research.

(b) Transfers may be made only to States, their political subdivisions and instrumentalities, tax-supported public health institutions, and nonprofit public health institutions which (except for institutions which lease property to assist the homeless under Title V of Pub. L. 100-77) have been held tax-exempt under section 501(c)(3) of the Internal Revenue Code of 1954.

(c) Real property will be requested for assignment only when the Department has determined that the property is suitable and needed for public health purposes. The amount of real and related personal property to be transferred shall not exceed normal operating requirements of the applicant. Such property will not be requested for assignment unless it is needed at the time of application for public health purposes or will be so needed within the immediate or foreseeable future. Where construction or major renovation is not required or proposed, the property must be placed into use within twelve (12) months from the date of transfer. When construction or major renovation is contemplated at the time of transfer, the property must be placed in use within 36 months from the date of transfer. If the applicable time limitation is not met, the transferee shall either commence payments in cash to the Department for each month thereafter during which the proposed use has not been implemented or take such other action as set forth in § 12.12 as is deemed appropriate by the Department. Such monthly payments shall be computed on the basis of the current fair market value of the property at the time of the first payment by subtracting therefrom any portion of the purchase price paid in cash at the time of transfer, and by dividing the balance by the total number of months in the period of restriction. If the facility has not been placed into use within eight (8) years of the date of the deed, title to the property will be revested in the United States, or, at the discretion of the Department, the

restrictions and conditions may be abrogated in accordance with § 12.9.

(d) Transfers will be made only after the applicant has certified that the proposed program is not in conflict with State or local zoning restrictions, building codes, or similar limitations.

(e) Organizations which may be eligible include those which provide care and training for the physically and mentally ill, including medical care of the aged and infirm; clinical services; services (including shelter) to homeless individuals; other public health services (including water and sewer); or similar services devoted primarily to the promotion and protection of public health. In addition, organizations which provide assistance to homeless individuals may be eligible for leases under title V of Public Law 100-77. Except for the provision of services (including shelter) to homeless individuals, organizations which have as their principal purpose the providing of custodial or domiciliary care are not eligible. The eligible organization must be authorized to carry out the activity for which it requests the property.

(f) An applicant's plan of operation will not be approved unless it provides that the applicant will not discriminate because of race, color, sex, handicap, or national origin in the use of the property.

[45 FR 72173, Oct. 31, 1980, as amended at 53 FR 7745, Mar. 10, 1988; 55 FR 32252, Aug. 8, 1990]

§ 12.4 Limitations.

(a) Surplus property transferred pursuant to this part will be disposed of on an "as is, where is," basis without warranty of any kind.

(b) Unless excepted by the General Services Administrator in his assignment, mineral rights will be conveyed together with the surface rights.

§ 12.5 Awards.

Where there is more than one applicant for the same property, it will be awarded to the applicant having a program of utilization which provides, in the opinion of the Department, the greatest public benefit. Where the property will serve more than one program, it will be apportioned to fit the

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needs of as many programs as is practicable.

§ 12.6 Notice of available property.

Reasonable publicity will be given to the availability of surplus real property which is suitable for assignment to the Department for transfer for public health uses. The Department will establish procedures reasonably calculated to afford all eligible users having a legitimate interest in acquiring the property for such uses an opportunity to make an application therefor. However, publicity need not be given to the availability of surplus real property which is occupied and being used for eligible public health purposes at the time the property is declared surplus, the occupant expresses interest in the property, and the Department determines that it has a continuing need therefor.

§ 12.7 Applications for surplus real property.

Applications for surplus real property for public health purposes shall be made to the Department through the office specified in the notice of availability.

[55 FR 32252, Aug. 8, 1990]

§ 12.8 Assignment of surplus real property.

(a) Notice of interest in a specific property for public health purposes will be furnished the General Services Administrator by the Department at the earliest possible date.

(b) Requests to the Administrator for assignment of surplus real property to the Department for transfer for public health purposes will be based on the following conditions:

(1) The Department has an acceptable application for the property.

(2) The applicant is willing, authorized, and in a position to assume immediate care, custody, and maintenance of the property.

(3) The applicant is able, willing and authorized to pay the administrative expenses incident to the transfer.

(4) The applicant has the necessary funds, or the ability to obtain such funds, to carry out the approved program of use of the property.

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§ 12.9 General disposal terms and conditions.

(a) Surplus real property transfers under this part will be limited to public health purposes. Transferees shall be entitled to a public benefit allowance in terms of a percentage which will be applied against the value of the property to be conveyed. Such an allowance will be computed on the basis of benefits to the United States from the use of such property for public health purposes. The computation of such public benefit allowances will be in accordance with Exhibit A attached hereto and made a part hereof.

(b) A transfer of surplus real property for public health purposes is subject to the disapproval of the Administrator within 30 days after notice is given to him of the proposed transfer.

(c) Transfers will be on the following terms and conditions:

(1) The transferee will be obligated to utilize the property continuously in accordance with an approved plan of operation.

(2) The transferee will not be permitted to sell, lease or sublease, rent, mortgage, encumber, or otherwise dispose of the property, or any part thereof, without the prior written authorization of the Department.

(3) The transferee will file with the Department such reports covering the utilization of the property as may be required.

(4) In the event the property is sold, leased or subleased, encumbered, disposed of, or is used for purposes other than those set forth in the approved plan without the consent of the Department, all revenues or the reasonable value of other benefits received by the transferee directly or indirectly from such use, as determined by the Department, will be considered to have been received and held in trust by the transferee for the account of the United States and will be subject to the direction and control of the Department. The provisions of this paragraph shall not impair or affect the rights reserved to the United States in paragraph (c)(6) of this section, or the right of the Department to impose conditions to its consent.

(5) Lessees will be required to carry all perils and liability insurance to

protect the Government and the Government's residual interest in the property. Transferees will be required to carry such flood insurance as may be required by the Department pursuant to Pub. L. 93-234. Where the transferee elects to carry insurance against damages to or loss of on-site property due to fire or other hazards, and where loss or damage to transferred Federal surplus real property occurs, all proceeds from insurance shall be promptly used by the transferee for the purpose of repairing and restoring the property to its former condition, or replacing it with equivalent or more suitable facilities. If not so used, there shall be paid to the United States that part of the insurance proceeds that is attributable to the Government's residual interest in the property lost, damaged, or destroyed in the case of leases, attributable to the fair market value of the leased facilities.

(6) With respect to on-site property, in the event of noncompliance with any of the conditions of the transfer as determined by the Department, title to the property transferred and the right to immediate possession shall, at the option of the Department, revert to the Government. In the event title is reverted to the United States for noncompliance or voluntarily reconveyed, the transferee shall, at the option of the Department, be required to reimburse the Government for the decrease in value of the property not due to reasonable wear and tear or acts of God or attributable to alterations completed by the transferee to adapt the property to the public health use for which the property was transferred. With respect to leased property, in the event of noncompliance with any of the conditions of the lease, as determined by the Department, the right of occupancy and possession shall, at the option of the Department, be terminated. In the event a leasehold is terminated by the United States for noncompliance or is voluntarily surrendered, the lessee shall be required at the option of the Department to reimburse the Government for the decrease in value of the property not due to reasonable wear and tear or acts of God or attributable to alterations completed by the lessee to adapt the property to the public

health use for which the property was leased.

With respect to any reverter of title or termination of leasehold resulting from noncompliance, the Government shall, in addition thereto, be reimbursed for such costs as may be incurred in recovering title to or possession of the property.

Any payments of cash made by the transferee against the purchase price of property transferred shall, upon a forfeiture of title to the property for breach of condition, be forfeited.

(7) With respect to off-site property, in the event of noncompliance with any of the terms and conditions of the transfer, the unearned public benefit allowance shall, at the option of the Department, become immediately due and payable or, if the property or any portion thereof is sold, leased, or otherwise disposed of without authorization from the Department, such sale, lease or sublease, or other disposal shall be for the benefit and account of the United States and the United States shall be entitled to the proceeds. In the event the transferee fails to remove the property or any portion thereof within the time specified, then in addition to the rights reserved above, at the option of the Department, all right, title, and interest in and to such unremoved property shall be retransferred to other eligible applicants or shall be forfeited to the United States.

(8) With respect only to on-site property which has been declared excess by the Department of Defense, such declaration having included a statement indicating the property has a known potential for use during a national emergency, the Department shall reserve the right during any period of emergency declared by the President of the United States or by the Congress of the United States to the full and unrestricted use by the Government of the surplus real property, or of any portion thereof, disposed of in accordance with the provisions of this part. Such use may be either exclusive or nonexclusive. Prior to the expiration or termination of the period of restricted use by the transferee, the Government will not be obligated to pay rent or any other fees or charges during the period

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of emergency, except that the Government will:

(i) Bear the entire cost of maintenance of such portion of the property used by it exclusively or over which it may have exclusive possession or control;

(ii) Pay the fair share, commensurate with the use of the cost of maintenance of such surplus real property as it may use nonexclusively or over which it may have nonexclusive possession or control;

(iii) Pay a fair rental for the use of improvements or additions to the surplus real property made by the purchaser or lessee without Government aid; and

(iv) Be responsible for any damage to the surplus real property caused by its use, reasonable wear and tear, the common enemy and acts of God excepted. Subsequent to the expiration or termination of the period of restricted use, the obligations of the Government will be as set forth in the preceding sentence and, in addition, the Government shall be obligated to pay a fair rental for all or any portion of the conveyed premises which it uses.

(9) The restrictions set forth in paragraphs (c) (1) through (7) of this section will extend for thirty (30) years for land with or without improvements; and for facilities being acquired separately from land whether they are for use on-site or off-site, the period of limitations on the use of the structures will be equal to their estimated economic life. The restrictions set forth in paragraphs (c) (1) through (7) of this section will extend for the entire initial lease period and for any renewal periods for property leased from the Department.

(d) Transferees, by obtaining the consent of the Department, may abrogate the restrictions set forth in paragraph (c) of this section for all or any portion of the property upon payment in cash to the Department of an amount equal to the then current fair market value of the property to be released, multiplied by the public benefit allowance granted at the time of conveyance, divided by the total number of months of the period of restriction set forth in the conveyance document and multiplied by the number of months that re-

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main in the period of restriction as determined by the Department. For purposes of abrogation payment computation, the current fair market value shall not include the value of any improvements placed on the property by the transferee.

(e) Related personal property will be transferred or leased as a part of the realty and in accordance with real property procedures. It will be subject to the same public benefit allowance granted for the real property. Where related personal property is involved in an on-site transfer, the related personal property may be transferred by a bill of sale imposing restrictions for a period not to exceed five years from the date of transfer, other terms and conditions to be the same as, and made a part of, the real property transaction.

§ 12.10 Compliance with the National Environmental Policy Act of 1969 and other related Acts (environmental impact).

(a) The Department will, prior to making a final decision to convey or lease, or to amend, reform, or grant an approval or release with respect to a previous conveyance or lease of, surplus real property for public health purposes, complete an environmental assessment of the proposed transaction in keeping with applicable provisions of the National Environmental Policy Act of 1969, the National Historic Preservation Act of 1966, the National Archeological Data Preservation Act, and other related acts. No permit to use surplus real property shall allow the permittee to make, or cause to be made, any irreversible change in the condition of said property, and no use permit shall be employed for the purpose of delaying or avoiding compliance with the requirements of these Acts.

(b) Applicants shall be required to provide such information as the Department deems necessary to make an assessment of the impact of the proposed Federal action on the human environment. Materials contained in the applicant's official request, responses to a standard questionnaire prescribed by the Public Health Service, as well as other relevant information, will be

used by the Department in making said assessment.

(c) If the assessment reveals (1) That the proposed Federal action involves properties of historical significance which are listed, or eligible for listing, in the National Register of Historic Places, or (2) that a more than insignificant impact on the human environment is reasonably foreseeable as a result of the proposed action, or (3) that the proposed Federal action could result in irreparable loss or destruction of archeologically significant items or data, the Department will, except as provided for in paragraph (d) of this section, prepare and distribute, or cause to be prepared or distributed, such notices and statements and obtain such approvals as are required by the above cited Acts.

(d) If a proposed action involves other Federal agencies in a sequence of actions, or a group of actions, directly related to each other because of their functional interdependence, the Department may enter into and support a lead agency agreement to designate a single lead agency which will assume primary responsibility for coordinating the assessment of environmental effects of proposed Federal actions, preparing and distributing such notices and statements, or obtaining such approvals, as are required by the above cited Acts. The procedures of the designated lead agency will be utilized in conducting the environmental assessment. In the event of disagreement between the Department and another Federal agency, the Department will reserve the right to abrogate its lead agency agreement with the other Federal Agency.

[45 FR 72173, Oct. 31, 1980, as amended at 55 FR 32252, Aug. 8, 1990]

§ 12.11 Special terms and conditions.

(a) Applicants will be required to pay all external administrative costs which will include, but not be limited to, taxes, surveys, appraisals, inventory costs, legal fees, title search, certificate or abstract expenses, decontamination costs, moving costs, closing fees in connection with the transaction and service charges, if any, made by State Agencies for Federal Property

Assistance under the terms of a cooperative agreement with the Department.

(b) In the case of off-site property, applicants will be required to post performance bonds, make performance guarantee deposits, or give such other assurances as may be required by the Department or the holding agency to insure adequate site clearance and to pay service charges, if any, made by State Agencies for Federal Property Assistance under the terms of a cooperative agreement with the Department.

(c) Whenever negotiations are undertaken for disposal to private nonprofit public health organizations of any surplus real property which cost the Government \$1 million or more, the Department will give notice to the Attorney General of the United States of the proposed disposal and the terms and conditions thereof. The applicant shall furnish to the Department such information and documents as the Attorney General may determine to be appropriate or necessary to enable him to give the advice as provided for by section 207 of the Act.

(d) Where an applicant proposes to acquire or lease and use in place improvements located on land which the Government does not own, he shall be required, before the transfer is consummated, to obtain a right to use the land commensurate with the duration of the restrictions applicable to the improvements, or the term of the lease. The applicant will be required to assume, or obtain release of, the Government's obligations respecting the land including but not limited to obligations relating to restoration, waste, and rent. At the option of the Department, the applicant may be required to post a bond to indemnify the Government against such obligations.

(e) The Department may require the inclusion in the transfer or lease document of any other provision deemed desirable or necessary.

(f) Where an eligible applicant for an on-site transfer proposes to construct new, or rehabilitate old, facilities, the financing of which must be accomplished through issuance of revenue bonds having terms inconsistent with the terms and conditions of transfer prescribed in §12.9 (c), (d), and (e) of this chapter, the Department may, in

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its discretion, impose such alternate terms and conditions of transfer in lieu thereof as may be appropriate to assure utilization of the property for public health purposes.

§ 12.12 Utilization.

(a) Where property or any portion thereof is not being used for the purposes for which transferred, the transferee will be required at the direction of the Department:

(1) To place the property into immediate use for an approved purpose;

(2) To retransfer such property to such other public health user as the Department may direct;

(3) To sell such property for the benefit and account of the United States;

(4) To return title to such property to the United States or to relinquish any leasehold interest therein;

(5) To abrogate the conditions and restrictions of the transfer, as set forth in § 12.9(d) of this chapter, except that, where property has never been placed in use for the purposes for which transferred, abrogation will not be permitted except under extenuating circumstances; or

(6) To make payments as provided for in § 12.3(c) of this chapter.

(b) Where the transferee or lessee desires to place the property in temporary use for a purpose other than

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that for which the property was transferred or leased, approval from the Department must be obtained, and will be conditioned upon such terms as the Department may impose.

§ 12.13 Form of conveyance.

(a) Transfers or leases of surplus real property will be on forms approved by the Office of General Counsel of the Department and will include such of the disposal or lease terms and conditions set forth in this part and such other terms and conditions as the Office of General Counsel may deem appropriate or necessary.

(b) Transfers of on-site property will normally be by quitclaim deed without warranty of title.

§ 12.14 Compliance inspections and reports.

The Department will make or have made such compliance inspections as are necessary and will require of the transferee or lessee such compliance reports and actions as are deemed necessary.

§ 12.15 Reports to Congress.

The Secretary will make such reports of real property disposal activities as are required by section 203 of the Act and such other reports as may be required by law.

EXHIBIT A TO PART 12—PUBLIC BENEFIT ALLOWANCE FOR TRANSFER OF REAL PROPERTY FOR HEALTH PURPOSES¹

Classification	Percent allowed											
	Organization allowances							Utilization allowances				Max- imum public benefit allow- ance
	Basic public ben- efit allow- ance	Tax sup- port	Ac- credi- tation	Hard- ship	Unmet needs			Inte- grated re- search pro- gram	Out- pa- tient servi- ces	Public servi- ces	Train- ing pro- gram	
					10 to 25%	26 to 50%	51 to 100%					
Hospitals	50	20	20	10	10	20	30	10	10	10	10	100
Clinics	50	20	20	10	10	20	30					100
Nursing Homes	50	20	20	10	10	20	30				10	100
Public Health Admin- istration	2 100											2 100
Public Refuse Dis- posal and Water Systems	2 100											2 100
Research	2 100											2 100
Rehabilitation Facility	50	20	20	10	10	20	30	10	10	10	10	100
Special Services	50	20	20	10	10	20	30			10		100

Classification	Percent allowed											
	Organization allowances							Utilization allowances				Maximum public benefit allowance
	Basic public benefit allowance	Tax support	Accreditation	Hardship	Unmet needs			Integrated re-search program	Out-patient services	Public services	Training program	
					10 to 25%	26 to 50%	51 to 100%					
Assistance to the Homeless	≥ 100											≥ 100

¹ This public benefit allowance applies only to surplus real property being sold for on-site use. When surplus real property is to be moved from the site, a basic public benefit allowance of 100% will be granted.

² Applicable when this is the primary use to be made of the property. The public benefit allowance for the overall health program is applicable when such facilities are conveyed as a minor component of other facilities.

[45 FR 72173, Oct. 31, 1980, as amended at 53 FR 7745, Mar. 10, 1988]

PART 12a—USE OF FEDERAL REAL PROPERTY TO ASSIST THE HOMELESS

Sec.

- 12a.1 Definitions.
- 12a.2 Applicability.
- 12a.3 General policies.
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- 12a.8 Compliance with the National Environmental Policy Act of 1969 and other related Acts (environmental impact).
- 12a.9 No applications approved.
- 12a.10 Utilization and enforcement.
- 12a.11 Other uses.
- 12a.12 Abrogation.
- 12a.13 Compliance inspections and reports.
- 12a.14 No right of administrative review for agency decisions.
- 12a.15 Severability.

AUTHORITY: 42 U.S.C. 11411; 40 U.S.C. 550.

SOURCE: 89 FR 89898, Nov. 13, 2024, unless otherwise noted.

§ 12a.1 Definitions.

Applicant means any eligible organization that has submitted an application to the Department of Health and Human Services to obtain use of a certain suitable property to assist the homeless.

Classification means a property's designation as unutilized, underutilized, excess, or surplus.

Day means one calendar day, including weekends and holidays.

Eligible organization means a State or local government agency, or a private, non-profit organization that provides assistance to the homeless, and that is authorized under the State law in

which the property is located to carry out the activity for which it requests property and enter into an agreement with the Federal Government for use of property for the purposes of this part. Eligible organizations that are private, non-profit organizations interested in applying for suitable property must be tax exempt under section 501(c)(3) of the Internal Revenue Code at the time of application and remain tax exempt throughout the time the Federal Government retains a reversionary interest in the property.

Encumbrance means any non-approved use by a transferee or a third party that limits the full utilization of the transferred property, regardless of time period, and includes liens, easements, restrictive covenants, licenses, leases, mortgages, informal agreements, and unaddressed trespass.

Excess property means any property under the control of a Federal executive agency that the head of the agency determines is not required to meet the agency's needs or responsibilities, pursuant to 40 U.S.C. 524.

GSA means the General Services Administration.

HHS means the Department of Health and Human Services.

Homeless is defined in 42 U.S.C. 11302. This term is synonymous with "homeless individual" and "homeless person."

HUD means the Department of Housing and Urban Development.

HUD website means a website maintained by HUD providing information about HUD, including any successor websites or technologies that are

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equally accessible and available to the public.

Landholding agency means the Federal department or agency with statutory authority to control property. For purposes of this part, the landholding agency is typically the Federal department or agency that had custody and accountability on behalf of the Federal Government, of a certain piece of property at the time that such property was reported to HUD for a suitability determination pursuant to 42 U.S.C. 11411.

Lease means an agreement in writing between either HHS for surplus property or landholding agencies for underutilized and unutilized properties and the applicant giving rise to the relationship of lessor and lessee for the use of Federal property for a term of at least one year under the conditions set forth in the lease document.

Non-profit organization means an organization recognized as a non-profit by the State in which the organization operates, no part of the net earnings of which inures to the benefit of any member, founder, contributor, or individual; that has a voluntary board; that has an accounting system or has designated an entity that will maintain a functioning accounting system for the organization in accordance with generally accepted accounting procedures; and that practices non-discrimination in the provision of assistance.

Permit means a license granted by a landholding agency to use unutilized or underutilized property for a specific amount of time, usually one year or less, under terms and conditions determined by the landholding agency. A permit does not grant to the recipient an estate in land or any interest in the property.

Property means real property consisting of vacant land or buildings, or a portion thereof, that is excess, surplus, or designated as unutilized or underutilized in surveys by the heads of landholding agencies conducted pursuant to 40 U.S.C. 524.

Related personal property means any personal property that is located on real property and is either an integral part of or useful in the operation of

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that property or is determined by GSA to be otherwise related to the property.

Representative of the homeless means a State or local government agency, or private nonprofit organization that provides, or proposes to provide, services to the homeless.

Screen means the process by which GSA surveys Federal executive agencies to determine if they have an interest in using excess Federal property to carry out a particular agency mission, and then surveys State, local, and nonprofit entities, to determine if any such entity has an interest in using surplus Federal property to carry out a specific public use.

State means a State of the United States, and includes the District of Columbia, the Commonwealth of Puerto Rico, and the Territories and possessions of the United States.

Suitable property means that HUD has determined that a certain property satisfies the criteria listed in 24 CFR 581.6.

Surplus property means any excess property not required by any Federal landholding agency for its needs or the discharge of its responsibilities, as determined by GSA.

Transfer document means a lease, deed, or permit transferring surplus, unutilized, or underutilized property.

Transferee means an eligible entity that acquires Federal property by lease, deed, or permit.

Underutilized means an entire property or portion thereof, with or without improvements which is used only at irregular periods or intermittently by the accountable landholding agency for current program purposes of that agency, or which is used for current program purposes that can be satisfied with only a portion of the property.

Unutilized property means an entire property or portion thereof, with or without improvements, not occupied for current program purposes for the accountable executive agency or occupied in caretaker status only.

§ 12a.2 Applicability.

(a) This part applies to Federal property that has been designated by Federal landholding agencies as unutilized, underutilized, excess, or surplus and is therefore subject to the provisions of

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Title V of the McKinney Act, as amended (42 U.S.C. 11411).

(b) The following categories of properties are not subject to this part (regardless of whether they may be unutilized or underutilized):

(1) Buildings and property at military installations that were approved for closure under the Defense Base Closure and Realignment Act of 1990 (part A of title XXIX of Pub. L. 101-510; 10 U.S.C. 2687 note) after October 25, 1994.

(2) Machinery and equipment not determined to be related personal property by the landholding agency or GSA or determined to be related personal property that the landholding agency or GSA chooses to dispose of separate from real property.

(3) Government-owned, contractor-operated machinery, equipment, land, and other facilities reported excess for sale only to the using contractor and subject to a continuing military requirement.

(4) Properties subject to special legislation directing a particular action.

(5) Properties subject to a court order that is binding on the Federal Government and, for any reason, precludes transfer for use to assist the homeless under the authority of 42 U.S.C. 11411.

(6) Property not subject to Federal Real Property Council reporting requirements in accordance with 40 U.S.C. 623(i).

(7) Mineral rights interests independent of surface rights.

(8) Air space interests independent of surface rights.

(9) Indian Reservation land subject to 40 U.S.C. 523.

(10) Property interests subject to reversion.

(11) Easements.

(12) Any building or fixture that is excess, or surplus, that is on land under the control of a landholding agency, where the underlying land is not excess or surplus.

(13) Property purchased in whole or in part with Federal funds if title to the property is not held by a Federal landholding agency as defined in this part.

§ 12a.3 General policies.

(a) It is the policy of HHS to foster and assure maximum utilization of sur-

plus property for homeless assistance purposes.

(b) Transfers may be made only to eligible organizations.

(c) Property will be requested for assignment only when HUD has made a final determination that the property is suitable for use to assist the homeless, GSA has determined it is available, and HHS has determined it is needed for homeless assistance purposes. The amount of real and related personal property to be transferred shall not exceed normal operating requirements of the applicant. Such property will not be requested for assignment unless it is needed at the time of application for homeless assistance purposes or will be so needed within the immediate or foreseeable future.

(d) Transfers by deed will be made only after the applicant's financial plan is approved and the applicant provides certification that the proposed program is permissible under all applicable State and local zoning restrictions, building codes, and similar limitations.

(e) In instances of noncompliance, transferees are provided an opportunity to cure the noncompliance pursuant to § 12a.10.

§ 12a.4 Expression of interest process.

(a) Properties published by HUD as suitable and available, pursuant to 24 CFR 581.8, for application for use to assist the homeless shall not be available for any other purpose for a period of 30 days beginning on the date the list of properties is published on the HUD website. Any eligible organization interested in any underutilized, unutilized, excess, or surplus property for use to assist the homeless must send HHS a written expression of interest in that property within 30 days after the property has been published on the HUD website.

(b) Although a property may be determined suitable by HUD, HUD's determination does not mean a property is necessarily fit for use for the purpose(s) stated in the application, nor does it guarantee subsequent conveyance or transfer of a property.

(c) If a written expression of interest to apply for suitable property for use

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to assist the homeless is received by HHS within the 30-day holding period, such property may not be made available for any other purpose until the date HHS or the appropriate landholding agency has completed action on the application submitted pursuant to that expression of interest.

(d)(1) The expression of interest should identify the specific property, briefly describe the proposed use, include the name of the organization, and indicate whether it is a public body or a private, non-profit organization. The expression of interest must be sent to HHS by email, rpb@psc.hhs.gov, or by mail at the following address: Department of Health and Human Services, Program Manager, Federal Real Property Assistance Program, Real Estate Logistics and Operations, 5600 Fishers Lane, Rockville, Maryland 20852.

(2) HHS will notify the landholding agency (for unutilized and underutilized properties) or GSA (for excess and surplus properties) when an expression of interest has been received for a certain property.

(e) An expression of interest may be sent to and accepted by HHS any time after the 30-day holding period has expired only if the property remains available as determined by GSA or the landholding agency for application to assist the homeless. In such a case, an application submitted pursuant to this expression of interest may be approved for use by the homeless if:

(1) There are no pending applications or written expressions of interest made under any law for use of the property for any purpose; and

(2) In the case of excess or surplus property, GSA has not received a bona fide offer to purchase that property or advertised for the sale of the property by public auction.

§ 12a.5 Application process and requirements.

(a) Upon receipt of an expression of interest, HHS will send an application packet to the interested entity. The application packet requires the applicant to provide certain information, including the following—

(1) *Acquisition type.* The applicant must state whether it is requesting ac-

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quisition of the property by lease, deed, or permit. A lease of one year, extendable at HHS's discretion, with the concurrence of GSA or the landholding agency, may be granted when the applicant's initial application is approved and the applicant's final application outlining the applicant's financial plan is found to be otherwise reasonable based on the criteria in paragraph (a)(7) of this section, but either a change in zoning is required or the financial plan proposes to utilize Low-Income Housing Tax Credits or other funding sources that typically take longer to process than other forms of financing. Applicants that initially apply for transfer by lease or permit and subsequently request transfer by deed will follow the same bifurcated application process, including deadlines, contained in 42 U.S.C. 11411. Should an applicant wish to transition from acquisition by lease to acquisition by deed, HHS will issue a letter of commitment to a lessee indicating that, provided its application meets all application criteria, including securing of all necessary financing that complies with Federal Government requirements, HHS will issue a deed.

(2) *Description of the applicant organization.* The applicant must document that it satisfies the definition of an *eligible organization* as specified in § 12a.1.

(3) *Description of the property desired.* The applicant must describe the listed property desired, including existing zoning. Applicants must certify that any modification(s) made to and use of the property will conform to all applicable building codes, and local use restrictions, or similar limitations. In accordance with GSA policy, determinations regarding parcelization are made prior to screening. Therefore, expressions of interest and applications for portions of listed properties will not be accepted.

(4) *Description of the proposed program.* The applicant must fully describe the proposed program and plan of use, including implementation plans.

(5) *Demonstration of need.* The applicant must demonstrate that the property is needed for homeless assistance purposes at the time of application and how the program will address the needs

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of the homeless population to be assisted. The applicant must demonstrate that it has an immediate need and ability to utilize all of the property for which it is applying.

(6) *Demonstrate that the property is suitable and adaptable for the proposed program and plan of use.* The applicant must fully explain why the property is suitable and describe what, if any, modification(s) will be made to the property before the program becomes operational.

(7) *Ability to finance and operate the proposed program.* If the applicant's initial application is approved, the applicant must set forth a reasonable plan to finance the approved program within 45 days of the initial approval. To be considered reasonable, the plan must, at a minimum:

(i) Specifically describe all anticipated costs and sources of funding for the proposed program, including any property modifications;

(ii) Be accompanied by supporting documentation which demonstrates that the proposed plan is likely to succeed;

(iii) Demonstrate that the applicant is ready, willing, able, and authorized to assume care, custody, and maintenance of the property;

(iv) Demonstrate that it has secured the necessary dedicated funds, or will obtain such funds, to carry out the approved proposed program and plan of use for the property, including administrative expenses incident to the transfer by deed, lease, or permit;

(v) Not diminish the value of the Federal Government's interest in the property nor impair the Federal Government's ability to revert and immediately dispose of the property free of any and all liens, encumbrances, or anything else which renders the property unmarketable. Deed transfers will only be made after an applicant demonstrates its financial plan adequately protects the Federal Government's interest in the property; and

(vi) Neither subject the Federal Government's interest in the property to foreclosure nor impose obligations (e.g., extended use agreements) on the Federal Government.

(8) *Compliance with non-discrimination requirements.* Each applicant under this

part must certify in writing that it will comply with all requirements of Federal law and HHS policy, as amended, relating to non-discrimination, including the following: the Fair Housing Act (42 U.S.C. 3601-3619) and implementing regulations at 24 CFR part 100; and, as applicable, Executive Order 11063 (Equal Opportunity in Housing) and implementing regulations at 24 CFR part 107; Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d to d-4) (Non-discrimination in Federally Assisted Programs) and implementing regulations at 45 CFR part 80; section 1557 of the Affordable Care Act and implementing regulations at 45 CFR part 92; the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975 (42 U.S.C. 6101-6107) and implementing regulations at 45 CFR part 91; and the prohibitions against discrimination against otherwise qualified individuals with disabilities under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and implementing regulations at 45 CFR part 84. The applicant must maintain the required records to demonstrate compliance with all applicable Federal laws and HHS policies related to non-discrimination.

(9) *Insurance and indemnification.* The applicant must certify that it will insure the property against loss, damage, or destruction to protect the residual financial interest of the United States. The United States shall be named as an additional insured. Applicants must provide proof of insurance annually or upon request. Failure to maintain sufficient insurance may result in adverse action, including reversion of the property, at the discretion of HHS. In the event of a covered loss, the transferee must hold all insurance proceeds in trust and obtain written concurrence from HHS before disbursing the funds. Applicants, and all affiliated parties utilizing the property, as approved by HHS, must indemnify the United States and hold the United States harmless for all actions involving use of the property.

(10) *Historic preservation.* Where applicable, the applicant must provide information that will enable HHS to comply with Federal historic preservation requirements.

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(11) *Environmental information.* The applicant must provide sufficient information to allow HHS to analyze the potential impact of the applicant's proposal on the environment, in accordance with the instructions provided with the application packet. HHS will assist applicants in obtaining any pertinent environmental information in the possession of HUD, GSA, or the landholding agency. However, the burden is on the applicant to submit sufficient documentation for analysis by HHS.

(12) *Local government notification.* The applicant must certify that it has notified the applicable unit of general local government responsible for sewer, water, police, and fire services, in writing, of its proposed program for the specific property and submit a copy of that written notification.

(13) *Zoning and local use restrictions.* An applicant requesting a deed must certify that it has consulted all State and local governmental entities that will have jurisdiction over the property and that the proposed use will comply with all applicable zoning and local use restrictions, including local building code requirements. An applicant that applies for a lease or permit is not required to comply with local zoning requirements, as long as the Federal Government retains ownership of the property. Deed transfers will only be made after the applicant has provided acceptable written proof that the proposed program is not in conflict with State or local zoning laws and restrictions, building codes, or similar limitations.

(b) *Scope of evaluations.* Due to the short time frame imposed by statute for evaluating applications, HHS's evaluation will, generally, be limited to the information contained in the application. It is therefore incumbent on applicants to provide thorough and complete applications.

(c) *Deadline for initial application.* An initial application must be received by HHS, at the email address in § 12a.4(d)(1) or other address indicated by HHS, within 75 days after an expression of interest is received from a particular applicant for that property. Upon written request from the applicant, HHS may, in its discretion, grant

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extensions authorized by 42 U.S.C. 11411(e)(2)(A), provided that the appropriate landholding agency or GSA concurs with the extension.

(d) *Evaluation of initial application.* (1) Upon receipt of an initial application, HHS will review it for completeness, and, if incomplete and time permits, may, in its discretion, return it or ask the applicant to furnish any missing or additional required information prior to final evaluation of the initial application.

(2) HHS will evaluate each initial application within 10 days of receipt and will promptly advise the applicant of its decision. All initial applications will be reviewed on the basis of the following elements:

(i) *Services offered.* The extent and range of proposed services, such as meals, shelter, job training, and counseling.

(ii) *Need.* The demand for the program, the program's ability to satisfy unmet needs of the community, and the degree to which the available property will be fully utilized.

(iii) *Experience.* Demonstrated ability to provide the services, such as prior success in operating similar programs and recommendations attesting to that fact by Federal, State, and local authorities.

(e) *Deadline and evaluation of final application.* (1) If HHS approves an initial application, HHS will notify the applicant and provide the applicant 45 days in which to provide a final application. The final application shall set forth a reasonable plan to finance, as specified in paragraph (a)(7) of this section, the approved program as set forth in the initial application. Applicants may not modify the approved initial application within its final application proposal.

(2) Upon receipt of the final application, HHS will make a determination within 15 days and notify the applicant.

(3) Unlike with initial applications, requests for extensions are not authorized by 42 U.S.C. 11411 and thus will not be considered for final applications.

(4) Applications are evaluated on a first-come, first-served basis. HHS will notify all organizations that have submitted expressions of interest for a particular property whether an earlier

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application received for that property has been approved.

(f) *Competing applications.* If HHS receives more than one final application simultaneously, HHS will evaluate all applications and make a determination based on each application's merit. HHS will rank approved applications based on the elements listed in paragraph (a) of this section, and notify the landholding agency, or GSA, as appropriate, of the approved applicant.

§ 12a.6 Action on approved applications.

(a) *Unutilized and underutilized properties.* (1) When HHS approves an application, it will so notify the applicant and forward a copy of the application to the landholding agency. The landholding agency will execute the lease, or permit document, as appropriate, in consultation with the applicant.

(2) The landholding agency maintains the discretion to decide the following:

(i) The length of time the property will be available.

(ii) The terms and conditions of the lease or permit document (except that a landholding agency may not charge any fees or impose any costs).

(b) *Excess and surplus properties.* (1) When HHS approves an application, it will so notify the applicant and request that GSA assign the property to HHS for transfer. Requests to GSA for the assignment of surplus property to HHS for homeless assistance purposes will be based on the following conditions:

(i) HHS has a fully approved application for the property;

(ii) The applicant is able, willing, and authorized to assume immediate care, custody, and maintenance of the property;

(iii) The applicant is able, willing and authorized to pay the administrative expenses incident to the transfer; and

(iv) The applicant has secured the necessary funds, or had demonstrated the ability to obtain such funds, to carry out the approved program of use of the property.

(2) Upon receipt of an acceptable assignment, HHS will execute the transfer document in accordance with the procedures and requirements set out in this part and any other terms and conditions HHS and GSA determine are

appropriate or necessary. Custody and accountability of the property will remain throughout the lease term with the landholding agency (*i.e.*, the agency which initially reported the property as excess) and throughout the deed term with the transferee.

(3) Prior to assignment to HHS, GSA may consider other Federal uses and other important national needs in deciding the disposition of surplus property. Priority of consideration will normally be given to uses to assist the homeless. However, both GSA and HHS may consider any competing request for the property made under 40 U.S.C. 550 that is so meritorious and compelling that it outweighs the needs of the homeless.

(4) Whenever GSA or HHS decides in favor of a competing request over a request for property for homeless assistance, the agency making the decision will transmit to the appropriate committees of Congress an explanatory statement which details the need satisfied by conveyance of the surplus property, and the reasons for determining that such need was so meritorious and compelling as to outweigh the needs of the homeless.

§ 12a.7 Transfer documents.

(a) Surplus property may be conveyed to eligible organizations pursuant to 40 U.S.C. 550(d) and 42 U.S.C. 11411, as amended, by lease or deed, at the applicant's discretion.

(b) Transfers of surplus property for homeless assistance purposes are in exchange for the transferee's agreement to fully utilize the property for homeless assistance purposes in accordance with the terms specified in the transfer document.

(c) A transfer of surplus property for homeless assistance purposes is subject to the disapproval of GSA within 30 days after notice is given to GSA of the proposed transfer.

(d) Surplus property transferred pursuant to this part will be disposed on an "as is, where is" basis without warranty of any kind except as may be stated in the transfer document.

(e) Unless excepted by GSA in its assignment, the disposal of property includes mineral rights associated with the surface estate.

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(f) Transfers of surplus property under this part will be made with the following general terms and conditions:

(1) For the period provided in the transfer document, the transferee shall utilize all the surplus property it receives solely and continuously for the approved program and plan of use, in accordance with 42 U.S.C. 11411 and this part, except that:

(i) The transferee has 12 months from the date of transfer to place the surplus property into use, if HHS did not approve in writing, construction of new facilities or major renovation of the property when it approved the final application;

(ii) The transferee has 48 months from the date of transfer to place the surplus property into use, if the transferee proposes construction of new facilities or major renovation of the property and HHS approves it in writing at the time it approves the final application;

(iii) If the applicable time limitation is not met, the transferee shall either commence payments in cash to the Federal Government for each month thereafter during which the proposed use has not been implemented or take such other action as set forth at §12a.10 as is deemed appropriate by HHS. Such monthly payments shall be computed on the basis of the current fair market value of the property, as conveyed, at the time of the first payment and dividing it by 360 months. At HHS's discretion, the payment may be waived if the transferee makes a sufficient showing of continued progress to place the property into use or if an unforeseeable event occurs which prevents the property from being put into use within the applicable timeframe; and

(iv) HHS may permit use of surplus property at any time during the period of restriction by an entity other than the transferee in accordance with §12a.11.

(2) The transferee will not be permitted to encumber, or dispose of the property, or impair full utilization thereof, without the prior written authorization of HHS. In the event the property is encumbered, sold, or disposed of, or is used for any purposes other than those set forth in an approved plan without the written con-

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sent of HHS, all revenues or the reasonable value of other benefits received by the transferee directly or indirectly from such use, as determined by HHS, will be considered to have been received and held in trust by the transferee for the account of the United States and will be subject to the direction and control of HHS. The provisions of this paragraph (f)(2) shall not impair or affect the rights reserved to the United States in paragraph (f)(8) of this section, or the right of HHS to impose conditions to its consent.

(3) The transferee will file with HHS such reports on its maintenance and use of the transferred property and any other reports or information deemed necessary by HHS.

(4) The transferee shall pay all administrative costs incidental to the transfer, including but not limited to—transfer taxes; surveys; appraisals; title searches; the transferee's legal fees; and recordation expenses. Transferee is solely responsible for such costs and may not seek reimbursement from the Federal Government for any reason.

(5) The transferee shall protect, preserve, maintain, and repair the property to ensure that the property remains in as good a condition as when received.

(6) The transferee shall protect the residual financial interest of the United States in the surplus property by insurance or such other means as HHS directs.

(7) The transferee shall abide by all applicable Federal civil rights laws including those specified in the covenants and conditions contained in the transfer document, prohibiting the transferee from discriminating on the basis of, including but not limited to, race, color, national origin, religion, sex, familial status, or disability in the use of the property.

(8) In the event of noncompliance with any conditions of the deed as determined by HHS, whether caused by the legal or other inability of the transferee, its successors and assigns, to perform any of the obligations of the transfer document, the Federal Government has an immediate right of reentry thereon, and to cause all right,

title, and interest in and to the property to revert to the United States, and the transferee shall forfeit all right, title, and interest in and to the property. In such event, transferee shall execute a quitclaim deed and take all other actions necessary to return the property to the United States within ninety (90) days of a written request from the Federal Government, extended only at the discretion of the Federal Government. Transferee shall cooperate with the United States in the event of a reversion and agrees that the United States need not seek judicial intervention before exercising its right to revert, reenter, and reconvey the property.

(9) In the event title is reverted to the United States for noncompliance or voluntarily reconveyed to the United States, the transferee shall, at the option of HHS, be required to: reimburse the United States for the decrease in value of the property not due to market conditions, reasonable wear and tear, acts of God, or approved alterations completed by the transferee to adapt the property to the homeless use for which the property was transferred; and reimburse the United States for any costs incurred in reverting title to or possession of the property, including reasonable attorneys' fees.

(10) With respect to leased property, in the event of noncompliance with any of the conditions of the lease, as determined by HHS or the landholding agency, the right of occupancy and possession shall, at the option of HHS or the landholding agency, be terminated. In the event a leasehold is terminated by the United States for noncompliance or is voluntarily surrendered, the lessee shall be required, at the option of HHS, to reimburse the United States for the decrease in value of the property not due to market conditions, reasonable wear and tear, acts of God, or approved alterations completed by the lessee to adapt the property to the homeless use for which the property was leased. With respect to any termination of leasehold resulting from noncompliance, the United States, shall, in addition thereto, be reimbursed for such costs as may be incurred in recovering possession of the property, including reasonable attorneys' fees.

(11) Any other term or condition that HHS and GSA determine appropriate or necessary.

(12) With respect to surplus property transferred by deed, the terms and conditions including those in this paragraph (f), apply for a period of three hundred sixty (360) months of use in accordance with a program of use approved in writing by HHS. The three hundred sixty months (360) period may, in HHS's sole discretion, be extended or restarted in the event the property is not fully utilized or is retransferred to a successor entity. Expiration of the terms and conditions in this paragraph (f) does not release the transferee from continuing compliance, as appropriate, with any conditions that may run with the land, *e.g.*, environmental conditions and/or historic preservation covenants. Such conditions will continue to be the responsibility of the transferee and successors.

(13) With respect to surplus property transferred by lease, the terms and conditions including those in this paragraph (f), extend for the entire initial lease and for any subsequent renewal periods, unless specifically excluded in writing by HHS.

(g) Related personal property may be transferred or leased as a part of the realty and in accordance with real property procedures.

(h) Transferees will be responsible for the protection and maintenance of the property during the time that they possess the property. Upon termination of the lease term or reversion of title to the United States, the transferee will be responsible for removing improvements made to the property if directed to by the United States and, in such event, will be responsible for restoration of the property or the costs associated with restoring the property. If improvements made by the transferee are not voluntarily removed by the transferee and the United States consents, they will become the property of the United States. If the United States does not consent, the transferee shall reimburse the United States for reasonable costs of removal. GSA or the landholding agency, as appropriate, will assume responsibility for protection and maintenance of a property

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when the lease terminates or title reverts.

(i) Transferees, by obtaining the written consent of HHS, may abrogate the restrictions set forth in paragraph (f) of this section for all or any portion of the property in accordance with the provisions of § 12a.12.

§ 12a.8 Compliance with the National Environmental Policy Act of 1969 and other related Acts (environmental impact).

(a) HHS, prior to making a final decision to convey or lease, or to amend, reform, or grant an approval or release with respect to a previous conveyance or lease of, surplus property for homeless purposes, will act in accordance with applicable provisions of the National Environmental Policy Act of 1969, the National Historic Preservation Act of 1966, the National Archeological Data Preservation Act, and other related acts. No lease to use surplus property shall allow the lessee to make, or cause to be made, any irreversible change in the conditions of said property, and no lease shall be employed for the purpose of delaying or avoiding compliance with the requirements of these Acts, unless approved by the United States.

(b) Applicants shall be required to provide such information as HHS deems necessary to make an assessment of the impact of the proposed Federal action on the human environment. Materials contained in the applicant's official request, responses to a standard questionnaire prescribed by HHS, as well as other relevant information, will be used by HHS in making said assessment.

(c) If the assessment reveals:

(1) That the proposed Federal action involved properties of historical significance which are listed, or eligible for listing, in the National Register of Historic Places; or

(2) That a more than insignificant impact on the human environment is reasonably foreseeable as a result of the proposed action; or

(3) That the proposed Federal action could result in irreparable loss or destruction of archeologically significant items or data, HHS will, except as provided for in paragraph (d) of this sec-

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tion, prepare and distribute, or cause to be prepared or distributed, such notices and statements and obtain such approvals as are required by the Acts cited in paragraph (a) of this section.

(d) If a proposed action involves other Federal agencies in a sequence of actions, or a group of actions, directly related to each other because of their functional interdependence, HHS may enter into and support a lead agency agreement to designate a single lead agency which will assume primary responsibility for coordinating the assessment of environmental effects of proposed Federal actions, preparing and distributing such notices and statements, or obtaining such approvals, as are required by the Acts cited in paragraph (a) of this section. The procedures of the designated lead agency will be utilized in conducting the environmental assessment. In the event of disagreement between HHS and another Federal agency, HHS will reserve the right to abrogate the lead agency agreement with the other Federal agency.

§ 12a.9 No applications approved.

(a) At the end of the 30-day holding period described in § 12a.4(a), HHS will notify GSA, or the landholding agency, as appropriate, if an expression of interest has been received for a certain property. Where there is no expression of interest, GSA or the landholding agency, as appropriate, will proceed with disposal in accordance with applicable law.

(b) Upon notice from HHS that all applications have been disapproved, or if no initial applications have been received within 75 days after an expression of interest, or no final application has been received within 45 days after an approved initial application, disposal may proceed in accordance with applicable law.

§ 12a.10 Utilization and enforcement.

(a) *Sanctions.* For instances of non-compliance relating to surplus property transfers, HHS may impose, after providing an opportunity to cure to the transferee, any or all of the following sanctions in its sole discretion, as applicable:

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(1) Where property or any portion thereof was not used or is not being used for the purposes for which transferred, or is sold, leased or subleased, encumbered, disposed of, or used for purposes other than those in the approved program and plan of use, without the prior written consent of HHS, HHS may require the transferee to—

(i) Place the property into immediate use for an approved purpose and extend the period of restriction in the transfer document for an additional term as determined by HHS;

(ii) Hold in trust all revenues and the reasonable value of other benefits received by the transferee directly or indirectly from that use for the United States subject to the direction and control of HHS;

(iii) Return title to such property to the United States or to relinquish any leasehold interest therein;

(iv) Abrogate the conditions and restrictions of the transfer, as set forth in § 12a.12;

(v) Make cash payments to the United States, as directed by HHS, equivalent to the current fair market rental value of the surplus property, as transferred, for each month during which the program and plan of use has not been implemented and continues to not be implemented; or

(vi) Any other remedy that HHS determines appropriate or necessary.

(2) Where the transferee desires to place the property into temporary use to assist the homeless other than that for which the property was transferred, written approval from HHS must be obtained, and will be conditioned upon HHS's authority to permit the use and such terms as HHS may impose.

(3) If HHS or the landholding agency determines that a lessee or sublessee of a transferee is in noncompliance with a term or condition of the lease, or if the lessee voluntarily surrenders the premises, HHS may require termination of the lease and impose sanctions described in paragraph (a)(1) of this section, as appropriate.

(b) *Reversion.* When HHS recommends reversion of the property for noncompliance, HHS will seek GSA's concurrence. GSA will respond to HHS's concurrence request within 30 days of its receipt. If GSA concurs, GSA will

work with HHS to complete the reversion of the property. If GSA does not concur to the reversion recommendation, GSA will issue, to HHS, a written determination: stating the reason(s) for the disapproval; and acknowledging that HHS has recommended reversion and, therefore, the property is no longer within HHS's Title V program. The Federal Government will implement a response to the noncompliance that is in its best interests.

§ 12a.11 Other uses.

(a) A transferee may permit the use of all or a portion of the surplus property by another eligible entity as described in § 12a.1 for homeless assistance purposes, only upon those terms and conditions HHS determines appropriate, if:

(1) The transferee submits a written request to HHS explaining the purpose of and need for another eligible entity's use of the property, program plan, and other relevant information requested by HHS;

(2) HHS determines that the proposed use would not substantially limit the program and plan of use by the transferee and that the use will not unduly burden the Federal Government;

(3) HHS's written consent is obtained by the transferee in advance;

(4) HHS approves the use instrument in advance and in writing;

(5) The transferee agrees to lengthen the period of restrictions as determined by HHS; and

(6) HHS advises GSA and there is no disapproval by GSA within thirty (30) days.

(b) A transferee that does not follow paragraph (a) of this section will be deemed to be not in compliance with the terms and conditions of the Title V program and subject to enforcement action, including reversion of the property.

§ 12a.12 Abrogation.

(a) HHS may abrogate the conditions and restrictions in the transfer document if:

(1) The transferee submits to HHS a written request that HHS abrogate the conditions and restrictions in the transfer document as to all or any portion of the surplus property;

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(2) HHS determines the terms and conditions of the proposed abrogation and determines that the proposed abrogation is in the best interest of the United States; and

(3) HHS transmits the abrogation request to GSA and there is no disapproval by GSA within 30 days after notice is given. If GSA disapproves, GSA will state, in writing, to HHS the reason(s) for the disapproval.

(b) HHS abrogates the conditions and restrictions in the transfer document only upon receipt of the appropriate consideration, including cash payment, to the United States, as directed by HHS, which is based on the formula contained in the transfer document, and any other terms and conditions HHS deems appropriate to protect the interest of the United States.

§ 12a.13 Compliance inspections and reports.

Transferees are required to allow HHS to conduct compliance inspections and to submit such compliance reports and actions as are deemed necessary by HHS. At a minimum, the transferee will be required to submit an annual utilization report regarding the operation and maintenance of the property, including current images of the entire property and such information as HHS shall require.

§ 12a.14 No right of administrative review for agency decisions.

There is no right to administrative review within HHS, including requests for reconsideration or appeal, of agency decisions on applications and other discretionary decisions.

§ 12a.15 Severability.

Any provision of this part held to be invalid or unenforceable with respect to certain parties or circumstances shall be construed so as to continue to give the maximum effect to the provision permitted by law unless such holding is that the provision of this part is invalid and unenforceable in all circumstances, in which event the provision shall be severable from the remainder of this part and shall not affect the remainder thereof.

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PART 13—IMPLEMENTATION OF THE EQUAL ACCESS TO JUSTICE ACT IN AGENCY PROCEEDINGS

Subpart A—General Provisions

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APPENDIX A TO PART 13

AUTHORITY: 5 U.S.C. 504(c)(1).

SOURCE: 48 FR 45252, Oct. 4, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 13.1 Purpose of these rules.

These rules implement section 203 of the Equal Access to Justice Act, 5 U.S.C. 504 and 504 note, for the Department of Health and Human Services. They describe the circumstances under which the Department may award attorney fees and certain other expenses to eligible individuals and entities who prevail over the Department in certain administrative proceedings (called “adversary adjudications”). The Department may reimburse parties for expenses incurred in adversary adjudications if the party prevails in the proceeding and if the Department’s position in the proceeding was not substantially justified or if the action is one to enforce compliance with a statutory or

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regulatory requirement and the Department's demand is substantially in excess of the ultimate decision and is unreasonable when compared with that decision. They also describe what proceedings constitute adversary adjudications covered by the Act, what types of persons and entities may be eligible for an award, and what procedures and standards the Department will use to make a determination as to whether a party may receive an award.

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2845, Jan. 21, 2004]

§ 13.2 When these rules apply.

These rules apply to adversary adjudications before the Department.

[69 FR 2845, Jan. 21, 2004]

§ 13.3 Proceedings covered.

(a) These rules apply only to adversary adjudications. For the purpose of these rules, only an adjudication required to be under 5 U.S.C. 554, in which the position of the Department or one of its components is represented by an attorney or other representative ("the agency's litigating party") who enters an appearance and participates in the proceeding, constitutes an adversary adjudication. These rules do not apply to proceedings for the purpose of establishing or fixing a rate or for the purpose of granting, denying, or renewing a license.

(b) If the agency's litigating party enters an appearance, Department proceedings listed in appendix A to this part are covered by these rules. Also covered are any other proceedings under statutes that incorporate by reference the procedures of sections 1128(f), 1128A(c)(2), or 1842(j)(2) of the Social Security Act, 42 U.S.C. 1320a-7(f), 1320a-7a(c)(2), or 1395u(j)(2). If a proceeding is not covered under either of the two previous sentences, a party may file a fee application as otherwise required by this part and may argue that the Act covers the proceeding. Any coverage issue shall be determined by the adjudicative officer and, if necessary, by the appellate authority on review.

(c) If a proceeding is covered by these rules, but also involves issues excluded under paragraph (a) of this section

from the coverage of these rules, reimbursement is available only for fees and expenses resulting from covered issues.

[45 FR 45252, Oct. 4, 1983, as amended at 69 FR 2845, Jan. 21, 2004]

§ 13.4 Eligibility of applicants.

(a) To be eligible for an award of attorney fees and other expenses under these regulations, the applicant must be a party, as defined in 5 U.S.C. 551(3), to the adversary adjudication for which it seeks an award. An applicant must show that it meets all conditions of eligibility set out in this subpart and in Subpart B.

(b) The categories of eligible applicants are as follows:

(1) Charitable or other tax-exempt organizations described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) with not more than 500 employees;

(2) Cooperative associations as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 1141j(a)) with not more than 500 employees;

(3) Individuals with a net worth of not more than \$2 million;

(4) Sole owners of unincorporated businesses if the owner has a net worth of not more than \$7 million, including both personal and business interests, and if the business has not more than 500 employees;

(5) All other partnerships, corporations, associations, local governmental units, and public and private organizations with a net worth of not more than \$7 million and with not more than 500 employees; and

(6) Where an award is sought on the basis stated in §13.5(c) of this part, small entities as defined in 5 U.S.C. 601.

(c) For the purpose of determining eligibility, the net worth and number of employees of an applicant is calculated as of the date the proceeding was initiated. The net worth of an applicant is determined by generally accepted accounting principles.

(d) Whether an applicant who owns an unincorporated business will be considered as an "individual" or a "sole owner of an unincorporated business"

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will be determined by whether the applicant's participation in the proceeding is related primarily to individual interests or to business interests.

(e) The employees of an applicant include all those persons regularly providing services for remuneration for the applicant, under the applicant's direction and control. Part-time employees shall be included on a proportional basis.

(f) The net worth and number of employees of the applicant and all of its affiliates shall be aggregated to determine eligibility. Any individual, corporation or other entity that directly or indirectly controls or owns a majority of the voting shares or other interest of the applicant, or any corporation or other entity of which the applicant directly or indirectly owns or controls a majority of the voting shares or other interest, will be considered an affiliate for purposes of this part, unless the adjudicative officer determines that such treatment would be unjust and contrary to the purposes of the Act in light of the actual relationship between the affiliated entities. In addition, the adjudicative officer may determine that financial relationships of the applicant other than those described in this paragraph constitute special circumstances that would make an award unjust.

(g) An applicant is not eligible if it appears from the facts and circumstances that it has participated in the proceedings only or primarily on behalf of other persons or entities that are ineligible.

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2846, Jan. 21, 2004]

§ 13.5 Standards for awards.

(a) An award of fees and expenses may be made either on the basis that the Department's position in the proceeding was not substantially justified or on the basis that, in a proceeding to enforce compliance with a statutory or regulatory requirement, the Department's demand substantially exceeded the ultimate decision and was unreasonable when compared with that decision. These two bases are explained in greater detail in paragraphs (b) and (c) of this section.

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(b) *Awards where the Department's position was not substantially justified.* (1) Awards will be made on this basis only where the Department's position in the proceeding was not substantially justified. The Department's position includes, in addition to the position taken by the agency in the proceeding, the agency action or failure to act that was the basis for the proceeding. Whether the Department's position was substantially justified is to be determined on the basis of the administrative record as a whole. The fact that a party has prevailed in a proceeding does not create a presumption that the Department's position was not substantially justified. The burden of proof as to substantial justification is on the agency's litigating party, which may avoid an award by showing that its position was reasonable in law and fact.

(2) When two or more matters are joined together for one hearing, each of which could have been heard separately (without regard to laws or rules fixing a jurisdictional minimum amount for claims), and an applicant has prevailed with respect to one or several of the matters, an eligible applicant may receive an award for expenses associated only with the matters on which it prevailed if the Department's position on those matters was not substantially justified.

(3) Awards for fees and expenses incurred before the date on which a proceeding was initiated will be made only if the applicant can demonstrate that they were reasonably incurred in preparation for the proceeding.

(4) Awards will be reduced or denied if the applicant has unduly or unreasonably protracted the proceeding or if other special circumstances make an award unjust.

(c) *Awards where the Department's demand was substantially excessive and unreasonable.* (1) Awards will be made on this basis only where the adversary adjudication arises from the Department's action to enforce a party's compliance with a statutory or regulatory requirement. An award may be made on this basis only if the Department's demand that led to the proceeding was substantially in excess of the ultimate

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decision in the proceeding, and that demand is unreasonable when compared with that decision, given all the facts and circumstances of the case.

(2) Any award made on this basis shall be limited to the fees and expenses that are primarily related to defending against the excessive nature of the demand. An award shall not include fees and expenses that are primarily related to defending against the merits of charges, or fees and expenses that are primarily related to defending against the portion of the demand that was not excessive, to the extent that these fees and expenses are distinguishable from the fees and expenses primarily related to defending against the excessive nature of the demand.

(3) Awards will be denied if the party has committed a willful violation of law or otherwise acted in bad faith, or if special circumstances make an award unjust.

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2846, Jan. 21, 2004]

§ 13.6 Allowable fees and expenses.

(a) Awards will be limited to the rates customarily charged by persons engaged in the business of acting as attorneys, agents and expert witnesses. If a party has already received, or is eligible to receive, reimbursement for any expenses under another statutory provision or another program allowing reimbursement, its award under these rules must be reduced by the amount the prevailing party has already received, or is eligible to receive, from the Federal government.

(b) An award for the fees of an attorney or agent may not exceed \$125.00 per hour, regardless of the actual rate charged by the attorney or agent. An award for the fees of an expert witness may not exceed the highest rate at which the Department pays expert witnesses, which is \$24.09 per hour, regardless of the actual rates charged by the witness. These limits apply only to fees; an award may include the reasonable expenses of the attorney, agent, or witness as a separate item, if the attorney, agent or witness ordinarily charges separately for such expenses.

(c) In determining the reasonableness of the fees sought for attorneys, agents or expert witnesses, the adjudicative

officer must consider factors bearing on the request, which include, but are not limited to:

(1) If the attorney, agent or witness is in private practice, his or her customary fee for like services; if the attorney, agent or witness is an employee of the applicant, the fully allocated cost of service;

(2) The prevailing rate for similar services in the community in which the attorney, agent or witness ordinarily performs services;

(3) The time actually spent in the representation of the applicant;

(4) The time reasonably spent in light of the difficulty or complexity of the issues in the proceeding; and

(5) Such other factors as may bear on the value of the services provided.

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2846, Jan. 21, 2004]

§ 13.7 Studies, exhibits, analyses, engineering reports, tests and projects.

The reasonable cost (or the reasonable portion of the cost) for any study, exhibit, analysis, engineering report, test, project or similar matter prepared on behalf of a party may be awarded to the extent that:

(a) The charge for the service does not exceed the prevailing rate payable for similar services,

(b) The study or other matter was necessary to the preparation for the administrative proceeding, and

(c) The study or other matter was prepared for use in connection with the administrative proceeding. No award will be made for a study or other matter which was necessary to satisfy statutory or regulatory requirements, or which would ordinarily be conducted as part of the party's business irrespective of the administrative proceeding.

Subpart B—Information Required from Applicants

§ 13.10 Contents of application.

(a) Applications for an award of fees and expenses must include:

(1) The name of the applicant and the identification of the proceeding;

(2) Where an award is sought on the basis stated in §13.5(b) of this part, a declaration that the applicant believes it has prevailed, and an identification

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of the position of the Department that the applicant alleges was not substantially justified. Where an award is sought on the basis stated in §13.5(c) of this part, an identification of the statutory or regulatory requirement that the applicant alleges the Department was seeking to enforce, and an identification of the Department's demand and of the document or documents containing that demand;

(3) Unless the applicant is an individual, a statement of the number of its employees on the date on which the proceeding was initiated, and a brief description of the type and purpose of its organization or business. However, where an award is sought solely on the basis stated in §13.5(c) of this part, the applicant need not state the number of its employees;

(4) A description of any affiliated individuals or entities, as the term "affiliate" is defined in §13.4(f), or a statement that none exist;

(5) A statement that the applicant's net worth as of the date on which the proceeding was initiated did not exceed the appropriate limits as stated in §13.4(b) of this part. However, an applicant may omit this statement if:

(i) It attaches a copy of a ruling by the Internal Revenue Service that it qualifies as an organization described in section 501(c)(3) of the Internal Revenue Code (26 U.S.C. 501(c)(3)) or, in the case of a tax-exempt organization not required to obtain a ruling from the Internal Revenue Service on its exempt status, a statement that describes the basis for the applicant's belief that it qualified under such section;

(ii) It states that it is a cooperative association as defined in section 15(a) of the Agricultural Marketing Act (12 U.S.C. 1141j(a)); or

(iii) It states that it is applying for an award solely on the basis stated in §13.5(c) of this part, and that it is a small entity as defined in 5 U.S.C. 601, and it describes the basis for its belief that it qualifies as a small entity under that section.

(6) A statement of the amount of fees and expenses for which an award is sought;

(7) A declaration that the applicant has not received, has not applied for, and does not intend to apply for reim-

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bursement of the cost of items listed in the Statement of Fees and Expenses under any other program or statute; or if the applicant has received or applied for or will receive or apply for reimbursement of those expenses under another program or statute, a statement of the amount of reimbursement received or applied for or intended to be applied for; and

(8) Any other matters the applicant wishes the Department to consider in determining whether and in what amount an award should be made.

(b) All applications must be signed by the applicant or by an authorized officer or attorney of the applicant. It shall also contain or be accompanied by a written verification under oath or under penalty of perjury that the information provided in the application is true and correct.

(Approved by the Office of Management and Budget under control number 0990-0118)

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2846, Jan. 21, 2004]

§ 13.11 Net worth exhibits.

(a) Each applicant must provide with its application a detailed exhibit showing the net worth of the applicant and any affiliates (as defined in §13.4(f) of this part) when the proceeding was initiated. This requirement does not apply to a qualified tax-exempt organization or cooperative association. Nor does it apply to a party that states that it is applying for an award solely on the basis stated in §13.5(c) of this part. If any individual, corporation, or other entity directly or indirectly controls or owns a majority of the voting shares or other interest of the applicant, or if the applicant directly or indirectly owns or controls a majority of the voting shares or other interest of any corporation or other entity, the exhibit must include a showing of the net worth of all such affiliates or of the applicant including the affiliates. The exhibit may be in any form convenient to the applicant that provides full disclosure of the applicant's and its affiliates' assets and liabilities and is sufficient to determine whether the applicant qualifies under the standards in this part. The adjudicative officer may require an applicant to file additional

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information to determine its eligibility for an award.

(b) The net worth exhibit shall describe any transfers of assets from, or obligations incurred by, the applicant or any affiliate, occurring in the one year period prior to the date on which the proceeding was initiated, that reduced the net worth of the applicant and its affiliates below the applicable net worth ceiling. If there were no such transactions, the applicant shall so state.

(c) Ordinarily, the net worth exhibit will be included in the public record of the proceeding. However, an applicant that objects to public disclosure of information in any portion of the exhibit and believes there are legal grounds for withholding it from disclosure may submit that portion of the exhibit directly to the adjudicative officer in a sealed envelope labeled "Confidential Financial Information," accompanied by a motion to withhold the information from public disclosure. The motion shall describe the information sought to be withheld and explain, in detail, why it falls within one or more of the specific exemptions from mandatory disclosure under the Freedom of Information Act, 5 U.S.C. 552(b)(1)-(9), why public disclosure of the information would adversely affect the applicant, and why disclosure is not required in the public interest. The material in question shall be served on counsel representing the agency against which the applicant seeks an award, but need not be served on any other party to the proceeding. If the adjudicative officer finds that the information should not be withheld from disclosure, it shall be placed in the public record of the proceeding. Otherwise, the officer will omit the material from the public record. In that case, any decision regarding disclosure of the material (whether in response to a request from an agency or person outside the Department or on the Department's own initiative) will be made in accordance with applicable statutes and Department rules and procedures for commercial and financial records which the submitter claims are confidential or privileged. In particular, this regulation is not a basis for a

promise or obligation of confidentiality.

(Approved by the Office of Management and Budget under control number 0990-0118)

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2846, Jan. 21, 2004]

§ 13.12 Documentation of fees and expenses.

(a) All applicants must be accompanied by full documentation of the fees and expenses, including the cost of any study, exhibit, analysis, report, test or other similar item, for which the applicant seeks reimbursement.

(b) The documentation shall include an affidavit from each attorney, agent, or expert witness representing or appearing in behalf of the party, stating the actual time expended, the rate at which fees and other expenses were computed, a description of the specific services performed, the total amount claimed, and the total amount paid or payable by the applicant or by any other person or entity for the services provided. Where the adversary adjudication includes covered proceedings (as described in §13.3) as well as excluded proceedings, or two or more matters, each of which could have been heard separately, the fees and expenses shall be shown separately for each proceeding or matter, and the basis for allocating expenses among the proceedings or matters shall be indicated.

(1) The affidavit shall itemize in detail the services performed by the date, number of hours per date and the services performed during those hours. In order to establish the hourly rate, the affidavit shall state the hourly rate which is billed and paid by the majority of clients during the relevant time periods.

(2) If no hourly rate is paid by the majority of clients because, for instance, the attorney or agent represents most clients on a contingency basis, the attorney or agent shall provide affidavits from two attorneys or agents with similar experience, who perform similar work, stating the hourly rate which they bill and are paid by the majority of their clients during a comparable time period.

(c) If the applicant seeks reimbursement of any expenses not covered by the affidavit described in paragraph

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(b), the documentation must also include an affidavit describing all such expenses and stating the amounts paid or payable by the applicant or by any other person or entity for the services provided.

(d) The adjudicative officer may require the applicant to provide vouchers, receipts, or other substantiation for any fees or expenses claimed, pursuant to § 13.25 of this part.

(Approved by the Office of Management and Budget under control number 0990-0118)

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2847, Jan. 21, 2004]

Subpart C—Procedures for Considering Applications

§ 13.21 Filing and service of pleadings.

All pleadings, including applications for an award of fees, answers, comments, and other pleadings related to the applications, shall be filed in the same manner as other pleadings in the proceeding and served on all other parties and participants, except as provided in § 13.11(b) of this part concerning confidential financial information.

§ 13.22 When an application may be filed.

(a) The applicant must file and serve its application no later than 30 calendar days after the Department's final disposition of the proceeding which makes the applicant a prevailing party.

(b) For purposes of this rule, final disposition means the date on which a decision or order disposing of the merits of the proceeding or any other complete resolution of the proceeding, such as a settlement or voluntary dismissal, becomes final and unappealable, both within the agency and to the courts.

(c) For purposes of this rule, an applicant has prevailed when the agency has made a final disposition favorable to the applicant with respect to any matter which could have been heard as a separate proceeding, regardless of whether it was joined with other matters for hearing.

(d) If review or reconsideration is sought or taken, whether within the agency or to the courts, of a decision as to which an applicant believes it has

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prevailed, proceedings on the application shall be stayed pending final disposition of the underlying controversy.

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2847, Jan. 21, 2004]

§ 13.23 Responsive pleadings.

(a) The agency's litigating party shall file an answer within 30 calendar days after service of the application or, where the proceeding is stayed as provided in § 13.22(d) of this part, within 30 calendar days after the final disposition of the underlying controversy. The answer shall either consent to the award or explain in detail any objections to the award requested and identify the facts relied on in support of the agency's position. The adjudicative officer may for good cause grant an extension of time for filing an answer.

(b) Within 15 calendar days after service of an answer, the applicant may file a reply. If the reply is based on any alleged facts not already in the record of the proceeding, the applicant shall include with the reply either supporting affidavits or a request for further proceedings under § 13.25.

(c) Any party to or participant in a proceeding may file comments on an application within 30 calendar days, or on an answer within 15 calendar days after service of the application or answer.

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2847, Jan. 21, 2004]

§ 13.24 Settlements.

The applicant and the agency's litigating party may agree on a proposed settlement of the award at any time prior to final action on the application. If the parties agree on a proposed settlement of an award before an application has been filed, the application shall be filed with the proposed settlement. All settlements must be approved by the adjudicative officer and the head of the agency or office or his or her designee before becoming final.

§ 13.25 Further proceedings.

(a) Ordinarily, a decision on an application will be made on the basis of the hearing record and pleadings related to the application. However, at the request of either the applicant or the

agency's litigating party, or on his or her own initiative, the adjudicative officer may order further proceedings, including an informal conference, oral argument, additional written submissions, or an evidentiary hearing. Such further proceedings shall be held only when necessary for full and fair resolution of the issues arising from the application, and shall be conducted as promptly as possible. In no such further proceeding shall evidence be introduced from outside the administrative record in order to prove that the Department's position was, or was not, substantially justified.

(b) A request that the adjudicative officer order additional written submissions or oral testimony shall identify the information sought and shall explain why the information is necessary to decide the issues.

(c) The adjudicative officer may impose sanctions on any party for failure to comply with his or her order to file pleadings, produce documents, or present witnesses for oral examination. These sanctions may include but are not limited to granting the application partly or completely, dismissing the application, and diminishing the award granted.

[48 FR 45252, Oct. 4, 1983, as amended at 69 FR 2847, Jan. 21, 2004]

§ 13.26 Decisions.

The adjudicative officer shall issue an initial decision on the application as promptly as possible after the filing of the last document or conclusion of the hearing. The decision must include written findings and conclusions on the applicant's eligibility and status as a prevailing party, including a finding on the net worth of the applicant. Where the adjudicative officer has determined under § 13.11(b) that the applicant's net worth information is exempted from disclosure under the Freedom of Information Act, the finding on net worth shall be kept confidential. The decision shall also include, if at issue, findings on whether the agency's position was substantially justified, whether the applicant unduly protracted the proceedings, an explanation of any difference between the amount requested and the amount awarded, and whether

any special circumstances make the award unjust.

§ 13.27 Agency review.

(a) The appellate authority for any proceedings shall be the official or component that would have jurisdiction over an appeal of the merits.

(b) If either the applicant or the agency's litigating party seeks review of the adjudicative officer's decision on the fee application, it shall file and serve exceptions within 30 days after issuance of the initial decision. Within another 30 days after receipt of such exceptions, the opposing party, if it has not done so previously, may file its own exceptions to the adjudicative officer's decision. The appellate authority shall issue a final decision on the application as soon as possible or remand the application to the adjudicative officer for further proceedings. Any party that does not file and serve exceptions within the stated time limit loses the opportunity to do so.

[69 FR 2847, Jan. 21, 2004]

§ 13.28 Judicial review.

Judicial review of final agency decisions on awards may be obtained as provided in 5 U.S.C. 504(c)(2).

§ 13.29 Payment of award.

The notification to an applicant of a final decision that an award will be made shall contain the name and address of the appropriate Departmental finance office that will pay the award. An applicant seeking payment of an award shall submit to that finance officer a copy of the final decision granting the award, accompanied by a statement that the applicant will not seek review of the decision in the United States courts. The Department will pay the amount awarded to the applicant within 60 days, unless judicial review of the award or of the underlying decision of the adversary adjudication has been sought by the applicant or any other party to the proceedings.

§ 13.30 Designation of adjudicative officer.

Upon the filing of an application pursuant to § 13.11(a), the officer who presided over the taking of evidence in the

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proceeding which gave rise to the application will, if available, be automatically designated as the adjudicative officer for the handling of the application.

APPENDIX A TO PART 13

Proceedings covered	Statutory authority	Applicable regulations
Office of Inspector General		
1. Proceedings to impose civil monetary penalties, assessments, or exclusions from Medicare and State health care programs.	42 U.S.C. 1320a–7a(c)(2); 1320b–10(c); 1395i–3(b)(3)(B)(ii), (g)(2)(A)(i); 1395f(h)(5)(D), (i)(6); 1395m(a)(11)(A), (a)(18), (b)(5)(C), (j)(2)(A)(iii); 1395u(j)(2), (k), (l)(3), (m)(3), (n)(3), (p)(3)(A); 1395y(b)(3)(C), (b)(6)(B); 1395cc(g); 1395dd(d)(1)(A), (B); 1395mm(i)(6)(B); 1395nn(g)(3), (4); 1395ss(d); 1395bbb(c)(1); 1396b(m)(5)(B); 1396r(b)(3)(B)(ii), (g)(2)(A)(i); 1396t(i)(3); 11131(c); 11137(b)(2).	42 CFR part 1003; 42 CFR part 1005.
2. Appeals of exclusions from Medicare and State health care programs and/or other programs under the Social Security Act.	42 U.S.C. 1320a–7(f); 1395f(h)(5)(D); 1395m(a)(11)(A), (b)(5)(C); 1395u(j)(2), (k), (l)(3), (m)(3), (n)(3), (p)(3)(B).	42 CFR part 1001; 42 CFR part 1005.
3. Appeal of exclusions from programs under the Social Security Act, for which services may be provided on the recommendation of a Peer Review Organization.	42 U.S.C. 1320c–5(b)(4), (5)	42 CFR part 1004; 42 CFR part 1005.
4. Proceedings to impose civil penalties and assessments for false claims and statements.	31 U.S.C. 3803	45 CFR part 79.
Centers for Medicare & Medicaid Services		
1. Proceedings to suspend or revoke licenses of clinical laboratories.	42 U.S.C. 263a(i); 1395w–2	42 CFR part 493, Subpart R.
2. Proceedings provided to a fiscal intermediary before assigning or reassigning Medicare providers to a different fiscal intermediary.	42 U.S.C. 1395h(e)(1)–(3)	42 CFR 421.114, 421.128.
3. Appeals of determinations that an institution or agency is not a Medicare provider of services, and appeals of terminations or nonrenewals of Medicare provider agreements.	42 U.S.C. 1395cc(h); 1395dd(d)(1)(A)	42 CFR 489.53(d); 42 CFR part 498.
4. Proceedings before the Provider Reimbursement Review Board when Department employees appear as counsel for the intermediary.	42 U.S.C. 1395oo	42 CFR part 405, Subpart R.
5. Appeals of CMS determinations that an intermediate care facility for the mentally retarded (ICFMR) no longer qualifies as an ICFMR for Medicaid purposes.	42 U.S.C. 1396i	42 CFR part 498.
6. Proceedings to impose civil monetary penalties, assessments, or exclusions from Medicare and State health care programs.	42 U.S.C. 1395i–3(h)(2)(B)(ii); 1395f(q)(2)(B)(i); 1395m(a)(11)(A), (c)(4)(C); 1395w–2(b)(2)(A); 1395w–4(g)(1), (g)(3)(B), (g)(4)(B)(ii); 1395nn(g)(5); 1395ss(a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), (t)(2); 1395bbb(f)(2)(A); 1396r(h)(3)(C)(ii); 1396–8(b)(3)(B), (C)(ii); 1396j(j)(2)(C); 1396u(h)(2).	42 CFR part 1003.
7. Appeals of exclusions from Medicare and State health care programs and/or other programs under the Social Security Act.	42 U.S.C. 1395f(q)(2)(B)(ii); 1395m(a)(11)(A), (c)(5)(C); 1395w–4(g)(1), (g)(3)(B), (g)(4)(B)(ii).	42 CFR part 498; 42 CFR 1001.107.
Food and Drug Administration		
1. Proceedings to withdraw approval of new drug applications.	21 U.S.C. 355(e)	21 CFR part 12; 21 CFR 314.200.

Proceedings covered	Statutory authority	Applicable regulations
2. Proceedings to withdraw approval of new animal drug applications and medicated feed applications.	21 U.S.C. 360b(e), (m)	21 CFR part 12; 21 CFR part 514, Subpart B.
3. Proceedings to withdraw approval of medical device premarket approval applications.	21 U.S.C. 306e(e), (g)	21 CFR part 12.
Office for Civil Rights		
1. Proceedings to enforce Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the basis of race, color or national origin by recipients of Federal financial assistance.	42 U.S.C. 2000d-1	45 CFR 80.9.
2. Proceedings to enforce section 504 of the Rehabilitation Act of 1973, which prohibits discrimination on the basis of handicap by recipients of Federal financial assistance.	29 U.S.C. 794a; 42 U.S.C. 2000d-1 ..	45 CFR 84.61.
3. Proceedings to enforce the Age Discrimination Act of 1975, which prohibits discrimination on the basis of age by recipients of Federal financial assistance.	42 U.S.C. 6104(a)	45 CFR 91.47.
4. Proceedings to enforce Title IX of the Education Amendments of 1972, which prohibits discrimination on the basis of sex in certain education programs by recipients of Federal financial assistance.	20 U.S.C. 1682	45 CFR 86.71.

[69 FR 2847, Jan. 21, 2004]

PART 15—UNIFORM RELOCATION ASSISTANCE AND REAL PROPERTY ACQUISITION FOR FEDERAL AND FEDERALLY ASSISTED PROGRAMS

AUTHORITY: Sec. 213, Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Pub. L. 91-646, 84 Stat. 1894 (42 U.S.C. 4633) as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987, Title IV of Pub. L. 100-17, 101 Stat. 246-256 (42 U.S.C. 4601 note).

§ 15.1 Uniform relocation assistance and real property acquisition.

Regulations and procedures for complying with the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Pub. L. 91-646, 84 Stat. 1894, 42 U.S.C. 4601 *et seq.*), as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987 (Title IV of Pub. L. 100-17, 101 Stat. 246-256, 42 U.S.C. 4601 note) are set forth in 49 CFR part 24.

[52 FR 48026, Dec. 17, 1987 and 54 FR 8912, Mar. 2, 1989]

PART 16—PROCEDURES OF THE DEPARTMENTAL GRANT APPEALS BOARD

Sec.

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- 16.22 The effect of an appeal.
- 16.23 How long an appeal takes.

APPENDIX A TO PART 16—WHAT DISPUTES THE BOARD REVIEWS

§ 16.1

AUTHORITY: 5 U.S.C. 301 and secs. 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 18 FR 2053, 67 Stat. 631 and authorities cited in the Appendix.

SOURCE: 46 FR 43817, Aug. 31, 1981, unless otherwise noted.

§ 16.1 What this part does.

This part contains requirements and procedures applicable to certain disputes arising under the HHS programs described in appendix A. This part is designed to provide a fair, impartial, quick and flexible process for appeal from written final decisions. This part supplements the provisions in 2 CFR parts 200 and 300.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016; 89 FR 80070, Oct. 2, 2024]

§ 16.2 Definitions.

(a) *Board* means the Departmental Grant Appeals Board of the Department of Health and Human Services. Reference below to an action of *the Board* means an action of the Chair, another Board member, or Board staff acting at the direction of a Board member. In certain instances, the provisions restrict action to particular Board personnel, such as the Chair or a Board member assigned to a case.

(b) Other terms shall have the meaning set forth in 2 CFR parts 200 and 300, unless the context below otherwise requires.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016; 89 FR 80070, Oct. 2, 2024]

§ 16.3 When these procedures become available.

Before the Board will take an appeal, three circumstances must be present:

(a) The dispute must arise under a program which uses the Board for dispute resolution, and must meet any special conditions established for that program. An explanation is contained in appendix A.

(b) The appellant must have received a final written decision, and must appeal that decision within 30 days after receiving it. Details of how final decisions are developed and issued, and what must be in them, are contained in 2 CFR 200.342.

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(c) The appellant must have exhausted any preliminary appeal process required by regulation. For example, see 42 CFR part 50 (subpart D) for Public Health Service programs. In such cases, the *final written decision* required for the Board's review is the decision resulting from the preliminary review or appeal process. appendix A contains further details.

[46 FR 43817, Aug. 31, 1981, as amended at 62 FR 38218, July 17, 1997; 81 FR 3012, Jan. 20, 2016; 89 FR 80070, Oct. 2, 2024]

§ 16.4 Summary of procedures below.

The Board's basic process is review of a written record (which both parties are given ample opportunity to develop), consisting of relevant documents and statements submitted by both parties (see §16.8). In addition, the Board may hold an informal conference (see §16.10). The informal conference primarily involves questioning of the participants by a presiding Board member. Conferences may be conducted by telephone conference call. The written record review also may be supplemented by a hearing involving an opportunity for examining evidence and witnesses, cross-examination, and oral argument (see §16.11). A hearing is more expensive and time-consuming than a determination on the written record alone or with an informal conference. Generally, therefore, the Board will schedule a hearing only if the Board determines that there are complex issues or material facts in dispute, or that the Board's review would otherwise be significantly enhanced by a hearing. Where the amount in dispute is \$25,000 or less, there are special expedited procedures (see §16.12 of this part). In all cases, the Board has the flexibility to modify procedures to ensure fairness, to avoid delay, and to accommodate the peculiar needs of a given case. The Board makes maximum feasible use of preliminary informal steps to refine issues and to encourage resolution by the parties. The Board also has the capability to provide mediation services (see §16.18).

§ 16.5 How the Board operates.

(a) The Board's professional staff consists of a Chair (who is also a Board member) and full- and part-time Board

members, all appointed by the Secretary; and a staff of employees and consultants who are attorneys or persons from other relevant disciplines, such as accounting.

(b) The Chair will assign a Board member to have lead responsibility for each case (the “presiding Board member”). The presiding Board member will conduct the conference or hearing, if one is held. Each decision of the Board is issued by the presiding Board member and two other Board members.

(c) The Board staff assists the presiding Board member, and may request information from the parties; conduct telephone conference calls to request information, to clarify issues, or to schedule events; and assist in developing decisions and other documents in a case.

(d) The Chair will assure that no Board or staff member will participate in a case where his or her impartiality could reasonably be questioned.

(e) The Board’s powers and responsibilities are set forth in § 16.13.

§ 16.6 Who represents the parties.

The appellant’s notice of appeal, or the first subsequent submission to the Board, should specify the name, address and telephone number of the appellant’s representative. In its first submission to the Board and the appellant, the respondent (i.e., the federal party to the appeal) should specify the name, address and telephone number of the respondent’s representative.

§ 16.7 The first steps in the appeal process: The notice of appeal and the Board’s response.

(a) As explained in 2 CFR 200.342, a prospective appellant must submit a notice of appeal to the Board within 30 days after receiving the final decision. The notice of appeal must include a copy of the final decision, a statement of the amount in dispute in the appeal, and a brief statement of why the decision is wrong.

(b) Within ten days after receiving the notice of appeal, the Board will send an acknowledgment, enclose a copy of these procedures, and advise the appellant of the next steps. The Board will also send a copy of the notice of appeal, its attachments, and the

Board’s acknowledgment to the respondent. If the Board Chair has determined that the appeal does not meet the conditions of § 16.3 or if further information is needed to make this determination, the Board will notify the parties at this point.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016; 89 FR 80070, Oct. 2, 2024]

§ 16.8 The next step in the appeal process: Preparation of an appeal file and written argument.

Except in expedited cases (generally those of \$25,000 or less; see § 16.12 for details), the appellant and the respondent each participate in developing an appeal file for the Board to review. Each also submits written argument in support of its position. The responsibilities of each are as follows:

(a) *The appellant’s responsibility.* Within 30 days after receiving the acknowledgment of the appeal, the appellant shall submit the following to the Board (with a copy to the respondent):

(1) An appeal file containing the documents supporting the claim, tabbed and organized chronologically and accompanied by an indexed list identifying each document. The appellant should include only those documents which are important to the Board’s decision on the issues in the case.

(2) A written statement of the appellant’s argument concerning why the respondent’s final decision is wrong (appellant’s brief).

(b) *The respondent’s responsibility.* Within 30 days after receiving the appellant’s submission under paragraph (a) of this section, the respondent shall submit the following to the Board (with a copy to the appellant):

(1) A supplement to the appeal file containing any additional documents supporting the respondent’s position, organized and indexed as indicated under paragraph (a) of this section. The respondent should avoid submitting duplicates of documents submitted by the appellant.

(2) A written statement (respondent’s brief) responding to the appellant’s brief.

(c) *The appellant’s reply.* Within 15 days after receiving the respondent’s submission, the appellant may submit

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a short reply. The appellant should avoid repeating arguments already made.

(d) *Cooperative efforts.* Whenever possible, the parties should try to develop a joint appeal file, agree to preparation of the file by one of them, agree to facts to eliminate the need for some documents, or agree that one party will submit documents identified by the other.

(e) *Voluminous documentation.* Where submission of all relevant documents would lead to a voluminous appeal file (for example where review of a disputed audit finding of inadequate documentation might involve thousands of receipts), the Board will consult with the parties about how to reduce the size of the file.

§ 16.9 How the Board will promote development of the record.

The Board may, at the time it acknowledges an appeal or at any appropriate later point, request additional documents or information; request briefing on issues in the case; issue orders to show cause why a proposed finding or decision of the Board should not become final; hold preliminary conferences (generally by telephone) to establish schedules and refine issues; and take such other steps as the Board determines appropriate to develop a prompt, sound decision.

§ 16.10 Using a conference.

(a) Once the Board has reviewed the appeal file, the Board may, on its own or in response to a party's request, schedule an informal conference. The conference will be conducted by the presiding Board member. The purposes of the conference are to give the parties an opportunity to make an oral presentation and the Board an opportunity to clarify issues and question both parties about matters which the Board may not yet fully understand from the record.

(b) If the Board has decided to hold a conference, the Board will consult or correspond with the parties to schedule the conference, identify issues, and discuss procedures. The Board will identify the persons who will be allowed to participate, along with the parties' representatives, in the conference. The

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parties can submit with their briefs under § 16.8 a list of persons who might participate with them, indicating how each person is involved in the matter. If the parties wish, they may also suggest questions or areas of inquiry which the Board may wish to pursue with each participant.

(c) Unless the parties and the Board otherwise agree, the following procedures apply:

(1) Conferences will be recorded at Department expense. On request, a party will be sent one copy of the transcript. The presiding Board member will insure an orderly transcript by controlling the sequence and identification of speakers.

(2) Only in exceptional circumstances will documents be received at a conference. Inquiry will focus on material in the appeal file. If a party finds that further documents should be in the record for the conference, the party should supplement the appeal file, submitting a supplementary index and copies of the documents to the Board and the other party not less than ten days prior to the conference.

(3) Each party's representative may make an oral presentation. Generally, the only oral communications of other participants will consist of statements requested by the Board or responses to the Board's questions. The Board will allow reply comment, and may allow short closing statements. On request, the Board may allow the participants to question each other.

(4) There will be no post-conference submissions, unless the Board determines they would be helpful to resolve the case. The Board may require or allow the parties to submit proposed findings and conclusions.

§ 16.11 Hearing.

(a) *Electing a hearing.* If the appellant believes a hearing is appropriate, the appellant should specifically request one at the earliest possible time (in the notice of appeal or with the appeal file). The Board will approve a request (and may schedule a hearing on its own or in response to a later request) if it finds there are complex issues or material facts in dispute the resolution of which would be significantly aided by a hearing, or if the Board determines

that its decisionmaking otherwise would be enhanced by oral presentations and arguments in an adversary, evidentiary hearing. The Board will also provide a hearing if otherwise required by law or regulation.

(b) *Preliminary conference before the hearing.* The Board generally will hold a prehearing conference (which may be conducted by telephone conference call) to consider any of the following: the possibility of settlement; simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; scheduling the hearing; and any other matter that may aid in resolving the appeal. Normally, this conference will be conducted informally and off the record; however, the Board, after consulting with the parties, may reduce results of the conference to writing in a document which will be made part of the record, or may transcribe proceedings and make the transcript part of the record.

(c) *Where hearings are held.* Hearings generally are held in Washington, DC. In exceptional circumstances, the Board may hold the hearing at an HHS Regional Office or other convenient facility near the appellant.

(d) *Conduct of the hearing.* (1) The presiding Board member will conduct the hearing. Hearings will be as informal as reasonably possible, keeping in mind the need to establish an orderly record. The presiding Board member generally will admit evidence unless it is determined to be clearly irrelevant, immaterial or unduly repetitious, so the parties should avoid frequent objections to questions and documents. Both sides may make opening and closing statements, may present witnesses as agreed upon in the prehearing conference, and may cross-examine. Since the parties have ample opportunity to develop a complete appeal file, a party may introduce an exhibit at the hearing only after explaining to the satisfaction of the presiding Board member why the exhibit was not submitted earlier (for example, because the information was not available).

(2) The Board may request the parties to submit written statements of witnesses to the Board and each other

prior to the hearing so that the hearing will primarily be concerned with cross-examination and rebuttal.

(3) False statements of a witness may be the basis for criminal prosecution under sections 287 and 1001 of Title 18 of the United States Code.

(4) The hearing will be recorded at Department expense.

(e) *Procedures after the hearing.* The Board will send one copy of the transcript to each party as soon as it is received by the Board. At the discretion of the Board, the parties may be required or allowed to submit post-hearing briefs or proposed findings and conclusions (the parties will be informed at the hearing). A party should note any major prejudicial transcript errors in an addendum to its post-hearing brief (or if no brief will be submitted, in a letter submitted within a time limit set by the Board).

§ 16.12 The expedited process.

(a) *Applicability.* Where the amount in dispute is \$25,000 or less, the Board will use these expedited procedures, unless the Board Chair determines otherwise under paragraph (b) of this section. If the Board and the parties agree, the Board may use these procedures in cases of more than \$25,000.

(b) *Exceptions.* If there are unique or unusually complex issues involved, or other exceptional circumstances, the Board may use additional procedures.

(c) *Regular expedited procedures.* (1) Within 30 days after receiving the Board's acknowledgment of the appeal (see § 16.7), each party shall submit to the Board and the other party any relevant background documents (organized as required under § 16.8), with a cover letter (generally not to exceed ten pages) containing any arguments the party wishes to make.

(2) Promptly after receiving the parties' submissions, the presiding Board member will arrange a telephone conference call to receive the parties' oral comments in response to each other's submissions. After notice to the parties, the Board will record the call. The Board member will advise the parties whether any opportunities for further briefing, submissions or oral presentations will be established. Cooperative efforts will be encouraged (see § 16.8(d)).

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(3) The Board may require the parties to submit proposed findings and conclusions.

(d) *Special expedited procedures where there has already been review.* Some HHS components (for example, the Public Health Service) use a board or other relatively independent reviewing authority to conduct a formal preliminary review process which results in a written decision based on a record including documents or statements presented after reasonable notice and opportunity to present such material. In such cases, the following rules apply to appeals of \$25,000 or less instead of those under paragraph (c) of this section:

(1) Generally, the Board's review will be restricted to whether the decision of the preliminary review authority was clearly erroneous. But if the Board determines that the record is inadequate, or that the procedures under which the record was developed in a given instance were unfair, the Board will not be restricted this way.

(2) Within 30 days after receiving the Board's acknowledgment of appeal (see § 16.7), the parties shall submit the following:

(i) The appellant shall submit to the Board and the respondent a statement why the decision was clearly erroneous. Unless allowed by the Board after consultation with the respondent, the appellant shall not submit further documents.

(ii) The respondent shall submit to the Board the record in the case. If the respondent has reason to believe that all materials in the record already are in the possession of the appellant, the respondent need only send the appellant a list of the materials submitted to the Board.

(iii) The respondent may, if it wishes, submit a statement why the decision was not clearly erroneous.

(3) The Board, in its discretion, may allow or require the parties to present further arguments or information.

§ 16.13 Powers and responsibilities.

In addition to powers specified elsewhere in these procedures, Board members have the power to issue orders (including "show cause" orders); to examine witnesses; to take all steps nec-

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essary for the conduct of an orderly hearing; to rule on requests and motions, including motions to dismiss; to grant extensions of time for good reasons; to dismiss for failure to meet deadlines and other requirements; to close or suspend cases which are not ready for review; to order or assist the parties to submit relevant information; to remand a case for further action by the respondent; to waive or modify these procedures in a specific case with notice to the parties; to reconsider a Board decision where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

§ 16.14 How Board review is limited.

The Board shall be bound by all applicable laws and regulations.

§ 16.15 Failure to meet deadlines and other requirements.

(a) Since one of the objectives of administrative dispute resolution is to provide a decision as fast as possible consistent with fairness, the Board will not allow parties to delay the process unduly. The Board may grant extensions of time, but only if the party gives a good reason for the delay.

(b) If the appellant fails to meet any filing or procedural deadlines, appeal file or brief submission requirements, or other requirements established by the Board, the Board may dismiss the appeal, may issue an order requiring the party to show cause why the appeal should not be dismissed, or may take other action the Board considers appropriate.

(c) If the respondent fails to meet any such requirements, the Board may issue a decision based on the record submitted to that point or take such other measures as the Board considers appropriate.

§ 16.16 Parties to the appeal.

(a) The only parties to the appeal are the appellant and the respondent. If the Board determines that a third person is a real party in interest (for example, where the major impact of an audit disallowance would be on the

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grantee's contractor, not on the grantee), the Board may allow the third person to present the case on appeal for the appellant or to appear with a party in the case, after consultation with the parties and if the appellant does not object.

(b) The Board may also allow other participation, in the manner and by the deadlines established by the Board, where the Board decides that the intervenor has a clearly identifiable and substantial interest in the outcome of the dispute, that participation would sharpen issues or otherwise be helpful in resolution of the dispute, and that participation would not result in substantial delay.

§ 16.17 Ex parte communications (communications outside the record).

(a) A party shall not communicate with a Board or staff member about matters involved in an appeal without notice to the other party. If such communication occurs, the Board will disclose it to the other party and make it part of the record after the other party has an opportunity to comment. Board members and staff shall not consider any information outside the record (see § 16.21 for what the record consists of) about matters involved in an appeal.

(b) The above does not apply to the following: Communications among Board members and staff; communications concerning the Board's administrative functions or procedures; requests from the Board to a party for a document (although the material submitted in response also must be given to the other party); and material which the Board includes in the record after notice and an opportunity to comment.

§ 16.18 Mediation.

(a) *In cases pending before the Board.* If the Board decides that mediation would be useful to resolve a dispute, the Board, in consultation with the parties, may suggest use of mediation techniques and will provide or assist in selecting a mediator. The mediator may take any steps agreed upon by the parties to resolve the dispute or clarify issues. The results of mediation are not binding on the parties unless the parties so agree in writing. The Board will internally insulate the mediator from

any Board or staff members assigned to handle the appeal.

(b) *In other cases.* In any other grants dispute, the Board may, within the limitations of its resources, offer persons trained in mediation skills to aid in resolving the dispute. Mediation services will only be offered at the request, or with the concurrence, of a responsible federal program official in the program under which the dispute arises. The Board will insulate the mediator if any appeal subsequently arises from the dispute.

§ 16.19 How to calculate deadlines.

In counting days, include Saturdays, Sundays, and holidays; but if a due date would fall on a Saturday, Sunday or Federal holiday, then the due date is the next Federal working day.

§ 16.20 How to submit material to the Board.

(a) Submissions should be addressed to the Board's current mailing address: Department of Health and Human Services, Departmental Appeals Board, Appellate Division—MS 6127, 330 Independence Ave. SW., Cohen Building—Rm. G-644, Washington, DC 20201; however, submissions to the Board in certain types of cases may be made by electronic filing using DAB E-File at <https://dab.efile.hhs.gov>. Changes to the mailing address will be made available on the Board's Web site at www.hhs.gov/dab/divisions/appellate.

(b) All submissions after the notice of appeal should identify the Board's docket number (the Board's acknowledgement under § 16.7 will specify the docket number).

(c) Unless the Board otherwise specifies, parties shall submit to the Board an original and two copies of all materials. Each submission other than the notice of appeal, must include a statement that one copy of the materials has been sent to the other party, identifying when and to whom the copy was sent.

(d) Unless hand delivered, all materials should be sent to the Board and the other party by certified or registered mail, return receipt requested.

(e) The Board considers material to be submitted on the date when it is

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postmarked or hand delivered to the Board.

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016]

§ 16.21 Record and decisions.

(a) Each decision is issued by three Board members (see § 16.5(b)), who base their decision on a record consisting of the appeal file; other submissions of the parties; transcripts or other records of any meetings, conferences or hearings conducted by the Board; written statements resulting from conferences; evidence submitted at hearings; and orders and other documents issued by the Board. In addition, the Board may include other materials (such as evidence submitted in another appeal) after the parties are given notice and an opportunity to comment.

(b) The Board will promptly notify the parties in writing of any disposition of a case and the basis for the disposition.

§ 16.22 The effect of an appeal.

(a) *General.* Until the Board disposes of an appeal, the respondent shall take no action to implement the final decision appealed.

(b) *Exceptions.* The respondent may—

(1) Suspend funding (see 2 CFR 200.339);

(2) Defer or disallow other claims questioned for reasons also disputed in the pending appeal;

(3) In programs listed in appendix A, B.(a)(1), to this part implement a decision to disallow Federal financial participation claimed in expenditures reported on a statement of expenditures, by recovering, withholding or offsetting payments, if the decision is issued before the reported expenditures are included in the calculation of a subsequent grant;

(4) Take other action to recover, withhold, or offset funds if specifically authorized by statute or regulation; or

(5) Take action to require a State to suspend procedural disenrollments, as defined at 42 CFR 430.5, or continue the accrual of the civil money penalties a State owes under 42 CFR 430.49(c).

[46 FR 43817, Aug. 31, 1981, as amended at 81 FR 3012, Jan. 20, 2016; 88 FR 84737, Dec. 6, 2023; 89 FR 80070, Oct. 2, 2024]

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§ 16.23 How long an appeal takes.

The Board has established general goals for its consideration of cases, as follows (measured from the point when the Board receives the first submission after the notice of appeal):

—For regular review based on a written record under § 16.8, 6 months. When a conference under § 16.10 is held, the goal remains at 6 months, unless a requirement for post-conference briefing in a particular case renders the goal unrealistic.

—For cases involving a hearing under § 16.11, 9 months.

—For the expedited process under § 16.12, 3 months.

These are goals, not rigid requirements. The paramount concern of the Board is to take the time needed to review a record fairly and adequately in order to produce a sound decision. Furthermore, many factors are beyond the Board's direct control, such as unforeseen delays due to the parties' negotiations or requests for extensions, how many cases are filed, and Board resources. On the other hand, the parties may agree to steps which may shorten review by the Board; for example, by waiving the right to submit a brief, by agreeing to shorten submission schedules, or by electing the expedited process.

APPENDIX A TO PART 16—WHAT DISPUTES THE BOARD REVIEWS

A. What this appendix covers.

This appendix describes programs which use the Board for dispute resolution, the types of disputes covered, and any conditions for Board review of final written decisions resulting from those disputes. Disputes under programs not specified in this appendix may be covered in a program regulation or in a memorandum of understanding between the Board and the head of the appropriate HHS operating component or other agency responsible for administering the program. If in doubt, call the Board. Even though a dispute may be covered here, the Board still may not be able to review it if the limits in paragraph F apply.

B. Mandatory grant programs.

(a) The Board reviews the following types of final written decisions in disputes arising in HHS programs authorizing the award of mandatory grants:

(1) Disallowances under Titles I, IV, VI, X, XIV, XVI(AABD), XIX, and XX of the Social Security Act, including penalty disallowances such as those under sections 403(g) and

1903(g) of the Act and fiscal disallowances based on quality control samples.

(2) Disallowances in mandatory grant programs administered by the Public Health Service, including Title V of the Social Security Act.

(3) Disallowances in the programs under sections 113 and 132 of the Developmental Disabilities Act.

(4) Disallowances under Title III of the Older American Act.

(5) Decisions relating to repayment and withholding under block grant programs as provided in 45 CFR 96.52.

(6) Decisions relating to repayment and withholding under State Legalization Impact Assistance Grants as provided in 45 CFR 402.24 and 402.25.

(7) Decisions relating to suspensions of procedural disenrollments and civil money penalties under 42 CFR 430.49(c).

(b) In some of these disputes, there is an option for review by the head of the granting agency prior to appeal to the Board. Where an appellant has requested review by the agency head first, the "final written decision" required by §16.3 for purposes of Board review will generally be the agency head's decision affirming the disallowance. If the agency head declines to review the disallowance or if the appellant withdraws its request for review by the agency head, the original disallowance decision is the "final written decision." In the latter cases, the 30-day period for submitting a notice of appeal begins with the date of receipt of the notice declining review or with the date of the withdrawal letter.

C. Direct, discretionary project programs.

(a) The Board reviews the following types of final written decisions in disputes arising in any HHS program authorizing the award of direct, discretionary project grants or cooperative agreements:

(1) A disallowance or other determination denying payment of an amount claimed under an award, or requiring return or set-off of funds already received. This does not apply to determinations of award amount or disposition of unobligated balances, or selection in the award document of an option for disposition of program-related income.

(2) A termination for failure to comply with the terms of an award.

(3) A denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award.

(4) A voiding (a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained).

(b) Where an HHS component uses a preliminary appeal process (for example, the Public Health Service), the "final written decision" for purposes of Board review is the decision issued as a result of that process.

D. Cost allocation and rate disputes.

The Board reviews final written decisions in disputes which may affect a number of HHS programs because they involve cost allocation plans or rate determinations. These include decisions related to cost allocation plans negotiated with State or local governments and negotiated rates such as indirect cost rates, fringe benefit rates, computer rates, research patient care rates, and other special rates.

E. SSI agreement disputes.

The Board reviews disputes in the Supplemental Security Income (SSI) program arising under agreements for Federal administration of State supplementary payments under section 1616 of the Social Security Act or mandatory minimum supplements under section 212 of Pub. L. 93-66. In these cases, the Board provides an opportunity to be heard and offer evidence at the Secretarial level of review as set out in the applicable agreements. Thus, the "final written decision" for purposes of Board review is that determination appealable to the Secretary under the agreement.

F. Where Board review is not available.

The Board will not review a decision if a hearing under 5 U.S.C. 554 is required by statute, if the basis of the decision is a violation of applicable civil rights or non-discrimination laws or regulations (for example, Title VI of the Civil Rights Act), or if some other hearing process is established pursuant to statute.

G. How the Board determines whether it will review a case.

Under §16.7, the Board Chair determines whether an appeal meets the requirements of this appendix. If the Chair finds that there is some question about this, the Board will request the written opinion of the HHS component which issued the decision. Unless the Chair determines that the opinion is clearly erroneous, the Board will be bound by the opinion. If the HHS component does not respond within a time set by the Chair, or cannot determine whether the Board clearly does or does not have jurisdiction, the Board will take the appeal.

[46 FR 43817, Aug. 31, 1981, as amended at 47 FR 29492, July 6, 1982; 53 FR 7864, Mar. 10, 1988; 62 FR 38218, July 17, 1997; 88 FR 84737, Dec. 6, 2023]

PART 17—RELEASE OF ADVERSE INFORMATION TO NEWS MEDIA

Sec.

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17.3 Precautions to be taken.

17.4 Regulatory investigations and trial-type proceedings.

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17.6 Advance notice.

17.7 Retractions or corrections.

AUTHORITY: 5 U.S.C. 301.

SOURCE: 41 FR 3, Jan. 2, 1976, unless otherwise noted.

§ 17.1 Definition.

Adverse information released by an agency means any statement or release by the Department or any principal operating component made to the news media inviting public attention to an action or a finding by the Department or principal operating component of the Department which may adversely affect persons or organizations identified therein. This part does not apply to nor is it affected by any disclosure of records to the public in response to requests made under the Freedom of Information Act (Pub. L. 90-23). The criteria for such disclosures are set forth in the Department's Public Information Regulation (45 CFR part 5).

§ 17.2 Basic policy.

All adverse information release to news media shall be factual in content and accurate in description. Disparaging terminology not essential to the content and purpose of the publicity shall be avoided.

§ 17.3 Precautions to be taken.

The issuing organization shall take reasonable precautions to assure that information released is accurate and that its release fulfills an authorized purpose.

§ 17.4 Regulatory investigations and trial-type proceedings.

Adverse information relating to regulatory investigations of specifically identified persons or organizations or to pending agency trial-type proceedings shall be released only in limited circumstances in accordance with the criteria outlined below:

(a) Where the Department or a principal operating component determines that there is a significant risk that the public health or safety may be impaired or substantial economic harm may occur unless the public is notified immediately, it may release information to news media as one of the means of notifying the affected public speedily and accurately. However, where the

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Department or principal operating component determines that public harm can be avoided by immediate discontinuance of an offending practice, a respondent shall be allowed an opportunity, where feasible, to cease the practice (pending a legal test) in lieu of release of adverse information by the agency.

(b) Where it is required in order to bring notice of pending agency adjudication to persons likely to desire to participate therein or likely to be affected by that or a related adjudication, the Department or principal operating component shall rely on the news media to the extent necessary to provide such notice even though it may be adverse to a respondent.

§ 17.5 Context to be reflected.

The authority for and the character of the information shall be made clear, where appropriate, the release shall explain the nature of any studies performed, the sources of relevant data, the areas in which administrative findings of fact were made, and whether the information is based on allegations subject to subsequent adjudication.

§ 17.6 Advance notice.

Any respondent or prospective respondent in an agency proceeding shall, if practicable and consistent with the nature of the proceeding, be given advance notice of information to be released about the proceeding and a reasonable opportunity to prepare in advance a response to the information released.

§ 17.7 Retractions or corrections.

Where the Assistant Secretary for Public Affairs finds that information released by the Department was misleading or a misstatement of fact and any person named therein requests a retraction or correction, the Department shall issue a retraction or correction in the same manner to all of the media outlets that received the original information (or as many of them as is feasible). Where information shown to be misleading or misstatement of fact has been released by a principal operating component of the Department and any person named therein requests a retraction or correction, the

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agency head shall issue a retraction or correction in the same manner to all of the media outlets that received the original information (or as many of them as is feasible).

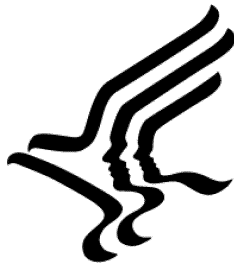
PART 18—OFFICIAL SYMBOL, LOGO, AND SEAL

AUTHORITY: 42 U.S.C. 3505 and 5 U.S.C. 301.

§ 18.1 Description of the Symbol, Logo, and Seal.

(a) The Departmental Symbol (Symbol) of the Department of Health and Human Services (HHS) is the key element in Department identification. It represents the American People sheltered in the wing of the American Eagle, suggesting the Department's concern and responsibility for the welfare of the people. This Symbol is the visual link which connects the graphic communications of all components and programs of the Department. It is the major design component for the Department Identifiers — the Department Logo, Seal, and Signatures.

(b) The Symbol is described as follows: The outline of an American Eagle, facing left, with one of its wings stretched upward and the other wing pointed downward, is flanked on its right side by two outlines of the profile of a human head, both of which are located in between the eagle's wings. One of the profile outlines is smaller than the other and is nestled in the larger outline.



(c) The HHS Departmental Logo (Logo) incorporates the Symbol and is described as follows: From the tip of the outstretched wing of the American Eagle in symbol to the tip of the other, downward-facing wing, the words, "DEPARTMENT OF HEALTH &

HUMAN SERVICES • USA" form a circular arc. The official colors of the Logo are either Black or Reflex Blue. Reflex Blue RGB Numbers: 0/0/153 (R0, G0, B153)



(d) The HHS Departmental Seal (Seal) incorporates the Symbol and is described as follows: Starting from the tip of the downward-facing wing of the American Eagle in the HHS symbol and forming a complete circle clockwise around the HHS symbol, the words, "DEPARTMENT OF HEALTH & HUMAN SERVICES • USA •" are printed, surrounded by a border composed of a solid inner ring at the base of the text and a triangular, scalloped edge at the top of the text. The official colors of the Seal are Reflex Blue and Gold [Reflex Blue RGB Numbers: 0/0/153 (R0, G0, B153); Reflex Gold RGB Numbers: 254/252/1 (R254, G252, B1)]. The Seal may also appear in Reflex Blue or Black.



(e) The HHS Departmental symbol, logo, and seal shall each be referred to as an HHS emblem and shall collectively be referred to as HHS emblems.

[80 FR 13252, Mar. 13, 2015]

PART 30—CLAIMS COLLECTION**Subpart A—General Provisions**

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- 30.14 Contracting with private collection contractors and with entities that locate and recover unclaimed assets.
- 30.15 Suspension or revocation of eligibility for loans and loan guarantees, licenses, permits or privileges.
- 30.16 Liquidation of collateral.
- 30.17 Collection in installments.
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- 30.32 Discharge of indebtedness; reporting requirements.

Subpart E—Referrals to the Department of Justice

- 30.33 Prompt referral.
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AUTHORITY: 31 U.S.C. 3711(d).

SOURCE: 72 FR 10409, Mar. 8, 2007, unless otherwise noted.

Subpart A—General Provisions**§ 30.1 Purpose, authority, and scope.**

(a) *Purpose.* This part prescribes the standards and procedures for the Department's use in the administrative collection, offset, compromise, and suspension or termination of collection activity for claims for funds or property, as defined by 31 U.S.C. 3701(b) and this part. Covered activities include the collection of debts in any amount; the compromise and suspension or termination of collection activity of debts that do not exceed \$100,000, or such higher amount as the Attorney General may prescribe, exclusive of interest, penalties, and administrative costs; and the referral of debts to the Department of the Treasury (Treasury), the Treasury-designated debt collection centers, or the Department of Justice (Justice) for collection by further administrative action or litigation, as applicable.

(b) *Authority.* The Secretary is issuing the regulations in this part under the authority contained in 31 U.S.C. 3711(d). The standards and procedures prescribed in this part are authorized under the Federal Claims Collection Act, as amended, Public Law No. 89–508, 80 Stat. 308 (July 19, 1966), the Debt Collection Act of 1982, Public Law No. 97–365, 96 Stat. 1749 (October 25, 1982), the Debt Collection Improvement Act of 1996, Public Law No. 104–134, 110 Stat. 1321, 1358 (April 26, 1996) and the Federal Claims Collection Standards at 31 CFR parts 900 through 904.

(c) *Scope.* (1) The standards and procedures prescribed in this part apply to all officers and employees of the Department, including officers and employees of the various Operating Divisions and Regional Offices of the Department, charged with the collection and disposition of debts owed to the United States.

(2) The standards and procedures set forth in this part will be applied except where specifically excluded herein or

where a statute, regulation or contract prescribes different standards or procedures.

(3) Regulations governing the use of certain debt collection procedures created under the Debt Collection Improvement Act of 1996, including tax refund offset, administrative wage garnishment, and Federal salary offset, are contained in parts 31 through 33 of this chapter.

§ 30.2 Definitions.

In this part—

Administrative offset means withholding funds payable by the United States to, or held by the United States for, a person to satisfy a debt.

Agency means a department, agency, court, court administrative office, or instrumentality in the executive, judicial, or legislative branch of the Government, including Government corporations.

Appropriate official means the Department official who, by statute or delegation of authority, determines the existence and amount of debt.

Business day means Monday through Friday. For purposes of computation, the last day of the period will be included unless it is a Federal holiday, in which case the next business day following the holiday will be considered the last day of the period.

Claim see the definition for the term “debt.” The terms “claim” and “debt” are synonymous and interchangeable.

Creditor agency means an agency to which a debt is owed, including a debt collection center acting on behalf of a creditor agency.

Day means calendar day. For purposes of computation, the last day of the period will be included unless it is a Saturday, Sunday, or a Federal holiday, in which case the next business day will be considered the last day of the period.

Debt or claim means an amount of funds or other property determined by an appropriate official of the Federal Government to be owed to the United States from any person, organization, or entity, except another Federal agency. For the purpose of administrative offset, the term includes an amount owed by an individual to a State, the District of Columbia, American Samoa,

Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, or the Commonwealth of Puerto Rico. Debts include, but are not limited to, amounts owed pursuant to: Loans insured or guaranteed by the United States; fees; leases; rents; royalties; services; sales of real or personal property; Federal salary overpayments; overpayments to program beneficiaries, contractors, providers, suppliers, and grantees; audit disallowance determinations; civil penalties and assessments; theft or loss; interest; fines and forfeitures (except those arising under the Uniform Code of Military Justice); and all other similar sources.

Debt collection center means the Department of the Treasury, or other Federal agency, subagency, unit, or division designated by the Secretary of the Treasury to collect debts owed to the United States.

Debtor means an individual, organization, association, partnership, corporation, or State or local government or subdivision indebted to the Government, or the person or entity with legal responsibility for assuming the debtor's obligation.

Debts arising under the Social Security Act are overpayments to, or contributions, reimbursements, penalties or assessments owed by, any entity, individual, or State under the Social Security Act. Such amounts include amounts owed to the Medicare program under section 1862(b) of the Social Security Act. Salary overpayments and other debts that result from the administration of the provisions of the Social Security Act are not deemed to “arise under” the Social Security Act for purposes of this part.

Delinquent debt means a debt which the debtor does not pay or otherwise resolve by the date specified in the initial demand for payment, or in an applicable written repayment agreement or other instrument, including a post-delinquency repayment agreement.

Department means the Department of Health and Human Services, and its Operating Divisions and Regional Offices.

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Disbursing official means an officer or employee who has authority to disburse public money pursuant to 31 U.S.C. 3321 or another law.

Disposable pay means that part of the debtor's current basic, special, incentive, retired, and retainer pay, or other authorized pay, remaining after deduction of amounts required by law to be withheld. For purposes of calculating disposable pay, legally required deductions that must be applied first include: Tax levies pursuant to the Internal Revenue Code (title 26, United States Code); properly withheld taxes, FICA, Medicare; health and life insurance premiums; and retirement contributions. Amounts deducted under garnishment orders, including child support garnishment orders, are not legally required deductions for calculating disposable pay.

Evidence of service means information retained by the Department indicating the nature of the document to which it pertains, the date of mailing of the document, and the address and name of the debtor to whom it is being sent. A copy of the dated and signed written notice provided to the debtor pursuant to this part may be considered evidence of service for purposes of this part. Evidence of service may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

FMS means the Financial Management Service, a bureau of the Department of the Treasury.

Hearing means a review of the documentary evidence to confirm the existence or amount of a debt or the terms of a repayment schedule. If the Secretary determines that the issues in dispute cannot be resolved by such a review, such as when the validity of the claim turns on the issue of credibility or veracity, the Secretary may provide an oral hearing. (See 45 CFR 33.6(c)(2) for oral hearing procedures that may be provided by the Secretary).

IRS means the Internal Revenue Service, a bureau of the Department of the Treasury.

Late charges means interest, penalties, and administrative costs required or permitted to be assessed on delinquent debts.

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Legally enforceable means that there has been a final agency determination that the debt, in the amount stated, is due and there are no legal bars to collection action.

Local government means a political subdivision, instrumentality, or authority of any State, the District of Columbia, American Samoa, Guam, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, or the Commonwealth of Puerto Rico, or an Indian tribe, band or nation.

Operating Division means each separate component, agency, subagency, and unit within the Department of Health and Human Services, including, but not limited to, the Administration for Children and Families, the Administration on Aging, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, the National Institutes of Health, Substance Abuse and Mental Health Services Administration, Indian Health Service, Health Resources and Services Administration, Agency for Toxic Substances and Disease Registry, Agency for Healthcare Research and Quality, and the Office of the Secretary.

OPM means the Office of Personnel Management.

Payment authorizing agency means an agency that transmits a voucher to a disbursing official for the disbursement of public money.

Payments made under the Social Security Act means payments by this Department or other agencies to beneficiaries, providers, intermediaries, physicians, suppliers, carriers, States, or other contractors or grantees under a Social Security Act program, including: Title I (Grants to States for Old-Age Assistance for the Aged); Title II (Federal Old-Age, Survivors, and Disability Insurance Benefits); Title III (Grants to States for Unemployment Compensation Administration); Title IV (Grants to States for Aid and Services to Needy Families with Children and for Child-Welfare Services); Title V (Maternal and Child Health Services Block Grant); Title IX (Miscellaneous Provisions Relating to Employment Security); Title X (Grants to States for Aid to the Blind); Title XI, part B (Peer

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Review of the Utilization and Quality of Health Care Services); Title XII (Advances to State Unemployment Funds); Title XIV (Grants to States for Aid to Permanently and Totally Disabled); Title XVI (Grants to States for Aid to the Aged, Blind, and Disabled); Title XVII (Grants for Planning Comprehensive Action to Combat Mental Retardation); Title XVIII (Health Insurance for the Aged and Disabled); Title XIX (Grants to States for Medical Assistance Programs); Title XX (Block Grants to States for Social Services); and Title XXI (State Children's Health Insurance Program). Federal employee salaries and other payments made by the Department or other agencies in the course of administering the provisions of the Social Security Act are not deemed to be "payable under" the Social Security Act for purposes of this part.

Private collection contractors means private debt collection under contract with the Department to collect a nontax debt or claim owed to the Department. The term includes private debt collectors, collection agencies, and commercial attorneys.

Salary offset means an administrative offset to collect a debt owed by a Federal employee through deductions at one or more officially established pay intervals from the current pay account of the employee without his or her consent.

Secretary means the Secretary of Health and Human Services, or the Secretary's designee.

Taxpayer identification number means the identifying number described under section 6109 of the Internal Revenue Code of 1986 (26 U.S.C. 6109). For an individual, the taxpayer identifying number is the individual's Social Security Number.

Tax refund offset means withholding or reducing a tax refund payment by an amount necessary to satisfy a debt.

§ 30.3 Antitrust, fraud, exception in the account of an accountable official, and interagency claims excluded.

(a) *Claims involving antitrust violations or fraud.* (1) The standards in this part relating to compromise, suspension, and termination of collection activity

do not apply to any debt based in whole or in part on conduct in violation of antitrust laws, or to any debt involving fraud, presentation of a false claim, or misrepresentation on the part of the debtor or any party having an interest in the claim, unless the Department of Justice returns a referred claim to the Department for further handling in accordance with parts 31 CFR 900 through 904 and this part.

(2) Upon identification of a debt suspected of involving an antitrust violation or fraud, a false claim, misrepresentation, or other criminal activity or misconduct, the Secretary shall refer the debt to the Office of the Inspector General for review.

(3) Upon the determination of the Office of the Inspector General that a claim is based in whole or in part on conduct in violation of the antitrust laws, or involves fraud, the presentation of a false claim, or misrepresentation on the part of the debtor or any party having an interest in the claim, the Secretary shall promptly refer the case to the Department of Justice for action.

(b) *Exception in the account of an accountable official.* The standards in this part do not apply to compromise of an exception in the account of an accountable official.

(c) *Interagency claims.* This part does not apply to claims between Federal agencies. The Department will attempt to resolve interagency claims by negotiation in accordance with EO 12146.

§ 30.4 Compromise, waiver, or disposition under other statutes not precluded.

Nothing in this part precludes the Department from disposing of any claim under statutes and implementing regulations other than subchapter II of chapter 37 of Title 31 of the United States Code and the Federal Claims Collection Standards, 31 CFR parts 900 through 904. Any statute and implementing regulation specifically applicable to the claims collection activities of the Department will take precedence over this part.

§ 30.5 Other administrative remedies.

The remedies and sanctions available under this part for collecting debts are

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not intended to be exclusive. Nothing contained in this part precludes using any other administrative remedy which may be available for collecting debts owed to the Department, such as converting the method of payment under a grant from an advancement to a reimbursement method or revoking a grantee's letter-of-credit.

§ 30.6 Form of payment.

Claims may be paid in the form of money or, when a contractual basis exists, the Department may demand the return of specific property or the performance of specific services.

§ 30.7 Subdivision of claims.

Debts may not be subdivided to avoid the monetary ceiling established by 31 U.S.C. 3711(a)(2). A debtor's liability arising from a particular transaction or contract shall be considered a single debt in determining whether the debt, exclusive of interest, penalties and administrative costs, does not exceed \$100,000, or such higher amount as prescribed by the Attorney General for purposes of compromise, or suspension or termination of collection activity.

§ 30.8 Required administrative proceedings.

This part does not supersede, or require omission or duplication of administrative proceedings required by contract, or other laws or regulations. See for example, 42 CFR part 50 (Public Health Service), 45 CFR part 16 (Departmental Grant Appeals Board), and 48 CFR part 33 (Federal Acquisition Regulation) and part 333 (HHS Acquisition Regulation).

§ 30.9 No private rights created.

The standards in this part do not create any right or benefit, substantive or procedural, enforceable at law or in equity by a party against the United States, the Department, its officers, or any other person, nor shall the failure of the Department to comply with any of the provisions of this part be available to any debtor as a defense.

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Subpart B—Standards for the Administrative Collection of Debts

§ 30.10 Collection activities.

(a) *General rule.* The Secretary shall aggressively and timely collect all debts arising out of activities of, or referred or transferred for collection actions to, the Department. Normally, an initial written demand for payment shall be made no later than 30 days after a determination by an appropriate official that a debt exists.

(b) *Cooperation with other agencies.* The Department shall cooperate with other agencies in their debt collection activities.

(c) *Transfer of delinquent debts—(1) Mandatory transfer.* The Department shall transfer legally enforceable debts 180 days or more delinquent to Treasury in accordance with the requirements of 31 CFR 285.12. This requirement does not apply to any debt that:

- (i) Is in litigation or foreclosure;
- (ii) Will be disposed of under an approved asset sale program within one year of becoming eligible for sale;
- (iii) Has been referred to a private collection contractor for a period of time acceptable to the Secretary of the Treasury;
- (iv) Is at a debt collection center for a period of time acceptable to the Secretary of the Treasury (see paragraph (c)(2) of this section);
- (v) Will be collected under internal offset procedures within three years after the debt first became delinquent; or
- (vi) Is exempt from this requirement based on a determination by the Secretary of the Treasury that exemption for a certain class of debt is in the best interest of the United States.

(2) *Permissive transfer.* The Secretary may refer debts less than 180 days delinquent, including debts referred to the Department by another agency, to the Treasury in accordance with the requirements of 31 CFR 285.12, or with the consent of the Treasury, to a Treasury-designated debt collection center to accomplish efficient, cost effective debt collection. Referrals to debt collection centers shall be at the discretion of, and for a time period acceptable to, the Secretary of the Treasury. Referrals may be for servicing,

collection, compromise, suspension, or termination of collection action.

§ 30.11 Demand for payment.

(a) *Written demand for payment.* (1) Written demand, as described in paragraph (b) of this section, shall be made promptly upon a debtor in terms that inform the debtor of the consequences of failing to cooperate with the Department to resolve the debt.

(2) Normally, the demand letter will be sent no later than 30 days after the appropriate official determines that the debt exists. The demand letter shall be sent by first class mail to the debtor's last known address.

(3) When necessary to protect the Government's interest, for example to prevent the running of a statute of limitations, the written demand for payment may be preceded by other appropriate action under this part, including immediate referral to Justice for litigation.

(b) *Demand letters.* The specific content, timing, and number of demand letters shall depend upon the type and amount of the debt and the debtor's response, if any, to the Department's letters or telephone calls. Generally, one demand letter should suffice; however, more may be used.

(1) The written demand for payment shall include the following information:

(i) The nature and amount of the debt, including the basis for the indebtedness;

(ii) The date by which payment should be made to avoid late charges and enforced collection, which generally shall be no later than 30 days from the date the demand letter is mailed;

(iii) The applicable standards for imposing any interest, penalties, or administrative costs (see § 30.18);

(iv) The rights, if any, the debtor may have to:

(A) Seek review of the Department's determination of the debt, and for purposes of administrative wage garnishment or salary offset, to request a hearing (see 45 CFR parts 32 and 33); and

(B) Enter into a reasonable repayment agreement.

(v) An explanation of how the debtor may exercise any of the rights described in paragraph (b)(1)(iv) of this section;

(vi) The name, address, and phone number of a contact person or office within the Department to address any debt-related matters; and

(vii) The Department's remedies to enforce payment of the debt, which may include:

(A) Garnishing the debtor's wages through administrative wage garnishment;

(B) Offsetting any Federal payments due the debtor, including income tax refunds, salary, certain benefit payments such as Social Security, retirement, and travel reimbursements and advances;

(C) Referring the debt to a private collection contractor;

(D) Reporting the debt to a credit bureau or other automated database;

(E) Referring the debt to Justice for litigation; and

(F) Referring the debt to Treasury for any of the collection actions described in paragraphs (b)(1)(vii)(A) through (E) of this section, advising the debtor that such referral is mandatory if the debt is 180 or more days delinquent.

(2) The written demand for payment should also include the following information:

(i) The debtor's right to inspect and copy all records of the Department pertaining to the debt, or if the debtor or the debtor's representative cannot personally inspect the records, to request and receive copies of such records;

(ii) The Department's willingness to discuss with the debtor alternative methods of payment;

(iii) A debtor delinquent on a debt is ineligible for Government loans, loan guarantees, or loan insurance until the debtor resolves the debt;

(iv) When seeking to collect statutory penalties, forfeiture or other similar types of claim, the debtor's licenses, permits, or other privileges may be suspended or revoked if failure to pay the debt is inexcusable or willful. Such suspension or revocation shall extend to programs or activities administered by the States on behalf of the Federal Government, to the extent

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that they affect the Federal Government's ability to collect money or funds owed by debtors;

(v) Knowingly making false statements or bringing frivolous actions may subject the debtor to civil or criminal penalties under 31 U.S.C. 3729–3731, 18 U.S.C. 286, 287, 1001, and 1002, or any other applicable statutory authority, and, if the debtor is a Federal employee, to disciplinary action under 5 CFR part 752 or other applicable authority;

(vi) Any amounts collected and ultimately found not to have been owed by the debtor will be refunded;

(vii) For salary offset, up to 15% of the debtor's current disposable pay may be deducted every pay period until the debt is paid in full; and

(viii) Dependent upon applicable statutory authority, the debtor may be entitled to consideration for a waiver.

(c) The Secretary will retain evidence of service indicating the date of mailing of the demand letter. The evidence of service, which may include a certificate of service, may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

(d) Prior to, during, or after the completion of the demand process, if the Secretary determines to pursue, or is required to pursue offset, the procedures applicable to offset should be followed (see § 30.12). The availability of funds for debt satisfaction by offset and the Secretary's determination to pursue collection by offset shall release the Secretary from the necessity of further compliance with paragraphs (a), (b), and (c) of this section.

(e) *Finding debtors.* The Secretary will use every reasonable effort to locate debtors, using such sources as telephone directories, city directories, postmasters, drivers license records, automobile title and license records in State and local government agencies, the IRS, credit reporting agencies and skip locator services. Referral of a confess-judgment note to the appropriate United States Attorney's Office for entry of judgment will not be delayed because the debtor cannot be located.

(f) *Communications from debtors.* The Secretary should respond promptly to communications from debtor, within 30

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days where feasible, and should advise debtors who dispute debts to furnish available evidence to support their contentions.

(g) *Exception.* This section does not require duplication of any notice already contained in a written agreement, letter or other document signed by, or provided to, the debtor.

§ 30.12 Administrative offset.

(a) *Scope.* (1) Administrative offset is the withholding of funds payable by the United States to, or held by the United States for, a person to satisfy a debt.

(2) This section does not apply to:

(i) Debts arising under the Social Security Act, except as provided in 42 U.S.C. 404;

(ii) Payments made under the Social Security Act, except as provided for in 31 U.S.C. 3716(c), and implementing regulation at 31 CFR 285.4;

(iii) Debts arising under, or payments made under, the Internal Revenue Code or the tariff laws of the United States;

(iv) Offsets against Federal salaries to the extent these standards are inconsistent with regulations published to implement such offsets under 5 U.S.C. 5514 and 31 U.S.C. 3716 (see 5 CFR part 550, subpart K; 31 CFR 285.7; and part 33 of this chapter);

(v) Offsets under 31 U.S.C. 3728 against a judgment obtained by a debtor against the United States;

(vi) Offsets or recoupments under common law, State law, or Federal statutes specifically prohibiting offsets or recoupments for particular types of debts; or

(vii) Offsets in the course of judicial proceedings, including bankruptcy.

(3) Unless otherwise provided for by contract or law, debts or payments that are not subject to administrative offset under 31 U.S.C. 3716 may be collected by administrative offset under the common law or other applicable statutory authority.

(4) Unless otherwise provided by law, collection by administrative offset under the authority of 31 U.S.C. 3716 may not be conducted more than 10 years after the Department's right to collect the debt first accrued, unless facts material to the Department's right to collect the debt were not

known and could not reasonably have been known by the Secretary. This limitation does not apply to debts reduced to judgment.

(5) Where there is reason to believe that a bankruptcy petition has been filed with respect to a debtor, the Office of the General Counsel should be contacted for legal advice concerning the impact of the Bankruptcy Code, particularly 11 U.S.C. 106, 362 and 553, on pending or contemplated collections by offset.

(b) *Centralized administrative offset.* (1) Except as provided in the exceptions listed in § 30.10(c)(1), legally enforceable debts which are 180 days delinquent shall be referred to the Secretary of the Treasury for collection by centralized administrative offset pursuant to and in accordance with 31 CFR 901.3(b). Debts which are less than 180 days delinquent, including debts referred to the Department by another agency, also may be referred to the Secretary of the Treasury for collection by centralized administrative offset.

(2) When referring delinquent debts to the Secretary of the Treasury for centralized administrative offset, the Department must certify, in a form acceptable to the Secretary of the Treasury, that:

(i) The debt is past due and legally enforceable; and

(ii) The Department has complied with all due process requirements under 31 U.S.C. 3716(a) and paragraph (c)(2) of this section.

(3) Payments that are prohibited by law from being offset are exempt from centralized administrative offset. The Secretary of the Treasury shall exempt payments under means-tested programs from centralized administrative offset when requested in writing by the head of the payment certifying or authorizing agency. Also, the Secretary of the Treasury may exempt other classes of payments from centralized offset upon the written request of the head of the payment certifying or authorizing agency.

(c) *Non-centralized administrative offset.* (1) Unless otherwise prohibited by law, when centralized administrative offset under paragraph (b) of this section is not available or appropriate, the Secretary may collect a delinquent

debt by conducting non-centralized administrative offset internally or in cooperation with the agency certifying or authorizing payments to the debtor.

(2) Except as provided in paragraph (c)(3) of this section, administrative offset may be initiated only after:

(i) The debtor has been sent written notice of the type and amount of the debt, the intention of the Department to initiate administrative offset to collect the debt, and an explanation of the debtor's rights under 31 U.S.C. 3716; and

(ii) The debtor has been given:

(A) The opportunity to inspect and copy Department records related to the debt;

(B) The opportunity for a review within the Department of the determination of indebtedness; and

(C) The opportunity to make a written agreement to repay the debt.

(3) The due process requirements under paragraph (c)(2) of this section may be omitted when:

(i) Offset is in the nature of a recoupment, i.e., the debt and the payment to be offset arise out of the same transaction or occurrence;

(ii) The debt arises under a contract as set forth in *Cecile Industries, Inc. v. Cheney*, 995 F.2d 1052 (Fed. Cir. 1993) (notice and other procedural protections set forth in 31 U.S.C. 3716(a) do not supplant or restrict established procedures for contractual offsets covered by the Contracts Disputes Act); or

(iii) In the case of non-centralized administrative offset conducted under paragraph (c)(1) of this section, the Department first learns of the existence of the amount owed by the debtor when there is insufficient time before payment would be made to the debtor/payee to allow for prior notice and an opportunity for review. When prior notice and an opportunity for review are omitted, the Secretary shall give the debtor such notice and an opportunity for review as soon as practical and shall promptly refund any money ultimately found not to have been owed to the Government.

(4) When the debtor previously has been given any of the required notice and review opportunities with respect to a particular debt, such as under § 30.11 of this part, the Department

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need not duplicate such notice and review opportunities before administrative offset may be initiated.

(5) Before requesting that a payment authorizing agency to conduct non-centralized administrative offset, the Department shall:

(i) Provide the debtor with due process as set forth in paragraph (c)(2) of this section; and

(ii) Provide the payment authorizing agency written certification that the debtor owes the past due, legally enforceable delinquent debt in the amount stated, and that the Department has fully complied with this section.

(6) When a creditor agency requests that the Department, as the payment authorizing agency, conduct non-centralized administrative offset, the Secretary shall comply with the request, unless the offset would not be in the best interest of the United States with respect to the program of the Department, or would otherwise be contrary to law. Appropriate use should be made of the cooperative efforts of other agencies in effecting collection by administrative offset, including salary offset.

(7) When collecting multiple debts by non-centralized administrative offset, the Department will apply the recovered amounts to those debts in accordance with the best interests of the United States, as determined by the facts and circumstances of the particular case, particularly the applicable statute of limitations.

(d) *Requests to OPM to offset a debtor's anticipated or future benefit payments under the Civil Service Retirement and Disability Fund and the Federal Employee Retirement System.* Upon providing OPM written certification that a debtor has been afforded the procedures provided in paragraph (c)(2) of this section, the Department may request OPM to offset a debtor's anticipated or future benefit payments under the Civil Service Retirement and Disability Fund (Fund) in accordance with 5 CFR part 831, subpart R, or under the Federal Employee Retirement System (FERS) in accordance with 5 CFR part 845, subpart D. Upon receipt of such a request, OPM will identify and "flag" a debtor's account in anticipation of the

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time when the debtor requests, or becomes eligible to receive, payments from the Fund or under FERS. This will satisfy any requirement that offset be initiated prior to the expiration of the time limitations referenced in 31 CFR 901.3(b)(4).

(e) *Review requirements.* (1) For purposes of this section, whenever the Secretary is required to afford a debtor a review within the Department, the debtor shall be provided with a reasonable opportunity for an oral hearing when the debtor requests reconsideration of the debt and the Secretary determines that the question of the indebtedness cannot be resolved by review of the documentary evidence, for example, when the validity of the debt turns on an issue of credibility or veracity.

(2) Unless otherwise required by law, an oral hearing under this section is not required to be a formal evidentiary hearing, although the Department will carefully document all significant matters discussed at the hearing.

(3) An oral hearing is not required with respect to debt collection systems where determinations of indebtedness rarely involve issues of credibility or veracity, and the Secretary has determined that a review of the written record is adequate to correct prior mistakes.

(4) In those cases when an oral hearing is not required by this section, the Secretary shall accord the debtor a "paper hearing," that is, a determination of the request for reconsideration based upon a review of the written record.

§ 30.13 Debt reporting and use of credit reporting agencies.

(a) *Reporting delinquent debts.* (1) The Secretary will report delinquent debts over \$100 to credit bureaus or other automated databases. Debts arising under the Social Security Act are excluded from paragraph (a).

(2) Debts owed by individuals will be reported to consumer reporting agencies pursuant to 5 U.S.C. 552a(b)(12).

(3) Once a debt has been referred to Treasury for collection, any subsequent reporting to or updating of a credit bureau or other automated database may be handled by the Treasury.

(4) Where there is reason to believe that a bankruptcy petition has been filed with respect to a debtor, the Office of the General Counsel should be contacted for legal advice concerning the impact of the Bankruptcy Code, particularly with respect to the applicability of the automatic stay, 11 U.S.C. 362, and the procedures for obtaining relief from such stay prior to proceeding under paragraph (a) of this section.

(5) If the debtor has not received prior written notice under § 30.11(b), before reporting a delinquent debt under this section, the Secretary shall provide the debtor at least 60 days written notice of the amount and nature of the debt; that the debt is delinquent and the Department intends to report the debt to a credit bureau (including the specific information that will be disclosed); that the debtor has the right to dispute the accuracy and validity of the information being disclosed; and, if a previous opportunity was not provided, that the debtor may request review within the Department of the debt or rescheduling of payment. The Secretary may disclose only the individual's name, address, and social security number and the nature, amount, status and history of the debt.

(b) *Use of credit reporting agencies.* The Secretary may also use credit reporting agencies to obtain credit reports to evaluate the financial status of loan applicants, potential contractors and grantees; to determine a debtor's ability to repay a debt; and to locate debtors. In the case of an individual, the Secretary may disclose, as a routine use under 5 U.S.C. 552a(b)(3), only the individual's name, address, and Social Security number and the purpose for which the information will be used.

§ 30.14 Contracting with private collection contractors and with entities that locate and recover unclaimed assets.

(a) Subject to the provisions of paragraph (b) of this section, the Secretary may contract with private collection contractors to recover delinquent debts, provided that:

(1) The Secretary retains the authority to resolve disputes, compromise debts, suspend or terminate collection

action, and refer debts to Justice for litigation;

(2) The private collection contractor is not allowed to offer the debtor, as an incentive for payment, the opportunity to pay the debt less the private collection contractor's fee unless the Secretary has granted such authority prior to the offer;

(3) The contract provides that the private collection contractor is subject to the Privacy Act of 1974 to the extent specified in 5 U.S.C. 552a(m), and to applicable Federal and State laws and regulations pertaining to debt collection practices, including but not limited to the Fair Debt Collection Practices Act, 15 U.S.C. 1692; and

(4) The private collection contractor is required to account for all amounts collected.

(b) The Secretary shall use government-wide debt collection contracts to obtain debt collection services provided by private collection contractors. However, the Secretary may refer debts to private collection contractors pursuant to a contract between the Department and the private collection contractor only if such debts are not subject to the requirement to transfer debts to the Department of the Treasury for debt collection under 31 U.S.C. 3711(g) and 31 CFR 285.12(e).

(c) Debts arising under the Social Security Act (which can be collected by private collection contractors only by Treasury after the debt has been referred to Treasury for collection) are excluded from this section.

(d) The Secretary may fund private collection contractor contracts in accordance with 31 U.S.C. 3718(d), or as otherwise permitted by law. A contract under paragraph (a) of this section may provide that the fee a private collection contractor charges the Department for collecting the debt is payable from the amounts collected.

(e) The Department may enter into contracts for locating and recovering assets of the United States including unclaimed assets. However, before entering into a contract to recover assets of the United States that may be held by a State government or financial institution, the Department must establish procedures that are acceptable to the Secretary of Treasury.

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(f) The Secretary may enter into contracts for debtor asset and income search reports. In accordance with 31 U.S.C. 3718(d), such contracts may provide that the fee a contractor charges the Department for such services may be payable from the amounts recovered, unless otherwise prohibited by statute.

§ 30.15 Suspension or revocation of eligibility for loans and loan guarantees, licenses, permits, or privileges.

(a)(1) Unless waived by the Secretary, financial assistance in the form of loans, loan guarantees, or loan insurance shall not be extended to any person delinquent on a non-tax debt owed to the United States. This prohibition does not apply to disaster loans, Grants, cooperative agreements, and contracts are not considered to be loans.

(2) The authority to waive the application of this section may be delegated to the Chief Financial Officer and re-delegated only to the Deputy Chief Financial Officer.

(3) States that manage Federal activities, pursuant to approval from the Secretary, should ensure that appropriate steps are taken to safeguard against issuing licenses, permits, or other privileges to debtors who fail to pay their debts to the Federal Government.

(b) The Secretary will report to Treasury any surety that fails to honor its obligations under 31 U.S.C. 9305.

(c) In non-bankruptcy cases, when seeking to collect statutory penalties, forfeitures, or other types of claims, the Secretary may suspend or revoke licenses, permits, or other privileges of a delinquent debtor if the failure to pay the debt is found to be inexcusable or willful. Such suspension or revocation will extend to programs or activities administered by the States on behalf of the Federal Government, to the extent that they affect the Federal Government's ability to collect money or funds owed by debtors.

(d) Where there is reason to believe that a bankruptcy petition has been filed with respect to a debtor, before taking any action to suspend or revoke under paragraph (c) of this section, the Office of the General Counsel should be

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contacted for legal advice concerning the impact of the Bankruptcy Code, particularly 11 U.S.C. 362 and 525, which may restrict such action.

§ 30.16 Liquidation of collateral.

(a)(1) The Secretary will liquidate security or collateral through the exercise of a power of sale in the security instrument or a non-judicial foreclosure, and apply the proceeds to the applicable debt(s), if the debtor fails to pay the debt(s) within a reasonable time after demand and if such action is in the best interests of the United States.

(2) Collection from other sources, including liquidation of security or collateral, is not a prerequisite to requiring payment by a surety, insurer, or guarantor unless such action is expressly required by statute or contract.

(3) The Secretary will give the debtor reasonable notice of the sale and an accounting of any surplus proceeds and will comply with other requirements under law or contract.

(b) Where there is reason to believe that a bankruptcy petition has been filed with respect to a debtor, the Office of the General Counsel should be contacted for legal advice concerning the impact of the Bankruptcy Code, particularly with respect to the applicability of the automatic stay, 11 U.S.C. 362, and the procedures for obtaining relief from such stay prior to proceeding under paragraph (a) of this section.

§ 30.17 Collection in installments.

(a) Whenever feasible, the total amount of a debt shall be collected in one lump sum payment. If a debtor is financially unable to pay a debt in one lump sum, either by funds or administrative offset, the Secretary may accept payment in regular installments. The Secretary will obtain financial statements from debtors who represent that they are unable to pay in one lump sum and independently verify such representations as described in § 30.22(a)(1).

(b)(1) When the Secretary agrees to accept payments in regular installments, a legally enforceable written agreement should be obtained from the debtor that specifies all the terms and

conditions of the agreement, and that includes a provision accelerating the debt in the event of a default.

(2) The size and frequency of the payments should reasonably relate to the size of the debt and the debtor's ability to pay. Whenever feasible, the installment agreement will provide for full payment of the debt, including interest and charges, in three years or less.

(3) In appropriate cases, the agreement should include a provision identifying security obtained from the debtor for the deferred payments.

§ 30.18 Interest, penalties, and administrative costs.

(a) *Generally.* Except as provided in paragraphs (g), (h), and (i) of this section, the Department shall charge interest, penalties, and administrative costs on delinquent debts owed to the United States. These charges shall continue to accrue until the debt is paid in full or otherwise resolved through compromise, termination, or waiver of the charges.

(b) *Interest.* The Department shall charge interest on delinquent debts owed the United States as follows:

(1) Interest shall accrue from the date of delinquency, or as otherwise provided by law. For debts not paid by the date specified in the written demand for payment made under § 30.11, the date of delinquency is the date of mailing of the notice. The date of delinquency for an installment payment is the due date specified in the payment agreement.

(2) Unless a different rate is prescribed by statute, contract, or a repayment agreement, the rate of interest charged shall be the rate established annually by the Secretary of the Treasury pursuant to 31 U.S.C. 3717. The Department may charge a higher rate if necessary to protect the rights of the United States and the Secretary has determined and documented a higher rate for delinquent debt is required to protect the Government's interests. Any such higher rate of interest charged will be based on Treasury's quarterly rate certification to the U.S. Public Health Service for delinquencies in the National Research Services Awards and the National Health Services Corps Scholarship Program. The

Department publishes this rate in the FEDERAL REGISTER quarterly.

(3) Unless prescribed by statute or contract, the rate of interest, as initially charged, shall remain fixed for the duration of the indebtedness. When a debtor defaults on a repayment agreement and seeks to enter into a new agreement, the Department may require payment of interest at a new rate that reflects the Treasury rate in effect at the time the new agreement is executed. Interest shall not be compounded, that is, interest shall not be charged on interest, penalties, or administrative costs required by this section, unless prescribed by statute or contract. If, however, the debtor defaults on a previous repayment agreement, charges that accrued but were not collected under the defaulted agreement shall be added to the principal under the new repayment agreement.

(c) *Administrative costs.* The Department shall assess administrative costs incurred for processing and handling delinquent debts. The calculation of administrative costs should be based on actual costs incurred or a valid estimate of the actual costs. Calculation of administrative costs shall include all direct (personnel, supplies, etc.) and indirect collection costs, including the cost of providing a hearing or any other form of administrative review requested by a debtor, and any costs charged by a collection agency under § 30.14. These charges will be assessed monthly, or per payment period, throughout the period that the debt is overdue. Such costs may also be in addition to other administrative costs if collection is being made for another Federal agency or unit.

(d) *Penalty.* Unless otherwise established by contract, repayment agreement, or statute, the Secretary will charge a penalty of six percent a year on the amount due on a debt that is delinquent for more than 90 days. This charge shall accrue from the date of delinquency.

(e) *Cost of living adjustment.* When there is a legitimate reason to do so, such as when calculating interest and penalties on a debt would be extremely difficult because of the age of the debt,

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an administrative debt may be increased by the cost of living adjustment in lieu of charging interest and penalties under this section. Administrative debt includes, but is not limited to, a debt based on fines, penalties, and overpayments, but does not include a debt based on the extension of Government credit, such as those arising from loans and loan guaranties. The cost of living adjustment is the percentage by which the Consumer Price Index for the month of June of the calendar year preceding the adjustment exceeds the Consumer Price Index for the month of June of the calendar year in which the debt was determined or last adjusted. Such increases to administrative debts shall be computed annually.

(f) *Priority.* When a debt is paid in partial or installment payments, amounts received shall be applied first to outstanding penalties, second to administrative charges, third to interest, and last to principal.

(g) *Waiver.* (1) The Secretary shall waive the collection of interest and administrative charges imposed pursuant to this section on the portion of the debt that is paid within 30 days after the date on which interest began to accrue. The Secretary may extend this 30-day period on a case-by-case basis if the Secretary determines that such action is in the best interest of the Government, or otherwise warranted by equity and good conscience.

(2) The Secretary also may waive interest, penalties, and administrative charges charged under this section, in whole or in part, without regard to the amount of the debt, based on:

(i) The criteria set forth at § 30.22(a)(1) through (4) for the compromise of debts; or

(ii) A determination by the Secretary that collection of these charges is:

(A) Against equity and good conscience; or

(B) Not in the best interest of the United States.

(h) *Review.* (1) Except as provided in paragraph (h)(2) of this section, administrative review of a debt will not suspend the assessment of interest, penalties, and administrative costs. While agency review of a debt is pending, the debtor either may pay the debt or be liable for interest and related charges

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on the uncollected debt. When agency review results in a final determination that any amount was properly a debt and the debtor chose to retain the amount in dispute, the Secretary shall collect from the debtor the amount determined to be due, plus interest, penalties and administrative costs on such debt amount, as calculated under this section, starting from the date the debtor was first made aware of the debt and ending when the debt is repaid.

(2) *Exception.* Interest, penalties, and administrative cost charges will not be imposed on a debt for periods during which collection activity has been suspended under § 30.29(c)(1) pending agency review or consideration of waiver if statute prohibits collection of the debt during this period.

(i) *Common law or other statutory authority.* The Department may impose and waive interest and related charges on debts not subject to 31 U.S.C. 3717 in accordance with the common law or other statutory authority.

§ 30.19 Review of cost effectiveness of collection.

Periodically, the Secretary will compare costs incurred and amounts collected. Data on costs and corresponding recovery rates for debts of different types and in various dollar ranges will be used to compare the cost effectiveness of alternative collection techniques, establish guidelines with respect to points at which costs of further collection efforts are likely to exceed recoveries, assist in evaluating offers in compromise, and establish minimum debt amounts below which collection efforts need not be taken.

§ 30.20 Taxpayer information.

(a) When attempting to locate a debtor in order to collect or compromise a debt under this part or any other authority, the Secretary may send a request to Treasury in accordance with 31 CFR 901.11 to obtain a debtor's mailing address from the records of the IRS.

(b) Mailing addresses obtained under paragraph (a) of this section may be used to enforce collection of a delinquent debt and may be disclosed to other agencies and to collection agencies for collection purposes.

Subpart C—Debt Compromise**§ 30.21 Scope and application.**

(a) *Scope.* The standards set forth in this subpart apply to the compromise of debts pursuant to 31 U.S.C. 3711. The Secretary may exercise such compromise authority for debts arising out of activities of, or referred or transferred for collection services to, the Department when the amount of the debt then due, exclusive of interest, penalties, and administrative costs, does not exceed \$100,000, or any higher amount authorized by the Attorney General.

(b) *Application.* Unless otherwise provided by law, when the principal balance of a debt, exclusive of interest, penalties, and administrative costs, exceeds \$100,000 or any higher amount authorized by the Attorney General, the authority to accept a compromise rests with Justice. The Secretary shall evaluate the compromise offer, using the factors set forth in this subpart. If an offer to compromise any debt in excess of \$100,000 is acceptable to the Department, the Secretary shall refer the debt to the Civil Division or other appropriate litigating division in Justice using a Claims Collection Litigation Report (CCLR), which may be obtained from Justice's National Central Intake Facility. The referral shall include appropriate financial information and a recommendation for the acceptance of the compromise offer. Justice approval is not required if the Secretary rejects a compromise offer.

§ 30.22 Bases for compromise.

(a) *Compromise.* The Secretary may compromise a debt if the full amount cannot be collected based upon inability to pay, inability to collect the full debt, cost of collection, or doubt debt can be proven in court.

(1) *Inability to pay.* The debtor is unable to pay the full amount in a reasonable time, as verified through credit reports or other financial information. In determining a debtor's inability to pay the full amount of the debt within a reasonable time, the Secretary will obtain and verify the debtor's claim of inability to pay by using credit reports or a current financial Statement from the debtor, executed under penalty of

perjury, showing the debtor's assets, liabilities, income, and expenses. The Secretary may use a Departmental financial information form or may request suitable forms from Justice or the local United States Attorney's Office. The Secretary also may consider other relevant factors such as:

- (i) Age and health of the debtor;
- (ii) Present and potential income;
- (iii) Inheritance prospects;
- (iv) The possibility that assets have been concealed or improperly transferred by the debtor; and
- (v) The availability of assets or income that may be realized by enforced collection proceedings.

(2) *Inability to collect full debt.* The Government is unable to collect the debt in full within a reasonable time by enforced collection proceedings.

(i) In determining the Government's ability to enforce collection, the Secretary will consider the applicable exemptions available to the debtor under State and Federal law, and may also consider uncertainty as to the price the collateral or other property will bring at a forced sale.

(ii) A compromise effected under this section should be for an amount that bears a reasonable relation to the amount that can be recovered by enforced collection procedures, with regard to the exemptions available to the debtor and the time that collection will take.

(3) *Cost of collection.* The cost of collecting the debt does not justify the enforced collection of the full amount.

(i) The Secretary may compromise a debt if the cost of collecting the debt does not justify the enforced collection of the full amount. The amount accepted in compromise of such cases may reflect an appropriate discount for the administrative and litigation costs of collection, with consideration given to the time it will take to effect collection. Collection costs may be a substantial factor in the settlement of small debts.

(ii) In determining whether the costs of collection justify enforced collection of the full amount, the Secretary will consider whether continued collection

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of the debt, regardless of cost, is necessary to further an enforcement principal, such as the Government's willingness to pursue aggressively defaulting and uncooperative debtors.

(4) *Doubt debt can be proven in court.* There is significant doubt concerning the Government's ability to prove its case in court.

(i) If there is significant doubt concerning the Government's ability to prove its case in court for the full amount claimed, either because of the legal issues involved or because of a bona fide dispute as to the facts, then the amount accepted in compromise of such cases should fairly reflect the probabilities of successful prosecution to judgment, with due regard to the availability of witnesses and other evidentiary support for the Government's claim.

(ii) In determining the litigation risks involved, the Secretary will consider the probable amount of court costs and attorney fees pursuant to the Equal Access to Justice Act, 28 U.S.C. 2412, that may be imposed against the Government if it is unsuccessful in litigation.

(b) *Installments.* The Secretary generally will not accept compromises payable in installments. This is not an advantageous form of compromise in terms of time and administrative expense. If, however, payment of a compromise in installments is necessary, the Secretary shall, except in the case of compromises based on paragraph (a)(4) of this section, obtain a legally enforceable written agreement providing that, in the event of default, the full original principal balance of the debt prior to compromise, less sums paid thereon, is reinstated. The Office of the General Counsel should be consulted concerning the appropriateness of including such a requirement in the case of compromises based on paragraph (a)(4) of this section. Whenever possible, the Secretary will obtain security for repayment in the manner set forth in subpart B of this part.

§ 30.23 Enforcement policy.

The Secretary may compromise statutory penalties, forfeitures, or claims established as an aid to enforcement and to compel compliance if the De-

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partment's enforcement policy, in terms of deterrence and securing compliance, present and future, will be adequately served by the Secretary's acceptance of the sum to be agreed upon.

§ 30.24 Joint and several liability.

(a) When two or more debtors are jointly and severally liable, the Secretary will pursue collection against all debtors, as appropriate. The Secretary will not attempt to allocate the burden of payment between the debtors but will proceed to liquidate the indebtedness as quickly as possible.

(b) The Secretary will ensure that a compromise agreement with one debtor does not automatically release the Department's claim against the remaining debtor(s). The amount of a compromise with one debtor shall not be considered a precedent or binding in determining the amount that will be required from other debtors jointly and severally liable on the claim.

§ 30.25 Further review of compromise offers.

If the Secretary is uncertain whether to accept a firm, written, substantive compromise offer on a debt that is within the Secretary's delegated compromise authority, the Secretary may refer the offer to the Civil Division or other appropriate litigating division in Justice, using a CCLR accompanied by supporting data and particulars concerning the debt. Justice may act upon such an offer or return it to the Secretary with instructions or advice.

§ 30.26 Consideration of tax consequences to the Government.

In negotiating a compromise, the Secretary will consider the tax consequences to the Government. In particular, the Secretary will consider requiring a waiver of tax-loss-carry-forward and tax-loss-carry-back rights of the debtor. For information on discharge of indebtedness reporting requirements see § 30.32.

§ 30.27 Mutual release of the debtor and the Government.

In all appropriate instances, a compromise that is accepted by the Secretary will be implemented by means of a mutual release. The terms of such

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mutual release shall provide that the debtor is released from further non-tax liability on the compromised debt in consideration of payment in full of the compromise amount and the Government and its officials, past and present, are released and discharged from any and all claims and causes of action arising from the same transaction that the debtor may have. In the event a mutual release is not executed when a debt is compromised, unless prohibited by law, the debtor is still deemed to have waived any and all claims and causes of action against the Government and its officials related to the transaction giving rise to the compromised debt.

Subpart D—Suspending and Terminating Collection Activities

§ 30.28 Scope and application.

(a) *Scope.* The standards set forth in this subpart apply to the suspension or termination of collection activity pursuant to 31 U.S.C. 3711 on debts that do not exceed \$100,000, or such other amount as the Attorney General may direct, exclusive of interest, penalties, and administrative costs, after deducting the amount of partial payments or collections, if any. Prior to referring a debt to Justice for litigation, the Secretary may suspend or terminate collection under this subpart with respect to debts arising out of activities of, or referred or transferred for collection services to, the Department.

(b) *Application.* (1) If, after deducting the amount of partial payments or collections, the principal amount of the debt exceeds \$100,000, or such other amount as the Attorney General may direct, exclusive of interest, penalties, and administrative costs, the authority to suspend or terminate rests solely with Justice.

(2) If the Secretary believes that suspension or termination of any debt in excess of \$100,000 may be appropriate, the Secretary shall refer the debt to the Civil Division or other appropriate litigating division in Justice, using the CCLR. The referral will specify the reasons for the Secretary's recommendation. If, prior to referral to Justice, the Secretary determines that a debt is plainly erroneous or clearly without

merit, the Secretary may terminate collection activity regardless of the amount involved without obtaining Justice concurrence.

§ 30.29 Suspension of collection activity.

(a) *Generally.* The Secretary may suspend collection activity on a debt when:

(1) The Department cannot locate the debtor;

(2) The debtor's financial condition is expected to improve; or

(3) The debtor has requested a waiver or review of the debt.

(b) *Financial condition.* Based on the current financial condition of a debtor, the Secretary may suspend collection activity on a debt when the debtor's future prospects justify retention of the debt for periodic review and collection activity, and:

(1) The applicable statute of limitations has not expired;

(2) Future collection can be effected by administrative offset, notwithstanding the expiration of the applicable statute of limitations for litigation of claims, with due regard to the 10-year limitation for administrative offset prescribed by 31 U.S.C. 3716(e)(1); or

(3) The debtor agrees to pay interest on the amount of the debt on which collection will be suspended, and such suspension is likely to enhance the debtor's ability to pay the full amount of the principal of the debt with interest at a later date.

(c) *Waiver or review.* (1) The Secretary shall suspend collection activity during the time required for consideration of the debtor's request for waiver or administrative review of the debt if the statute under which the request is sought prohibits the Secretary from collecting the debt during that time.

(2) If the statute under which the waiver or administrative review request is sought does not prohibit collection activity pending consideration of the request, the Secretary may use discretion, on a case-by-case basis, to suspend collection. Collection action ordinarily will be suspended upon a request for waiver or review if the Secretary is prohibited by statute or regulation from issuing a refund of

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amounts collected prior to agency consideration of the debtor's request. However, collection will not be suspended when the Secretary determines that the request for waiver or review is frivolous or was made primarily to delay collection.

(d) *Bankruptcy*. Upon learning that a bankruptcy petition has been filed with respect to a debtor, in most cases the Secretary must suspend collection activity on the debt, pursuant to the provisions of 11 U.S.C. 362, 1201, and 1301, unless the Secretary can clearly establish that the automatic stay has been lifted or is no longer in effect. The Office of the General Counsel should be contacted immediately for legal advice, and the Secretary will take the necessary legal steps to ensure that no funds or money are paid by the Department to the debtor until relief from the automatic stay is obtained.

§ 30.30 Termination of collection activity.

(a) The Secretary may terminate collection activity when:

(1) The Department is unable to collect any substantial amount through its own efforts or through the efforts of others;

(2) The Department is unable to locate the debtor;

(3) Costs of collection are anticipated to exceed the amount recoverable;

(4) The debt is legally without merit or enforcement of the debt is barred by any applicable statute of limitations;

(5) The debt cannot be substantiated; or

(6) The debt against the debtor has been discharged in bankruptcy.

(b)(1) Collection activity will not be terminated before the Secretary has pursued all appropriate means of collection and determined, based upon the results of the collection activity, that the debt is uncollectible.

(2) Termination of collection activity ceases active collection of the debt. The termination of collection activity does not preclude the Secretary from retaining a record of the account for purposes of:

(i) Selling the debt, if the Secretary of the Treasury determines that such sale is in the best interest of the United States;

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(ii) Pursuing collection at a subsequent date in the event there is a change in the debtor's status or a new collection tool becomes available;

(iii) Offsetting against future income or assets not available at the time of termination of collection activity; or

(iv) Screening future applicants for prior indebtedness.

(c) Generally, the Secretary shall terminate collection activity on a debt that has been discharged in bankruptcy, regardless of the amount. The Secretary may continue collection activity, however, subject to the provisions of the Bankruptcy Code, for any payments provided under a plan of reorganization. Offset and recoupment rights may survive the discharge of the debtor in bankruptcy and, under some circumstances, claims also may survive the discharge. For example, when the Department is a known creditor of a debtor the claims of the Department may survive a discharge if the Department did not receive formal notice of the bankruptcy proceedings. When the Department believes that it has claims or offsets that may have survived the discharge of the debtor, the Office of the General Counsel should be contacted for legal advice.

§ 30.31 Exception to termination.

When a significant enforcement policy is involved, or recovery of a judgment is a prerequisite to the imposition of administrative sanctions, the Secretary may refer debts to Justice for litigation even though termination of collection activity may otherwise be appropriate.

§ 30.32 Discharge of indebtedness; reporting requirements.

(a)(1) Before discharging a delinquent debt, also referred to as close out of the debt, the Secretary shall take all appropriate steps to collect the debt in accordance with 31 U.S.C. 3711(g)(9), and parts 30 through 33 of this chapter, including, as applicable, administrative offset; tax refund offset; Federal salary offset; credit bureau reporting; administrative wage garnishment; litigation; foreclosure; and referral to Treasury, Treasury-designated debt collection centers, or private collection contractors.

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(2) Discharge of indebtedness is distinct from termination or suspension of collection activity under this subpart, and is governed by the Internal Revenue Code. When collection action on a debt is suspended or terminated, the debt remains delinquent and further collection action may be pursued at a later date in accordance with the standards set forth in this part and 31 CFR parts 900 through 904.

(3) When the Department discharges a debt in full or in part, further collection action is prohibited. Therefore, before discharging a debt, the Secretary must:

(i) Make the determination that collection action is no longer warranted; and

(ii) Terminate debt collection action.

(b) In accordance with 31 U.S.C. 3711(i), the Secretary shall use competitive procedures to sell a delinquent debt upon termination of collection action if the Secretary of the Treasury determines such a sale is in the best interests of the United States. Since the discharge of a debt precludes any further collection action, including the sale of a delinquent debt, the Secretary may not discharge a debt until the requirements of 31 U.S.C. 3711(i) have been met.

(c) Upon discharge of an indebtedness, the Secretary must report the discharge to the IRS in accordance with the requirements of 26 U.S.C. 6050P and 26 CFR 1.6050P-1. The Secretary may request that Treasury or Treasury-designated debt collection centers file such a discharge report to the IRS on the Department's behalf.

(d) When discharging a debt, the Secretary must request that litigation counsel release any liens of record securing the debt.

Subpart E—Referrals to the Department of Justice

§ 30.33 Prompt referral.

(a)(1) The Secretary promptly shall refer to Justice for litigation debts on which aggressive collection activity has been taken in accordance with subpart B of this part, and that cannot be compromised, or on which collection activity cannot be suspended or termi-

nated, in accordance with subpart D of this part.

(2) The Secretary may refer to Justice for litigation those debts arising out of activities of, or referred or transferred for collection services to, the Department.

(b)(1) Debts for which the principal amount is over \$1,000,000, or such other amount as the Attorney General may direct, exclusive of interest, penalties, and administrative costs shall be referred to the Civil Division or other division responsible for litigating such debts at the Department of Justice, Washington DC.

(2) Debts for which the principal amount is \$1,000,000 or less, or such other amount as the Attorney General may direct, exclusive of interest, penalties, and administrative costs shall be referred to the Nationwide Central Intake Facility at Justice as required by the CCLR instructions.

(c)(1) Consistent with aggressive agency collection activity and the standards contained in this part and 31 CFR parts 900 through 904, debts shall be referred to Justice as early as possible, and, in any event, well within the period for initiating timely lawsuits against the debtors.

(2) The Secretary shall make every effort to refer delinquent debts to Justice for litigation within one year of the date such debts last became delinquent. In the case of guaranteed or insured loans, the Secretary will make every effort to refer these delinquent debts to Justice for litigation within one year from the date the loan was presented to the Department for payment or re-insurance.

(d) Justice has exclusive jurisdiction over debts referred to it pursuant to this subpart. Upon referral of a debt to Justice, the Secretary shall:

(1) Immediately terminate the use of any administrative collection activities to collect the debt;

(2) Advise Justice of the collection activities utilized to date, and their result; and

(3) Refrain from having any contact with the debtor and direct all debtor inquiries concerning the debt to Justice.

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(e) After referral of a debt under this subpart, the Secretary shall immediately notify the Department of Justice of any payments credited by the Department to the debtor's account. Pursuant to 31 CFR 904.1(b), after referral of the debt under this subpart, Justice shall notify the Secretary of any payment received from the debtor.

§ 30.34 Claims Collection Litigation Report.

(a)(1) Unless excepted by Justice, the Secretary will complete the CCLR, accompanied by a signed Certificate of Indebtedness, to refer all administratively uncollectible claims to the Department of Justice for litigation.

(2) The Secretary shall complete all of the sections of the CCLR appropriate to each debt as required by the CCLR instructions, and furnish such other information as may be required in specific cases.

(b) The Secretary shall indicate clearly on the CCLR the actions that the Department wishes Justice to take with respect to the referred debt. The Secretary may indicate specifically any of a number of litigation activities which Justice may pursue, including enforced collection, judgement lien only, renew judgement lien only, renew judgement lien and enforced collection, program enforcement, foreclosure only, and foreclosure and deficiency judgment.

(c) The Secretary also shall use the CCLR to refer a debt to Justice for the purpose of obtaining approval of a proposal to compromise the debt, or to suspend or terminate administrative collection activity of the debt.

§ 30.35 Preservation of evidence.

The Secretary will maintain and preserve all files and records that may be needed by Justice to prove the Department's claim in court. When referring debts to Justice for litigation, certified copies of the documents that form the basis for the claim should be provided along with the CCLR. Upon its request, the original documents will be provided to Justice.

§ 30.36 Minimum amount of referrals.

(a) Except as in paragraph (b) of this section, claims of less than \$2,500 ex-

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clusive of interest, penalties, and administrative costs, or such other amount as the Attorney General may prescribe, shall not be referred for litigation.

(b) The Secretary shall not refer claims of less than the minimum amount unless:

(1) Litigation to collect such smaller amount is important to ensure compliance with the policies and programs of the Department;

(2) The claim is being referred solely for the purpose of securing a judgment against the debtor, which will be filed as a lien against the debtor's property pursuant to 28 U.S.C. 3201 and returned to the Department for enforcement; or

(3) The debtor has the clear ability to pay the claim and the Government effectively can enforce payment, with due regard for the exemptions available to the debtor under State and Federal law and the judicial remedies available to the Government.

(c) The Secretary should consult with the Financial Litigation Staff of the Executive Office for United States Attorneys in Justice prior to referring claims valued at less than the minimum amount.

PART 31—TAX REFUND OFFSET

Sec.

31.1 Purpose and scope.

31.2 Definitions.

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31.7 Review of a determination that a debt is past-due and legally enforceable.

AUTHORITY: 31 U.S.C. 3720A, 31 CFR 285.2, E.O. 12866, E.O. 13258.

SOURCE: 68 FR 70445, Dec. 18, 2003, unless otherwise noted.

§ 31.1 Purpose and scope.

(a) *Purpose.* This part prescribes the Department's standards and procedures for submitting past-due, legally enforceable debts to the Department of the Treasury for collection by tax refund offset.

(b) *Authority.* These standards and procedures are authorized under the tax refund offset provision of the Deficit Reduction Act of 1984, as amended

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by the Debt Collection Improvement Act of 1996, codified at 31 U.S.C. 3720A, and the implementing regulations issued by the Department of the Treasury at 31 CFR 285.2.

(c) *Scope.* (1) This part applies to all Departmental Operating Divisions and Regional Offices that administer a program that gives rise to a past-due non-tax debt owed to the United States, and to all officers or employees of the Department authorized to collect such debt. This part does not apply to any debt or claim owed to the Department of Health and Human Services by another Federal agency.

(2) Nothing in this part precludes the Department from pursuing other debt collection procedures, including administrative wage garnishment under part 32 of this title, to collect a debt that has been submitted to the Department of the Treasury under this part. The Department may use such debt collection procedures separately or in conjunction with the offset collection procedures of this part.

§31.2 Definitions.

In this part, unless the context otherwise requires:

Administrative offset means withholding funds payable by the United States (including funds payable by the United States on behalf of a State government) to, or held by the United States for, a person to satisfy a claim.

Day means calendar day. For purposes of computation, the last day of the period will be included unless it is a Saturday, Sunday, or a Federal legal holiday, in which case the next business day will be considered the last day of the period.

Debt or *claim* means an amount of money, funds, or other property determined by an appropriate official to be owed to the United States from any individual, entity, organization, association, partnership, corporation, or State or local government or subdivision, except another Federal agency.

Debtor means an individual, organization, association, partnership, corporation, or State or local government or subdivision indebted to the Government, or the person or entity with legal responsibility for assuming the debtor's obligation.

Department means the Department of Health and Human Services, and each of its Operating Divisions and regional offices.

Evidence of service means information retained by the Department indicating the nature of the document to which it pertains, the date of mailing of the document, and the address and name of the debtor to whom it is being sent. A copy of the dated and signed written notice of intent to offset provided to the debtor pursuant to this part may be considered evidence of service for purposes of this regulation. Evidence of service may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

FMS means the Financial Management Service, a bureau within the Department of the Treasury.

IRS means the Internal Revenue Service, a bureau of the Department of the Treasury.

Legally enforceable means that there has been a final agency determination that the debt, in the amount stated, is due and there are no legal bars to collection action.

Operating division means each separate component, within the Department of Health and Human Services, including, but not limited to, the Administration for Children and Families, Administration on Aging, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, the National Institutes of Health, and the Office of the Secretary.

Past-due debt means a debt which the debtor does not pay or otherwise resolve by the date specified in the initial demand for payment, or in an applicable written repayment agreement or other instrument, including a post-delinquency repayment agreement.

Secretary means the Secretary of the Department of Health and Human Services, or the Secretary's designee within any Operating Division or Regional Office.

Taxpayer identifying number means the identifying number described under section 6109 of the Internal Revenue Code of 1986 (26 U.S.C. 6109). For an individual, the taxpayer identifying

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number is the individual's social security number.

Tax refund offset means withholding or reducing a tax refund payment by an amount necessary to satisfy a debt owed to the United States by the payee(s) of a tax refund payment.

Tax refund payment means any overpayment of Federal taxes to be refunded to the person making the overpayment after the IRS makes the appropriate credits as provided in 26 U.S.C. 6402 for any liabilities for any tax on the part of the person who made the overpayment.

§ 31.3 General rule.

(a) Any past-due, legally enforceable debt of at least \$25, or such other minimum amount as determined by the Secretary of the Treasury, shall be submitted to FMS for collection by tax refund offset.

(b) FMS will compare tax refund payment records, as certified by the IRS, with records of debts submitted by the Department under this part. A match will occur when the taxpayer identification number and name of a payment certification record are the same as the taxpayer identifying number and name control of a debtor record. When a match occurs and all other requirements for tax refund offset have been met, FMS will reduce the amount of any tax refund payment payable to a debtor by the amount of any past-due legally enforceable debt. Any amounts not offset will be paid to the payee(s) listed in the payment certification record.

§ 31.4 Certification and referral of debt.

(a) *Certification.* The Secretary shall certify to FMS that:

(1) The debt is past-due and legally enforceable in the amount submitted and that the Department will ensure that collections are properly credited to the debt;

(2) Except in the case of a judgment debt or as otherwise allowed by law, the debt is referred within ten (10) years after the Department's right of action accrues;

(3) The Department has made reasonable efforts to obtain payment of the debt, and has:

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(i) Submitted the debt to FMS for collection by offset and complied with the administrative offset provision of 31 U.S.C. 3716(a) and related regulations, to the extent that collection by administrative offset is not prohibited by statute;

(ii) Notified, or made a reasonable attempt to notify, the debtor that the debt is past-due, and unless paid within 60 days of the date of the notice, the debt may be referred to Treasury for tax refund offset. For purposes of this regulation, the Department has made a reasonable attempt to notify the debtor if the agency uses the current address information contained in the Department's records related to the debt. If address validation is desired or necessary, the Department may obtain information from the IRS pursuant to 26 U.S.C. 6103(m)(2)(4) or (5).

(iii) Given the debtor at least 60 days to present evidence that all or part of the debt is not past-due or not legally enforceable, considered any evidence presented by the debtor, and determined that the debt is past-due and legally enforceable; and

(iv) Provided the debtor with an opportunity to make a written agreement to repay the debt; and

(4) The debt is at least \$25.

(b) *Referral.* (1) The Secretary shall submit past-due, legally enforceable debt information for tax refund offset in the time and manner prescribed by the Department of the Treasury.

(2) For each debt referred under this part, the Secretary will include the following information:

(i) The name and taxpayer identifying number, as defined in 26 U.S.C. 6109, of the debtor responsible for the debt;

(ii) The amount of such past-due and legally enforceable debt;

(iii) The date on which the debt became past-due; and

(iv) The designation of the Department referring the debt.

(c) *Correcting and updating referral.* (1) After referring a debt under this part, the Secretary shall promptly notify the Department of the Treasury if:

(i) An error was made with respect to information transmitted to the Department of the Treasury;

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(ii) The Department receives a payment or credits a payment to the account of a debtor referred for tax refund offset; or

(iii) The debt amount is otherwise incorrect.

(2) The Department shall provide the certification required under paragraph (a) of this section for any increases to amounts owed.

(d) *Rejection of certification.* If the Department of Treasury rejects a certification because it does not comply with the requirements of paragraph (a) of this section, upon notification of the rejection and the reason(s) for rejection, the Secretary will resubmit the debt with a corrected certification.

§31.5 Notice.

(a) *Requirements.* If not previously included in the initial demand letter provided under section 30.11, at least 60 days before referring a debt for tax refund offset, the Secretary shall mail, by first class mail to the debtor's last known address, written notice informing the debtor of:

(1) The nature and amount of the debt;

(2) The determination that the debt is past-due and legally enforceable, and unless paid within 60 days after the date of the notice, the Secretary intends to enforce collection by referring the debt the Department of the Treasury for tax refund offset; and

(3) The debtor's rights to:

(i) Inspect and copy Department records relating to the debt;

(ii) Enter into written agreement to repay the amount of the debt;

(iii) Request review and present evidence that all or part of the debt is not past-due or not legally enforceable.

(b) The Secretary will retain evidence of service indicating the date of mailing of the notice. The notice may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes

§31.6 Review of Departmental records.

(a) To inspect or copy Departmental records relating to the debt, the debtor must send a written request to the address designated in the notice described in section 31.5. The request must be re-

ceived by the Department within 60 days from the date of the notice.

(b) In response to a timely request as described in paragraph (a) of this section, the designated Department official shall notify the debtor of the location and time when the debtor may inspect and copy such records. If the debtor is unable to personally inspect such records as the result of geographical or other constraints, the Department will arrange to send copies of the records to the debtor.

§31.7 Review of a determination that a debt is past-due and legally enforceable.

(a) *Requesting a review.* (1) If the debtor believes that all or part of the debt is not past-due or not legally enforceable, the debtor may request a review by the Department by sending a written request to the address provided in the notice. The written request must be received by the Department within 60 days from the date of the notice or, if the debtor has requested to inspect the records, within 30 days from the debtor's inspection of the records or the Department's mailing of the records under section 31.6(b), whichever is later.

(2) The request for review must be signed by the debtor, state the amount disputed, and fully identify and explain the evidence that the debtor believes supports the debtor's position. The debtor must submit with the request any documents that the debtor wishes to be considered, or the debtor must state in the request that additional information will be submitted within the above specified time period.

(3) Failure to timely request a review will be deemed an admission by the debtor that the debt is past-due and legally enforceable, and will result in a referral of the debt to the Department of the Treasury without further action.

(b) *Review.* Upon the timely submission of evidence by the debtor, the Department shall review the dispute and shall consider its records and any documentation and evidence submitted by the debtor. The Department shall make a determination based on the review of the written record, and shall send a written notice of its decision to the

debtor. There is no administrative appeal of this decision.

(c) A debt that previously has been reviewed pursuant to this part, or that has been reduced to a judgment, will not be reconsidered under this part unless the evidence presented by the debtor disputes payments made or events occurring subsequent to the previous review or judgment.

PART 32—ADMINISTRATIVE WAGE GARNISHMENT

Sec.

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AUTHORITY: 31 U.S.C. 3720D, 5 U.S.C. 552, 553, E.O. 12866, 12988, 13808.

SOURCE: 68 FR 15093, Mar. 28, 2003, unless otherwise noted.

§ 32.1 Purpose and scope.

(a) *Purpose.* This part prescribes the standards and procedures for the Department to collect money from a debtor's disposable pay by means of administrative wage garnishment to satisfy delinquent non-tax debts owed to the United States.

(b) *Authority.* These standards and procedures are authorized under the wage garnishment provisions of the Debt Collection Improvement Act of 1996, codified at 31 U.S.C. 3720D, and the Department of the Treasury Administrative Wage Garnishment Regulations at 31 CFR 285.11.

(c) *Scope.* (1) This part applies to all Departmental Operating Divisions and Regional Offices that administer a program that gives rise to a delinquent non-tax debt owed to the United States and to all officers or employees of the Department authorized to collect such debt.

(2) This part shall apply notwithstanding any provision of State law.

(3) Nothing in this part precludes the compromise of a debt or the suspension

or termination of collection action in accordance with part 30 of this title, or other applicable law or regulation.

(4) The receipt of payments pursuant to this part does not preclude the Department from pursuing other debt collection remedies, including the offset of Federal payments to satisfy delinquent non-tax debt owed to the United States. The Department may pursue such debt collection remedies separately or in conjunction with administrative wage garnishment.

(5) This part does not apply to the collection of delinquent non-tax debts owed to the United States from the wages of Federal employees from their Federal employment. Federal pay is subject to the Federal salary offset procedures set forth in 5 U.S.C. 5514 and other applicable laws.

(6) Nothing in this part requires the Department to duplicate notices or administrative proceedings required by contract or other laws or regulations.

§ 32.2 Definitions.

In this part, unless the context otherwise requires:

Business day means Monday through Friday. For purposes of computation, the last day of the period will be included unless it is a Federal legal holiday, in which case the next business day following the holiday will be considered the last day of the period.

Certificate of service means a certificate signed by an employee of the Department indicating the nature of the document to which it pertains, the date of mailing of the document, and to whom it is being sent.

Day means calendar day. For purposes of computation, the last day of the period will be included unless it is a Saturday, Sunday, or a Federal legal holiday, in which case the next business day will be considered the last day of the period.

Debt or claim means an amount of money, funds, or property that has been determined by the Secretary to be owed to the United States by an individual, including debt administered by a third party as an agent of the Federal Government. A debt or claim includes, but is not limited to: amounts owed on

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account of loans made, insured or guaranteed by the Federal Government, including any deficiency or difference between the price obtained by the Federal Government upon selling the property and the amount owed to the Federal Government; overpayments to program beneficiaries; any amount the Federal Government is authorized by statute to collect for the benefit of any person; the unpaid share of any non-Federal partner in a program involving a Federal payment, including a matching or cost-sharing payment of the non-Federal partner; any fine, civil penalty or assessment; and other amounts or money or property owed to the Federal Government.

Debtor means an individual who owes a delinquent non-tax debt to the United States.

Delinquent debt means any non-tax debt that has not been paid by the date specified in the Department's initial written demand for payment, or applicable payment agreement or instrument, unless other satisfactory payment arrangements have been made. For purposes of this part, "delinquent" and "overdue" have the same meaning.

Department means the United States Department of Health and Human Services, including each of its Operating Divisions and Regional Offices.

Disposable pay means that part of the debtor's compensation (including, but not limited to, salary, bonuses, commissions, and vacation pay) from an employer remaining after the deduction of health insurance premiums and any amounts required by law to be withheld. For purposes of this part, "amounts required by law to be withheld" include amounts for deductions such as social security taxes and withholding taxes, but do not include any amount withheld pursuant to a court order.

Employer means a person or entity that employs the services of others and that pays their wages or salaries. The term employer includes, but is not limited to, State and local Governments, but does not include an agency of the Federal Government as defined by 31 CFR 285.11(c).

Garnishment means the process of withholding amounts from an employee's disposable pay and paying those

amounts to a creditor in satisfaction of a withholding order.

Hearing means a review of the documentary evidence concerning the existence or amount of a debt, or the terms of a repayment schedule, provided such repayment schedule is established other than by a written agreement entered into pursuant to this part. If the hearing official determines that the issues in dispute cannot be resolved solely by review of the written record, such as when the validity of the debt turns on the issue of credibility or veracity, an oral hearing may be provided.

Hearing official means any qualified individual, as determined by the Secretary, including a Departmental Appeals Board administrative law judge.

Secretary means the Secretary of Health and Human Services, or the Secretary's designee within the Department.

Withholding order for purposes of this part means "Wage Garnishment Order (SF329B)." Also for purposes of this part, the terms "wage garnishment order" and "garnishment order" have the same meaning as "withholding order."

§ 32.3 General rule.

(a) Except as provided in paragraph (b) of this section, whenever a delinquent debt is owed by an individual, the Secretary, or another federal agency collecting a debt on the Department's behalf (*See* 45 CFR part 30), may initiate proceedings administratively to garnish the wages of the delinquent debtor.

(b) The Secretary may not garnish the wages of a debtor who the Secretary knows has been involuntarily separated from employment until the debtor has been re-employed continuously for at least 12 months. The debtor has the burden of informing the Secretary of the circumstances surrounding an involuntary separation from employment.

§ 32.4 Notice.

(a) Notice requirements. At least 30 days before the initiation of garnishment proceedings, the Secretary shall

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mail, by first class mail, to the debtor's last known address a written notice informing the debtor of:

(1) The nature and amount of the debt;

(2) The intention of the Secretary to initiate proceedings to collect the debt through deductions from pay until the debt and all accumulated interest, penalties, and administrative costs are paid in full;

(3) The debtor's right—

(i) To inspect and copy Department records related to the debt;

(ii) To enter into a written repayment agreement with the Department under terms agreeable to the Department;

(iii) To a hearing, in accordance with § 32.5, concerning the existence or the amount of the debt or the terms of the proposed repayment schedule under the garnishment order, except that the debtor is not entitled to a hearing concerning the proposed repayment schedule if the terms were established by written agreement pursuant to paragraph (a)(3)(ii) of this section; and

(4) The time frames within which the debtor may exercise his or her rights.

(b) The Secretary will keep a copy of the dated notice. The notice may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

§ 32.5 Hearing.

(a) *In general.* Upon timely written request of the debtor, the Secretary shall provide a hearing, which at the Department's option may be oral or written, concerning the existence or amount of the debt, or the terms of a repayment schedule established other than by written agreement under § 32.4(a)(3)(ii).

(b) *Request for hearing.* (1) The request for a hearing must be signed by the debtor, state each issue being disputed, and identify and explain with reasonable specificity all facts and evidence that the debtor believes supports the debtor's position. Supporting documentation identified by the debtor should be attached to the request.

(2) *Effect of timely request.* Subject to paragraph (j) of this section, if the debtor's written request is received on or before the 15th business day fol-

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lowing the mailing of the written notice required under this part, a withholding order shall not be issued under § 32.6 until the debtor has been provided the requested hearing and a decision in accordance with paragraphs (g) and (h) of this section has been rendered.

(3) *Failure to timely request a hearing.* If the debtor's written request is received after the 15th business day following the mailing of the written notice required under this part, the Secretary shall provide a hearing to the debtor. However, the Secretary shall not delay the issuance of a withholding order unless the Secretary determines that the delay in submitting such request was caused by factors beyond the control of the debtor, or the Secretary receives information that the Secretary determines justifies a delay or cancellation of the withholding order.

(c) *Oral hearing.* (1) For purposes of this section, a debtor shall be provided a reasonable opportunity for an oral hearing when the hearing official determines that the issues in dispute cannot be resolved by review of the documentary evidence, such as when the validity of the claim turns on the issue of credibility or veracity.

(2) If the hearing official determines an oral hearing is appropriate, the hearing official will establish the date, time and location of the hearing. At the debtor's option, the oral hearing may be conducted in person or by telephone conference. The hearing official will notify the debtor of the date, time, and in the case of an in-person hearing, the location of the hearing. All travel expenses incurred by the debtor in connection with an in-person hearing will be borne by the debtor.

(d) *Paper hearing.* (1) If the hearing official determines an oral hearing is not required by this section, the hearing official shall afford the debtor a paper hearing, that is, the issues in dispute will be decided based upon a review of the written record.

(2) The hearing official shall notify the debtor of the deadline for the submission of additional evidence if necessary for a review of the record.

(e) *Burden of proof.* (1) The Secretary has the initial burden of proving the existence or amount of the debt.

(2) Thereafter, if the debtor disputes the existence or amount of the debt, the debtor must present by a preponderance of the evidence that no debt exists or that the amount is incorrect. When challenging the terms of a repayment schedule, the debtor must establish by a preponderance of the evidence that the terms of the repayment schedule are unlawful, would cause financial hardship to the debtor, or that collection of the debt may not be pursued due to operation of law.

(f) *Record.* The hearing official shall maintain a summary record of any hearing provided under this part. A hearing is not required to be a formal evidentiary-type hearing, but witnesses who testify in an oral hearing must do so under oath or affirmation.

(g) *Date of decision.* (1) The hearing official shall issue a written decision, as soon as practicable, but no later than sixty (60) days after the date on which the request for the hearing was received by the Department.

(2) If the hearing official is unable to provide the debtor with a hearing and render a decision within 60 days after the receipt of the request for such hearing:

(i) A withholding order may not be issued until the hearing is held and a decision is rendered; or

(ii) A withholding order previously issued to the debtor's employer must be suspended beginning on the 61st day after the receipt of the hearing request and continuing until a hearing is held and a decision is rendered.

(h) *Content of decision.* The written decision shall include:

(1) A summary of the facts presented;

(2) The hearing official's findings, analysis, and conclusions; and

(3) The terms of any repayment schedule, if applicable.

(i) *Final agency action.* The hearing official's decision will be the final agency action for the purposes of judicial review under the Administrative Procedure Act, 5 U.S.C. 701 *et seq.*

(j) *Failure to appear.* In the absence of good cause shown, a debtor who fails to appear at a hearing will be deemed as not having timely filed a request for a hearing.

§ 32.6 Withholding order.

(a) Unless the Secretary receives information that the Secretary determines justifies a delay or cancellation of a withholding order, the Secretary shall send, by first class mail, an SF-329A "Letter to Employer & Important Notice to Employer," an SF-329B "Wage Garnishment Order," an SF-329C "Wage Garnishment Worksheet," and an SF-329D "Employer Certification," to the debtor's employer within 30 days after the debtor fails to make a timely request for a hearing, *i.e.*, within 15 business days after mailing the notice required under this part, or, if the timely request for a hearing is made by the debtor, within 30 days after a final decision is made by the Secretary to proceed with garnishment.

(b) The Secretary shall keep a copy of the dated letter to the employer and a copy of the wage garnishment order. The certificate of service may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

§ 32.7 Certification by employer.

The employer must complete and return the SF-329D, "Employer Certification" to the Department within 20 days of receipt.

§ 32.8 Amounts withheld.

(a) After receipt of a withholding order issued under this part, the employer shall deduct from all disposable pay paid to the debtor during each pay period the amount of garnishment described in paragraph (b) of this section. The employer may use the SF-329C "Wage Garnishment Worksheet" to calculate the amount to be deducted from the debtor's disposable pay.

(b) Subject to paragraphs (c) and (d) of this section, the amount of garnishment shall be the lesser of:

(1) The amount indicated on the garnishment order up to 15% of the debtor's disposable pay; or

(2) The amount set forth in 15 U.S.C. 1673(a)(2) (Maximum allowable garnishment). The amount set forth at 15 U.S.C. 1673(a)(2) is the amount by which a debtor's disposable pay exceeds an amount equivalent to thirty times the minimum wage. *See* 29 CFR 870.10.

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(c)(1) Except as provided in paragraph (c)(2) of this section, when a debtor's pay is subject to multiple withholding orders, unless otherwise provided by Federal law, withholding orders issued pursuant to this part shall have priority over other withholding orders that are served later in time.

(2) Notwithstanding the foregoing, withholding orders for family support shall have priority over withholding orders issued under this part.

(3) If amounts are being withheld from a debtor's pay pursuant to a withholding order served on an employer before a withholding order issued pursuant to this part, or if a withholding order for family support is served on an employer at any time, the amounts withheld pursuant to a withholding order issued under this part shall be the lesser of:

(i) The amount calculated under paragraph (b) of this section, or

(ii) An amount equal to 25% of the debtor's disposable pay less the amount(s) withheld under the withholding order(s) with priority.

(d) If the debtor owes more than one debt to the Department, the Secretary may issue multiple withholding orders provided that the total amount garnished from the debtor's pay for such orders does not exceed the amount set forth in paragraph (b) of this section.

(e) An amount greater than that set forth in paragraphs (b) or (c) of this section may be withheld upon the written consent of the debtor.

(f) The employer shall promptly pay to the Department all amounts withheld in accordance with the withholding order issued pursuant to this part.

(g) The employer is not required to vary its normal pay and disbursement cycles in order to comply with the withholding order.

(h) Any assignment or allotment by an employee shall be void to the extent it interferes with or prohibits execution of the withholding order issued under this part, except for any assignment or allotment made pursuant to a family support judgment or order.

(i) The employer shall withhold the appropriate amount from the debtor's wages for each pay period until the employer receives notification from the

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Secretary to discontinue wage withholding.

(j) The withholding order, SF-329B "Wage Garnishment Order," sent to the employer under § 32.6, requires the employer to commence wage withholding on the first pay day after the employer receives the order. However, if the first pay day is within 10 days after receipt of the order, the employer may begin deductions on the second pay day.

(k) An employer may not discharge, refuse to employ, or take disciplinary action against any debtor as a result of the issuance of a withholding order under this part.

[68 FR 15093, Mar. 28, 2003; 68 FR 24052, May 6, 2003]

§ 32.9 Financial hardship.

(a) A debtor whose wages are subject to a withholding order may, at any time, request a review by the Department of the amount garnished, based on materially changed circumstances such as disability, divorce, or catastrophic illness which result in financial hardship.

(b) A debtor requesting such a review under paragraph (a) of this section shall submit the basis for claiming that the current amount of garnishment results in a financial hardship to the debtor, along with supporting documentation. The Secretary shall consider any information submitted in accordance with this part.

(c) If a financial hardship is found, the Secretary shall downwardly adjust, by an amount and for a period of time established by the Secretary, the amount garnished to reflect the debtor's financial condition. The Secretary will notify the employer of any adjustments to the amount to be withheld.

§ 32.10 Refunds.

(a) If the hearing official, pursuant to a hearing under this part, determines that a debt is not legally due and owing to the United States, the Secretary shall promptly refund any amount collected by means of administrative wage garnishment.

(b) Unless required by Federal law or contract, refunds under this part shall not bear interest.

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§ 32.11 Ending garnishment.

(a) Once the Department has fully recovered the amounts owed by the debtor, including interest, penalties, and administrative costs assessed pursuant to and in accordance with part 30 of this title, the Secretary shall send the debtor's employer notification to discontinue wage withholding.

(b) At least annually, the Secretary shall review its debtors' accounts to ensure that garnishment has been terminated for accounts that have been paid in full.

§ 32.12 Right of action.

(a) The employer of a debtor subject to wage withholding pursuant to this part shall pay to the Department as directed in a withholding order issued under this part.

(b) The Secretary may bring suit against an employer for any amount that the employer fails to withhold from wages owed and payable to a debtor in accordance with §§32.6 and 32.8, plus attorney's fees, costs, and, if applicable, punitive damages.

(c) A suit under this section may not be filed before the termination of the collection action involving a particular debtor, unless earlier filing is necessary to avoid expiration of any applicable statute of limitations period. For purposes of this section, "termination of collection action" occurs when the Secretary has terminated collection action in accordance with part 30 of this title, or other applicable law or regulation.

(d) Notwithstanding deemed to occur if from a debtor whose paragraph (c) of this section, termination of the collection action will be a period of one (1) year the Department does not receive any payments wages were subject to a garnishment order issued under this part.

PART 33—SALARY OFFSET

Sec.

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AUTHORITY: 5 U.S.C. 5514; 5 CFR Part 550, Subpart K.

SOURCE: 72 FR 10421, Mar. 8, 2007, unless otherwise noted.

§ 33.1 Purpose, authority, and scope.

(a) *Purpose.* This part prescribes the Department's standards and procedures for the collection of debts owed by Federal employees to the United States through involuntary salary offset.

(b) *Authority.* 5 U.S.C. 5514; 5 CFR part 550, subpart K.

(c) *Scope.* (1) This part applies to internal and Government-wide collections of debts owed by Federal employees by administrative offset from the current pay account of the debtor without his or her consent.

(2) The procedures contained in this part do not apply to any case where an employee consents to collection through deduction(s) from the employee's pay account, or to debts arising under the Internal Revenue Code or the tariff laws of the United States, or where another statute explicitly provides for, or prohibits, collection of a debt by salary offset (e.g., travel advances in 5 U.S.C. 5705 and employee training expenses in 5 U.S.C. 4108).

(3) This part does not preclude an employee from requesting waiver of an erroneous payment under 5 U.S.C. 5584, 10 U.S.C. 2774, or 32 U.S.C. 716, or in any way questioning the amount or validity of a debt, in the manner prescribed by the Secretary. Similarly, this part does not preclude an employee from requesting waiver of the collection of a debt under any other applicable statutory authority.

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(4) Nothing in this part precludes the compromise of the debt, or the suspension or termination of collection actions, in accordance with part 30 of this title.

§ 33.2 Definitions.

In this part—

Administrative offset means withholding funds payable by the United States to, or held by the United States for, a person to satisfy a debt owed by the payee.

Agency means an executive department or agency; a military department; the United States Postal Service; the Postal Rate Commission; the United States Senate; the United States House of Representatives; and court, court administrative office, or instrumentality in the judicial or legislative branches of the Government; or a Government Corporation.

Creditor agency means the agency to which the debt is owed, including a debt collection center when acting on behalf of a creditor agency in matters pertaining to the collection of a debt.

Day means calendar day. For purposes of computation, the last day of the period will be included unless it is a Saturday, Sunday, or a Federal holiday, in which case the next business day will be considered the last day of the period.

Debt means an amount determined by an appropriate official to be owed to the United States from sources which include loans insured or guaranteed by the United States and all other amounts due the United States from fees, leases, rents, royalties, services, sales of real or personal property, overpayments, penalties, damages, interest, fines and forfeitures (except those arising under the Uniform Code of Military Justice), and all other similar sources.

Debt collection center means the Department of the Treasury or other Government agency or division designated by the Secretary of the Treasury with authority to collect debts on behalf of creditor agencies in accordance with 31 U.S.C. 3711(g).

Debtor means a Federal employee who owes a debt to the United States.

Delinquent debt means a debt which the debtor does not pay or otherwise resolve by the date specified in the ini-

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tial demand for payment, or in an applicable written repayment agreement or other instrument, including a post-delinquency repayment agreement.

Department means the Department of Health and Human Services, its Staff Divisions, Operating Divisions, and Regional Offices.

Disposable pay means that part of the debtor's current basic, special, incentive, retired, and retainer pay, or other authorized pay, remaining after deduction of amounts required by law to be withheld. For purposes of calculating disposable pay, legally required deductions that must be applied first include: Tax levies pursuant to the Internal Revenue Code (title 26, United States Code); properly withheld taxes, FICA, Medicare; health and life insurance premiums; and retirement contributions. Amounts deducted under garnishment orders, including child support garnishment orders, are not legally required deductions for calculating disposable pay.

Employee means any individual currently employed by an agency, as defined in this section, including seasonal and temporary employees and current members of the Armed Forces or a Reserve of the Armed Forces (Reserves).

Evidence of service means information retained by the Department indicating the nature of the document to which it pertains, the date of mailing the document, and the address and name of the debtor to whom it is being sent. A copy of the dated and signed written notice of intent to offset provided to the debtor pursuant to this part may be considered evidence of service for purposes of this part. Evidence of service may be retained electronically so long as the manner of retention is sufficient for evidentiary purposes.

Hearing means a review of the documentary evidence to confirm the existence or amount of a debt or the terms of a repayment schedule. If the Secretary determines that the issues in dispute cannot be resolved by such a review, such as when the validity of the claim turns on the issue of credibility or veracity, the Secretary may provide an oral hearing.

Hearing official means a Departmental Appeals Board administrative

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law judge or appropriate alternate as outlined in § 33.7(a)(2).

Paying agency means the agency employing the individual and authorizing the payment of his or her current pay.

Salary offset means an administrative offset to collect a debt under 5 U.S.C. 5514 owed by a federal employee through deductions at one or more officially established pay intervals from the current pay account of the employee without his or her consent.

Secretary means the Secretary of Health and Human Services, or the Secretary's designee within any Staff Division, Operating Division or Regional Office.

Waiver means the cancellation, remission, forgiveness, or non-recovery of a debt owed by an employee to this Department or another agency as required or permitted by 5 U.S.C. 5584, 8346(b), 10 U.S.C. 2774, 32 U.S.C. 716, or any other law.

§ 33.3 General rule.

(a) Whenever a delinquent debt is owed to the Department by an employee, the Secretary may, subject to paragraphs (b) through (d) of this section, involuntarily offset the amount of the debt from the employee's disposable pay.

(b) Unless provided by another statute pertaining to a particular type of debt (e.g., 42 U.S.C. 292r, Health professionals education, 42 U.S.C. 297b, Nurse education), the Department may not initiate salary offset to collect a debt more than 10 years after the Government's right to collect the debt first accrued, unless facts material to the Government's right to collect the debt were not known and could not reasonably have been known by the official or officials of the Government who were charged with the responsibility to discover and collect such debts.

(c) Except as provided in paragraph (d) of this section, prior to initiating collection through salary offset under this part, the Secretary must first provide the employee with the following:

(1) Written notice of intent to offset as described in § 33.4; and

(2) An opportunity to petition for a hearing, and, if a hearing is provided, to receive a written decision from the

hearing official within 60 days on the following issues:

(i) The determination of the Department concerning the existence or amount of the debt; and

(ii) The repayment schedule, unless it was established by written agreement between the employee and Department.

(d) The provisions of paragraph (c) of this section do not apply to:

(1) Any adjustment to pay arising out of an employee's election of coverage or a change in coverage under a federal benefits program requiring periodic deduction from pay, if the amount to be recovered was accumulated over four pay periods or less;

(2) A routine intra-agency adjustment of pay that is made to correct an overpayment of pay attributable to clerical or administrative errors or delays in processing pay documents, if the overpayment occurred within the four pay periods preceding the adjustment and, at the time of such adjustment, or as soon thereafter as practical, the individual is provided written notice of the nature and the amount of the adjustment and point of contact for contesting such adjustment; or

(3) Any adjustment to collect a debt amounting to \$50 or less, if, at the time of such adjustment, or as soon thereafter as practical, the individual is provided written notice of the nature and the amount of the adjustment and a point of contact for contesting such adjustment.

§ 33.4 Notice requirements before offset.

(a) At least 30 days before the initiation of salary offset under this part, the Secretary shall mail, by first class mail, to the employee's last known address, a written notice informing the debtor of the following:

(1) The Secretary has reviewed the records relating to the debt and has determined that a debt is owed, the amount of the debt, and the facts giving rise to the debt;

(2) The Secretary's intention to collect the debt by means of deduction from the employee's current disposable pay account until the debt and all accumulated interest, penalties, and administrative costs are paid in full;

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(3) The amount, stated either as a fixed dollar amount or as a percentage of pay not to exceed 15 percent of disposable pay, the frequency, the commencement date, and the duration of the intended deductions;

(4) An explanation of the Department's policies concerning the assessment of interest, penalties, and administrative costs, stating that such assessments must be made unless waived in accordance with 31 CFR 901.9 and § 30.18 of this title;

(5) The employee's right to inspect and copy all records of the Department pertaining to the debt or, if the employee or the employee's representative cannot personally inspect the records, to request and receive copies of such records;

(6) If not previously provided, the opportunity to establish a schedule for the voluntary repayment of the debt through offset, or to enter into an agreement to establish a schedule for repayment of the debt in lieu of offset, provided the agreement is in writing, signed by both the employee and the Department, and documented in the Department's files;

(7) The right to a hearing conducted by an impartial hearing official with respect to the existence and amount of the debt, or the repayment schedule, so long as a petition is filed by the employee as prescribed in § 33.6;

(8) Time limitations and other procedures or conditions for inspecting Department records pertaining to the debt, establishing an alternative repayment agreement, and requesting a hearing;

(9) The name, address, and telephone number of the person or office within the Department who may be contacted concerning the procedures for inspecting Department records, establishing an alternative repayment agreement, and requesting a hearing;

(10) The name and address of the office within the Department to which the petition for a hearing should be sent, which generally will be the Operating Division or Staff Division responsible for collecting the debt;

(11) A timely and properly filed petition for a hearing will stay the commencement of the collection proceeding;

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(12) The Department will initiate action to effect salary offset not less than 30 days from the date of mailing the notice of intent, unless the employee properly files a timely petition for a hearing,

(13) A final decision on a hearing, if one is requested, will be issued at the earliest practical date, but not later than 60 days after the filing of the petition requesting the hearing unless the employee requests and the hearing official grants a delay in the proceeding;

(14) Knowingly false or frivolous statements, representations or evidence may subject the employee to:

(i) Disciplinary procedures appropriate under chapter 75 of title 5, United States Code; part 752 of title 5, Code of Federal Regulations; or any other applicable statutes or regulations;

(ii) Penalties under the False Claims Act, 31 U.S.C. 3729–3731, or under any other applicable statutory authority; and

(iii) Criminal penalties under 18 U.S.C. 286, 287, 1001, and 1002, or under any other applicable statutory authority;

(15) Any other rights and remedies available to the employee under statutes or regulations governing the program for which the collection is being made;

(16) Unless there are applicable contractual or statutory provisions to the contrary, amounts paid on or deducted for the debt, which are later waived or found not owed to the United States, will be promptly refunded to the employee; and

(17) Proceedings with respect to such debt are governed by 5 U.S.C. 5514.

(b) The Secretary will retain evidence of service indicating the date of mailing of the notice.

§ 33.5 Review of department records relating to the debt.

(a) To inspect or copy Department records relating to the debt, the employee must send a written request to the Department official or office designated in the notice of intent to offset stating his or her intention. The written request must be received by the Department within 15 days from the employee's receipt of the notice.

(b) In response to a timely request as described in paragraph (a) of this section, the designated Department official shall notify the employee of the location and time when the employee may inspect and copy such records. If the employee or employee's representative is unable to personally inspect such records as the result of geographical or other constraints, the Department shall arrange to send copies of such records to the employee.

§ 33.6 Hearings.

(a) *Petitions for hearing.* (1) To request a hearing concerning the existence or amount of the debt or the offset schedule established by the Department, the employee must send a written petition to the office designated in the notice of intent to offset, see § 33.4(a)(10), within 15 days of receipt of the notice.

(2) The petition must:

- (i) Be signed by the employee;
- (ii) Fully identify and explain with reasonable specificity all the facts, evidence, and witnesses, if any, that the employee believes support his or her position; and
- (iii) Specify whether an oral or paper hearing is requested. If an oral hearing is requested, the request should explain why the matter cannot be resolved by review of the documentary evidence alone.

(3) The timely filing of a petition for hearing shall stay any further collection proceedings.

(b) *Failure to timely request.* (1) If the petition for hearing is filed after the 15-day period provided for in paragraph (a)(1) of this section, the Secretary may grant the request if the employee can establish that the delay was the result of circumstances beyond the employee's control, or that the employee failed to receive actual notice of the filing deadline.

(2) An employee waives the right to a hearing, and will have his or her disposable pay offset in accordance with the offset schedule established by the Department, if the employee:

- (i) Fails to file a timely request for a hearing, unless such failure is excused; or
- (ii) Fails to appear at an oral hearing, of which the employee was notified, unless the hearing official deter-

mines that the failure to appear was due to circumstances beyond the employee's control.

(c) *Form of hearings*—(1) *General.* After the employee requests a hearing, the hearing official shall notify the employee of the form of the hearing to be provided. If the hearing will be oral, the notice shall set forth the date, time, and location of the hearing. If the hearing will be a review of the written record, the employee shall be notified that he or she should submit evidence and arguments in writing to the hearing official by a specified date, after which the record shall be closed. The date specified shall give the employee reasonable time to submit documentation.

(2) *Oral hearing.* An employee who requests an oral hearing shall be provided an oral hearing if the hearing official determines that the matter cannot be resolved by review of documentary evidence alone because an issue of credibility or veracity is involved. Where an oral hearing is appropriate, the hearing is not an adversarial adjudication and need not take the form of an evidentiary hearing, i.e., the rules of evidence need not apply. *Oral hearings may take the form of, but are not limited to:*

(i) Informal conferences with the hearing official in which the employee and agency representative will be given full opportunity to present evidence, witnesses, and arguments;

(ii) Informal meetings in which the hearing official interviews the employee; or

(iii) Formal written submissions with an opportunity for oral presentations.

(3) *Paper hearing.* If the hearing official determines that an oral hearing is not necessary, the hearing official will make the determination based upon a review of the available written record.

(4) *Record.* The hearing official shall maintain a summary record of any hearing conducted under this part. Witnesses who testify in oral hearings will do so under oath or affirmation.

(d) *Written decision.* (1) Date of decision. The hearing officer shall issue a written opinion stating his or her decision, based upon documentary evidence and information developed at the hearing, as soon as practicable after the

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hearing, but not later than sixty (60) days after the date on which the hearing petition was received by the creditor agency, unless the employee requested a delay in the proceedings, in which case the 60-day decision period shall be extended by the number of days by which the hearing was postponed. The recipient of an employee's request for a hearing must forward the request expeditiously to the Departmental Appeals Board so as to not jeopardize the Board's ability to issue a decision within this 60-day period.

(2) *Content of decision.* The written decision shall include:

(i) A statement of the facts presented to support the origin, nature, and amount of the debt;

(ii) The hearing official's findings, analysis, and conclusions, including a determination whether the employee's petition for hearing was baseless and resulted from an intent to delay creditor agency collection activity; and

(iii) The terms of any repayment schedule, if applicable.

(e) *Failure to appear.* In the absence of good cause shown, an employee who fails to appear at a hearing shall be deemed, for the purpose of this part, to admit the existence and amount of the debt as described in the notice of intent. If the representative of the creditor agency fails to appear, the hearing official shall proceed with the hearing as scheduled and make a determination based upon oral testimony presented and the documentary evidence submitted by both parties. With the agreement of both parties, the hearing official shall schedule a new hearing date, and both parties shall be given reasonable notice of the time and place of the new hearing.

§ 33.7 Obtaining the services of a hearing official.

(a)(1) When the Department is the creditor agency, the office designated in § 33.4(a)(10) shall schedule a hearing, if one is requested by an employee, before a hearing official.

(2) When the Department cannot provide a prompt and appropriate hearing before an administrative law judge or a hearing official furnished pursuant to another lawful arrangement, the office designated in § 33.4(a)(10) may:

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(i) When the debtor is not an employee of the Department, contact an agent of the employee's paying agency designated in 5 CFR part 581, appendix A, to arrange for a hearing official; or

(ii) When the debtor is an employee of the Department, contact an agent of any agency designated in 5 CFR part 581, appendix A, to arrange for a hearing official.

(b)(1) When another agency is the creditor agency, it is the responsibility of that agency to arrange for a hearing if one is requested. The Department will provide a hearing official upon the request of a creditor agency when the debtor is employed by the Department and the creditor agency cannot provide a prompt and appropriate hearing before a hearing official furnished pursuant to another lawful arrangement.

(2) Services rendered to a creditor agency under paragraph (b)(1) of this section will be provided on a fully reimbursable basis pursuant to the Economy Act of 1932, as amended, 31 U.S.C. 1535.

(c) The determination of a hearing official designated under this section is considered to be an official certification regarding the existence and amount of the debt for purposes of executing salary offset under 5 U.S.C. 5514 and this part. A creditor agency may make a certification to the Secretary of the Treasury under 5 CFR 550.1108 or a paying agency under 5 CFR 550.1109 regarding the existence and amount of the debt based on the certification of a hearing official. If a hearing official determines that a debt may not be collected via salary offset, but the creditor agency finds that the debt is still valid, the creditor agency may still seek collection of the debt through other means, such as offset of other Federal payments or litigation.

§ 33.8 Voluntary repayment agreement in lieu of salary offset.

(a)(1) In response to the notice of intent to offset, the employee may propose to establish an alternative schedule for the voluntary repayment of the debt by submitting a written request to the Department official designated in the notice of intent to offset. An employee who wishes to repay the debt without salary offset shall also submit

a proposed written repayment agreement. The proposal shall admit the existence of the debt, and the agreement must be in such form that it is legally enforceable. The agreement must:

- (i) Be in writing;
- (ii) Be signed by both the employee and the Department;
- (iii) Specify all the terms of the arrangement for payment; and
- (iv) Contain a provision accelerating the debt in the event of default by the employee, but such an increase may not result in a deduction that exceeds 15 percent of the employee's disposable pay unless the employee has agreed in writing to deduction of a greater amount.

(2) Any proposal under paragraph (a)(1) of this section must be received by the Department within 30 days of the date of the notice of intent to offset.

(b) In response to a timely request as described in paragraph (a) of this section, the designated Department official shall notify the employee whether the proposed repayment schedule is acceptable. It is within the Secretary's discretion to accept a proposed alternative repayment schedule, and to set the necessary terms of a voluntary repayment agreement.

(c) No voluntary repayment agreement will be binding on the Secretary unless it is in writing and signed by both the Secretary and the employee.

§ 33.9 Special review.

(a) A Department employee subject to salary offset or a voluntary repayment agreement may, at any time, request a special review by the Secretary of the amount of the salary offset or voluntary repayment installments, based on materially changed circumstances, such as, but not limited to, catastrophic illness, divorce, death, or disability.

(b)(1) In determining whether an offset would prevent the employee from meeting essential subsistence expenses, e.g., food, housing, clothing, transportation, and medical care, the employee shall submit a detailed statement and supporting documents for the employee, his or her spouse, and dependents indicating:

- (i) Income from all sources;

- (ii) Assets and liabilities;
- (iii) Number of dependents;
- (iv) Food, housing, clothing, transportation, and medical expenses; and
- (v) Exceptional and unusual expenses, if any.

(2) When requesting a special review under this section, the employee shall file an alternative proposed offset or payment schedule and a statement, with supporting documents as described in paragraph (b)(1) of this section, stating why the current salary offset or payments result in an extreme financial hardship to the employee.

(c)(1) The Secretary shall evaluate the statement and supporting documents, and determine whether the original offset or repayment schedule imposes extreme financial hardship on the employee.

(2) Within 30 calendar days of the receipt of the request and supporting documents, the Secretary shall notify the employee in writing of such determination, including, if appropriate, a revised offset or repayment schedule.

(d) If the special review results in a revised offset or repayment schedule, the Secretary shall provide a new certification to the paying agency.

§ 33.10 Procedures for salary offset.

(a) *Method and source of deductions.* Unless the employee and the Secretary have agreed to an alternative repayment arrangement under § 33.8, a debt shall be collected in lump sum or by installment deductions at officially established pay intervals from an employee's current pay account.

(b) *Limitation on amount of deduction.* Ordinarily, the size of installment deductions must bear a reasonable relationship to the size of the debt and the employee's ability to pay. However, the amount deducted for any pay period must not exceed 15 percent of the disposable pay from which the deduction is made, unless the employee has agreed in writing to the deduction of a greater amount, as outlined in § 33.8.

(c) *Duration of deductions.* (1) *Lump sum.* If the amount of the debt is equal to or less than 15 percent of the employee's disposable pay for an officially established pay interval, the debt generally will be collected in one lump-sum deduction.

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(2) If the employee is deemed financially unable to pay in one lump-sum or the amount of the debt exceeds 15 percent of the employee's disposable pay for an officially established pay interval, the debt shall be collected in installments. Except as provided in paragraphs (e) and (f) of this section, installment deductions must be made over a period not greater than the anticipated period of active duty or employment.

(d) *When deductions may begin.* (1) Deductions will begin on the date stated in the notice of intent, unless an alternative repayment agreement under § 33.8 has been accepted or the employee has filed a timely request for a hearing.

(2) If the employee files a timely petition for hearing as provided in § 33.6, deductions will begin after the hearing official has provided the employee with a hearing and a final written decision has been rendered in favor of the Department.

(e) *Liquidation from final check.* If an employee retires, resigns, or the period of employment ends before collection of the debt is completed, the remainder of the debt will be offset under 31 U.S.C. 3716 from subsequent payments of any nature (e.g., final salary payment or lump-sum leave) due the employee from the paying agency as of the date of separation.

(f) *Recovery from other payments due a separated employee.* If the debt cannot be satisfied by offset from any final payment due the employee on the date of separation, the Secretary will liquidate the debt, where appropriate, by administrative offset under 31 U.S.C. 3716 from later payments of any kind due the former employee (e.g., lump sum leave payment).

§ 33.11 Salary offset when the Department is the creditor agency but not the paying agency.

(a) *Centralized administrative offset.* (1) Under 31 U.S.C. 3716, the Department shall notify the Secretary of the Treasury of all past-due, legally enforceable debts which are 180 days delinquent for purposes of collection by centralized administrative offset. This includes debts which the Department seeks to recover from the pay account of an em-

ployee of another agency via salary offset. The Secretary of the Treasury and other Federal disbursing officials will match payments, including Federal salary payments, against these debts. Where a match occurs, and all the requirements for offset have been met, the payments will be offset to collect the debt.

(2) Prior to offset of the pay account of an employee, the Department must comply with the requirements of 5 U.S.C. 5514; 5 CFR part 550, subpart K, and this part. Specific procedures for notifying the Secretary of the Treasury of a debt for purposes of collection by administrative offset, including salary offset, are contained in 31 CFR parts 285 and 901 and part 30 of this title.

(b) *Non-centralized administrative offset.* When salary offset through centralized administrative offset under paragraph (a) of this section is not possible, the Department may attempt to collect a debt through non-centralized administrative offset in accordance with part 30 of this title.

(1) *Format of the request.* Upon completion of the procedures established in this part and pursuant to 5 U.S.C. 5514, the Department shall:

(i) Certify in writing to the paying agency that the employee owes the debt, the amount and basis of the debt, the date on which payment(s) is due, the date the Government's right to collect the debt first accrued, and that the Departmental regulations implementing 5 U.S.C. 5514 have been approved by the Office of Personnel Management.

(ii) If the collection is to be made in installments, advise the paying agency of the number of installments to be collected, the amount or percentage of disposable pay to be collected in each installment, and the commencement date of the installments, if a date other than the next officially established pay period is required.

(iii) Unless the employee has consented in writing to the salary deductions or signed a statement acknowledging receipt of the required procedures and this written consent or statement is forwarded to the paying agency, advise the paying agency of the action(s) taken under 5 U.S.C. 5514

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and this part, and give the date(s) the action(s) was taken.

(2) *Requesting recovery from current paying agency.* (i) Except as otherwise provided in this paragraph, the Department shall submit a certified debt claim containing the information specified in paragraph (a) of this section, and an installment agreement, or other instruction on the payment schedule, if applicable, to the employee's paying agency.

(ii) If the employee is in the process of separating from the Federal Government, the Department shall submit the certified debt claim to the employee's paying agency for collection as provided in § 33.10(e). The paying agency must certify the total amount of its collection on the debt and send a copy of the certification to the employee and another copy to the Department. If the paying agency's collection does not fully satisfy the debt, and the paying agency is aware that the employee is entitled to payments from the Civil Service Retirement and Disability Fund, or other similar payments that may be due the employee from other Federal Government sources, the paying agency will provide written notification of the outstanding debt to the agency responsible for making such payments to the employee, stating the employee owes a debt, the amount of the debt, and that the provisions of this section have been fully complied with. The Department must submit a properly certified claim to the agency responsible for making such payments before the collection can be made.

(iii) If the employee is already separated and all payments due from the employee's former paying agency have been paid, the Department may request, unless otherwise prohibited, that money due and payable to the employee from the Civil Service Retirement and Disability Fund (5 CFR 831.1801 or 5 CFR 845.401) or other similar funds, be administratively offset to collect the debt. See 31 U.S.C. 3716 and 31 CFR 901.3.

(iv) If the employee transfers to another paying agency, the Department must submit a properly certified debt claim to the new paying agency before collection can be resumed; however, the Department need not repeat the

due process procedures described in 5 U.S.C. 5514 and this part. The Department shall review the debt to ensure that collection is resumed by the new paying agency.

§ 33.12 Salary offset when the Department is the paying agency but not the creditor agency.

(a) *Format of the request.* (1) When the Department is the paying agency and another agency is the creditor agency, the creditor agency must certify, in writing, to the Department that the employee owes the debt, the amount and basis of the debt, the date on which payment(s) is due, the date the Government's right to collect the debt first accrued, and that the creditor agency's regulations implementing 5 U.S.C. 5514 have been approved by the Office of Personnel Management.

(2) If the collection is to be made in installments, the creditor agency must also advise the Department of the number of installments to be collected, the amount or percentage of disposable pay to be collected in each installment, and the commencement date of the installments, if a date other than the next officially established pay period is required.

(3) Unless the employee has consented in writing to the salary deductions or signed a statement acknowledging receipt of the required procedures and the written consent or statement is forwarded to the Department, the creditor agency must advise the Department of the action(s) taken under 5 U.S.C. § 5514, and give the date(s) the action(s) was taken.

(b) *Requests for recovery.* (1) Complete claim. When the Department receives a properly certified debt claim from a creditor agency, deductions should be scheduled to begin prospectively at the next officially established pay interval. The employee must receive written notice as described in § 33.10 that the Department has received a certified debt claim from the creditor agency, including the amount, and written notice of the date deductions from salary will commence and the amount of such deductions.

(2) *Incomplete claim.* When the Department receives an incomplete debt

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claim from a creditor agency, the Secretary shall return the debt claim with a notice that procedures under 5 U.S.C. 5514 and 5 CFR part 550, subpart K, must be provided and a properly certified debt claim received before action will be taken to collect from the employee's current pay account.

(c) *Review.* The Secretary is not required or authorized to review the merits of the determination with respect to the amount or validity of the debt certified by the creditor agency.

(d) *Employees separating.* If an employee begins separation action before the Department collects the total debt due the creditor agency, the following actions will be taken:

(1) To the extent possible, the balance owed the creditor agency will be liquidated from a final salary check, or other final payments of any nature due the employee from the Department;

(2) The Secretary will certify the total amount of the Department's collection on the debt and send a copy of the certification to the employee and another copy to the creditor agency; and

(3) If the Department's collection does not fully satisfy the debt, and the Secretary is aware that the employee is entitled to payments from the Civil Service Retirement and Disability Fund, or other similar payments that may be due the employee from other Federal Government sources, the Secretary will provide written notification of the outstanding debt to the agency responsible for making such payments to the employee. The written notification shall state that the employee owes a debt, the amount of the debt, and that the provisions of this section have been fully complied with. The Department shall furnish a copy of this written notification to the creditor agency so that it can file a properly certified debt claim with the agency responsible for making such payments.

(e) *Employees who transfer to another paying agency.* If, after the creditor agency has submitted a debt claim to the Department, the employee transfers from the Department to a different paying agency before the debt is collected in full, the Secretary shall:

(1) Certify the total amount of the collection made on the debt; and

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(2) Furnish a copy of the certification to the employee and another copy to the creditor agency along with notice of the employee's transfer.

§ 33.13 Interest, penalties, and administrative costs.

Debts owed to the Department shall be assessed interest, penalties and administrative costs in accordance with 45 CFR 30.18.

§ 33.14 Non-waiver of rights.

An employee's involuntary payment of all or any portion of a debt collected under this part shall not be construed as a waiver of any rights which the employee may have under 5 U.S.C. 5514 or any other provision of law or contract, unless there are statutory or contractual provisions to the contrary.

§ 33.15 Refunds.

(a) The Secretary shall promptly refund any amounts paid or deducted under this part when:

(1) A debt is waived or otherwise found not owing to the United States; or

(2) The employee's paying agency is directed by administrative or judicial order to refund amount deducted from the employee's current pay.

(b) Unless required or permitted by law or contract, refunds shall not bear interest.

§ 33.16 Additional administrative collection action.

Nothing contained in this part is intended to preclude the use of any other appropriate administrative remedy.

PART 34—CLAIMS FILED UNDER THE MILITARY PERSONNEL AND CIVILIAN EMPLOYEES ACT

Sec.

34.1 Purpose and scope.

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AUTHORITY: 31 U.S.C. 3721.

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SOURCE: 69 FR 13257, Mar. 22, 2004, unless otherwise noted.

§ 34.1 Purpose and scope.

(a) *Purpose.* This part prescribes policies and procedures for handling claims not in excess of \$40,000.00 filed by employees against the Department of Health and Human Services under the Military Personnel and Civilian Employees Claims (MPCE) Act of 1964, 31 U.S.C. 3721, for damage to, or loss of, property against the Department. Under the MPCE Act, the Secretary may approve claims made against the Government by a federal government employee for damage to or loss of personal property that is incident to employment when the loss or damage is not due to any negligence on the part of employee.

(b) *Scope.* This part applies to all Departmental Operating Divisions and Regional Offices that process and review claims under the MPCE Act. Nothing in this part shall be construed to bar other types of claims that are payable under other statutory authority such as, but not limited to, the Federal Tort Claims Act (28 U.S.C. 2671–2680).

§ 34.2 Definitions.

In this part, unless the context otherwise requires:

Claim means any claim filed by or on behalf of an employee for damage to, or loss of, property that is incident to the claimant's employment. This definition includes claims where the claimant is not the legal owner of the property in question, but has obtained authorization from the legal owner to possess or control the property.

Claimant means an employee who has filed a claim with the Department under the MPCE Act.

Damage or loss means total or partial destruction or loss of the item claimed.

Department means the Department of Health and Human Services.

Employee means an officer or employee of the Department.

Quarters means a house, apartment or other residence assigned by the government to an employee of the Department.

§ 34.3 Filing procedures and time limits.

(a) *Who may file a claim.* A claim may be filed by the following individuals:

- (1) An employee;
- (2) An authorized agent or representative of an employee or employee's estate, regardless of whether the claim arose before or concurrent with an employee's death; and
- (3) A former employee or his authorized agent or representative if damage or loss occurred prior to the separation from the Department.

(b) *Requirements.* A claim submitted under this part must be presented in writing to the Claims Officer (See paragraph (c) of this section). Claims may be submitted on a HHS-481 form, Employee Claim for Loss or Damage to Personal Property. All claims must be signed by the claimant or his authorized agent or representative. The HHS-Form can be obtained from the Claims Officer or downloaded from the Program Support Center's webpage at www.psc.gov. All claims must include the following:

- (1) Name and address of the claimant;
- (2) The office in which the claimant was employed at the time of loss, current office, if different, and telephone number;
- (3) Date of loss or damage;
- (4) Amount of claim;
- (5) Description of the property, including but not limited to type, design, model number, date acquired, value when acquired, value when lost, and estimation of repair or replacement cost;
- (6) Description of incident; and
- (7) If property was insured when loss or damage occurred, a statement indicating whether a claim was filed with an insurance carrier.

(c) *Where to file your claim.* (1) Claimants employed with the Regional Offices should submit claims to the Chief Regional Counsel, Office of the General Counsel, within the claimant's Region.

(2) All other claimants must submit claims to the Office of the General Counsel, General Law Division, Claims and Employment Law Branch, 330 Independence Ave., SW., Room 4760, Cohen Building, Washington, DC 20201.

(d) *Evidence required.* You must submit the following:

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(1) Not less than two itemized signed estimates for the cost of repairs, or an itemized bill of repair for the damaged property;

(2) In the event the property is not economically repairable or is totally lost or destroyed, proof of this fact, its market value before or after loss, purchase price, and date of acquisition of the property;

(3) Proof of ownership or right to recover for the damage such as a receipt;

(4) Police/incident report;

(5) If property is insured, insurance information, such as insurance carrier, type of coverage, deductible, and whether claim has been filed and/or paid;

(6) Travel orders, if applicable;

(7) Any citations or traffic tickets, if applicable; and

(8) Any other evidence required by the claims officer not specified above.

(e) *Time limit.* (1) A claim filed under this section must be filed in writing with the Department within two years from the date of the incident.

(2) If the claim accrues in the time of war or in the time of armed conflict in which any armed forces of the United States are engaged or if such a war or armed conflict occurs within two years after the claim accrues, and if good cause is shown, the claim shall be presented no more than two years after that cause ceases to exist, or two years after the war or armed conflict is terminated, whichever is earlier.

(3) All required evidence in support of a claim submitted under this section must be forwarded to the claims officer within sixty days after request. Failure to do so will be deemed as an abandonment of the claim and the claim will be disallowed.

§ 34.4 Allowable claims.

(a) *What you can claim.* (1) Claims for damage or loss may be allowed where possession of the property was lawful and reasonable under circumstances.

(2) Claims for property damage or loss by fire, flood, hurricane, theft, or other serious occurrence may be allowed when the property is located inside:

(i) Quarters that have been assigned or provided by the government; or

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(ii) Quarters outside the United States whether assigned by the government or not, except when a civilian employee outside the U.S. is a local inhabitant.

(3) Claims for damage to, or loss of, property may be allowed when caused by:

(i) Marine, air disaster, enemy action or threat thereof, or other extraordinary risks incurred incident to the performance of official duties by the claimant; and

(ii) Efforts by the claimant to save human life or government property.

(4) Property used for the benefit of the government. Claims may be allowed for damage to, or loss of, property used for the benefit of the government at the request, or with the knowledge and consent of, superior authority.

(5) Claims for clothing and accessories may be allowed when loss or damage was caused by faulty or defective equipment or furnishings owned or managed by the Department.

(6) Claims for stolen property, only if it is determined that the claimant exercised due care in protecting his property and there is clear evidence that a burglary or theft occurred.

(7) Claims for automobiles, only when required to perform official business or parked on a government-owned or operated parking lot or garage incident to employment. This subsection does not include claims for damage or loss when traveling between place of residence and duty station, or when the loss or damage was caused by the negligence of a third party. If the automobile is a total loss, the maximum amount allowed is the value of the vehicle at the time of loss as determined by the National Automobile Dealer Association Appraisal Guide or similar publications.

(8) Claims for any other meritorious claims in exceptional cases may be allowed by the Claims Officer.

(9) Transportation or travel losses. Damage or loss of personal property, including baggage and household items, while being transported by a carrier, agent or agency of the government, or private conveyance, may be allowed only if the property is shipped

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under orders or in connection with travel orders.

(b) [Reserved]

§ 34.5 Unallowable claims.

(a) *What you cannot claim.* (1) Claims for money or currency, such as intangible property (*i.e.* bankbooks, check, money orders, promissory notes, stock certificates, etc.).

(2) Worn-out or unserviceable property.

(3) Easily pilferable articles, such as jewelry, cameras, watches, and binoculars when they are shipped with household goods by a moving company or unaccompanied baggage. This does not apply to checked property or property in personal custody of the claimant or his agent provided proper security measures have been taken.

(4) Government property.

(5) Appraisal or estimate fees.

(6) Automobiles, except when required to perform official business or parked on a government-owned or operated parking lot or garage incident to employment.

(7) Loss or damage caused in whole or in part by the negligent or wrongful act of the claimant or his agent or employee.

(8) Claims under \$30.00.

(9) Stolen property when it's determined that claimant failed to exercise due care in protecting his or her property.

(10) Sales tax. Reimbursements for the payment of sales tax incurred in connection with repairs or replacing an item will not be allowed.

(b) [Reserved]

§ 34.6 Reconsideration or appeal.

(a) Requests for reconsideration or appeal shall be forwarded to the Associate General Counsel, General Law Division, Office of the General Counsel, within sixty days from the date of the Claims Officer's decision along with any new evidence supporting the claim.

(b) A voucher or a supplemental voucher will be prepared by the Claims Officer if it is determined that the claimant's request for reconsideration should be allowed.

§ 34.7 Payment procedures.

(a) For all claims that are approved in whole or part, the claims officer shall prepare and mail a payment voucher to the claimant.

(b) This voucher shall be mailed to the claimant with appropriate instructions.

(c) Upon receipt of the signed payment voucher, the claims officer shall sign and forward the signed voucher to the office where the claimant is or was employed for processing.

(d) Upon receipt of the signed payment voucher, the office in which the claimant is or was employed will submit the voucher for transmission to the Treasury Department for issuance of a check in the sum allowed.

(e) Funds paid for settlement of allowed claims shall be made from appropriations of the office in which the claimant is or was employed.

§ 34.8 Computation of award and settlement.

(a) The amount awarded on any item of property shall not exceed the adjusted cost of the item based on the cost of replacing it with a similar one of the same quality minus the appropriate depreciation rate. The amount normally payable on property damaged beyond economical repair shall not exceed its depreciated value. If the cost of repairs is less than the depreciated value it shall be considered economically repairable and the costs of repairs shall be the amount payable.

(b) Depreciation in value of an item shall be determined by considering the type of article involved, its replacement cost, condition when lost or damaged beyond economical repair, and the time elapsed between the date of acquisition and the date of accrual of the claim.

(c) Notwithstanding any other provision of law, settlements of claims under the MPCE Act are final and conclusive. The acceptance of a settlement constitutes a complete release of any claim against the United States and any employee of the government whose act or omission gave rise to the claim by reason of the same claim.

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§ 34.9 Claims involving carriers or insurers.

(a) *Carriers.* (1) If property is damaged, lost or destroyed while being shipped pursuant to authorized travel orders, the owner shall file a written claim for reimbursement against the carrier no later than nine months from the date of delivery or should have been made according to the terms of the contract. It shall be filed before or concurrent with submitting a claim against the government under this part.

(2) The demand shall be made against the responsible carrier if more than one contract was issued, a separate demand shall be made against the last carrier on each such document, unless claimant knows which carrier was in possession of the property when the damage or loss occurred.

(b) *Insurers.* (1) If property which is damaged, lost, or destroyed incident to the claimant's service is insured in whole or in part, the claimant shall inform the Claims Officer whether a claim was made with the insurance carrier.

(2) The claimant shall inform the claims officer if he or she received a reimbursement from the insurance carrier for the item that was damaged or lost. The exact amount of the reimbursement must be reported.

(3) If the claimant receives a reimbursement for the lost or damaged property from an insurance carrier, the maximum amount that can be recovered from the Department is the difference between an appropriate award under this regulation and the amount recovered from the insurance carrier. The claimant is responsible for submitting to the Department documentation that identifies the exact amount of the reimbursement.

PART 35—TORT CLAIMS AGAINST THE GOVERNMENT

Subpart A—General

Sec.

35.1 Scope of regulations.

Subpart B—Procedures

35.2 Administrative claim; when presented; place of filing.

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35.3 Administrative claim; who may file.

35.4 Administrative claims; evidence and information to be submitted.

35.5 Investigation, examination, and determination of claims.

35.6 Final denial of claim.

35.7 Payment of approved claims.

35.8 Release.

35.9 Penalties.

35.10 Limitation on Department's authority.

AUTHORITY: Sec. 1(a), 80 Stat. 306; 28 U.S.C. 2672; 28 CFR Part 14.

SOURCE: 32 FR 14101, Oct. 11, 1967, unless otherwise noted.

Subpart A—General

§ 35.1 Scope of regulations.

The regulations in this part shall apply only to claims asserted under the Federal Tort Claims Act, as amended, 28 U.S.C. sections 2671–2680, accruing on or after January 18, 1967, for money damages against the United States for damage to or loss of property or personal injury or death caused by the negligent or wrongful act or omission of any employee of the Department of Health and Human Services while acting within the scope of his office or employment.

Subpart B—Procedures

§ 35.2 Administrative claim; when presented; place of filing.

(a) For purposes of the regulations in this part, a claim shall be deemed to have been presented when the Department of Health and Human Services receives, at a place designated in paragraph (b) of this section, an executed Standard Form 95 or other written notification of an incident accompanied by a claim for money damages in a sum certain for damage to or loss of property, for personal injury, or for death, alleged to have occurred by reason of the incident. A claim which should have been presented to the Department but which was mistakenly addressed to or filed with another Federal agency, shall be deemed to be presented to the Department as of the date that the claim is received by the Department. A claim mistakenly addressed to or filed with the Department shall forthwith be transferred to the appropriate Federal

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agency, if ascertainable, or returned to the claimant.

(b) A claim presented in compliance with paragraph (a) of this section may be amended by the claimant at any time prior to final action by the Department Claims Officer or prior to the exercise of the claimant's option to bring suit under 28 U.S.C. 2675(a). Amendments shall be submitted in writing and signed by the claimant or his duly authorized agent or legal representative. Upon the timely filing of an amendment to a pending claim, the Department shall have 6 months in which to make a final disposition of the claim as amended and the claimant's option under 28 U.S.C. 2675(a) shall not accrue until 6 months after the filing of an amendment.

(c) Forms may be obtained and claims may be filed, with the office, local, regional, or headquarters, of the constituent organization having jurisdiction over the employee involved in the accident or incident, or with the Department of Health and Human Services Claims Officer, Washington, DC 20201.

[32 FR 14101, Oct. 11, 1967, as amended at 35 FR 4517, Mar. 13, 1970]

§ 35.3 Administrative claim; who may file.

(a) A claim for injury to or loss of property may be presented by the owner of the property interest which is the subject of the claim, his duly authorized agent, or his legal representative.

(b) A claim for personal injury may be presented by the injured person, his duly authorized agent, or his legal representative.

(c) A claim based on death may be presented by the executor or administrator of the decedent's estate or by any other person legally entitled to assert such a claim under applicable state law.

(d) A claim for loss wholly compensated by an insurer with the rights of a subrogee may be presented by the insurer. A claim for loss partially compensated by an insurer with the rights of a subrogee may be presented by the insurer or the insured individually, as their respective interests appear, or jointly. Whenever an insurer presents a

claim asserting the rights of a subrogee, he shall present with his claim appropriate evidence that he has the rights of a subrogee.

(e) A claim presented by an agent or legal representative shall be presented in the name of the claimant, be signed by the agent or legal representative, show the title or legal capacity of the person signing, and be accompanied by evidence of his authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian, or other representative.

§ 35.4 Administrative claims; evidence and information to be submitted.

(a) *Death.* In support of a claim based on death, the claimant may be required to submit the following evidence or information:

(1) An authenticated death certificate or other competent evidence showing cause of death, date of death, and age of the decedent.

(2) Decedent's employment or occupation at time of death, including his monthly or yearly salary or earnings (if any), and the duration of his last employment or occupation.

(3) Full names, addresses, birth dates, kinship, and marital status of the decedent's survivors, including identification of those survivors who were dependent for support upon the decedent at the time of his death.

(4) Degree of support afforded by the decedent to each survivor dependent upon him for support at the time of his death.

(5) Decedent's general physical and mental condition before death.

(6) Itemized bills for medical and burial expenses incurred by reason of the incident causing death, or itemized receipts of payments for such expenses.

(7) If damages for pain and suffering prior to death are claimed, a physician's detailed statement specifying the injuries suffered, duration of pain and suffering, any drugs administered for pain and the decedent's physical condition in the interval between injury and death.

(8) Any other evidence or information which may have a bearing on either the responsibility of the United States for the death or the damages claimed.

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(b) *Personal injury.* In support of a claim for personal injury, including pain and suffering, the claimant may be required to submit the following evidence or information:

(1) A written report by his attending physician or dentist setting forth the nature and extent of the injury, nature and extent of treatment, any degree of temporary or permanent disability, the prognosis, period of hospitalization, and any diminished earning capacity. In addition, the claimant may be required to submit to a physical or mental examination by a physician employed or designated by the Department or the constituent organization. A copy of the report of the examining physician shall be made available to the claimant upon the claimant's written request provided that claimant has, upon request, furnished the report referred to in the first sentence of this subparagraph and has made or agrees to make available to the Department or the operating agency any other physician's reports previously or thereafter made of the physical or mental condition which is the subject matter of his claim.

(2) Itemized bills for medical, dental, and hospital expenses incurred, or itemized receipts of payment for such expenses.

(3) If the prognosis reveals the necessity for future treatment, a statement of expected duration of and expenses for such treatment.

(4) If a claim is made for loss of time from employment, a written statement from his employer showing actual time lost from employment, whether he is a full or part-time employee, and wages or salary actually lost.

(5) If a claim is made for loss of income and the claimant is self-employed, documentary evidence showing the amount of earnings actually lost.

(6) Any other evidence or information which may have a bearing on either the responsibility of the United States for the personal injury or the damages claimed.

(c) *Property damage.* In support of a claim for damage to or loss of property, real or personal, the claimant may be required to submit the following evidence or information:

(1) Proof of ownership.

45 CFR Subtitle A (10-1-25 Edition)

(2) A detailed statement of the amount claimed with respect to each item of property.

(3) An itemized receipt of payment for necessary repairs or itemized written estimates of the cost of such repairs.

(4) A statement listing date of purchase, purchase price, market value of the property as of date of damage, and salvage value, where repair is not economical.

(5) Any other evidence or information which may have a bearing either on the responsibility of the United States for the injury to or loss of property or the damages claimed.

(d) *Time limit.* All evidence required to be submitted by this section shall be furnished by the claimant within a reasonable time. Failure of a claimant to furnish evidence necessary to a determination of his claim within three months after a request therefor has been mailed to his last known address may be deemed an abandonment of the claim. The claim may be thereupon disallowed.

§ 35.5 Investigation, examination, and determination of claims.

When a claim is received, the constituent agency out of whose activities the claim arose shall make such investigation as may be necessary or appropriate for a determination of the validity of the claim and thereafter shall forward the claim, together with all pertinent material, and a recommendation based on the merits of the case, with regard to allowance or disallowance of the claim, to the Department Claims Officer to whom authority has been delegated to adjust, determine, compromise and settle all claims hereunder.

§ 35.6 Final denial of claim.

(a) Final denial of an administrative claim shall be in writing and sent to the claimant, his attorney, or legal representative by certified or registered mail. The notification of final denial may include a statement of the reasons for the denial and shall include a statement that, if the claimant is dissatisfied with the Department's action, he may file suit in an appropriate U.S. District Court not later than 6

months after the date of mailing of the notification.

(b) Prior to the commencement of suit and prior to the expiration of the 6-month period after the date of mailing, by certified or registered mail of notice of final denial of the claim as provided in 28 U.S.C. 2401(b), a claimant, his duly authorized agent, or legal representative, may file a written request with the Department for reconsideration of a final denial of a claim under paragraph (a) of this section. Upon the timely filing of a request for reconsideration the Department shall have 6 months from the date of filing in which to make a final disposition of the claim and the claimant's option under 28 U.S.C. 2675(a) to bring suit shall not accrue until 6 months after the filing of a request for reconsideration. Final Department action on a request for reconsideration shall be effected in accordance with the provisions of paragraph (a) of this section.

[32 FR 14101, Oct. 11, 1967, as amended at 35 FR 4517, Mar. 13, 1970]

§ 35.7 Payment of approved claims.

(a) Upon allowance of his claim, claimant or his duly authorized agent shall sign the voucher for payment, Standard Form 1145, before payment is made.

(b) When the claimant is represented by an attorney, the voucher for payment (SF 1145) shall designate both the claimant and his attorney as "payees." The check shall be delivered to the attorney whose address shall appear on the voucher.

§ 35.8 Release.

Acceptance by the claimant, his agent or legal representative, of any award, compromise or settlement made hereunder, shall be final and conclusive on the claimant, his agent or legal representative and any other person on whose behalf or for whose benefit the claim has been presented, and shall constitute a complete release of any claim against the United States and against any employee of the Government whose act or omission gave rise to the claim, by reason of the same subject matter.

§ 35.9 Penalties.

A person who files a false claim or makes a false or fraudulent statement in a claim against the United States may be liable to a fine of not more than \$10,000 or to imprisonment of not more than 5 years, or both (18 U.S.C. 287.1001), and, in addition, to a forfeiture of \$2,000 and a penalty of double the loss or damage sustained by the United States (31 U.S.C. 231).

§ 35.10 Limitation on Department's authority.

(a) An award, compromise or settlement of a claim hereunder in excess of \$25,000 shall be effected only with the prior written approval of the Attorney General or his designee. For the purposes of this paragraph, a principal claim and any derivative or subrogated claim shall be treated as a single claim.

(b) An administrative claim may be adjusted, determined, compromised or settled hereunder only after consultation with the Department of Justice when, in the opinion of the Department:

(1) A new precedent or a new point of law is involved; or

(2) A question of policy is or may be involved; or

(3) The United States is or may be entitled to indemnity or contribution from a third party and the Department is unable to adjust the third party claim; or

(4) The compromise of a particular claim, as a practical matter, will or may control the disposition of a related claim in which the amount to be paid may exceed \$25,000.

(c) An administrative claim may be adjusted, determined, compromised or settled only after consultation with the Department of Justice when it is learned that the United States or an employee, agent or cost plus contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

PART 36—INDEMNIFICATION OF HHS EMPLOYEES

§ 36.1 Policy.

(a) The Department of Health and Human Services may indemnify, in whole or in part, its employees (which for the purpose of this regulation includes former employees) for any verdict, judgment or other monetary award which is rendered against any such employee, provided that the conduct giving rise to the verdict, judgment or award was taken within the scope of his or her employment with the Department and that such indemnification is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(b) The Department of Health and Human Services may settle or compromise a personal damage claim against its employee by the payment of available funds, at any time, provided the alleged conduct giving rise to the personal damage claim was taken within the scope of employment and that such settlement or compromise is in the interest of the United States, as determined by the Secretary, or his or her designee, in his or her discretion.

(c) Absent exceptional circumstances, as determined by the Secretary or his or her designee, the Department will not entertain a request either to agree to indemnify or to settle a personal damage claim before entry of an adverse verdict, judgment or monetary award.

(d) When an employee of the Department of Health and Human Services becomes aware that an action has been filed against the employee in his or her individual capacity as a result of conduct taken within the scope of his or her employment, the employee should immediately notify the Department that such an action is pending.

(e) The employee may, thereafter, request either (1) indemnification to satisfy a verdict, judgment or award entered against the employee or (2) payment to satisfy the requirements of a settlement proposal. The employee shall submit a written request, with documentation including copies of the verdict, judgment, award or settlement proposal, as appropriate, to the head of

his employing component, who shall thereupon submit to the General Counsel, in a timely manner, a recommended disposition of the request. The General Counsel shall also seek the views of the Department of Justice. The General Counsel shall forward the request, the employing component's recommendation and the General Counsel's recommendation to the Secretary for decision.

(f) Any payment under this section either to indemnify a Department of Health and Human Services employee or to settle a personal damage claim shall be contingent upon the availability of appropriated funds of the employing component of the Department of Health and Human Services.

(Authority: 5 U.S.C. 301)

[53 FR 11280, Apr. 6, 1988]

PART 46—PROTECTION OF HUMAN SUBJECTS

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

Sec.

- 46.101 To what does this policy apply?
- 46.102 Definitions for purposes of this policy.
- 46.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.
- 46.104 Exempt research.
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- 46.107 IRB membership.
- 46.108 IRB functions and operations.
- 46.109 IRB review of research.
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- 46.111 Criteria for IRB approval of research.
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- 46.121 [Reserved]
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- 46.202 Definitions.
- 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.
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- 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

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- 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

- 46.408 Requirements for permission by parents or guardians and for assent by children.
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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289(a); 42 U.S.C. 300v-1(b).

EDITORIAL NOTE: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost-sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

Subpart A—Basic HHS Policy for Protection of Human Research Subjects

SOURCE: 82 FR 7259, 7273, Jan. 19, 2017, unless otherwise noted.

§ 46.101 To what does this policy apply?

(a) Except as detailed in § 46.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States. Institutions that are engaged in research described in this paragraph and institutional review boards (IRBs) reviewing research that is subject to this policy must comply with this policy.

(b) [Reserved]

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy and this judgment shall be exercised consistent with the ethical principles of the Belmont Report.⁶²

(d) Department or agency heads may require that specific research activities or classes of research activities conducted, supported, or otherwise subject to regulation by the Federal department or agency but not otherwise covered by this policy comply with some or all of the requirements of this policy.

(e) Compliance with this policy requires compliance with pertinent federal laws or regulations that provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations that may otherwise be applicable and that provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise

published as provided in department or agency procedures.

(i) Unless otherwise required by law, department or agency heads may waive the applicability of some or all of the provisions of this policy to specific research activities or classes of research activities otherwise covered by this policy, provided the alternative procedures to be followed are consistent with the principles of the Belmont Report.⁶³ Except when otherwise required by statute or Executive Order, the department or agency head shall forward advance notices of these actions to the Office for Human Research Protections, Department of Health and Human Services (HHS), or any successor office, or to the equivalent office within the appropriate Federal department or agency, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures. The waiver notice must include a statement that identifies the conditions under which the waiver will be applied and a justification as to why the waiver is appropriate for the research, including how the decision is consistent with the principles of the Belmont Report.

(j) Federal guidance on the requirements of this policy shall be issued only after consultation, for the purpose of harmonization (to the extent appropriate), with other Federal departments and agencies that have adopted this policy, unless such consultation is not feasible.

(k) [Reserved]

(1) Compliance dates and transition provisions:

(1) *Pre-2018 Requirements.* For purposes of this section, the *pre-2018 Requirements* means this subpart as published in the 2016 edition of the Code of Federal Regulations.

(2) *2018 Requirements.* For purposes of this section, the *2018 Requirements* means the Federal Policy for the Protection of Human Subjects requirements contained in this subpart. The general compliance date for the 2018 Requirements is January 21, 2019. The

⁶²The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.— Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979.

⁶³*Id.*

compliance date for § 46.114(b) (cooperative research) of the 2018 Requirements is January 20, 2020.

(3) *Research subject to pre-2018 requirements.* The pre-2018 Requirements shall apply to the following research, unless the research is transitioning to comply with the 2018 Requirements in accordance with paragraph (1)(4) of this section:

(i) Research initially approved by an IRB under the pre-2018 Requirements before January 21, 2019;

(ii) Research for which IRB review was waived pursuant to § 46.101(i) of the pre-2018 Requirements before January 21, 2019; and

(iii) Research for which a determination was made that the research was exempt under § 46.101(b) of the pre-2018 Requirements before January 21, 2019.

(4) *Transitioning research.* If, on or after July 19, 2018, an institution planning or engaged in research otherwise covered by paragraph (1)(3) of this section determines that such research instead will transition to comply with the 2018 Requirements, the institution or an IRB must document and date such determination.

(i) If the determination to transition is documented between July 19, 2018, and January 20, 2019, the research shall:

(A) Beginning on the date of such documentation through January 20, 2019, comply with the pre-2018 Requirements, except that the research shall comply with the following:

(1) Section 46.102(l) of the 2018 Requirements (definition of research) (instead of § 46.102(d) of the pre-2018 Requirements);

(2) Section 46.103(d) of the 2018 Requirements (revised certification requirement that eliminates IRB review of application or proposal) (instead of § 46.103(f) of the pre-2018 Requirements); and

(3) Section 46.109(f)(1)(i) and (iii) of the 2018 Requirements (exceptions to mandated continuing review) (instead of § 46.103(b), as related to the requirement for continuing review, and in addition to § 46.109, of the pre-2018 Requirements); and

(B) Beginning on January 21, 2019, comply with the 2018 Requirements.

(ii) If the determination to transition is documented on or after January 21, 2019, the research shall, beginning on the date of such documentation, comply with the 2018 Requirements.

(5) *Research subject to 2018 Requirements.* The 2018 Requirements shall apply to the following research:

(i) Research initially approved by an IRB on or after January 21, 2019;

(ii) Research for which IRB review is waived pursuant to paragraph (i) of this section on or after January 21, 2019; and

(iii) Research for which a determination is made that the research is exempt on or after January 21, 2019.

(m) *Severability:* Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

[82 FR 7259, 7273, Jan. 19, 2017, as amended at 83 FR 28518, June 19, 2018]

§ 46.102 Definitions for purposes of this policy.

(a) *Certification* means the official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

(b) *Clinical trial* means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

(c) *Department or agency head* means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency

to whom the authority provided by these regulations to the department or agency head has been delegated.

(d) *Federal department or agency* refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (e.g., the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

(e)(1) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(2) *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(3) *Interaction* includes communication or interpersonal contact between investigator and subject.

(4) *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(6) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

(7) Federal departments or agencies implementing this policy shall:

(i) Upon consultation with appropriate experts (including experts in data matching and re-identification), reexamine the meaning of “identifiable private information,” as defined in paragraph (e)(5) of this section, and “identifiable biospecimen,” as defined in paragraph (e)(6) of this section. This reexamination shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. If appropriate and permitted by law, such Federal departments and agencies may alter the interpretation of these terms, including through the use of guidance.

(ii) Upon consultation with appropriate experts, assess whether there are analytic technologies or techniques that should be considered by investigators to generate “identifiable private information,” as defined in paragraph (e)(5) of this section, or an “identifiable biospecimen,” as defined in paragraph (e)(6) of this section. This assessment shall take place within 1 year and regularly thereafter (at least every 4 years). This process will be conducted by collaboration among the Federal departments and agencies implementing this policy. Any such technologies or techniques will be included on a list of technologies or techniques that produce identifiable private information or identifiable biospecimens. This list will be published in the FEDERAL REGISTER after notice and an opportunity for public comment. The Secretary, HHS, shall maintain the list on a publicly accessible Web site.

(f) *Institution* means any public or private entity, or department or agency (including federal, state, and other agencies).

(g) *IRB* means an institutional review board established in accord with and for the purposes expressed in this policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

(i) *Legally authorized representative* means an individual or judicial or

other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

(j) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(k) *Public health authority* means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

(l) *Research* means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

(1) Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

(m) *Written, or in writing*, for purposes of this part, refers to writing on a tangible medium (*e.g.*, paper) or in an electronic format.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal department or agency.

(a) Each institution engaged in research that is covered by this policy, with the exception of research eligible for exemption under § 46.104, and that is conducted or supported by a Federal department or agency, shall provide written assurance satisfactory to the department or agency head that it will comply with the requirements of this policy. In lieu of requiring submission of an assurance, individual department or agency heads shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for Federal-

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wide use by that office. When the existence of an HHS-approved assurance is accepted in lieu of requiring submission of an assurance, reports (except certification) required by this policy to be made to department and agency heads shall also be made to the Office for Human Research Protections, HHS, or any successor office. Federal departments and agencies will conduct or support research covered by this policy only if the institution has provided an assurance that it will comply with the requirements of this policy, as provided in this section, and only if the institution has certified to the department or agency head that the research has been reviewed and approved by an IRB (if such certification is required by § 46.103(d)).

(b) The assurance shall be executed by an individual authorized to act for the institution and to assume on behalf of the institution the obligations imposed by this policy and shall be filed in such form and manner as the department or agency head prescribes.

(c) The department or agency head may limit the period during which any assurance shall remain effective or otherwise condition or restrict the assurance.

(d) Certification is required when the research is supported by a Federal department or agency and not otherwise waived under § 46.101(i) or exempted under § 46.104. For such research, institutions shall certify that each proposed research study covered by the assurance and this section has been reviewed and approved by the IRB. Such certification must be submitted as prescribed by the Federal department or agency component supporting the research. Under no condition shall research covered by this section be initiated prior to receipt of the certification that the research has been reviewed and approved by the IRB.

(e) For nonexempt research involving human subjects covered by this policy (or exempt research for which limited IRB review takes place pursuant to § 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall docu-

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ment the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (*e.g.*, in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).

(Approved by the Office of Management and Budget under Control Number 0990–0260)

§ 46.104 Exempt research.

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) *Subpart B.* Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) *Subpart C.* The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) *Subpart D.* The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

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(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such

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projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was

obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

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§ 46.105–46.106 [Reserved]

§ 46.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

(b) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

(c) Each IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(d) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

(e) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ 46.108 IRB functions and operations.

(a) In order to fulfill the requirements of this policy each IRB shall:

(1) Have access to meeting space and sufficient staff to support the IRB's review and recordkeeping duties;

(2) Prepare and maintain a current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;

(3) Establish and follow written procedures for:

(i) Conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution;

(ii) Determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and

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(iii) Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

(4) Establish and follow written procedures for ensuring prompt reporting to the IRB; appropriate institutional officials; the department or agency head; and the Office for Human Research Protections, HHS, or any successor office, or the equivalent office within the appropriate Federal department or agency of

(i) Any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and

(ii) Any suspension or termination of IRB approval.

(b) Except when an expedited review procedure is used (as described in § 46.110), an IRB must review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

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§ 46.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under § 46.104 for which limited IRB review is a condition of exemption (under § 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

(b) An IRB shall require that information given to subjects (or legally authorized representatives, when appropriate) as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in

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§ 46.116, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

(c) An IRB shall require documentation of informed consent or may waive documentation in accordance with § 46.117.

(d) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

(e) An IRB shall conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § 46.109(f).

(f)(1) Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

(i) Research eligible for expedited review in accordance with § 46.110;

(ii) Research reviewed by the IRB in accordance with the limited IRB review described in § 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);

(iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

(A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

(B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

(2) [Reserved]

(g) An IRB shall have authority to observe or have a third party observe the consent process and the research.

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§ 46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

(a) The Secretary of HHS has established, and published as a Notice in the FEDERAL REGISTER, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The Secretary will evaluate the list at least every 8 years and amend it, as appropriate, after consultation with other federal departments and agencies and after publication in the FEDERAL REGISTER for public comment. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b)(1) An IRB may use the expedited review procedure to review the following:

(i) Some or all of the research appearing on the list described in paragraph (a) of this section, unless the reviewer determines that the study involves more than minimal risk;

(ii) Minor changes in previously approved research during the period for which approval is authorized; or

(iii) Research for which limited IRB review is a condition of exemption under § 46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

(2) Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in § 46.108(b).

(c) Each IRB that uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals that have been approved under the procedure.

(d) The department or agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

§ 46.111 Criteria for IRB approval of research.

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

(ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (*e.g.*, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § 46.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with § 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

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(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

(ii) [Reserved]

(8) For purposes of conducting the limited IRB review required by § 46.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § 46.116(a)(1)–(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § 46.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

§ 46.112 Review by institution.

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

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§ 46.113 Suspension or termination of IRB approval of research.

An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

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§ 46.114 Cooperative research.

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

(b)(1) Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

(2) The following research is not subject to this provision:

(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or

(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

(c) For research not subject to paragraph (b) of this section, an institution participating in a cooperative project may enter into a joint review arrangement, rely on the review of another

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IRB, or make similar arrangements for avoiding duplication of effort.

§ 46.115 IRB records.

(a) An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

(1) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent forms, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(3) Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in § 46.109(f)(1).

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described in § 46.108(a)(2).

(6) Written procedures for the IRB in the same detail as described in § 46.108(a)(3) and (4).

(7) Statements of significant new findings provided to subjects, as required by § 46.116(c)(5).

(8) The rationale for an expedited reviewer's determination under § 46.110(b)(1)(i) that research appearing on the expedited review list described in § 46.110(a) is more than minimal risk.

(9) Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in § 46.103(e).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be

accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner.

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§ 46.116 General requirements for informed consent.

(a) *General.* General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials is described in paragraph (e) of this section. General waiver or alteration of informed consent is described in paragraph (f) of this section. Except as provided elsewhere in this policy:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate,

and an opportunity to discuss that information.

(5) Except for broad consent obtained in accordance with paragraph (d) of this section:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

(b) *Basic elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(c) *Additional elements of informed consent.* Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo

or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.*, sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(d) *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.* Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided

to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private

information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

(e) *Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials*—(1) *Waiver*. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (e)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration*. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (e)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration*. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(A) Public benefit or service programs;

(B) Procedures for obtaining benefits or services under those programs;

(C) Possible changes in or alternatives to those programs or procedures; or

(D) Possible changes in methods or levels of payment for benefits or services under those programs; and

(ii) The research could not practicably be carried out without the waiver or alteration.

(f) *General waiver or alteration of consent*—(1) *Waiver*. An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements of paragraph (f)(3) of this section. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

(2) *Alteration*. An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in paragraphs (b) and (c) of this section provided the IRB satisfies the requirements of paragraph (f)(3) of this section. An IRB may not omit or alter any of the requirements described in paragraph (a) of this section. If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under paragraph (d) of this section.

(3) *Requirements for waiver and alteration*. In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:

(i) The research involves no more than minimal risk to the subjects;

(ii) The research could not practicably be carried out without the requested waiver or alteration;

(iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;

(iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

(g) *Screening, recruiting, or determining eligibility.* An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

(1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

(2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

(h) *Posting of clinical trial consent form.* (1) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

(2) If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

(3) The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

(i) *Preemption.* The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.

(j) *Emergency medical care.* Nothing in this policy is intended to limit the authority of a physician to provide emer-

gency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

(Approved by the Office of Management and Budget under Control Number 0990-0260)

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.

(b) Except as provided in paragraph (c) of this section, the informed consent form may be either of the following:

(1) A written informed consent form that meets the requirements of § 46.116. The investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative.

(2) A short form written informed consent form stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative, and that the key information required by § 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. The IRB shall approve a written summary of what is to be said to the subject or the legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Only the short form itself is to be signed by the subject or the subject's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the subject's

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legally authorized representative, in addition to a copy of the short form.

(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

§ 46.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in

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which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. Except for research waived under § 46.101(i) or exempted under § 46.104, no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

§ 46.119 Research undertaken without the intention of involving human subjects.

Except for research waived under § 46.101(i) or exempted under § 46.104, in the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted by the institution to the Federal department or agency component supporting the research, and final approval given to the proposed change by the Federal department or agency component.

§ 46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the Federal department or agency through such officers and employees of the Federal department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

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§ 46.122 Use of Federal funds.

Federal funds administered by a Federal department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 46.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that Federal department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has/have directed the scientific and technical aspects of an activity has/have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 46.124 Conditions.

With respect to any research project or any class of research projects the department or agency head of either the conducting or the supporting Federal department or agency may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

Subpart B—Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

SOURCE: 66 FR 56778, Nov. 13, 2001, unless otherwise noted.

§ 46.201 To what do these regulations apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all research involving pregnant women, human fetuses, neonates of uncertain viability, or nonviable neonates conducted or supported by the Department of Health and Human Services (DHHS). This includes all research conducted in DHHS facilities by any person and all research conducted in any facility by DHHS employees.

(b) The *pre-2018 Requirements* means 45 CFR part 46, subpart A, as revised October 1, 2016. The *2018 Requirements* means 45 CFR part 46, subpart A, as revised October 1, 2018.

(1) For research subject to the pre-2018 Requirements and this subpart, the exemptions at § 46.101(b)(1) through (6) of the pre-2018 Requirements are applicable to this subpart.

(2) For research subject to the 2018 Requirements and this subpart, the exemptions at § 46.104(d)(1) through (8) of the 2018 Requirements may be applied.

(c) The provisions of § 46.101(c) through (i) are applicable to this subpart. Reference to State or local laws in this subpart and in § 46.101(f) is intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

[66 FR 56778, Nov. 13, 2001, as amended at 89 FR 84825, Oct. 24, 2024]

§ 46.202 Definitions.

The definitions in § 46.102 of the pre-2018 Requirements and the 2018 Requirements, as applicable, shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous

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movement of voluntary muscles, nor pulsation of the umbilical cord.

(b) Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

(c) Fetus means the product of conception from implantation until delivery.

(d) Neonate means a newborn.

(e) Nonviable neonate means a neonate after delivery that, although living, is not viable.

(f) Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

(g) Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(h) *Viable*, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart-beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the FEDERAL REGISTER guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of the pre-2018 Requirements or the 2018 Requirements, as applicable, and subpart D of this part.

[66 FR 56778, Nov. 13, 2001, as amended at 89 FR 84825, Oct. 24, 2024]

§ 46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart and the other subparts of this part.

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§ 46.204 Research involving pregnant women or fetuses.

Pregnant women or fetuses may be involved in research if all of the following conditions are met:

(a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(b) The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

(c) Any risk is the least possible for achieving the objectives of the research;

(d) If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of the pre-2018 Requirements or the 2018 Requirements, as applicable;

(e) If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of the pre-2018 Requirements or the 2018 Requirements, as applicable, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest;

(f) Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

(g) For children as defined in § 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

(h) No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

(i) Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

(j) Individuals engaged in the research will have no part in determining the viability of a neonate.

[66 FR 56778, Nov. 13, 2001, as amended at 89 FR 84825, Oct. 24, 2024]

§ 46.205 Research involving neonates.

(a) Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:

(1) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

(2) Each individual providing consent under paragraph (b)(2) or (c)(5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

(3) Individuals engaged in the research will have no part in determining the viability of a neonate.

(4) The requirements of paragraph (b) or (c) of this section have been met as applicable.

(b) *Neonates of uncertain viability.* Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions are met:

(1) The IRB determines that:

(i) The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or

(ii) The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

(2) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent

because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the pre-2018 Requirements or the 2018 Requirements, as applicable, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

(c) *Nonviable neonates.* After delivery nonviable neonate may not be involved in research covered by this subpart unless all of the following additional conditions are met:

(1) Vital functions of the neonate will not be artificially maintained;

(2) The research will not terminate the heartbeat or respiration of the neonate;

(3) There will be no added risk to the neonate resulting from the research;

(4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

(5) The legally effective informed consent of both parents of the neonate is obtained in accord with the pre-2018 Requirements or the 2018 Requirements, as applicable, except that the waiver and alteration provisions of § 46.116 of the pre-2018 Requirements or the 2018 Requirements do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c)(5).

(d) *Viable neonates.* A neonate, after delivery, that has been determined to be viable may be included in the research only to the extent permitted by and in accord with the requirements of the pre-2018 Requirements or the 2018 Requirements, as applicable, and subpart D of this part.

[66 FR 56778, Nov. 13, 2001, as amended at 89 FR 84825, Oct. 24, 2024]

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§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

(a) Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

(b) If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

§ 46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

The Secretary will conduct or fund research that the IRB does not believe meets the requirements of § 46.204 or § 46.205 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the FEDERAL REGISTER, has determined either:

(1) That the research in fact satisfies the conditions of § 46.204, as applicable; or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;

(ii) The research will be conducted in accord with sound ethical principles; and

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(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

Subpart C—Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

SOURCE: 43 FR 53655, Nov. 16, 1978, unless otherwise noted.

§ 46.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Department of Health and Human Services involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts in this part and includes the pre-2018 Requirements and the 2018 Requirements, as applicable. The *pre-2018 Requirements* means 45 CFR part 46, subpart A, as revised October 1, 2016. The *2018 Requirements* means 45 CFR part 46, subpart A, as revised October 1, 2018.

[43 FR 53655, Nov. 16, 1978, as amended at 89 FR 84825, Oct. 24, 2024]

§ 46.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

§ 46.303 Definitions.

As used in this subpart:

(a) *Secretary* means the Secretary of Health and Human Services and any

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other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

(b) *DHHS* means the Department of Health and Human Services.

(c) *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

(d) *Minimal risk* is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

§ 46.304 Composition of Institutional Review Boards where prisoners are involved.

In addition to satisfying the requirements in § 46.107 of the pre-2018 Requirements or the 2018 Requirements, as applicable, an Institutional Review Board, carrying out responsibilities with respect to this subpart, shall also meet the following specific requirements:

(a) A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.

(b) At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

[43 FR 53655, Nov. 16, 1978, as amended at 46 FR 8386, Jan. 26, 1981; 89 FR 84826, Oct. 24, 2024]

§ 46.305 Additional duties of the Institutional Review Boards where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the

Board shall review research covered by this subpart and approve such research only if it finds that:

(1) The research under review represents one of the categories of research permissible under § 46.306(a)(2);

(2) Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;

(4) Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) The information is presented in language which is understandable to the subject population;

(6) Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The Board shall carry out such other duties as may be assigned by the Secretary.

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(c) The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

§ 46.306 Permitted research involving prisoners.

(a) Nonexempt biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

(1) The institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under § 46.305 of this subpart; and

(2) In the judgment of the Secretary the proposed research involves solely the following:

(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or

(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with

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appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners except as follows:

(1) For research subject to the pre-2018 Requirements and this subpart, except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

(2) For research subject to the 2018 Requirements and this subpart, except as provided in paragraph (a) of this section or for research that is exempt pursuant to § 46.104(b)(2) and (d)(1) through (8) of the 2018 Requirements, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

[43 FR 53655, Nov. 16, 1978, as amended at 89 FR 84826, Oct. 24, 2024]

Subpart D—Additional Protections for Children Involved as Subjects in Research

SOURCE: 48 FR 9818, Mar. 8, 1983, unless otherwise noted.

§ 46.401 To what does this subpart apply?

(a) The *pre-2018 Requirements* means 45 CFR part 46, subpart A, as revised October 1, 2016. The *2018 Requirements* means 45 CFR part 46, subpart A, as revised October 1, 2018.

(b) This subpart applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such non-substantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Department of Health and Human Services outside the United States, but in appropriate circumstances, the Secretary may,

under § 46.101(i) of the pre-2018 Requirements or the 2018 Requirements, waive the applicability of some or all of the requirements of this subpart for research of this type.

(c) The application of the exemptions to this subpart is as follows:

(1) For research subject to the pre-2018 Requirements and this subpart, the exemptions at § 46.101(b)(1) and (b)(3) through (6) of the pre-2018 Requirements are applicable to this subpart. The exemption at § 46.101(b)(2) of the pre-2018 Requirements regarding educational tests also is applicable to this subpart. However, the exemption at § 46.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(2) For research subject to the 2018 Requirements and this subpart, the exemptions at § 46.104(d)(1), (4), (5), (6), (7), and (8) of the 2018 Requirements are applicable to this subpart. The exemptions at § 46.104(d)(2)(i) and (ii) of the 2018 Requirements may only apply to research subject to this subpart that involves educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. The exemptions at § 46.104(d)(2)(iii) and (d)(3) of the 2018 Requirements may not be applied to research subject to this subpart.

(d) The exceptions, additions, and provisions for waiver as they appear in § 46.101(c) through (i) of the pre-2018 Requirements or the 2018 Requirements are applicable to this subpart.

[89 FR 84826, Oct. 24, 2024]

§ 46.402 Definitions.

The definitions in § 46.102 of the pre-2018 Requirements and the 2018 Requirements, as applicable, shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

[48 FR 9818, Mar. 8, 1983, as amended at 89 FR 84826, Oct. 24, 2024]

§ 46.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

§ 46.404 Research not involving greater than minimal risk.

HHS will conduct or fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

(a) The risk is justified by the anticipated benefit to the subjects;

(b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

(c) Adequate provisions are made for soliciting the assent of the children

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and permission of their parents or guardians, as set forth in § 46.408.

§ 46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that:

(a) The risk represents a minor increase over minimal risk;

(b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

(d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in § 46.408.

§ 46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

HHS will conduct or fund research that the IRB does not believe meets the requirements of § 46.404, § 46.405, or § 46.406 only if:

(a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

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(1) That the research in fact satisfies the conditions of § 46.404, § 46.405, or § 46.406, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in § 46.408.

§ 46.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 46.116 of the pre-2018 Requirements or of the 2018 Requirements, as applicable.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by

§ 46.116 of the pre-2018 Requirements or the 2018 Requirements, as applicable, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 46.404 or § 46.405. Where research is covered by §§ 46.406 and 46.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 46.116 of the pre-2018 Requirements or the 2018 Requirements, as applicable, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in § 46.116 of the pre-2018 Requirements or 2018 Requirements, as applicable, and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by § 46.117 of the pre-2018 Requirements or the 2018 Requirements, as applicable.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

[48 FR 9818, Mar. 8, 1983, as amended at 89 FR 84826, Oct. 24, 2024]

§ 46.409 Wards.

(a) Children who are wards of the state or any other agency, institution, or entity can be included in research

approved under § 46.406 or § 46.407 only if such research is:

(1) Related to their status as wards; or

(2) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Subpart E—Registration of Institutional Review Boards

SOURCE: 74 FR 2405, Jan. 15, 2009, unless otherwise noted.

§ 46.501 What IRBs must be registered?

Each IRB that is designated by an institution under an assurance of compliance approved for federalwide use by the Office for Human Research Protections (OHRP) under § 46.103(a) and that reviews research involving human subjects conducted or supported by the Department of Health and Human Services (HHS) must be registered with HHS. An individual authorized to act on behalf of the institution or organization operating the IRB must submit the registration information.

§ 46.502 What information must be provided when registering an IRB?

The following information must be provided to HHS when registering an IRB:

(a) The name, mailing address, and street address (if different from the mailing address) of the institution or organization operating the IRB(s); and the name, mailing address, phone number, facsimile number, and electronic

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mail address of the senior officer or head official of that institution or organization who is responsible for overseeing activities performed by the IRB.

(b) The name, mailing address, phone number, facsimile number, and electronic mail address of the contact person providing the registration information.

(c) The name, if any, assigned to the IRB by the institution or organization, and the IRB's mailing address, street address (if different from the mailing address), phone number, facsimile number, and electronic mail address.

(d) The name, phone number, and electronic mail address of the IRB chairperson.

(e)(1) The approximate numbers of:

(i) All active protocols; and

(ii) Active protocols conducted or supported by HHS.

(2) For purpose of this regulation, an "active protocol" is any protocol for which the IRB conducted an initial review or a continuing review at a convened meeting or under an expedited review procedure during the preceding twelve months.

(f) The approximate number of full-time equivalent positions devoted to the IRB's administrative activities.

§ 46.503 When must an IRB be registered?

An IRB must be registered before it can be designated under an assurance approved for federalwide use by OHRP under § 46.103(a). IRB registration becomes effective when reviewed and accepted by OHRP. The registration will be effective for 3 years.

§ 46.504 How must an IRB be registered?

Each IRB must be registered electronically through <http://ohrp.cit.nih.gov/efile> unless an institution or organization lacks the ability to register its IRB(s) electronically. If an institution or organization lacks the ability to register an IRB electronically, it must send its IRB registration information in writing to OHRP.

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§ 46.505 When must IRB registration information be renewed or updated?

(a) Each IRB must renew its registration every 3 years.

(b) The registration information for an IRB must be updated within 90 days after changes occur regarding the contact person who provided the IRB registration information or the IRB chairperson. The updated registration information must be submitted in accordance with § 46.504.

(c) Any renewal or update that is submitted to, and accepted by, OHRP begins a new 3-year effective period.

(d) An institution's or organization's decision to disband a registered IRB which it is operating also must be reported to OHRP in writing within 30 days after permanent cessation of the IRB's review of HHS-conducted or -supported research.

PART 50—U.S. EXCHANGE VISITOR PROGRAM—REQUEST FOR WAIVER OF THE TWO-YEAR FOREIGN RESIDENCE REQUIREMENT

Sec.

50.1 Authority.

50.2 Exchange Visitor Waiver Review Board.

50.3 Policy.

50.4 Waivers for research.

50.5 Waivers for the delivery of health care service.

50.6 Procedures for submission of application to HHS.

50.7 Personal hardship, persecution and visa extension considerations.

50.8 Compliance.

AUTHORITY: 75 Stat. 527 (22 U.S.C. 2451 *et seq.*); 84 Stat. 116 (8 U.S.C. 1182(e)).

SOURCE: 49 FR 9900, Mar. 16, 1984, unless otherwise noted.

§ 50.1 Authority.

Under the authority of Mutual Educational and Cultural Exchange Act of 1961 (75 Stat. 527) and the Immigration and Nationality Act as amended (84 Stat. 116), the Department of Health and Human Services is an "interested United States Government agency" with the authority to request the Department of State to recommend to the Attorney General waiver of the two-year foreign residence requirement for Exchange Visitors under the Mutual

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Educational and Cultural Exchange Program. HHS eligibility requirement criteria for waivers are in addition to and independent of the existing waiver and visa criteria established by the Immigration and Naturalization Service (INS), the Department of State, and the Department of Labor. The waiver regulations described in this part do not relieve alien physicians seeking a waiver of the 2-year foreign residence requirement from complying with the terms and conditions imposed on their admission to the United States.

[67 FR 77695, Dec. 19, 2002]

§ 50.2 Exchange Visitor Waiver Review Board.

(a) *Establishment.* The Exchange Visitor Waiver Review Board is established to carry out the Department's responsibilities under the Exchange Visitor Program.

(b) *Functions.* The Exchange Visitor Waiver Review Board is responsible for making thorough and equitable evaluations of applications submitted by institutions, acting on behalf of Exchange Visitors, to HHS for a favorable recommendation to the Department of State that the two-year foreign residence requirement for Exchange Visitors under the Exchange Visitor Program be waived.

(c) *Membership.* The Exchange Visitor Waiver Review Board consists of no fewer than three members and two alternates, of whom no fewer than three will consider any particular application. The Director of the Office of Global Health Affairs, Office of the Secretary, is an ex officio member of the Board and serves as its Chairman. The Director may designate a staff member of the Office of the Secretary to serve as member and Chairman of the Board in the Director's absence. The Assistant Secretary for Health appoints two regularly assigned members and two alternates to consider applications concerning health, biomedical research, and related fields. The Chairman may request the heads of operating divisions of the Department to appoint additional members to consider applications in other fields of interest to the Department. The Board may obtain expert advisory opinions from other sources. The Board may es-

tablish a workgroup from the operating divisions of the Department to consider applications for waivers based on the need for the delivery of health care services to underserved populations.

[49 FR 9900, Mar. 16, 1984, as amended at 67 FR 77695, Dec. 19, 2002]

§ 50.3 Policy.

(a) *Policy for waivers.* The Department of Health and Human Services endorses the philosophy that Exchange Visitors are committed to return home for at least two years after completing their program. This requirement was imposed to prevent the Program from becoming a stepping stone to immigration and to ensure that Exchange Visitors make available to their home countries their new knowledge and skills obtained in the United States. The Department will request waivers for the delivery of health care service to carry out the Department's mission to increase access to care for the nation's most medically underserved individuals. However, in keeping with the philosophy of the Program, the Exchange Visitor Waiver Review Board may determine the appropriate numbers and geographic areas for waivers for the delivery of health care service.

(b) *Criteria for waivers.* The Exchange Visitor Waiver Review Board carefully applies stringent and restrictive criteria to its consideration of requests that it support waivers for Exchange Visitors. Each application is evaluated individually based on the facts available.

(c) *Waiver for members of Exchange Visitor's family.* Where a decision is made to request a waiver for an Exchange Visitor, a waiver will also be requested for the spouse and children, if any, if they have J-2 visa status. When both members of a married couple are Exchange Visitors in their own right (*i.e.*, each has J-1 visa status), separate applications must be submitted for each of them.

[67 FR 77696, Dec. 19, 2002]

§ 50.4 Waivers for research.

In determining whether to request a waiver for an Exchange Visitor engaged in the conduct of research, the

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Board considers the following key factors:

(a) The program or activity at the applicant institution or organization in which the Exchange Visitor is employed must be of high priority and of national or international significance in an area of interest to the Department.

(b) The Exchange Visitor must be needed as an integral part of the program or activity, or of an essential component thereof, so that loss of his/her services would necessitate discontinuance of the program, or a major phase of it. Specific evidence must be provided on how the loss or unavailability of the individual's services would adversely affect the initiation, continuance, completion, or success of the program or activity. The applicant organization/institution must clearly demonstrate that a suitable replacement for the Exchange Visitor cannot be found through recruitment or any other means. The Board will not request a waiver when the principal problem appears to be one of administrative, budgetary, or program inconvenience to the institution or other employer.

(c) The Exchange Visitor must possess outstanding qualifications, training and experience well beyond the usually expected accomplishments at the graduate, postgraduate, and residency levels, and must clearly demonstrate the capability to make original and significant contributions to the program. The Board will not request a waiver simply because an individual has specialized training or experience or is occupying a senior staff position in a university, hospital, or other institution.

[67 FR 77696, Dec. 19, 2002]

§ 50.5 Waivers for the delivery of health care service.

In determining whether to request a waiver for an Exchange Visitor to deliver health care service, the Board will consider information from and coordinate with State Departments of Public Health (or the equivalent), other "interested government agencies" which request waivers, and other relevant agencies. The Board requires the following criteria for requests for

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waivers for the delivery of health care service:

(a) The Exchange Visitor must submit a statement that he or she does not have pending and will not submit any other "interested government agency" waiver request while HHS processes the waiver request being submitted.

(b) Waivers are limited to primary care physicians and general psychiatrists who have completed their primary care or psychiatric residency training programs no more than 12 months before the date of commencement of employment under the contract described in subparagraph (d). This 12-month eligibility limitation is to ensure that the physicians' primary care training is current and they are not engaged in subspecialty training. This HHS eligibility requirement relates only to eligibility for an HHS waiver request and does not relieve physicians of the responsibility to maintain lawful status. Alien physicians are strongly encouraged to begin the waiver process as early as they possibly can while still in the residency training program. Early filing of the waiver request by the alien physician, coupled with timely processing of the request by the relevant government agencies, will facilitate the timely completion of the waiver process before the authorized J-1 admission expires, and the physician's subsequent application for change of nonimmigrant status from J-1 to H-1B.

(c) Primary care physicians are defined as: physicians practicing general internal medicine, pediatrics, family practice or obstetrics/gynecology willing to work in a primary care Health Professional Shortage Area (HPSA) or Medically Underserved Area or Population (MUA/P); and general psychiatrists who are willing to work in a Mental Health HPSA. Note: these HHS eligibility criteria for waivers are in addition to and independent of the existing waiver and visa criteria established by the Immigration and Naturalization Service (INS), the Department of State, and the Department of Labor.

(d) The Exchange Visitor must have entered a contract with the applicant employer. This contract must:

(1) Require the Exchange Visitor to provide primary medical care in a facility physically located in an HHS-designated primary care HPSA or MUA/P, or general psychiatric care in a Mental Health HPSA.

(2) Require the Exchange Visitor to complete a term of employment of not less than three years providing primary care health services for not less than 40 hours per week.

(3) Require the Exchange Visitor to:

(i) Be licensed by the State where he or she will practice;

(ii) Have completed a residency in one of the following specialties: family practice, general pediatrics, obstetrics/gynecology, general internal medicine, or general psychiatry; and

(iii) Be either board certified or board eligible in the relevant primary care discipline.

(4) Be terminable only for cause until completion of the three-year commitment, except that, with the agreement of the alien physician, the employer may assign the contract to another eligible employer with the prior approval of HHS and compliance with all applicable INS and Department of Labor requirements. Prior to approving an assignment of the contract, HHS will review and consider the health care needs of the alien physician's current and proposed new locations, as well as the reasons for the request.

(5) Not contain a restrictive covenant or non-compete clause which prevents or discourages the physician from continuing to practice in any HHS-designated primary care HPSA or MUA/P or Mental Health HPSA after the period of obligation under the contract has expired.

(6) Provide that any amendment to the contract complies with all applicable Federal statutes, regulations and HHS policy.

(7) Be consistent with all applicable Federal statutes, regulations and HHS policy.

(e) The facility or practice sponsoring the physician:

(1) Must provide health services to individuals without discriminating against them because either they are unable to pay for those services or payment for those health services will be made under Medicare or Medicaid.

(2) May charge no more than the usual and customary rate prevailing in the geographic area in which the services are provided.

(3) Must provide care on a sliding fee scale for persons at or below 200 percent of poverty income level. Persons with third-party insurance may be charged the full fee for service.

(4) Must post a notice in a conspicuous location in the patient waiting area at the practice site to notify patients of the charges for service as required in this paragraph.

(5) Must provide evidence that the applicant facility made unsuccessful efforts to recruit a physician who is a United States physician for the position to be filled by the Exchange Visitor.

(6) Must provide a statement by the head of the facility to confirm the facility is located in a specific, designated HPSA or MUA/P, and that it provides medical care to Medicaid and Medicare eligible patients and to the uninsured indigent.

(f) The employer and the alien physician must submit information to the Secretary at the times and in the manner that the Secretary may reasonably require.

[67 FR 77696, Dec. 19, 2002]

§ 50.6 Procedures for submission of application to HHS.

(a) The Exchange Visitor Waiver Review Board will review applications submitted by private or non-federal institutions, organizations, or agencies or by a component agency of HHS. The Board will not accept applications submitted by Exchange Visitors or, unless under extenuating and exceptional circumstances, other U.S. Government Agencies.

(b) Applications, instruction sheets and information are available from the Executive Secretary, Exchange Visitor Waiver Review Board. An authorized official of the applicant institution (educational institution, hospital, laboratory, corporation, etc.) must sign the completed application. The applicant institution must send the completed application to the address indicated on the instruction sheet.

[67 FR 77697, Dec. 19, 2002]

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§ 50.7 Personal hardship, persecution and visa extension considerations.

(a) It is *not* within the Department's jurisdiction to consider applications for waiver based on:

(1) Exceptional hardship to the exchange visitor's American or legally resident alien spouse or child; or

(2) The alien's unwillingness to return to the country of his/her nationality or last residence on the grounds that he/she or family members would be subject to persecution on account of race, religion or political opinion.

(b) Likewise, this Department is not responsible for considering requests to extend visas.

(c) Inquiries concerning the above should be directed to the District Office of the Immigration and Naturalization Service which has jurisdiction over the exchange visitor's place of residence in the United States.

[49 FR 9900, Mar. 16, 1984. Redesignated at 67 FR 77696, Dec. 19, 2002]

§ 50.8 Compliance.

If an alien physician acquires H-1B nonimmigrant status following approval by the INS of a request for waiver, then he or she becomes subject not only to the terms and conditions of the waiver, but also the terms and conditions of the H-1B nonimmigrant status. Failure to comply with those conditions will make that physician subject to removal from the United States by the INS.

[67 FR 77697, Dec. 19, 2002]

PART 51—CRITERIA FOR EVALUATING COMPREHENSIVE PLAN TO REDUCE RELIANCE ON ALIEN PHYSICIANS

Sec.

51.1 Purpose.

51.2 Application.

51.3 Who is eligible to apply?

51.4 How will the plans be evaluated?

AUTHORITY: Sec. 212, Immigration and Nationality Act, Pub. L. 82-114, as amended by Pub. L. 97-116, 95 Stat. 1611 (8 U.S.C. 1182(j)(2)(A)).

SOURCE: 48 FR 2539, Jan. 20, 1983, unless otherwise noted.

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§ 51.1 Purpose.

The purpose of this regulation is to establish criteria for review and evaluation of the comprehensive plans of Graduate Medical Education Programs to reduce reliance on alien physicians, as required by the Immigration and Nationality Act Amendments of 1981, Pub. L. 97-116, for the waiver of certain requirements for exchange visitors who are coming to the United States to participate in programs of graduate medical education or training.

§ 51.2 Application.

Materials covering procedures for applying for substantial disruption waivers (including the comprehensive plan) may be obtained from the Educational Commission for Foreign Medical Graduates, 3624 Market Street, Philadelphia, Pennsylvania 19104.

EXPLANATORY NOTE: The Department of State entered into an agreement with the Educational Commission for Foreign Medical Graduates in 1971 whereby the latter was designated the authority to administer the issuance of the Form IAP-66 in all cases involving the admission, certification, transfer or extension of stay for foreign physicians in exchange visitor status who are receiving graduate medical education or training. The Commission was further designated the authority (FEDERAL REGISTER, Volume 44, No. 59, March 26, 1979), to process waiver requests under the "substantial disruption" provision of Pub. L. 94-484, as amended, within criteria to be provided by the United States Information Agency on advice from the Department of Health and Human Services (formerly Department of Health, Education, and Welfare).

§ 51.3 Who is eligible to apply?

Sponsors which had alien physicians in their exchange visitor programs on January 10, 1978, are eligible to apply. For purposes of this regulation, the term "program" relates to a graduate medical education program having an exchange visitor program for physicians participating in graduate medical education or training. An "exchange visitor program" is a program of a sponsor, designed to promote interchange of persons, knowledge and skills, and the interchange of developments in the field of education, the arts and sciences, and is concerned

with one or more categories of participants to promote mutual understanding between the people of the United States and the people of other countries.

§51.4 How will the plans be evaluated?

After consultation with the Federal Substantial Disruption Waiver Board (seven Federal representatives charged with the responsibility of reviewing substantial disruption waiver applications), the Secretary of Health and Human Services will make recommendations to the Director, United States Information Agency, for the purpose of granting waivers. The Secretary will consider the following factors in determining whether or not a plan is satisfactory:

(a) The extent of the specific problems that the program or institution anticipates without a waiver, including, for example,

(1) Curtailment of services currently provided,

(2) Downgrading of medical care currently being provided,

(3) Reduction in the number of inpatients and outpatients receiving care,

(4) Inadequate medical coverage for population served, or

(5) Inadequate supervision of junior residents.

(b) The adequacy of the alternative resources and methods (including use of physician assistants (as defined in 42 CFR 57.802), nurse practitioners (as defined in 42 CFR 57.2402), and other non-physician providers) that have been considered and have been and will be applied to reduce such disruption in the delivery of health services, especially in primary medical care manpower shortage areas, as established under section 332 of the Public Health Service Act, and for medicaid patients. This may include, for example:

(1) Greater reliance on fully licensed physicians, and on physician assistants, nurse practitioners and other non-physician personnel in an expanded role in the delivery of health care, such as admission patient histories, making patient rounds, recording patient progress notes, doing the initial and follow-up evaluation of patients, performing routine laboratory and related studies, or

(2) Utilization of the team approach to health care delivery (individuals functioning as an integral part of an interprofessional team of health personnel organized under the leadership of a physician working toward more efficient and/or more effective delivery of health services).

(c) The extent to which changes (including improvement of educational and medical services) have been considered and which have been or will be applied to make the program more attractive to graduates of medical schools who are citizens of the United States, as demonstrated, for example, by:

(1) Adding additional services to the existing programs to provide a broader educational experience for residents,

(2) Expanding affiliations with other residency programs to offer a broader experience for residents,

(3) Expanding undergraduate clerkships to provide a broader educational experience.

(4) Creating or modifying administrative units which will provide broader clinical experiences, or

(5) Initiating research projects.

(d) The adequacy of the recruitment efforts which have been and will be undertaken to attract graduates of medical schools who are citizens of the United States, as demonstrated, for example, by:

(1) Broad-based advertisement of the program and of the institution through notices in journals, contacts with medical schools, etc.

(2) Forming committees for the purpose of recruiting U.S. citizens.

(3) Working with national organizations which are involved with medical students and U.S. graduate medical trainees, e.g., the American Medical Student Association and the Physician National House Staff Association, to attract U.S. citizens.

(e) The extent to which the program on a year-by-year basis has phased down its dependence upon aliens who are graduates of foreign medical schools so that the program will not be dependent upon the admission to the program of any additional such aliens after December 31, 1983.

PART 57—VOLUNTEER SERVICES

Sec.

57.1 Applicability.

57.2 Definitions.

57.3 Volunteer service programs.

57.4 Acceptance and use of volunteer services.

57.5 Services and benefits available to volunteers.

AUTHORITY: Sec. 223, 58 Stat. 683, as amended by 81 Stat. 539; 42 U.S.C. 217b.

SOURCE: 34 FR 13868, Aug. 29, 1969, unless otherwise noted.

§ 57.1 Applicability.

The regulations in this part apply to the acceptance of volunteer and uncompensated services for use in the operation of any health care facility of the Department or in the provision of health care.

§ 57.2 Definitions.

As used in the regulations in this part:

Secretary means the Secretary of Health and Human Services.

Department means the Department of Health and Human Services.

Volunteer services are services performed by individuals (hereafter called volunteers) whose services have been offered to the Government and accepted under a formal agreement on a without compensation basis for use in the operation of a health care facility or in the provision of health care.

Health care means services to patients in Department facilities, beneficiaries of the Federal Government, or individuals or groups for whom health services are authorized under the programs of the Department.

Health care facility means a hospital, clinic, health center, or other facility established for the purpose of providing health care.

§ 57.3 Volunteer service programs.

Programs for the use of volunteer services may be established by the Secretary, or his designee, to broaden and strengthen the delivery of health services, contribute to the comfort and well being of patients in Department hospitals or clinics, or expand the services required in the operation of a health care facility. Volunteers may be

used to supplement, but not to take the place of, personnel whose services are obtained through the usual employment procedures.

§ 57.4 Acceptance and use of volunteer services.

The Secretary, or his designee, shall establish requirements for: Accepting volunteer services from individuals or groups of individuals, using volunteer services, giving appropriate recognition to volunteers, and maintaining records of volunteer services.

§ 57.5 Services and benefits available to volunteers.

(a) The following provisions of law may be applicable to volunteers whose services are offered and accepted under the regulations in this part:

(1) Subchapter I of Chapter 81 of Title 5 of the United States Code relating to medical services for work related injuries;

(2) Title 28 of the United States Code relating to tort claims;

(3) Section 7903 of Title 5 of the United States Code relating to protective clothing and equipment; and

(4) Section 5703 of Title 5 of the United States Code relating to travel and transportation expenses.

(b) Volunteers may also be provided such other benefits as are authorized by law or by administrative action of the Secretary or his designee.

PART 60—NATIONAL PRACTITIONER DATA BANK

Subpart A—General Provisions

Sec.

60.1 The National Practitioner Data Bank.

60.2 Applicability.

60.3 Definitions.

Subpart B—Reporting of Information

60.4 How information must be reported.

60.5 When information must be reported.

60.6 Reporting errors, omissions, revisions, or whether an action is on appeal.

60.7 Reporting medical malpractice payments.

60.8 Reporting licensure actions taken by Boards of Medical Examiners.

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- 60.11 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.
- 60.12 Reporting adverse actions taken against clinical privileges.
- 60.13 Reporting Federal or state criminal convictions related to the delivery of a health care item or service.
- 60.14 Reporting civil judgments related to the delivery of a health care item or service.
- 60.15 Reporting exclusions from participation in Federal or state health care programs.
- 60.16 Reporting other adjudicated actions or decisions.

Subpart C—Disclosure of Information by the National Practitioner Data Bank

- 60.17 Information which hospitals must request from the National Practitioner Data Bank.
- 60.18 Requesting information from the National Practitioner Data Bank.
- 60.19 Fees applicable to requests for information.
- 60.20 Confidentiality of National Practitioner Data Bank information.
- 60.21 How to dispute the accuracy of National Practitioner Data Bank information.
- 60.22 Immunity.

AUTHORITY: 42 U.S.C. 11101–11152; 42 U.S.C. 1396r–2; 42 U.S.C. 1320a–7e

SOURCE: 78 FR 20484, Apr. 5, 2013, unless otherwise noted.

Subpart A—General Provisions

§ 60.1 The National Practitioner Data Bank.

The Health Care Quality Improvement Act of 1986 (HCQIA), as amended, title IV of Public Law 99–660 (42 U.S.C. 11101 *et seq.*) (hereinafter referred to as “title IV”), authorizes the Secretary to establish (either directly or by contract) a National Practitioner Data Bank (NPDB) to collect and release certain information relating to the professional competence and conduct of physicians, dentists, and other health care practitioners. Section 1921 of the Social Security Act (hereinafter referred to as “section 1921”), as amended, (42 U.S.C. 1396r–2) expanded the requirements under the NPDB and requires each state to adopt a system of reporting to the Secretary adverse licensure or certification actions taken against health care practitioners,

health care entities, providers, and suppliers, as well as certain final adverse actions taken by state law and fraud enforcement agencies against health care practitioners, providers, and suppliers. Section 1128E of the Social Security Act (hereinafter referred to as “section 1128E”), as amended, (42 U.S.C. 1320a–7e) authorizes the Secretary to implement a national healthcare fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken by Federal Government agencies and health plans against health care practitioners, providers, and suppliers. Information from section 1921 and section 1128E is to be reported and distributed through the NPDB. The regulations in this part set forth the reporting and disclosure requirements for the NPDB, as well as procedures to dispute the accuracy of information contained in the NPDB.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.2 Applicability.

The regulations in this part establish reporting requirements applicable to hospitals, health care entities, Boards of Medical Examiners, and professional societies of health care practitioners which take adverse licensure or professional review actions; state licensing or certification authorities, peer review organizations, and private accreditation entities that take licensure or certification actions or negative actions or findings against health care practitioners, health care entities, providers, or suppliers; entities (including insurance companies) making payments as a result of medical malpractice actions or claims; and Federal government agencies, state law and fraud enforcement agencies and health plans that take final adverse actions against health care practitioners, providers, and suppliers. They also establish procedures to enable individuals or entities to obtain information from the NPDB or to dispute the accuracy of NPDB information.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

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§ 60.3 Definitions.

Adversely affecting means reducing, restricting, suspending, revoking, or denying clinical privileges or membership in a health care entity.

Affiliated or associated refers to health care entities with which a subject of a final adverse action has a business or professional relationship. This includes, but is not limited to, organizations, associations, corporations, or partnerships. This also includes a professional corporation or other business entity composed of a single individual.

Board of Medical Examiners, or Board, means a body or subdivision of such body which is designated by a state for the purpose of licensing, monitoring, and disciplining physicians or dentists. This term includes a Board of Osteopathic Examiners or its subdivision, a Board of Dentistry or its subdivision, or an equivalent body as determined by the state. Where the Secretary, pursuant to section 423(c)(2) of the HCQIA (42 U.S.C. 11112(c)), has designated an alternate entity to carry out the reporting activities of § 60.12 of this part due to a Board's failure to comply with § 60.8 of this part, the term Board of Medical Examiners or Board refers to this alternate entity.

Civil judgment means a court-ordered action rendered in a Federal or state court proceeding, other than a criminal proceeding. This reporting requirement does not include Consent Judgments that have been agreed upon and entered to provide security for civil settlements in which there was no finding or admission of liability.

Clinical privileges means the authorization by a health care entity to a health care practitioner for the provision of health care services, including privileges and membership on the medical staff.

Criminal conviction means a conviction as described in section 1128(i) of the Social Security Act.

Dentist means a doctor of dental surgery, doctor of dental medicine, or the equivalent who is legally authorized to practice dentistry by a state (or who, without authority, holds himself or herself out to be so authorized).

Exclusion means a temporary or permanent debarment of an individual or entity from participation in any Fed-

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eral or state health-related program, in accordance with which items or services furnished by such person or entity will not be reimbursed under any Federal or state health-related program.

Federal Government agency includes, but is not limited to:

- (1) The U.S. Department of Justice;
- (2) The U.S. Department of Health and Human Services;
- (3) Federal law enforcement agencies, including law enforcement investigators;
- (4) Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to the U.S. Department of Defense and the U.S. Department of Veterans Affairs; and
- (5) Federal agencies responsible for the licensing and certification of health care practitioners, providers, and suppliers.

Formal peer review process means the conduct of professional review activities through formally adopted written procedures which provide for adequate notice and an opportunity for a hearing.

Formal proceeding means a proceeding held before a state licensing or certification authority, peer review organization, or private accreditation entity that maintains defined rules, policies, or procedures for such a proceeding.

Health care entity means, for purposes of this part:

- (1) A hospital;
- (2) An entity that provides health care services, and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care, or a committee of that entity; or
- (3) A professional society or a committee or agent thereof, including those at the national, state, or local level, of health care practitioners that engages in professional review activity through a formal peer review process, for the purpose of furthering quality health care.

(4) For purposes of paragraph (2) of this definition, an entity includes: a health maintenance organization which is licensed by a state or determined to be qualified as such by the Department of Health and Human Services; and any group or prepaid

medical or dental practice which meets the criteria of paragraph (2).

Health care practitioner, licensed health care practitioner, licensed practitioner, or practitioner means an individual who is licensed or otherwise authorized by a state to provide health care services (or any individual who, without authority, holds himself or herself out to be so licensed or authorized).

Health care provider means, for purposes of this part, a provider of services as defined in section 1861(u) of the Social Security Act; any organization (including a health maintenance organization, preferred provider organization or group medical practice) that provides health care services and follows a formal peer review process for the purpose of furthering quality health care, and any other organization that, directly or through contracts, provides health care services.

Health care supplier means, for purposes of this part, a provider of medical and other health care services as described in section 1861(s) of the Social Security Act; or any individual or entity, other than a provider, who furnishes, whether directly or indirectly, or provides access to, health care services, supplies, items, or ancillary services (including, but not limited to, durable medical equipment suppliers, manufacturers of health care items, pharmaceutical suppliers and manufacturers, health record services [such as medical, dental, and patient records], health data suppliers, and billing and transportation service suppliers). The term also includes any individual or entity under contract to provide such supplies, items, or ancillary services; health plans as defined in this section (including employers that are self-insured); and health insurance producers (including but not limited to agents, brokers, solicitors, consultants, and re-insurance intermediaries).

Health plan means, for purposes of this part, a plan, program or organization that provides health benefits, whether directly, through insurance, reimbursement or otherwise, and includes but is not limited to:

(1) A policy of health insurance;

(2) A contract of a service benefit organization;

(3) A membership agreement with a health maintenance organization or other prepaid health plan;

(4) A plan, program, agreement, or other mechanism established, maintained, or made available by a self-insured employer or group of self-insured employers, a health care practitioner, provider, or supplier group, third-party administrator, integrated health care delivery system, employee welfare association, public service group or organization or professional association;

(5) An insurance company, insurance service, or insurance organization that is licensed to engage in the business of selling health care insurance in a state and which is subject to state law which regulates health insurance; and

(6) An organization that provides benefit plans whose coverage is limited to outpatient prescription drugs.

Hospital means, for purposes of this part, an entity described in paragraphs (1) and (7) of section 1861(e) of the Social Security Act.

Medical malpractice action or claim means a written complaint or claim demanding payment based on a 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.

Negative action or finding by a Federal or State licensing or certification authority, peer review organization, or private accreditation entity means:

(1) A final determination of denial or termination of an accreditation status from a private accreditation entity that indicates a risk to the safety of a patient(s) or quality of health care services;

(2) Any recommendation by a peer review organization to sanction a health care practitioner; or

(3) Any negative action or finding that, under the state's law, is publicly available information and is rendered by a licensing or certification authority, including but not limited to, limitations on the scope of practice, liquidations, injunctions, and forfeitures. This definition also includes final adverse actions rendered by a Federal or state licensing or certification authority, such as exclusions, revocations, or

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suspension of license or certification, that occur in conjunction with settlements in which no finding of liability has been made (although such a settlement itself is not reportable under the statute). This definition excludes administrative fines or citations and corrective action plans and other personnel actions, unless they are:

(i) Connected to the delivery of health care services; or

(ii) Taken in conjunction with other adverse licensure or certification actions such as revocation, suspension, censure, reprimand, probation, or surrender.

Organization name means the subject's business or employer at the time the underlying acts occurred. If more than one business or employer is applicable, the one most closely related to the underlying acts should be reported as the "organization name," with the others being reported as "affiliated or associated health care entities."

Organization type means a description of the nature of that business or employer.

Other adjudicated actions or decisions means formal or official final actions taken against a health care practitioner, provider, or supplier by a Federal governmental agency, a state law or fraud enforcement agency, or a health plan, which include the availability of a due process mechanism, and are based on acts or omissions that affect or could affect the payment, provision, or delivery of a health care item or service. For example, a formal or official final action taken by a Federal governmental agency, a state law or fraud enforcement agency, or a health plan may include, but is not limited to, a personnel-related action such as suspensions without pay, reductions in pay, reductions in grade for cause, terminations, or other comparable actions. A hallmark of any valid adjudicated action or decision is the availability of a due process mechanism. The fact that the subject elects not to use the due process mechanism provided by the authority bringing the action is immaterial, as long as such a process is available to the subject before the adjudicated action or decision is made final. In general, if an "adjudicated action or decision" follows an

agency's established administrative procedures (which ensure that due process is available to the subject of the final adverse action), it would qualify as a reportable action under this definition. This definition specifically excludes clinical privileging actions taken by Federal Government agencies or state law and fraud enforcement agencies and similar paneling decisions made by health plans. This definition does not include overpayment determinations made by Federal or state government programs, their contractors or health plans, and it does not include denial of claims determinations made by Federal Government agencies, state law or fraud enforcement agencies, or health plans. This definition also does not include business or administrative decisions taken by health plans that result in contract terminations unrelated to health care fraud or abuse or quality of care (e.g., when a practitioner's contract is terminated because the practitioner no longer practices at a facility in the health plan's network, or a health plan terminates all provider contracts in a certain geographic area because it ceases business operations in that area). For health plans that are not government entities, an action taken following adequate notice and the opportunity for a hearing that meets the standards of due process set out in section 412(b) of the HCQIA (42 U.S.C. 11112(b)) also would qualify as a reportable action under this definition.

Peer review organization means, for purposes of this part, an organization with the primary purpose of evaluating the quality of patient care practices or services ordered or performed by health care practitioners measured against objective criteria which define acceptable and adequate practice through an evaluation by a sufficient number of health care practitioners in such an area to ensure adequate peer review. The organization has due process mechanisms available to health care practitioners. This definition excludes utilization and quality control peer review organizations described in Part B of Title XI of the Social Security Act

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(referred to as QIOs) and other organizations funded by the Centers for Medicare & Medicaid Services (CMS) to support the QIO program.

Physician means, for purposes of this part, a doctor of medicine or osteopathy legally authorized to practice medicine or surgery by a state (or who, without authority, holds himself or herself out to be so authorized).

Private accreditation entity means an entity or organization that:

(1) Evaluates and seeks to improve the quality of health care provided by a health care entity, provider, or supplier;

(2) Measures a health care entity's, provider's, or supplier's performance based on a set of standards and assigns a level of accreditation;

(3) Conducts ongoing assessments and periodic reviews of the quality of health care provided by a health care entity, provider, or supplier; and

(4) Has due process mechanisms available to health care entities, providers, or suppliers.

Professional review action means an action or recommendation of a health care entity:

(1) Taken in the course of professional review activity;

(2) Based on the professional competence or professional conduct of an individual health care practitioner which affects or could affect adversely the health or welfare of a patient or patients; and

(3) Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the health care practitioner.

(4) This term excludes actions which are primarily based on:

(i) The health care practitioner's association, or lack of association, with a professional society or association;

(ii) The health care practitioner's fees or the health care practitioner's advertising or engaging in other competitive acts intended to solicit or retain business;

(iii) The health care practitioner's participation in prepaid group health plans, salaried employment, or any other manner of delivering health services whether on a fee-for-service or other basis;

(iv) A health care practitioner's association with, supervision of, delegation of authority to, support for, training of, or participation in a private group practice with, a member or members of a particular class of health care practitioner or professional; or

(v) Any other matter that does not relate to the competence or professional conduct of a health care practitioner.

Professional review activity means an activity of a health care entity with respect to an individual health care practitioner:

(1) To determine whether the health care practitioner may have clinical privileges with respect to, or membership in, the entity;

(2) To determine the scope or conditions of such privileges or membership; or

(3) To change or modify such privileges or membership.

Quality Improvement Organization means a utilization and quality control peer review organization (as defined in part B of title XI of the Social Security Act) that:

(1)(i) Is composed of a substantial number of the licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representative of the practicing physicians in the area, designated by the Secretary under section 1153, with respect to which the entity shall perform services under this part, or

(ii) Has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;

(2) Is able, in the judgment of the Secretary, to perform review functions required under section 1154 in a manner consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and

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(3) Has at least one individual who is a representative of consumers on its governing body.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State means the fifty states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

State law or fraud enforcement agency includes, but is not limited to:

- (1) A state law enforcement agency;
- (2) A state Medicaid fraud control unit (as defined in section 1903(q) of the Social Security Act); and
- (3) A state agency administering (including those providing payment for services) or supervising the administration of a state health care program (as defined in section 1128(h) of the Social Security Act).

State licensing or certification agency includes, but is not limited to, any authority of a state (or of a political subdivision thereof) responsible for the licensing or certification of health care practitioners (or any peer review organization or private accreditation entity reviewing the services provided by health care practitioners), health care entities, providers, or suppliers. Examples of such state agencies include Departments of Professional Regulation, Health, Social Services (including State Survey and Certification and Medicaid Single State agencies), Commerce, and Insurance.

Voluntary surrender of license or certification means a surrender made after a notification of investigation or a formal official request by a Federal or state licensing or certification authority for a health care practitioner, health care entity, provider, or supplier to surrender the license or certification (including certification agreements or contracts for participation in Federal or state health care programs). The definition also includes those instances where a health care practitioner, health care entity, provider, or supplier voluntarily surrenders a license or certification (including program participation agreements or con-

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tracts) in exchange for a decision by the licensing or certification authority to cease an investigation or similar proceeding, or in return for not conducting an investigation or proceeding, or in lieu of a disciplinary action.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

Subpart B—Reporting of Information

§ 60.4 How information must be reported.

Information must be reported to the NPDB as required under §§ 60.7, 60.8, 60.9, 60.10, 60.11, 60.12, 60.13, 60.14, 60.15 and 60.16 in such form and manner as the Secretary may prescribe.

§ 60.5 When information must be reported.

Information required under §§ 60.7, 60.8, and 60.12 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after September 1, 1990; information required under § 60.11 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after January 1, 1992; and information required under §§ 60.9, 60.10, 60.13, 60.14, 60.15, and 60.16 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after August 21, 1996. Persons or entities responsible for submitting reports of malpractice payments (§ 60.7), negative actions or findings (§ 60.11), or adverse actions (§ 60.12) must additionally provide to their respective state authorities a copy of the report they submit to the NPDB. Following is the list of reportable actions:

- (a) Malpractice payments (§ 60.7);
- (b) Licensure and certification actions (§§ 60.8, 60.9, and 60.10);
- (c) Negative actions or findings (§ 60.11);
- (d) Adverse actions (§ 60.12);
- (e) Health Care-related Criminal Convictions (§ 60.13);
- (f) Health Care-related Civil Judgments (§ 60.14);
- (g) Exclusions from Federal or state health care programs (§ 60.15); and

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(h) Other adjudicated actions of decisions (§ 60.16).

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.6 Reporting errors, omissions, revisions or whether an action is on appeal.

(a) Persons and entities are responsible for the accuracy of information which they report to the NPDB. If errors or omissions are found after information has been reported, the person or entity which reported it must send an addition or correction to the NPDB and, in the case of reports made under § 60.12 of this part, also to the Board of Medical Examiners, as soon as possible. The NPDB will not accept requests for readjudication of the case by the NPDB, and will not examine the underlying merits of a reportable action.

(b) An individual or entity which reports information on licensure or certification, negative actions or findings, clinical privileges, criminal convictions, civil or administrative judgments, exclusions, or adjudicated actions or decisions under § 60.8, § 60.9, § 60.10, § 60.11, § 60.12, § 60.13, § 60.14, § 60.15, or § 60.16 must also report any revision of the action originally reported. Revisions include, but are not limited to, reversal of a professional review action or reinstatement of a license. In the case of actions reported under § 60.9, § 60.10, § 60.13, § 60.14, § 60.15 or § 60.16, revisions also include whether an action is on appeal. Revisions are subject to the same time constraints and procedures of § 60.5, § 60.8, § 60.9, § 60.10, § 60.11, § 60.12, § 60.13, § 60.14, § 60.15, or § 60.16 as applicable to the original action which was reported.

(c) The subject will be sent a copy of all reports, including revisions and corrections to the report.

(d) Upon receipt of a report, the subject:

- (1) Can accept the report as written;
- (2) May provide a statement to the NPDB that will be permanently appended to the report, either directly or through a designated representative; (The NPDB will distribute the statement to queriers, where identifiable, and to the reporting entity and the subject of the report. Only the subject can, upon request, make changes to the

statement. The NPDB will not edit the statement; however the NPDB reserves the right to redact personal identifying and offensive language that does not change the factual nature of the statement.); or

(3) May follow the dispute process in accordance with § 60.21.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report.* Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such health care practitioner for medical malpractice, must report information as set forth in paragraph (b) of this section to the NPDB and to the appropriate state licensing board(s) in the state in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a “payment” and is not required to be reported.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

(1) With respect to the health care practitioner for whose benefit the payment is made:

- (i) Name,
- (ii) Work address,
- (iii) Home address, if known,
- (iv) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),
- (v) Date of birth,
- (vi) Name of each professional school attended and year of graduation,
- (vii) For each professional license: the license number, the field of licensure, and the name of the state or territory in which the license is held,
- (viii) Drug Enforcement Administration registration number, if known, and
- (ix) Name of each hospital with which he or she is affiliated, if known;

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(2) With respect to the reporting entity:

(i) Name and address of the entity making the payment,

(ii) Name, title, and telephone number of the responsible official submitting the report on behalf of the entity, and

(iii) Relationship of the reporting entity to the health care practitioner for whose benefit the payment is made;

(3) With respect to the judgment or settlement resulting in the payment:

(i) Where an action or claim has been filed with an adjudicative body, identification of the adjudicative body and the case number,

(ii) Date or dates on which the act(s) or omission(s) which gave rise to the action or claim occurred,

(iii) Date of judgment or settlement,

(iv) Amount paid, date of payment, and whether payment is for a judgment or a settlement,

(v) Description and amount of judgment or settlement and any conditions attached thereto, including terms of payment,

(vi) A description of the acts or omissions and injuries or illnesses upon which the action or claim was based,

(vii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary, and

(viii) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(c) *Sanctions.* Any entity that fails to report information on a payment required to be reported under this section is subject to a civil money penalty not to exceed the amount specified at 42 CFR 1003.103(c).

(d) *Interpretation of information.* A payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.8 Reporting licensure actions taken by Boards of Medical Examiners.

(a) *What actions must be reported.* Each Board of Medical Examiners must report to the NPDB any action based

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on reasons relating to a physician's or dentist's professional competence or professional conduct:

(1) Which revokes or suspends (or otherwise restricts) a physician's or dentist's license,

(2) Which censures, reprimands, or places on probation a physician or dentist, or

(3) Under which a physician's or dentist's license is surrendered.

(b) *Information that must be reported.* The Board must report the following information for each action:

(1) The physician's or dentist's name,

(2) The physician's or dentist's work address,

(3) The physician's or dentist's home address, if known,

(4) The physician's or dentist's Social Security number or Individual Tax Identification Number (ITIN), if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),

(5) National Provider Identifier (NPI),

(6) The physician's or dentist's date of birth,

(7) Name of each professional school attended by the physician or dentist and year of graduation,

(8) For each professional license, the physician's or dentist's license number, the field of licensure and the name of the state or territory in which the license is held,

(9) The physician's or dentist's Drug Enforcement Administration registration number, if known,

(10) A description of the acts or omissions or other reasons for the action taken,

(11) A description of the Board action, the date the action was taken, its effective date and duration,

(12) Classification of the action in accordance with a reporting code adopted by the Secretary, and

(13) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(c) *Sanctions.* If, after notice of non-compliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to submit a report as required by

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this section, the Secretary will designate another qualified entity for the reporting of information under § 60.12 of this part.

§ 60.9 Reporting licensure and certification actions taken by states.

(a) *What actions must be reported.* Each state is required to adopt a system of reporting to the NPDB actions, as listed below, which are taken against a health care practitioner, health care entity, provider, or supplier (all as defined in § 60.3 of this part). The actions taken must be as a result of formal proceedings (as defined in § 60.3). The actions which must be reported are:

(1) Any adverse action taken by the licensing or certification authority of the state as a result of a formal proceeding, including revocation or suspension of a license, or certification agreement or contract for participation in a government health care program (and the length of any such suspension), reprimand, censure, or probation;

(2) Any dismissal or closure of the formal proceeding by reason of the health care practitioner, health care entity, provider, or supplier surrendering the license or certification agreement or contract for participation in a government health care program, or leaving the state or jurisdiction;

(3) Any other loss of license or loss of the certification agreement or contract for participation in a government health care program, or the right to apply for, or renew, a license or certification agreement or contract of the health care practitioner, health care entity, provider or supplier, whether by operation of law, voluntary surrender, nonrenewal (excluding non-renewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise;

(4) Any negative action or finding by such authority, organization, or entity regarding the health care practitioner, health care entity, provider, or supplier.

(b) *What information must be reported.* Each state must report the following information (not otherwise reported under § 60.8 of this part):

(1) If the subject is an individual, personal identifiers, including:

- (i) Name,
- (ii) Social Security Number or ITIN, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),
- (iii) Home address or address of record,
- (iv) Sex, and
- (v) Date of birth.

(2) If the subject is an individual, employment or professional identifiers, including:

- (i) Organization name and type,
- (ii) Occupation and specialty, if applicable,
- (iii) National Provider Identifier (NPI),
- (iv) Name of each professional school attended and year of graduation, and
- (v) With respect to the professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the state or territory in which the license is held.

(3) If the subject is an organization, identifiers, including:

- (i) Name,
- (ii) Business address,
- (iii) Federal Employer Identification Number (FEIN), or Social Security Number when used by the subject as a Taxpayer Identification Number (TIN),
- (iv) The NPI,
- (v) Type of organization, and
- (vi) With respect to the license (including certification and registration) on which the reported action was taken, the license and the name of the state or territory in which the license is held.

(4) For all subjects:

- (i) A narrative description of the acts or omissions and injuries upon which the reported action was based,
- (ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,
- (iii) Classification of the action taken in accordance with a reporting code adopted by the Secretary, and the amount of any monetary penalty resulting from the reported action,
- (iv) The date the action was taken, its effective date and duration,

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(v) Name of the agency taking the action,

(vi) Name and address of the reporting entity, and

(vii) The name, title and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known.* Reporting entities described in paragraph (a) of this section may voluntarily report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Other name(s) used,

(ii) Other address,

(iii) FEIN, when used by the individual as a TIN, and

(iv) If deceased, date of death.

(2) If the subject is an individual, employment or professional identifiers, including:

(i) Other state professional license number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,

(ii) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s),

(iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is an organization, identifiers, including:

(i) Other name(s) used,

(ii) Other address(es) used,

(iii) Other FEIN(s) or Social Security Number(s) used,

(iv) Other NPI(s) used,

(v) Other state license number(s) and the name(s) of the state or territory in which the license is held,

(vi) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s),

(vii) Names and titles of principal officers and owners,

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(viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all subjects:

(i) Whether the subject will be automatically reinstated.

(ii) The date of appeal, if any.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) Sanctions for failure to report. The Secretary will provide for a publication of a public report that identifies failures to report information on adverse actions as required to be reported under this section.

§ 60.10 Reporting Federal licensure and certification actions.

(a) *What actions must be reported.* Federal licensing and certification agencies must report to the NPDB the following final adverse actions that are taken against a health care practitioner, physician, dentist, provider, or supplier (regardless of whether the final adverse action is the subject of a pending appeal):

(1) Formal or official actions, such as revocation or suspension of a license or certification agreement or contract for participation in government health care programs (and the length of any such suspension), reprimand, censure or probation,

(2) Any dismissal or closure of the proceedings by reason of the health care practitioner, provider, or supplier surrendering their license or certification agreement or contract for participation in government health care programs, or leaving the state or jurisdiction,

(3) Any other loss of the license or loss of the certification agreement or contract for participation in government health care programs, or the right to apply for, or renew, a license

or certification agreement or contract of the health care practitioner, provider, or supplier, whether by operation of law, voluntary surrender, non-renewal (excluding non-renewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise, and

(4) Any other negative action or finding by such Federal agency that is publicly available information.

(b) *What information must be reported.* Each Federal agency described in paragraph (a) of this section must report the following information:

(1) If the subject is an individual, personal identifiers, including:

- (i) Name,
- (ii) Social Security Number or ITIN,
- (iii) Home address or address of record,
- (iv) Sex, and
- (v) Date of birth.

(2) If the subject is an individual, employment or professional identifiers, including:

- (i) Organization name and type,
- (ii) Occupation and specialty, if applicable,
- (iii) National Provider Identifier (NPI),
- (iv) Name of each professional school attended and year of graduation, and
- (v) With respect to the state professional license (including professional certification and registration) on which the reported action was taken, the license number, the field of licensure, and the name of the state or territory in which the license is held.

(3) If the subject is an organization, identifiers, including:

- (i) Name,
- (ii) Business address,
- (iii) Federal Employer Identification Number (FEIN), or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),
- (iv) The NPI,
- (v) Type of organization, and
- (vi) With respect to the state license (including certification and registration) on which the reported action was taken, the license and the name of the state or territory in which the license is held.

(4) For all subjects:

(i) A narrative description of the acts or omissions and injuries upon which the reported action was based,

(ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,

(iii) Classification of the action taken in accordance with a reporting code adopted by the Secretary, and the amount of any monetary penalty resulting from the reported action,

(iv) The date the action was taken, its effective date and duration,

(v) Name of the agency taking the action,

(vi) Name and address of the reporting entity, and

(vii) The name, title, and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known.* Reporting entities described in paragraph (a) of this section may voluntarily report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

- (i) Other name(s) used,
- (ii) Other address,
- (iii) FEIN, when used by the individual as a TIN, and
- (iv) If deceased, date of death.

(2) If the subject is an individual, employment or professional identifiers, including:

- (i) Other state professional license number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,
- (ii) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s),
- (iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and
- (iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is an organization, identifiers, including:

- (i) Other name(s) used,
- (ii) Other address(es) used,
- (iii) Other FEIN(s) or Social Security Number(s) used,
- (iv) Other NPI(s) used,

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(v) Other state license number(s) and the name(s) of the state or territory in which the license is held,

(vi) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s),

(vii) Names and titles of principal officers and owners,

(viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all subjects:

(i) Whether the subject will be automatically reinstated.

(ii) The date of appeal, if any.

(d) Sanctions for failure to report. The Secretary will provide for a publication of a public report that identifies those agencies that have failed to report information on adverse actions as required to be reported under this section.

§ 60.11 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.

(a) *What actions must be reported.* Peer review organizations and private accreditation entities are required to report any negative actions or findings (as defined in § 60.3 of this part) which are taken against a health care practitioner, health care entity, provider, or supplier to the NPDB and provide a copy to the appropriate state licensing or certification agency. The health care practitioner, health care entity, provider, or supplier must be licensed or otherwise authorized by the state to provide health care services. The actions taken must be as a result of formal proceedings (as defined in § 60.3).

(b) *What information must be reported.* Each peer review organization and private accreditation entity must report the information as required in § 60.9(b) of this part.

(c) *What information may be reported, if known.* Each peer review organization and private accreditation entity

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should report, if known, the information as described in § 60.9(c).

(d) *Access to documents.* Each peer review organization and private accreditation entity must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in this section as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

§ 60.12 Reporting adverse actions taken against clinical privileges.

(a) *Reporting by health care entities to the NPDB—*(1) *Actions that must be reported and to whom the report must be made.* Each health care entity must report to the NPDB and provide a copy of the report to the Board of Medical Examiners in the state in which the health care entity is located the following actions:

(i) Any professional review action that adversely affects the clinical privileges of a physician or dentist for a period longer than 30 days,

(ii) Acceptance of the surrender of clinical privileges or any restriction of such privileges by a physician or dentist:

(A) While the physician or dentist is under investigation by the health care entity relating to possible incompetence or improper professional conduct, or

(B) In return for not conducting such an investigation or proceeding, or

(iii) In the case of a health care entity which is a professional society, when it takes a professional review action concerning a physician or dentist.

(2) *Voluntary reporting on other health care practitioners.* A health care entity may report to the NPDB information as described in paragraph (a)(3) of this section concerning actions described in paragraph (a)(1) in this section with respect to other health care practitioners.

(3) *What information must be reported.* The health care entity must report the following information concerning actions described in paragraph (a)(1) of this section with respect to a physician or dentist:

(i) Name,

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- (ii) Work address,
- (iii) Home address, if known,
- (iv) Social Security Number, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974,
- (v) Date of birth,
- (vi) Name of each professional school attended and year of graduation,
- (vii) For each professional license: the license number, the field of licensure, and the name of the state or territory in which the license is held,
- (viii) DEA registration number, if known,
- (ix) A description of the acts or omissions or other reasons for privilege loss, or, if known, for surrender,
- (x) Action taken, date the action was taken, and effective date of the action, and
- (xi) Other information as required by the Secretary from time to time after publication in the FEDERAL REGISTER and after an opportunity for public comment.

(b) *Reporting by the Board of Medical Examiners to the NPDB.* Each Board must report any known instances of a health care entity's failure to report information as required under paragraph (a)(1) of this section. In addition, each Board of Medical Examiners must simultaneously report this information to the appropriate state licensing board in the state in which the health care entity is located, if the Board of Medical Examiners is not such licensing board.

(c) *Sanctions—(1) Health care entities.* If the Secretary has reason to believe that a health care entity has substantially failed to report information in accordance with this section, the Secretary will conduct an investigation. If the investigation shows that the health care entity has not complied with this section, the Secretary will provide the entity with a written notice describing the noncompliance, giving the health care entity an opportunity to correct the noncompliance, and stating that the entity may request, within 30 days after receipt of such notice, a hearing with respect to the noncompliance. The request for a hearing must contain a statement of the material factual issues in dispute to demonstrate that there is cause for a hearing. These

issues must be both substantive and relevant. The hearing will be held in the Washington, DC, metropolitan area. The Secretary will deny a hearing if:

- (i) The request for a hearing is untimely,
- (ii) The health care entity does not provide a statement of material factual issues in dispute, or
- (iii) The statement of factual issues in dispute is frivolous or inconsequential.

In the event that the Secretary denies a hearing, the Secretary will send a written denial to the health care entity setting forth the reasons for denial. If a hearing is denied, or, if as a result of the hearing the entity is found to be in noncompliance, the Secretary will publish the name of the health care entity in the FEDERAL REGISTER. In such case, the immunity protections provided under section 411(a) of HCQIA will not apply to the health care entity for professional review activities that occur during the 3-year period beginning 30 days after the date of publication of the entity's name in the FEDERAL REGISTER.

(2) *Board of Medical Examiners.* If, after notice of noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board of Medical Examiners has failed to report information in accordance with paragraph (b) of this section, the Secretary will designate another qualified entity for the reporting of this information.

§ 60.13 Reporting Federal or state criminal convictions related to the delivery of a health care item or service.

(a) *Who must report.* Federal and state prosecutors must report criminal convictions against health care practitioners, providers, and suppliers related to the delivery of a health care item or service (regardless of whether the conviction is the subject of a pending appeal).

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

- (1) If the subject is an individual, personal identifiers, including:

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- (i) Name,
- (ii) Social Security Number (or ITIN) (states must report this information, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974),
- (iii) Home address or address of record,
- (iv) Sex, and
- (v) Date of birth.
- (2) If the subject is an individual, that individual's employment or professional identifiers, including:
 - (i) Organization name and type,
 - (ii) Occupation and specialty, if applicable, and
 - (iii) National Provider Identifier (NPI).
- (3) If the subject is an organization, identifiers, including:
 - (i) Name,
 - (ii) Business address,
 - (iii) Federal Employer Number (FEIN), or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),
 - (iv) The NPI, and
 - (v) Type of organization.
- (4) For all subjects:
 - (i) A narrative description of the acts or omissions and injuries upon which the reported action was based,
 - (ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,
 - (iii) Name and location of court or judicial venue in which the action was taken,
 - (iv) Docket or court file number,
 - (v) Type of action taken,
 - (vi) Statutory offense(s) and count(s),
 - (vii) Name of primary prosecuting agency (or the plaintiff in civil actions),
 - (viii) Date of sentence or judgment,
 - (ix) Length of incarceration, detention, probation, community service, or suspended sentence,
 - (x) Amounts of any monetary judgment, penalty, fine, assessment, or restitution,
 - (xi) Other sentence, judgment, or orders,
 - (xii) If the action is on appeal,
 - (xiii) Name and address of the reporting entity, and
 - (xiv) The name, title, and telephone number of the responsible official sub-

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mitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known.* Entities described in paragraph (a) of this section and each state should report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

- (i) Other name(s) used,
- (ii) Other address(es), and
- (iii) FEIN, when used by the individual as a TIN.

(2) If the subject is an individual, that individual's employment or professional identifiers, including:

- (i) State professional license (including professional certification and registration) number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,
- (ii) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s);
- (iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and
- (iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is an organization, identifiers, including:

- (i) Other name(s) used,
- (ii) Other address(es) used,
- (iii) Other FEIN(s) or Social Security Numbers(s) (or ITINs) used,
- (iv) Other NPI(s) used,
- (v) State license (including certification and registration) number(s) and the name(s) of the state or territory in which the license is held,
- (vi) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s),
- (vii) Names and titles of principal officers and owners,
- (viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all subjects:

- (i) Prosecuting agency's case number,
- (ii) Investigative agencies involved,
- (iii) Investigative agencies case or file number(s), and
- (iv) The date of appeal, if any.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) *Sanctions for failure to report.* The Secretary will provide for publication of a public report that identifies those agencies that have failed to report information on criminal convictions as required to be reported under this section.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.14 Reporting civil judgments related to the delivery of a health care item or service.

(a) *Who must report.* Federal and state attorneys and health plans must report civil judgments against health care practitioners, providers, or suppliers related to the delivery of a health care item or service (regardless of whether the civil judgment is the subject of a pending appeal). If a government agency is party to a multi-claimant civil judgment, it must assume the responsibility for reporting the entire action, including all amounts awarded to all the claimants, both public and private. If there is no government agency as a party, but there are multiple health plans as claimants, the health plan which receives the largest award must be responsible for reporting the total action for all parties.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the information as required in § 60.13(b) of this part.

(c) *What information may be reported, if known.* Entities described in para-

graph (a) of this section should report, if known the information as described in § 60.13(c) of this part.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) *Sanctions for failure to report.* Any health plan that fails to report information on a civil judgment required to be reported under this section will be subject to a civil money penalty (CMP) of not more than \$25,000 for each such adverse action not reported. Such penalty will be imposed and collected in the same manner as CMPs under subsection (a) of section 1128A of the Social Security Act. The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on civil judgments as required to be reported under this section.

§ 60.15 Reporting exclusions from participation in Federal or state health care programs.

(a) *Who must report.* Federal Government agencies and state law and fraud enforcement agencies must report health care practitioners, providers, or suppliers excluded from participating in Federal or state health care programs, including exclusions that were made in a matter in which there was also a settlement that is not reported because no findings or admissions of liability have been made (regardless of whether the exclusion is the subject of a pending appeal).

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

(1) If the subject is an individual, personal identifiers, including:

- (i) Name,
 - (ii) Social Security Number (or ITIN)
- (state law and fraud enforcement agencies must report this information if known, and if obtained in accordance

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with section 7 of the Privacy Act of 1974),

(iii) Home address or address of record,

(iv) Sex, and

(v) Date of birth.

(2) If the subject is an individual, that individual's employment or professional identifiers, including:

(i) Organization name and type,

(ii) Occupation and specialty, if applicable, and

(iii) National Provider Identifier (NPI).

(3) If the subject is an organization, identifiers, including:

(i) Name,

(ii) Business address,

(iii) Federal Employer Identification Number (FEIN) or Social Security Number (or ITIN) when used by the subject as a Taxpayer Identification Number (TIN),

(iv) The NPI, and

(v) Type of organization.

(4) For all subjects:

(i) A narrative description of the acts or omissions and injuries upon which the reported action was based,

(ii) Classification of the acts or omissions in accordance with a reporting code adopted by the Secretary,

(iii) Classification of the action taken in accordance with a reporting code adopted by the Secretary, and the amount of any monetary penalty resulting from the reported action,

(iv) The date the action was taken, its effective date and duration,

(v) If the action is on appeal,

(vi) Name of the agency taking the action,

(vii) Name and address of the reporting entity, and

(viii) The name, title, and telephone number of the responsible official submitting the report on behalf of the reporting entity.

(c) *What information may be reported, if known.* Entities described in paragraph (a) of this section should report, if known, the following information:

(1) If the subject is an individual, personal identifiers, including:

(i) Other name(s) used,

(ii) Other address(es),

(iii) FEIN, when used by the individual as a TIN,

(iv) Name of each professional school attended and year of graduation, and

(v) If deceased, date of death.

(2) If the subject is an individual, that individual's employment or professional identifiers, including:

(i) State professional license (including professional registration and certification) number(s), field(s) of licensure, and the name(s) of the state or territory in which the license is held,

(ii) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Unique Physician Identification Number(s) (UPIN), and Medicaid and Medicare provider number(s),

(iii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(iv) Nature of the subject's relationship to each associated or affiliated health care entity.

(3) If the subject is an organization, identifiers, including:

(i) Other name(s) used,

(ii) Other address(es) used,

(iii) Other FEIN(s) or Social Security Numbers(s) (or ITINs) used,

(iv) Other NPI(s) used,

(v) State license (including registration and certification) number(s) and the name(s) of the state or territory in which the license is held,

(vi) Other numbers assigned by Federal or state agencies, including, but not limited to DEA registration number(s), Clinical Laboratory Improvement Act (CLIA) number(s), Food and Drug Administration (FDA) number(s), and Medicaid and Medicare provider number(s),

(vii) Names and titles of principal officers and owners,

(viii) Name(s) and address(es) of any health care entity with which the subject is affiliated or associated, and

(ix) Nature of the subject's relationship to each associated or affiliated health care entity.

(4) For all subjects:

(i) If the subject will be automatically reinstated, and

(ii) The date of appeal, if any.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1)

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through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) *Sanctions for failure to report.* The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on exclusions or debarments as required to be reported under this section.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.16 Reporting other adjudicated actions or decisions.

(a) *Who must report.* Federal Government agencies, state law or fraud enforcement agencies, and health plans must report other adjudicated actions or decisions as defined in § 60.3 of this part related to the delivery, payment or provision of a health care item or service against health care practitioners, providers, and suppliers (regardless of whether the other adjudicated action or decision is subject to a pending appeal).

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the information as required in § 60.15(b) of this part.

(c) *What information may be reported, if known.* Entities described in paragraph (a) of this section should report, if known, the information as described in § 60.15(c) of this part.

(d) *Access to documents.* Each state must provide the Secretary (or an entity designated by the Secretary) with access to the documents underlying the actions described in paragraphs (a)(1) through (4) of this section, as may be necessary for the Secretary to determine the facts and circumstances concerning the actions and determinations for the purpose of carrying out section 1921.

(e) *Sanctions for failure to report.* Any health plan that fails to report information on another adjudicated action or decision required to be reported under this section will be subject to a civil money penalty (CMP) of not more than \$25,000 for each such action not reported. Such penalty will be imposed

and collected in the same manner as CMPs under subsection (a) of section 1128A of the Social Security Act. The Secretary will provide for publication of a public report that identifies those government agencies that have failed to report information on other adjudicated actions as required to be reported under this section.

Subpart C—Disclosure of Information by the National Practitioner Data Bank

§ 60.17 Information which hospitals must request from the National Practitioner Data Bank.

(a) *When information must be requested.* Each hospital, either directly or through an authorized agent, must request information from the NPDB concerning a health care practitioner, as follows:

(1) At the time a health care practitioner applies for a position on its medical staff (courtesy or otherwise) or for clinical privileges at the hospital; and

(2) Every 2 years for any health care practitioner who is on its medical staff (courtesy or otherwise) or has clinical privileges at the hospital.

(b) *Failure to request information.* Any hospital which does not request the information as required in paragraph (a) of this section is presumed to have knowledge of any information reported to the NPDB concerning this health care practitioner.

(c) *Reliance on the obtained information.* Each hospital may rely upon the information provided by the NPDB to the hospital. A hospital shall not be held liable for this reliance unless the hospital has knowledge that the information provided was false.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.18 Requesting information from the National Practitioner Data Bank.

(a) *Who may request information and what information may be available.* Information in the NPDB will be available, upon request, to the persons or entities, or their authorized agents, as described below:

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(1) Information reported under §§ 60.7, 60.8, and 60.12 of this part is available to:

(i) A hospital that requests information concerning a health care practitioner who is on its medical staff (courtesy or otherwise) or has clinical privileges at the hospital,

(ii) A health care practitioner who requests information concerning himself or herself,

(iii) A State Medical Board of Examiners or other state authority that licenses health care practitioners,

(iv) A health care entity which has entered or may be entering into an employment or affiliation relationship with a health care practitioner, or to which the health care practitioner has applied for clinical privileges or appointment to the medical staff,

(v) An attorney, or individual representing himself or herself, who has filed a medical malpractice action or claim in a state or Federal court or other adjudicative body against a hospital, and who requests information regarding a specific health care practitioner who is also named in the action or claim. This information will be disclosed only upon the submission of evidence that the hospital failed to request information from the NPDB, as required by § 60.17(a) of this part, and may be used solely with respect to litigation resulting from the action or claim against the hospital,

(vi) A health care entity with respect to professional review activity, and

(vii) A person or entity requesting statistical information, in a form which does not permit the identification of any individual or entity.

(2) Information reported under §§ 60.9, 60.10, 60.11, 60.13, 60.14, 60.15, and 60.16 of this part is available to the agencies, authorities, and officials listed below that request information on licensure or certification actions, any other negative actions or findings, or final adverse actions concerning an individual practitioner, health care entity, provider, or supplier. These agencies, authorities, and officials may obtain data for the purposes of determining the fitness of individuals to provide health care services, protecting the health and safety of individuals receiving health care through programs administered by

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the requesting agency, and protecting the fiscal integrity of these programs.

(i) Agencies administering (including those providing payment for services) Federal health care programs, including private entities administering such programs under contract,

(ii) State licensing or certification agencies and Federal agencies responsible for the licensing and certification of health care practitioners, providers, or suppliers,

(iii) State agencies administering or supervising the administration of state health care programs (as defined in 42 U.S.C. 1128(h)),

(iv) State law or fraud enforcement agencies,

(v) Law enforcement officials and agencies such as:

(A) United States Attorney General,

(B) United States Chief Postal Inspector,

(C) United States Inspectors General;

(D) United States Attorneys,

(E) United States Comptroller General,

(F) United States Drug Enforcement Administration,

(G) United States Nuclear Regulatory Commission, or

(H) Federal Bureau of Investigation,

(vi) Utilization and quality control peer review organizations described in part B of title XI and to appropriate entities with contracts under section 1154(a)(4)(C) of the Social Security Act with respect to eligible organizations reviewed under the contracts, but only with respect to information provided pursuant to §§ 60.9, 60.10, and 60.11 of this part, as well as information provided pursuant to §§ 60.13, 60.14, 60.15, and 60.16 of this part by Federal agencies and health plans,

(vii) Hospitals and other health care entities (as defined in section 431 of the Health Care Quality Improvement Act of 1986), with respect to health care practitioners who have entered (or may be entering) into employment or affiliation relationships with, or have applied for clinical privileges or appointments to the medical staff of such hospitals or other health care entities, but only with respect to information provided pursuant to §§ 60.9, 60.10, and 60.11, as well as information provided pursuant to §§ 60.13, 60.14, 60.15, and

60.16 by Federal agencies and health plans.

(viii) Health plans,

(ix) A health care practitioner, health care entity, provider, or supplier who requests information concerning himself, herself, or itself, and

(x) A person or entity requesting statistical information, in a form which does not permit the identification of any individual or entity. (For example, researchers may use statistical information to identify the total number of nurses with adverse licensure actions in a specific state. Similarly, researchers may use statistical information to identify the total number of health care entities denied accreditation.)

(b) *Procedures for obtaining NPDB information.* Persons and entities may obtain information from the NPDB by submitting a request in such form and manner as the Secretary may prescribe. These requests are subject to fees as described in § 60.19 of this part.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.19 Fees applicable to requests for information.

(a) *Policy on fees.* The fees described in this section apply to all requests for information from the NPDB. The amount of such fees will be sufficient to recover the full costs of operating the NPDB. The actual fees will be announced by the Secretary in periodic notices in the FEDERAL REGISTER. However, for purposes of verification and dispute resolution at the time the report is accepted, the NPDB will provide a copy—at the time a report has been submitted, automatically, without a request and free of charge, of the record to the health care practitioner, entity, provider, or supplier who is the subject of the report and to the reporter.

(b) *Criteria for determining the fee.* The amount of each fee will be determined based on the following criteria:

(1) Direct and indirect personnel costs, including salaries and fringe benefits such as medical insurance and retirement,

(2) Physical overhead, consulting, and other indirect costs (including materials and supplies, utilities, insur-

ance, travel, and rent and depreciation on land, buildings, and equipment),

(3) Agency management and supervisory costs,

(4) Costs of enforcement, research, and establishment of regulations and guidance,

(5) Use of electronic data processing equipment to collect and maintain information—the actual cost of the service, including computer search time, runs and printouts, and

(6) Any other direct or indirect costs related to the provision of services.

(c) *Assessing and collecting fees.* The Secretary will announce through notice in the FEDERAL REGISTER from time to time the methods of payment of NPDB fees. In determining these methods, the Secretary will consider efficiency, effectiveness, and convenience for the NPDB users and the Department. Methods may include: credit card, electronic fund transfer, and other methods of electronic payment.

§ 60.20 Confidentiality of National Practitioner Data Bank information.

(a) *Limitations on disclosure.* Information reported to the NPDB is considered confidential and shall not be disclosed outside the Department of Health and Human Services, except as specified in §§ 60.17, 60.18, and 60.21 of this part. Persons and entities receiving information from the NPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided. The Data Bank report may not be disclosed, but nothing in this section will prevent the disclosure of information by a party from its own files used to create such reports where disclosure is otherwise authorized under applicable state or Federal law.

(b) *Penalty for violations.* Any person who violates paragraph (a) of this section shall be subject to a civil money penalty of up to \$11,000 for each violation. This penalty will be imposed pursuant to procedures at 42 CFR part 1003.

§ 60.21 How to dispute the accuracy of National Practitioner Data Bank information.

(a) *Who may dispute the NPDB information.* The NPDB will routinely mail or transmit electronically to the subject a copy of the report filed in the NPDB. In addition, as indicated in § 60.18, the subject may also request a copy of such report. The subject of the report or a designated representative may dispute the accuracy of a report concerning himself, herself, or itself as set forth in paragraph (b) of this section.

(b) *Procedures for disputing a report with the reporting entity.* (1) If the subject disagrees with the reported information, the subject must request in the format as determined by the Secretary that the NPDB enter the report into “disputed status.”

(2) The NPDB will send the report, with a notation that the report has been placed in “disputed status,” to queriers (where identifiable), the reporting entity and the subject of the report.

(3) The subject must attempt to enter into discussion with the reporting entity to resolve the dispute. If the reporting entity revises the information originally submitted to the NPDB, the NPDB will notify the subject and all entities to whom reports have been sent that the original information has been revised. If the reporting entity does not revise the reported information, or does not respond to the subject within 60 days, the subject may request that the Secretary review the report for accuracy. The Secretary will decide whether to correct the report within 30 days of the request. This time frame may be extended for good cause. The subject also may provide a statement to the NPDB, either directly or through a designated representative that will permanently append the report.

(c) *Procedures for requesting a review of a disputed report.* (1) The subject must request, in the format as determined by the Secretary, that the Secretary review the report for accuracy. The subject must return this request to the NPDB along with appropriate materials that support the subject’s position. The Secretary will only review

the accuracy of the reported information, and will not consider the merits or appropriateness of the action or the due process that the subject received.

(2) After the review, if the Secretary:

(i) Concludes that the information is accurate and reportable to the NPDB, the Secretary will inform the subject and the NPDB of the determination. The Secretary will include a brief statement (Secretarial Statement) in the report that describes the basis for the decision. The report will be removed from “disputed status.” The NPDB will distribute the corrected report and statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(ii) Concludes that the information contained in the report is inaccurate, the Secretary will inform the subject of the determination and direct the NPDB or the reporting entity to revise the report. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The NPDB will distribute the corrected report and statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(iii) Determines that the disputed issues are outside the scope of the Department’s review, the Secretary will inform the subject and the NPDB of the determination. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The report will be removed from “disputed status.” The NPDB will distribute the report and the statement(s) to previous queriers (where identifiable), the reporting entity and the subject of the report.

(iv) Determines that the adverse action was not reportable and therefore should be removed from the NPDB, the Secretary will inform the subject and direct the NPDB to void the report. The NPDB will distribute a notice to previous queriers (where identifiable), the reporting entity and the subject of the report that the report has been voided.

§ 60.22 Immunity.

Individuals, entities or their authorized agents, and the NPDB shall not be

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held liable in any civil action filed by the subject of a report unless the individual, entity, or authorized agent submitting the report has actual knowledge of the falsity of the information contained in the report.

PART 63—GRANT PROGRAMS ADMINISTERED BY THE OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

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Sec.

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AUTHORITY: Sec. 602, Community Services Act (42 U.S.C. 2942); sec. 1110, Social Security Act (42 U.S.C. 1310).

SOURCE: 40 FR 23295, May 29, 1975, unless otherwise noted.

Subpart A—General

§ 63.1 Purpose and scope.

(a) *Applicability.* Except to the extent inconsistent with an applicable Federal

statute the regulations in this part apply to all grant awards of Federal assistance made by the Assistant Secretary for Planning and Evaluation or his designee, hereinafter referred to in this part as the Assistant Secretary. Such grants include those under section 232 of the Community Services Act (42 U.S.C. 2835), section 1110 of the Social Security Act (42 U.S.C. 1310), section 392A of the Communications Act of 1934, and such other authority as may be delegated to the Assistant Secretary for policy research activities.

(b) *Exceptions to applicability.* The award and administration of contracts and cooperative agreements by the Assistant Secretary shall not be covered by this subchapter. Contracts entered into by the Assistant Secretary shall be subject to the regulations in CFR Title 48, Chapter 3. Generally, the Assistant Secretary will select between grant and contract procedures and instruments, both with regard to the solicitation process and with respect to unsolicited proposals, on the basis of criteria set forth in the proposed revision of 45 CFR 75.201(a) published at 39 FR 27469 at any subsequent revision thereof.

(c) *Objectives*—(1) *Policy research.* The overall objective of policy research activities is to obtain information, as it relates to the mission of the Department of Health and Human Services, about the basic causes of and methods for preventing and eliminating poverty and dependency and about improved methods for delivering human resources services. Such information is obtained through the conduct of basic and applied research, statistical analyses, and demonstrations and evaluations which have demonstrated a high probability of impacting on the formulation or modification of major Departmental policies and programs.

(2) *Telecommunications demonstrations.* The overall objective of the Telecommunications Demonstration Program is to promote the development of nonbroadcast telecommunications facilities and services for the transmission, distribution, and delivery of

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health, education, and social service information.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977; 85 FR 72911, Nov. 16, 2020]

§ 63.2 Eligibility for award.

(a) *Groups and organizations eligible.* Except where otherwise prohibited by law, any public or nonprofit private agency, institution, or organization which is found by the Assistant Secretary to be authorized and qualified by educational, scientific, or other relevant competence to carry out a proposed project in accordance with the regulations of this subchapter shall be eligible to receive a grant under this part.

(b) *Project eligible—(1) Policy research.* Any project found by the Assistant Secretary to be a research, pilot, evaluation, or demonstration project within the meaning of this section and § 63.1 shall be eligible for an award. Eligible projects may include planning, policy modeling or research utilization studies; experiments; demonstrations; field investigations; statistical data collections or analyses; or other types of investigation or studies, or combinations thereof, and may either be limited to one aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation and may involve multiple disciplines, facilities, and resources.

(2) *Telecommunications demonstrations.* Any projects which meet the special criteria in § 63.6(c) shall be eligible for a telecommunications demonstration grant.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977]

§ 63.3 Program announcements and solicitations.

(a) In each fiscal year the Assistant Secretary may from time to time solicit applications through one or more general or specialized program announcements. Such announcements will be published in the FEDERAL REGISTER as notices and will include:

(1) A clear statement of the type(s) of applications requested;

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(2) A specified plan, time(s) of application, and criteria for reviewing and approving applications;

(3) Any grant terms or conditions of general applicability (other than those set forth in this part) which are necessary (i) to meet the statutory requirements of applicable legislation, (ii) to assure or protect the advancement of the project, or (iii) to conserve grant funds.

(b) Applications for grants: Any applicant eligible for grant assistance may submit on or before such cutoff date or dates as the Assistant Secretary may announce in program solicitations, an application containing such pertinent information and in accordance with the forms and instructions as prescribed herein and additional forms and instructions as may be specified by the Assistant Secretary. Such application shall be executed by the applicant or an official or representative of the applicant duly authorized to make such application. The Assistant Secretary may require any party eligible for assistance under this subchapter to submit a preliminary proposal for review and approval prior to the acceptance of an application submitted under these provisions.

(c) All applications and preliminary proposals should be addressed to:

Grants Officer, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 330 Independence Avenue, SW, Room 5027, Washington, DC 20201.

§ 63.4 Cooperative arrangements.

(a) Eligible parties may enter into cooperative arrangements with other eligible parties, including those in another State, to apply for assistance.

(b) A joint application made by two or more applicants for assistance under this subchapter may have separate budgets corresponding to the programs, services and activities performed by each of the joint applicants or may have a combined budget. If joint applications present separate budgets, the Assistant Secretary may make separate awards, or may award a single grant authorizing separate amounts for each of the joint applicants.

(c) In the case of each cooperative arrangement authorized under paragraph

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(a) of this section and receiving assistance, except where the Assistant Secretary makes separate awards under paragraph (b) of this section all such applicants (1) shall be deemed to be joint legal recipients of the grant award and (2) shall be jointly and severally responsible for administering the project assisted under such grant.

§ 63.5 Effective date of approved grant.

Federal financial participation is normally available only with respect to obligations incurred subsequent to the effective date of an approved project. The effective date of the project will be set forth in the notification of grant award. Grantees may be reimbursed for costs resulting from obligations incurred before the effective date of the grant award if such costs are authorized by the Assistant Secretary in the notification of grant award or subsequently in writing, and otherwise would be allowable as costs of the grant under the applicable regulations and grant terms and conditions.

§ 63.6 Evaluation of applications.

(a) *Review procedures.* All applications filed in accordance with § 63.3 shall be evaluated by the Assistant Secretary through officers, employees, and such experts or consultants engaged for this purpose as he/she determines are specially qualified in the areas of research pursued by this office. The evaluation criteria below will be supplemented each fiscal year by a program announcement outlining priorities and objectives for policy research, and by other general or specialized solicitations. Such supplements may modify the criteria in paragraphs (b) and (c) of this section to provide greater specificity or otherwise improve their applicability to a given announcement or solicitation.

(b) *Criteria for evaluation of Policy Research Projects.* Review of applications under paragraph (a) of this section will take into account such factors as:

(1) Scientific merit and the significance of the project in relation to policy objectives;

(2) Feasibility of the project;

(3) Soundness of research design, statistical technique, and procedures and methodology;

(4) Theoretical and technical soundness of the proposed plan of operation including consideration of the extent to which:

(i) The objectives of the proposed project are sharply defined, clearly stated, and capable of being attained by the proposed procedures;

(ii) The objectives of the proposed project show evidence of contributing to the achievement of policy objectives;

(iii) Provisions are made for adequate evaluation of the effectiveness of the project and for determining the extent to which the objectives are accomplished; and

(iv) Appropriate provisions are made for satisfactory inservice training connected with project services.

(5) Expected potential for utilizing the results of the proposed project in other projects or programs for similar purposes;

(6) Sufficiency of size, scope, and duration of the project so as to secure productive results;

(7) Adequacy of qualifications and experience, including managerial, of personnel;

(8) Adequacy of facilities and other resources; and

(9) Reasonableness of estimated cost in relation to anticipated results.

(c) *Criteria for evaluation of Telecommunications Demonstrations Projects.* Review of applications for Telecommunications Demonstrations grants will take into account such factors as are listed in paragraphs (c) (1) through (10) of this section. Each applicant must include in the application, prior to final evaluation by the Assistant Secretary, documentation indicating specifically and separately how and to what extent each of these criteria have been or will be met:

(1) That the project for which application is made demonstrates innovative methods or techniques of utilizing nonbroadcast telecommunications equipment or facilities to satisfy the purpose of this authority;

(2) That the project will have original research value which will demonstrate to other potential users that such methods or techniques are feasible and cost-effective;

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(3) That the services to be provided are responsive to local needs as identified and assessed by the applicant;

(4) That the applicant has assessed existing telecommunications facilities (if any) in the proposed service area and explored their use of interconnection in conjunction with the project;

(5) That there is significant local commitment (e.g., evidence of support, participation, and contribution by local institutions and agencies) to the proposed project, indicating that it fulfills local needs, and gives some promise that operational systems will result from successful demonstrations and will be supported by service recipients or providers;

(6) That demonstrations and related activities assisted under this section will remain under the administration and control of the applicant;

(7) That the applicant has the managerial and technical capability to carry out the project for which the application is made;

(8) That the facilities and equipment acquired or developed pursuant to the applications will be used substantially for the transmission, distribution, and delivery of health, education, or social service information, and that use of such facilities and equipment may be shared among these and additional public or other services;

(9) That the provision has been made to submit a summary and factual evaluation of the results of the demonstration at least annually for each year in which funds are received, in the form of a report suitable for dissemination to groups representative of national health, education, and social service telecommunications interests; and,

(10) That the project has potential for stimulating cooperation and sharing among institutions and agencies, both within and across disciplines.

(d) *Applicant's performance on prior award.* Where the applicant has previously received an award from the Department of Health and Human Services, the applicant's compliance or noncompliance with requirements applicable to such prior award as reflected in past written evaluation reports, memoranda on performance, and completeness of required submissions: *Provided*, That in any case where the

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Assistant Secretary proposes to deny assistance based upon the applicant's noncompliance with requirements applicable to a prior award, he shall do so only after affording the applicant reasonable notice and an opportunity to rebut the proposed basis for denial of assistance.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977]

§ 63.7 Disposition of applications.

(a) *Approval, disapproval, or deferral.* On the basis of the review of an application pursuant to § 63.6 the Assistant Secretary will either (1) approve the application in whole or in part, for such amount of funds and subject to such conditions as he/she deems necessary or desirable for the completion of the approved project, (2) disapprove the application, or (3) defer action on the application for such reasons as lack of funds or a need for further review.

(b) *Notification of disposition.* The Assistant Secretary will notify the applicant in writing of the disposition of its application. A signed notification of grant award will be issued to notify the applicant of an approved project application.

§ 63.8 Supplemental regulations and grant conditions.

(a) *Grants under section 232 of the Community Services Act.* (1) Any grants awarded with funds appropriated under section 232 of the Community Services Act shall be subject to the following regulations issued by the Director of the Community Services Administration (formerly the Office of Economic Opportunity):

45 CFR 1060.2	(Income Poverty Guidelines.)
45 CFR 1060.3	(Limitation on Benefits to Those Voluntarily Poor.)
45 CFR 1067.1	(Suspension and Termination of Assistance.)
45 CFR 1068.6	(Grantee Compliance with IRS Requirements for Withheld Federal Income and Social Security Taxes.)
45 CFR 1069.1	(Employee Participation in Direct Action.)
45 CFR 1069.2	(Limitations with Respect to Unlawful Demonstrations, Rioting, and Civil Disturbances.)
45 CFR 1070.1	(Public Access to Grantee Information.)

No other portions of Chapter X of this title are applicable to such grants.

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(2) Grants awarded with funds appropriated under section 232 of the Community Services Act shall also be subject to the applicable statutory requirements in sections 242, 243, and 244, and title VI of the Community Services Act. The Assistant Secretary will advise grantees of the nature of these requirements at or prior to the time of award.

(3) In the event that any provision of this part is inconsistent with a provision of law or a regulation referenced in paragraphs (a)(1) and (2) of this section with respect to any grant funded under section 232 of the Community Services Act, the provision of this part shall, to the extent of any such inconsistency, not be effective.

(b) *Grants under other statutory authority.* Grants awarded by the Assistant Secretary may be subject to regulations, other than those set forth in this part, which have been issued under the authority of statutes authorizing particular awards. In such a case, that fact will be set forth in the program announcement soliciting applications for such grants published in the FEDERAL REGISTER pursuant to § 63.3.

(c) *Other regulations applicable to grants under this part.* Federal financial assistance provided under this part shall be subject to the following additional regulations except as otherwise provided in this part:

(1) Title 2 CFR parts 200 and 300, establishing uniform administrative requirements, cost principles and audit requirements for Federal awards.

(2) Part 80 of this title, effectuating the provisions of title VI of the Civil Rights Act of 1964; and

(3) Part 16 of this title, establishing a Departmental Grant Appeals Board for the resolution of specified post-award grant disputes.

[40 FR 23295, May 29, 1975, as amended at 81 FR 3012, Jan. 20, 2016; 89 FR 80070, Oct. 2, 2024]

Subpart B—Financial Provisions

§ 63.16 Scope of subpart.

This subpart sets forth supplemental financial provisions which apply to all grants awarded by the Assistant Sec-

retary, except as specified in § 63.23 of this subpart.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977]

§ 63.17 Amount of award.

Federal assistance shall be provided only to meet allowable costs incurred by the award recipient in carrying out an approved project in accordance with the authorizing legislation and the regulations of this part.

§ 63.18 Limitations on costs.

The amount of the award shall be set forth in the grant award document. The total cost to the Government will not exceed the amount set forth in the grant award document or any modification thereof approved by the Assistant Secretary which meets the requirements of applicable statutes and regulations. The Government shall not be obligated to reimburse the grantee for costs incurred in excess of such amount unless and until the Assistant Secretary has notified the grantee in writing that such amount has been increased and has specified such increased amount in a revised grant award document. Such revised amount shall thereupon constitute the maximum cost to the Government for the performance of the grant.

§ 63.19 Budget revisions and minor deviations.

Pursuant to § 74.102(d) of this title, paragraphs (b)(3) and (b)(4) of that section are waived.

§ 63.20 Period during which grant funds may be obligated.

(a) The amount of the grant award shall remain available for obligation by the grantee during the period specified in the grant award or until otherwise terminated. Such period may be extended by revision of the grant with or without additional funds pursuant to paragraph (b) of this section where otherwise permitted by law.

(b) When it is determined that special or unusual circumstances will delay the completion of the project beyond the period for obligation, the grantee must in writing request the Assistant Secretary to extend such period and must indicate the reasons therefor.

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§ 63.21 Obligation and liquidation by grantee.

Obligations will be considered to have been incurred by a grantee on the basis of documentary evidence of binding commitments for the acquisition of goods or property or for the performance of work, except that funds for personal services, for services performed by public utilities, for travel, and for the rental of facilities, shall be considered to have been obligated as of the time such services were rendered, such travel was performed, and such rented facilities were used, respectively.

§ 63.22 Cost sharing.

Policy Research funds shall not be used to pay any recipient of a grant for the conduct of a research project an amount equal to as much as the entire cost of the project.

§ 63.23 Telecommunications Demonstration Grants.

The provisions of this section apply only to grants awarded under authority of 392A of the Communications Act of 1934.

(a) Funds provided under the Telecommunications Demonstrations Program shall be available to support the planning, development, and acquisition or leasing of facilities and equipment necessary to the demonstration. However, funds shall not be available for the construction, remodeling, or repair of structures to house facilities or equipment acquired or developed with such funds, except that such funds may be used for minor remodeling which is necessary for and incident to the installation of such facilities or equipment.

(b) Funds shall not be available for the development of programming materials or content.

(c) The funding of any demonstration under this authority shall continue for not more than three years from the date of the original grant or contract.

(1) Applications for assistance under the Act may project goals and activities over a period of up to three years. Approval of a multi-year project is intended to offer the project a reasonable degree of stability over time and to facilitate additional long range planning.

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(2) Applications proposing a multi-year project must be accompanied by an explanation of the need for multi-year support, an overview of the objectives and activities proposed, and budget estimates to attain these objectives in any proposed subsequent year.

(3) Subject to the availability of funds, an application for assistance to continue a project during the project period will be reviewed on a non-competitive basis to determine—

(i) If the award recipient has complied with the award terms and conditions, the Act, and applicable regulations;

(ii) The effectiveness of the project to date in terms of progress toward its goals, or the constructive changes proposed as a result of the ongoing evaluation of the project; and,

(iii) If continuation of the project would be in the best interests of the Government.

(d) The use of equipment in demonstration projects shall be subject to the rules and regulations of the Federal Communications Commission (FCC), and grant funds may not be expended or obligated for purchase, lease, or use of such equipment prior to appropriate and necessary coordination by the grantee with the Commission. In particular:

(1) For any project requiring a new or modification of an existing authorization(s) from the FCC, application(s) to the FCC for such authorization(s) must have been tendered for filing prior to the closing date established by any solicitation for grant applications offered under the Telecommunications Demonstration Program.

(2) If the project is to be associated with an existing telecommunications activity requiring an FCC authorization, such operating authority for that activity must be current and valid.

(3) For any project requiring a new or modification of an existing authorization(s) from the FCC, the applicant must file with the Secretary of Health and Human Services a copy of each FCC application and any amendments thereto.

(4) For any project requiring a new or modification of an existing authorization(s) from the FCC, the applicant must tender for filing with the FCC a

copy of the application to the Secretary for a telecommunications demonstration grant.

(5) If the applicant fails to file required applications by the closing date established by the solicitation for grant applications, or if the FCC returns as substantially incomplete or deficient, dismisses, or denies an application required for the project, or any part thereof, or for the operation of any facility with which the project is associated, the Secretary may return the application for Federal assistance.

(e) For the purposes of this program, the term "non-broadcast telecommunications facilities" includes but is not limited to, cable television systems, communications satellite systems and related terminal equipment, and other methods of transmitting, emitting, or receiving images and sounds or intelligence by means of wire, radio, optical, electromagnetic, and other means (including non-broadcast utilization of telecommunications equipment normally associated with broadcasting use).

(f) Each applicant shall provide such information as the Assistant Secretary deems necessary to make a Federal assessment of the impact of the project on the quality of the human environment in accordance with section 102(2)(C) of the National Environmental Policy Act of 1969 (including the National Historical Preservation Act and other environmental acts). (42 U.S.C. 4332(2)(C)).

[42 FR 36149, July 13, 1977]

Subpart C—Special Provisions

§ 63.30 Scope of subpart.

This subpart sets forth supplemental special provisions which apply to all grants awarded by the Assistant Secretary.

§ 63.31 Protection of human subjects.

All grants made pursuant to this part are subject to the specific provisions of part 46 of this subtitle relating to the protection of human subjects.

§ 63.32 Data collection instruments.

(a) *Definitions.* For the purposes of this section "Child" means an indi-

vidual who has not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which such research is to be conducted.

"Data-collection instruments" means tests, questionnaires, inventories, interview schedules or guides, rating scales, and survey plans or any other forms which are used to collect information on substantially identical items from 10 or more respondents.

"Respondents" means individuals or organizations from whom information is collected.

(b) *Applicability.* This section does not apply to instruments which deal solely with (1) functions of technical proficiency, such as scholastic aptitude or school achievement, or (2) routine demographic information.

(c) *Protection of privacy.* (1) No project supported under this part may involve the use of data collection instruments which constitute invasion of personal privacy through inquiries regarding such matters as religion, sex, race, or politics.

(2) A grantee which proposes to use a data collection instrument shall set forth in the grant application an explanation of the safeguards which will be used to restrict the use and disclosure of information so obtained to purposes directly connected with the project, including provisions for the destruction of such instruments where no longer needed for the purposes of the project.

(d) *Clearance of instruments.* (1) Grantees will not be required to submit data-collection instruments to the Assistant Secretary or obtain the Assistant Secretary's approval for the use of these instruments, except where the notification of grant award specifically so provides.

(2) If a grantee is required under paragraph (d)(1) of this section to submit data-collection instruments for the approval of the Assistant Secretary or if a grantee wishes the Assistant Secretary to review a data-collection instrument, the grantee shall submit seven copies of the document to the Assistant Secretary along with seven copies of the Office of Management and Budget's standard form No. 83 and seven copies of the Supporting Statement as required in the "Instructions

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for Requesting OMB Approval under the Federal Reports Act” (Standard form No. 83A).

(e) *Responsibility for collection of information.* A grantee shall not in any way represent or imply (either in a letter of transmittal, in the data-gathering instruments themselves, or in any other manner) that the information is being collected by or for the Federal Government or any department, agency or instrumentality thereof. Basic responsibility for the study and the data-gathering instruments rests with the grantee.

(f) *Parental consent.* In the case of any survey using data-collection instruments in which children are involved as respondents, the grantee, in addition to observing the other requirements contained in this section, and in part 46 of this subtitle as appropriate, shall provide assurances satisfactory to the Assistant Secretary that informed consent will be obtained from the parents of each such respondent prior to the use of such instruments, except that a waiver from the requirements of this paragraph for specific data-collection activities may be granted upon the written request by the grantee and a determination by the Assistant Secretary that a waiver is necessary in order to fully carry out the purposes of the grant.

§ 63.33 Treatment of animals.

If animals are utilized in any project receiving assistance, the applicant for such assistance shall provide assurances satisfactory to the Assistant Secretary that such animals will be provided with proper care and humane treatment; in accordance with the Animal Welfare Act (7 U.S.C. 2131 *et seq.*) and regulations set forth in (9 CFR parts 1, 2, 3, 4).

§ 63.34 Principal investigators.

The principal investigator(s) designated in successful grant applications as responsible for the conduct of the approved project, shall not be replaced without the prior approval of the Assistant Secretary or his designee. Failure to seek and acquire such approval may result in the grant award being terminated in accordance with the procedures set forth in 2 CFR

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200.340 of this subtitle or such other regulations as may be indicated in the grant terms and conditions.

[40 FR 23295, May 29, 1975, as amended at 81 FR 3012, Jan. 20, 2016; 89 FR 80070, Oct. 2, 2024]

§ 63.35 Dual compensation.

If a project staff member or consultant of one grantee is involved simultaneously in two or more projects supported by any funds either under this part or otherwise, he/she may not be compensated for more than 100 percent of his/her time from any funds during any part of the period of dual involvement.

§ 63.36 Fees to Federal employees.

The grantee shall not use funds from any sources to pay a fee to, or travel expenses of, employees of the Federal Government for lectures, attending program functions, or any other activities in connection with the grant.

§ 63.37 Leasing facilities.

In the case of a project involving the leasing of a facility, the grantee shall demonstrate that it will have the right to occupy, to operate, and, if necessary, to maintain and improve the leased facility during the proposed period of the project.

§ 63.38 Publications.

Any publication or presentation resulting from or primarily related to Federal financial assistance under this part shall contain an acknowledgement essentially as follows:

The activity which is the subject of this report was supported in whole or part by a grant from the Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services. However, the opinions expressed herein do not necessarily reflect the position or policy of that Office and no official endorsement by that Office should be inferred.

§ 63.39 Religious worship or instruction.

Federal funds shall not be used for the making of any payment for religious worship or instruction, or for the construction, operation, or maintenance of so much of any facility as is

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used or to be used for sectarian instruction or as a place for religious instruction.

PART 73—STANDARDS OF CONDUCT

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APPENDIX A TO PART 73—LIST OF SOME OFFENSES FOR WHICH DISCIPLINARY ACTION MAY BE TAKEN

APPENDIX B TO PART 73—CODE OF ETHICS FOR GOVERNMENT SERVICE

AUTHORITY: 5 U.S.C. 7301, 42 U.S.C. 216; E.O. 11222, 30 FR 6469; 5 CFR 735.101 *et seq.*

SOURCE: 46 FR 7369, Jan. 23, 1981, unless otherwise noted.

EFFECTIVE DATE NOTE: At 90 FR 40978, Aug. 22, 2025, part 73 was revised and republished, effective Oct. 21, 2025. At 90 FR 43158, Sept. 8, 2025, this rule was corrected, effective Oct. 21, 2025.

Subpart A—General Provisions

§ 73.735–101 Purpose.

To assure that the business of the Department of Health and Human Services (HHS) is conducted effectively, objectively, and without improper influence or the appearance of improper influence, employees and special Government employees must be persons of integrity and must observe high standards of honesty, impartiality, and behavior. They must not engage in any conduct prejudicial to the Government and must avoid conflicts of private interests with public duties and responsibilities. In accord with these principles, the regulations in this part are issued to inform HHS employees and special Government employees what standards of conduct are expected of them in performing their duties and what activities are permitted or prohibited both while they are employed and after their employment with the Department is ended.

§ 73.735–102 Definitions.

In this part:

(a) *Employee* means an officer or employee of HHS other than a special Government employee and includes Commissioned Officers of the Public Health Service who are on active duty, and individuals on assignment or detail to HHS pursuant to the Intergovernmental Personnel Act (5 U.S.C. 3371–

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3376). The term also includes HHS employees who are detailed to non-Federal or other Federal organizations. At times the term “regular employee” is used in place of “employee” to make a clear distinction between special Government employees and others employed by the Federal government.

(b) *Special Government employee* means an individual who is retained, designated, appointed, or employed to perform temporary duties either on a full-time or intermittent basis, with or without compensation, for not to exceed 130 days during any period of 365 consecutive days.

(c) *Person* means an individual, a corporation, a company, an association, a firm, a partnership or any other organization.

(d) *Former employee* means a former employee of HHS or former special Government employee as defined in paragraph (b) of this section.

(e) *Principal Operating Component* has the meaning given to that term in the Department’s General Administration Manual. In addition, when used in these regulations, it includes the Office of the Secretary.

(f) *Department* means the Department of Health and Human Services.

§ 73.735–103 Applicability.

(a) The regulations in this part apply to all employees of the Department and to special Government employees to the extent indicated in Subparts J and K. They apply whether an employee is on leave, including leave without pay, or on duty.

(b) These regulations may be supplemented by regulations governing principal operating components, or subunits of principal operating components, provided the clearance and publication requirements for standards of conduct regulations are met and approval is obtained from the Department Ethics Counselor and the Assistant Secretary for Personnel Administration.

Subpart B—Responsibilities

§ 73.735–201 Employees and supervisors.

(a) Employees and special Government employees shall be responsible

for observing all generally accepted rules of conduct and the specific provisions of law and the regulations of this part that apply to them. They are required to become familiar with these regulations and to exercise informed judgments to avoid misconduct or conflicts of interest. They shall secure approvals when required and file financial disclosure reports or statements in accordance with the provisions of this part. Failure to observe any of these regulations may be cause for disciplinary action. Some of the provisions are required by law and carry criminal penalties which are in addition to any disciplinary action which could be taken. When employees have doubts about any provision, they should consult their supervisor, personnel office, or the Department Ethics Counselor or a deputy counselor.

(b) Supervisors, because of their day-to-day relationships with employees, are responsible to a large degree for making sure high standards of conduct are maintained. They must become familiar with the Department's standards of conduct regulations and apply the standards to the work they do and supervise. Supervisors shall take suitable action, including disciplinary action in accordance with subpart L of these regulations, when violations occur.

§ 73.735–202 Management officials.

(a) The Department has an obligation to enforce the requirements of this part in all respects and to help employees, special Government employees, and supervisors carry out their responsibilities to maintain high standards of ethical conduct. This includes an obligation for managers to provide information and training concerning the HHS conduct regulations, to provide advice and guidance with respect to them, and to review for possible conflicts of interest certain outside activities and financial interests of employees. The officials responsible for discharging the Department's obligations in this regard are identified in paragraphs (b) through (f) of this section.

(b) Department Ethics Counselor. The Assistant General Counsel, Business and Administrative Law Division, shall be the Department Ethics Coun-

selor and shall serve as the Designated Agency Official for matters arising under the Ethics in Government Act of 1978, (Pub. L. 95-521). The responsibilities of the Department Ethics Counselor shall include:

(1) Rendering authoritative advice and guidance on matters of general applicability under the standards of this part and all other laws and regulations governing employee conduct, with particular reference to conflicts of interest matters.

(2) Coordinating the Department's counselling and training services regarding conflicts of interest and assuring that employees of the Department are kept informed of developments in conflict of interest laws and other related matters of ethics.

(3) Receiving information on conflicts of interest and appearances of conflicts of interest involving employees of the Department and forwarding this information to the appropriate management official, or the Inspector General, as necessary, with his or her legal evaluation of the matters addressed.

(4) Reviewing the financial disclosure reports, requests for approval of outside activities, and similar reports filed by Executive level officers, non-career executives, deputy ethics counselors, and Schedule C employees in the Office of the Secretary for the purpose of identifying and resolving possible and actual conflicts of interest.

(5) Maintaining liaison with the Office of Government Ethics.

(6) Advising management officials on the resolution of conflicts of interest by any of the remedies set forth in § 73.735–904 of this part.

(7) Maintaining accurate and complete documentation of all formal guidance and advice regarding conflict of interest matters subject to the provisions of this part, except for routine or repetitious cases where the guidance given is not precedential.

(8) Maintaining and publishing from time to time a list of those circumstances or situations which have resulted or may result in noncompliance with conflict of interest laws or regulations. [Section 206(b)(7), Pub. L. 95-521].

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(9) Designating and training an appropriate number of reviewing officials to assist him or her in carrying out the duties of the Designated Agency Official under the Ethics in Government Act.

(10) Maintaining effective lines of communication with deputy ethics counselors on all matters regarding employee conduct and ethics.

(c) Deputy Ethics Counselors. Assistant General Counsels and Regional Attorneys are designated deputy ethics counselors to assist the Department's Counselor in carrying out his or her responsibilities, particularly with respect to employees in the organization in which the deputy counselor serves. Regional Attorneys shall provide such assistance for all employees of the Department in organizations for which the Principal Regional Official provides personnel services.

(d) The Assistant Secretary for Personnel Administration shall be responsible for developing and issuing procedures and requirements for the implementation of these regulations and for monitoring the application of such procedures and requirements throughout the Department.

(e) Heads of Principal Operating Components and the Assistant Secretary for Management and Budget for the Office of the Secretary shall be ultimately responsible for assuring that persons who work for their respective organizations comply with the standards of this part. Their responsibilities shall include:

(1) Designating officials to review and approve outside activity requests in accordance with § 73.735–708 of this part or statements of employment or financial interests under § 73.735–902. A list of the officials designated for these purposes shall be provided to the Department Ethics Counselor and to the Assistant Secretary for Personnel Administration and shall be updated in January and July of each year.

(2) Designating for the components of his or her organization, other than those for which a principal regional official provides personnel services, one or more individuals to oversee and coordinate the administrative aspects of these regulations. Responsibilities of such a person include making sure each employee or special government em-

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ployee is provided a copy of these regulations, or an appropriate summary thereof; ensuring that training in the requirements of the regulations is provided to supervisors and to new employees; providing for the distribution, receipt, review and retention of financial interest reports and statements as directed by the Department Ethics Counselor and the Assistant Secretary for Personnel Administration; sending annual reminders as required; providing for a file of outside work requests; giving information and assistance to employees on a day-to-day basis; and making available to employees the names and addresses of the Department's Ethics Counselor and deputy ethics counselors.

(f) Principal Regional Officials (PROs) shall designate one or more regional employees to perform, for components for which personnel services are provided by the PROs, the responsibilities in paragraph (e)(2) of this section.

Subpart C—Conduct on the Job

§ 73.735–301 Courtesy and consideration for others.

(a) An employee's conduct on the job is, in all respects, of concern to the Federal government. Courtesy, consideration, and promptness in dealing with the public must be shown in carrying out official responsibilities, and actions which deny the dignity of individuals or conduct which is disrespectful to others must be avoided. Employees must recognize that inattention to matters of common courtesy can adversely affect the quality of service the Department is responsible for providing. Where appropriate, courtesy to the public should be included in the standards for employee performance.

(b) Of equal importance is the requirement that courtesy be shown in day-by-day interaction with co-workers. Employees shall be polite to and considerate of other employees, and shall respect their needs and concerns in the work environment.

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§ 73.735–302 Support of department programs.

(a) When a Department program is based on law, Executive Order or regulation, every employee has a positive obligation to make it function as efficiently and economically as possible and to support it as long as it is a part of recognized public policy. An employee may, therefore, properly make an address explaining and interpreting such a program, citing its achievements, defending it against uninformed or unjust criticism, or soliciting views for improving it.

(b) An employee shall not, either directly or indirectly, use appropriated funds to influence, or attempt to influence, a Member of Congress to favor or oppose legislation. However, when authorized by his or her supervisor, an employee is not prohibited from:

(1) Testifying, on request, as a representative of the Department on pending legislation or proposals before Congressional Committees; or

(2) Assisting Congressional Committees in drafting bills or reports on request, when it is clear that the employee is serving solely as a technical expert under the direction of committee leadership.

(c) All employees shall be familiar with regulations and published instructions that relate to their official duties and responsibilities and shall comply with those directives. This includes carrying out proper orders from officials authorized to give them.

(d) Employees are required to assist the Inspector General and other investigative officials in the performance of their duties or functions. This requirement includes the giving of statements or evidence to investigators of the Inspector General's office or other HHS investigators authorized to conduct investigations into potential violations.

§ 73.735–303 Use of government funds.

(a) An employee shall not:

(1) Improperly use official travel;

(2) Improperly use payroll and other vouchers and documents on which Government payments are based;

(3) Take or fail to account for funds with which the employee is entrusted in his or her official position; or

(4) Take other Government funds for personal use. Violation of these prohibitions carry criminal penalties.

(b) In addition, employees shall avoid wasteful actions or behavior in the performance of their assigned duties.

§ 73.735–304 Use of government property.

(a) An employee shall not directly or indirectly use, or allow the use of, Government property of any kind, including property leased to the Government, for other than officially approved activities. An Employee has a positive duty to protect and conserve Government property, including equipment, supplies, and other property entrusted or issued to him or her. For example:

(1) Only official documents and materials may be processed on Government reproduction facilities. Both supervisors and employees must assure that this rule is strictly followed. (Exception for employee welfare and recreation associations is stated in Chapter 25–10, General Administration Manual. Exception for labor organizations is stated in Personnel Instruction 711–1.)

(2) Employees may drive or use Government automobiles or aircraft only on official business. Use of a Government owned, leased, or rented vehicle or aircraft for non-official purposes may result in suspension for at least 30 days or removal from the Federal service. 31 U.S.C. 638a.

Example: Normally, use of a Government automobile by travel between home and place of duty would not be considered official business and could not be authorized. An exception to this rule might be appropriate in a situation where an employee is required to leave early in the morning to attend a meeting in a distant city, or to return late in the day from such a meeting. Allowing the employee to drive a government car to his or her home the night before in order to leave from home, or to return to his or her home in the evening upon completion of the trip is permissible, provided the employee does not use the car for any personal reason.

§ 73.735–305 Conduct in Federal buildings.

(a) An employee shall not participate while on Government-owned or leased

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property or while on duty for the Government, in any gambling activity including the operation of a gambling device, in conducting a lottery or pool, in a game for money or property, or in selling or purchasing a numbers slip or ticket.

(b) An employee shall not while in or on Government-owned or leased property or while on duty for the Government solicit alms and contributions, engage in commercial soliciting and vending, display or distribute commercial advertisements, or collect private debts.

(c) The prohibitions in paragraphs (a) and (b) of this section do not preclude:

(1) Activities necessitated by an employee's law enforcement duties;

(2) Participation in Federally sponsored fund-raising activities conducted pursuant to Executive Order 10927, or similar HHS-approved activities; or

(3) Buying a lottery ticket at an authorized State lottery outlet for a lottery authorized by State law and conducted by an agency of a State within that State.

(d) General Services Administration regulations on "Conduct on Federal Property" apply to all property under the control of the General Services Administration, and they are also applicable to all buildings and space under the control of this Department. These regulations prohibit, among other things, gambling, being intoxicated, and possession, distribution, or use of narcotic or dangerous drugs on the premises. The GSA regulations are found in Subpart 101–20.3 of the GSA Regulations, 41 CFR 101–20.3.

§ 73.735–306 Sexual harassment.

Sexual harassment is deliberate unsolicited verbal comments, gestures, or physical contact of a sexual nature which are unwelcome. Sexual harassment is unacceptable conduct and is expressly prohibited. In addition, supervisors and managers are prohibited from taking or promising personnel actions in exchange for sexual favors, or failing to take an action because an employee or applicant for employment, refuses to engage in sexual conduct. This same prohibition applies to relationships between Department personnel who take or recommend action

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on a grant or contract and the grantee or contractor. Those employees who wish to file a complaint of sexual harassment should contact the Office of Equal Employment Opportunity (EEO) within their respective agencies for guidance. (Time frames for pursuing a charge alleging sexual harassment are the same as for any other complaint based on allegations of sex discrimination.)

§ 73.735–307 Use of official information.

(a) The public interest requires that certain information in the possession of the Government be kept confidential, and released only with general or specific authority under Department or operating component regulations. Such information may involve the national security or be private, personal, or business information which has been furnished to the Government in confidence. In addition, information in the possession of the Government and not generally available may not be used for private gain. The following paragraphs set forth the rules to be followed by Department employees in handling information in official files or documents:

(1) *Classified information.* Employees who have access to information which is classified for security reasons in accordance with Executive Order 12065 are responsible for its custody and safekeeping, and for assuring that it is not disclosed to unauthorized persons. See the Department's Security Manual, Part 3 for details.

(2) *Security and investigative information.* Security and investigative data received from Government agencies or other sources for official use only within the Department or developed under a pledge of confidence is not to be divulged to unauthorized persons or agencies.

(3) *Information obtained in confidence.* Certain Department units (e.g., Food and Drug Administration, and the Social Security Administration) obtain in the course of their program activities certain information from businesses or individuals which they are forbidden by law from disclosing. These statutory prohibitions are found in 21 U.S.C. 331j,

and 18 U.S.C. 1905. Each employee is responsible for observing these laws.

(4) *Use of information for private gain.* Government employees are sometimes able to obtain information about some action the Government is about to take or some other matter which is not generally known. Information of this kind shall not be used by the employee to further his or her or someone else's private financial or other interests. Such a use of official information is clearly a violation of a public trust. Employees shall not, directly or indirectly, make use of, or permit others to make use of, for the purpose of furthering any private interest, official information not made available to the general public.

(b) The Privacy Act provides criminal penalties for an employee who willfully discloses individually identifiable information from records, disclosure of which is prohibited by that Act. 5 U.S.C. 552a(i).

Subpart D—Financial Obligations

§ 73.735–401 General provisions.

(a) The Department considers the indebtedness of its employees to be a matter of their own concern. However, employees shall not by failure to meet their just financial obligations reflect adversely on the Government as their employer. Employees are expected to pay each just financial obligation in a proper and timely manner. A “just financial obligation” is one acknowledged by the employee or reduced to judgment by a court, or one imposed by law such as Federal, State, or local taxes. “In a proper and timely manner” is a manner which the Department determines does not, under the circumstances, reflect adversely on the part of an employee in meeting his or her financial obligations, particularly those that relate to support of the employee's family, to payment of Federal, State, or local taxes, or to payments to tax-supported institutions such as a city or State hospital, or educational institution. If for some reason an employee is unable to pay these obligations promptly, he or she is expected to make satisfactory arrangements for payment and abide by these arrangements.

(b) Disciplinary action may be considered when an employee has handled his or her financial affairs in such a way that:

(1) Action on complaints received from creditors requires the use of a considerable amount of official time, or

(2) It appears that financial difficulties are impairing the employee's efficiency on the job, or

(3) Because of the employee's financial irresponsibility, the attitude of the general public toward the Department may be adversely affected; and the employee after counseling does not make arrangements to meet his or her financial obligations.

Subpart E—Gifts, Entertainment, and Favors

§ 73.735–501 Prohibited acceptance of gifts, entertainment, and favors.

(a) Except as provided in §§ 73.735–502 and 73.735–506, an employee shall not directly or indirectly solicit or accept anything of monetary value, including gifts, gratuities, favors, entertainment or loans from a person who the employee knows, or should know because of the nature of the employee's work:

(1) Has, or is seeking to obtain, contractual or other business or financial relations with the employee's principal operating component, or sub-unit thereof; or with a component of the Department with respect to which the employee has official duties;

(2) Conducts operations or activities that are regulated by the employee's principal operating component, or sub-unit thereof or by a component of the Department with respect to which the employee has official duties; or

(3) Has interests that may be substantially affected by the performance or non-performance of the employee's official duties.

(b) Employees may not designate a person or an organization, including charitable or non-profit organizations, to accept any gift which an employee is prohibited from accepting directly.

§ 73.735–502 Permissible acceptance of gifts, entertainment, and favors.

(a) An employee may accept a gift, gratuity, favor, entertainment, loan or

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similar favor of monetary value which stems from a family relationship such as that between the employee and his or her parents, spouse or children, if it is clear that the relationship is the motivating factor.

(b) Loans from banks or other financial institutions may be accepted on customary terms.

(c) Unsolicited advertising or promotional material such as pens, note pads, calendars and similar items of nominal intrinsic value may be accepted.

(d) An employee may accept food or refreshment of nominal value on infrequent occasions in the ordinary course of a luncheon or dinner meeting or on an inspection tour only if the employee is properly in attendance and there is not a reasonable opportunity to pay.

Example 1: Employee is on the premises of Company participating in a meeting at a normal mealtime. A representative of Company provides a meal for all meeting participants from a Company facility and there is no established method for payment. Employee may accept.

Example 2: Employee is on the premises of Company and he or she goes outside for lunch with a representative of the Company. The representative offers to pay the bill. Since it is practical for the employee to pay for his or her own meal, the employee may not accept.

(e) An employee may also accept food or refreshment of nominal value on infrequent occasions if the food and/or refreshment is offered to all participants or attendees of a meeting or convention.

Example 1: During the course of a convention of a professional organization a luncheon open to all attendees is sponsored by a corporation which conducts business with the Department and the employee has official dealings with representatives of the corporation. The employee may attend the luncheon.

§ 73.735-503 Criminal provisions relating to gifts, entertainment, and favors.

(a) The law provides criminal penalties for whoever, directly or indirectly:

(1) Receives or accepts anything of value for or because of any official act the employee has performed or will perform; or

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(2) Gives, offers or promises anything of value for the performance of an official act or to influence the performance of an official act. 18 USC 201.

(b) The law prohibits an employee from receiving any salary or any contribution to, or supplementation of, his or her salary as compensation for services as an officer or employee of the Government from any source other than the United States or any State, county or municipality. This law does not prohibit an employee from continuing to participate in a bona fide pension, retirement, group life, health or accident insurance, profit-sharing, stock bonus or other employee welfare or benefit plan maintained by a former employer. 18 U.S.C. 209.

Example 1: A corporate executive is asked to accept a position in the Department. The corporation offers to continue to pay the executive the difference between his or her salary as a Government employee and that received by an employee of the corporation. Such payment would be considered to be "compensation for" the employee's Government service and is prohibited.

Example 2: A corporate executive is asked to accept a position in the Department. The corporation proposes to pay him or her a special severance payment in anticipation of this or her serving in the Government. This proposal would be prohibited because there is no distinction between the proposed lump-sum payment and the prohibited continuation of salary payments described in the example above.

Example 3: A corporate executive is asked to accept a position in the Department. The corporation has an established policy which provides for an amount of severance pay to be paid any departing executive and proposes to make payment based on that policy when the executive leaves. The executive may accept the payment. Under these circumstances it is clear that the severance pay is in payment for past services not in anticipation of the future services for the Government.

§ 73.735-504 Gifts to official superiors.

An employee shall not solicit a contribution from another employee for a gift to an official superior, make a donation as a gift to an official superior, or accept a gift from an employee receiving less pay than himself or herself. 5 U.S.C. 7351. This section does not prohibit a voluntary gift of nominal value or donation in nominal amount

made on a special occasion such as marriage, illness or retirement.

§ 73.735–505 Acceptance of awards and prizes.

(a) Employees may accept awards, including cash awards, given in recognition of a meritorious public contribution or achievement. However, if there is any indication that the award may improperly influence the employee in the performance of his or her official duties, advice about the acceptance of it should be sought from a deputy ethics counselor. Also, an employee may not accept an award from an organization which the employee knows, or should know, has a contractual or other business arrangement with, or is regulated by, the principal operating component, or a sub-unit, in which he or she is employed or with respect to which the employee has official duties, unless acceptance is approved by the head of the employee's principal operating component. The head of the component may not approve acceptance unless he or she is satisfied that no actual conflict of interest would result.

(b) Employees may generally accept trophies, entertainment, rewards, and prizes given to competitors in contests or events which are open to the public.

(c) Employees may not accept gifts, awards, decorations or other things of value from a foreign government except as provided in § 73.735–506.

§ 73.735–506 Gifts and decorations from foreign governments.

(a) An employee may not request or otherwise encourage the tender of a gift or decorations from a foreign government or official thereof.

(b) An employee may accept from a foreign government:

(1) A gift which is in the nature of medical treatment or an educational scholarship;

(2) A tangible gift of minimal value tendered or received as a mark of courtesy; ("Minimal value" means a retail value in the United States at the time of acceptance of not more than one hundred dollars, unless the Administrator of the General Services Administration adjusts the value by regulation.) or

(3) A tangible gift of more than minimal value when it appears that to refuse the gift would be likely to cause offense or embarrassment or otherwise adversely affect the foreign relations of the United States. However, the acceptance of such a gift would be on behalf of the United States and the gift would become the property of the United States. See the Department's General Administration Manual, Chapter 20–25 for information regarding the disposition of a gift accepted under these circumstances.

(c) An employee may also accept from a foreign government gifts of travel or expenses for travel (such as transportation, food and lodging) that take place entirely outside the United States and are of more than minimal value, if such acceptance is consistent with the interests of the United States and is approved by the travel approving authority in accordance with the Department's Travel Manual. See General Administration Manual, Chapter 20–25 for a requirement to report such travel.

(d) An employee may accept, retain, and wear a decoration tendered in recognition of active field service in time of combat operations or awarded for other outstanding or unusually meritorious performance, subject to the approval of the Secretary or his or her designee.

(e) Members of an employee's family and household are also subject to the regulations in this section. A member of an employee's family and household is a relative by blood, marriage or adoption who is a resident of the household. However, if a member of an employee's family and household is employed by another agency of the Government, the offer or acceptance of a gift shall be treated under the regulations of that agency.

(f) For purposes of this section "foreign government" means:

(1) Any unit of foreign government authority including any foreign national, state, local and municipal government;

(2) Any international or multinational organization whose membership is composed of any unit of foreign government described in paragraph (f)(1) of this section; or

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(3) Any agent or representative of any such unit or organization when acting as such agent or representative. (5 U.S.C. 7342)

§ 73.735–507 Acceptance of travel and subsistence.

(a) Except as provided in paragraph (b) of this section, employees may accept accommodations, subsistence, and travel in cash or in kind in connection with official travel for attendance at meetings, conferences, training in non-Governmental facilities or for performing advisory services, if approved in accordance with the provisions of the HHS Travel Manual. (5 U.S.C. 4111; 42 U.S.C. 3506)

(b) Employees may not accept accommodations, subsistence, or travel in cash or in kind in connection with official travel from a non-Governmental source with which they have official dealings unless Government or commercial travel and/or accommodations are not available. If travel and/or subsistence is accepted for official travel under these circumstances, such acceptance and the basis for it must be reported in writing to the Head of the Principal Operating Component or Assistant Secretary for Management and Budget for the Office of the Secretary.

§ 73.735–508 Other prohibitions.

Employees shall avoid any action whether or not specifically prohibited by this part, which might result in or create the appearance of:

- (a) Using public office for private gain;
- (b) Giving preferential treatment to any person;
- (c) Impeding Government efficiency or economy;
- (d) Losing complete independence or impartiality in the performance of their Government duties;
- (e) Making a Government decision outside official channels; or
- (f) Affecting adversely the confidence of the public in the integrity of the Government.

Subpart F—Political Activity

§ 73.735–601 Applicability.

(a) All employees in the Executive Branch of the Federal Government, in-

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cluding non-career employees, are subject to basic political activity restrictions in subchapter III of chapter 73 of title 5, United States Code (the former Hatch Act) and Civil Service Rule IV. Employees are individually responsible for refraining from prohibited political activity. Ignorance of a prohibition does not excuse a violation. This subpart summarizes provisions of law and regulation concerning political activity of employees. The Federal Personnel Manual and other publications of the Office of Personnel Management contain more detailed information on this subject. These may be reviewed in Department personnel offices, or will be made available by the Ethics Counselor, or the deputy counselor for the employee's organizational component.

(b) The Secretary and Under Secretary are exempt from the prohibitions concerning active participation in political management and political campaigns. Also exempt are other officials of the Department, except the Inspector General and Deputy Inspector General, who are appointed by the President by and with the advice and consent of the Senate, and who determine policies to be pursued by the United States in the nationwide administration of Federal laws.

(c) Intermittent employees are subject to the restrictions when in active duty status only and for the entire 24 hours of any day of actual employment.

(d) Employees on leave, on leave without pay, or on furlough even though an employee's resignation has been accepted, are subject to the restrictions. Separated employees who have received a lump-sum payment for annual leave are not subject to the restriction during the period covered by the lump-sum payment or thereafter, provided they do not return to Federal employment during that period. Employees are not permitted to take a leave of absence to work with a political candidate, committee, or organization or to become a candidate for office with the understanding that they will resign their position if nominated or elected.

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(e) Employees are accountable for political activity by another person acting as their agent or under the employee's direction or control, if they are thus accomplishing indirectly what they may not lawfully do directly and openly.

(f) Though officers in the Public Health Service Commissioned Corps are not subject to the restrictions in Subchapter III of Chapter 73 of Title 5, United States Code, the provisions of this subpart apply to them.

§ 73.735-602 Permissible activities.

(a) Section 7324 of Title 5, United States Code, provides that employees have the right to vote as they please and to express their opinions on political subjects and candidates. Generally, however, employees are prohibited from taking an active part in political management or political campaigns or using official authority or influence to interfere with an election or affect its results. There are some exemptions from the restrictions of the statute:

(1) Employees may engage in political activity in connection with any question not specifically identified with a national or State political party. They also may engage in political activity in connection with an election, if none of the candidates represents a party any of whose candidates for presidential elector received votes at the last preceding election at which presidential electors were selected.

(2) An exception relates to political campaigns within, or in communities adjacent to, the District of Columbia, or in communities the majority of whose voters are employees of the Federal government. Communities to which the exception applies are specifically designated by the Office of Personnel Management. Information regarding the localities and the conditions under which the exceptions are granted may be obtained from personnel offices or the Department Counselor or deputy counselors.

(b) A covered employee is permitted to:

- (1) Register and vote in any election;
- (2) Express his or her opinion as an individual citizen privately and pub-

licly on political subjects and candidates;

(3) Display a political picture, sticker, badge or button;

(4) Participate in the nonpartisan activities of a civic, community, social, labor, or professional organization, or of a similar organization;

(5) Be a member of a political party or other political organization and participate in its activities to the extent consistent with law;

(6) Attend a political convention, rally, fund raising function; or other political gathering;

(7) Sign a political petition as an individual citizen;

(8) Make a financial contribution to a political party organization;

(9) Take an active part, as an independent candidate, or support of an independent candidate, in a partisan election in localities identified as permissible for such activities by the Office of Personnel Management;

(10) Take an active part, as a candidate or in support of a candidate, in a nonpartisan election;

(11) Be politically active in connection with a question which is not specifically identified with a political party, such as a constitutional amendment, referendum, approval of a municipal ordinance or any other question or issue of a similar character;

(12) Serve as an election judge or clerk, or in a similar position to perform nonpartisan duties as prescribed by State or local law; and

(13) Otherwise participate fully in public affairs, except as prohibited by law, in a manner which does not materially compromise his or her efficiency or integrity as an employee or the neutrality, efficiency, or integrity of his or her agency.

(c) The head of a principal operating component may prohibit or limit the participation of an employee or class of employees of his or her component in an activity permitted by paragraph (b) of this section, if participation in the activity would interfere with the efficient performance of official duties, or create a conflict or apparent conflict of interest.

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§ 73.735–603 Prohibited activities.

(a) The following are prohibited activities:

(1) Serving as an officer of a political party, a member of a national, State or local committee of a political party, an officer or member of a committee of a partisan political club, or being a candidate for any of these positions;

(2) Organizing or reorganizing a political party organization or political club;

(3) Directly or indirectly soliciting, receiving, collecting, handling, disbursing, or accounting for assessments, contributions, or other funds for a partisan political purpose or in connection with a partisan election;

(4) Organizing, selling tickets to, seeking support for, or actively participating in a fund-raising activity of, a political party or political club;

(5) Taking an active part in managing the political party campaign of a candidate for public office or political office;

(6) Being a candidate for, or campaigning for, an elective public office, except as permitted in § 73.735–602(b)(9);

(7) Taking an active part in an organized solicitation of votes in support of or in opposition to a candidate for public office or political party office;

(8) Acting as recorder, watcher, challenger, or similar officer at the polls on behalf of a political party or candidate in a partisan election;

(9) Driving voters to the polls on behalf of a political party or a candidate in a partisan election;

(10) Endorsing or opposing a candidate in a partisan election in a political advertisement, a broadcast, campaign literature, or similar material;

(11) Serving as a delegate, alternate, or proxy to a political party convention;

(12) Addressing a State or national convention or caucus, or a rally or similar gathering of a political party, in support of or in opposition to a candidate for public or political party office, or on a partisan political question; and

(13) Initiating or circulating a nominating petition for a candidate in a partisan election.

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(b) In addition, certain political activities are prohibited by Federal criminal law:

(1) Officers and employees may not directly or indirectly solicit or receive, or be in any way involved in soliciting or receiving, any assessment, subscription or contribution for any political purpose whatever from another officer or employee. This prohibition extends to one who acts as a mere agent or messenger for the purpose of turning the contribution over to a political organization. 18 U.S.C. 602.

(2) All persons, whether employees or not, are prohibited from soliciting in any manner, or receiving a contribution of, money or a thing of value, in any room or building occupied in the discharge of official duties by any officer or employee of the United States. 18 U.S.C. 603. This prohibition extends to the sending of a letter soliciting political contributions for delivery in a Government building.

(3) No officer or employee may directly or indirectly give to any other officer, employee or person in the service of the United States, any money or other thing of value to be applied to the promotion of any political objective. 18 U.S.C. 607.

(4) Discrimination for giving or withholding any contribution for any political purpose and discrimination based on political influence or recommendations is prohibited.

(c) Various other laws prohibit certain activities in connection with political campaigns and elections. They include:

(1) Intimidating, threatening, or coercing voters in Federal elections (18 U.S.C. 594).

(2) Using official authority in interfering with a Federal election by a person employed in any administrative position by the United States or by any department, independent establishment, or agency of the United States or by any State, agency, or political subdivision thereof in connection with any activity financed in whole or in part by Federal funds (18 U.S.C. 595).

(3) Promising Federal employment, compensation, or any benefit from Federal funds, in return for political activity or support (18 U.S.C. 600).

(4) Depriving anyone of employment, compensation, or any benefit derived from Federal relief or work relief funds on account of race, creed, color, or political activity (18 U.S.C. 601).

(5) Soliciting, assessing, or receiving subscriptions or contributions for political purpose from anyone on Federal relief or work relief (18 U.S.C. 604).

Subpart G—Outside Activities

§ 73.735–701 General provisions.

(a) Outside employment may be appropriate when it will not adversely affect performance of an employee's official duties and will not reflect discredit on the Government or the Department. Such work may include civic, charitable, religious, and community undertakings. There are certain types of outside work, however, which give rise to a real or apparent conflict of interest. Some of these are prohibited by law. Others are prohibited by regulation, as discussed in paragraph (b) of this section, or by criteria developed by heads of operating components for application within a particular component. All of these provisions are binding, but they do not necessarily include all possible conflicts of interest. In all instances, good judgment must be used to avoid a conflict between an employee's Federal responsibilities and outside activities.

(b) An employee shall not engage in outside employment or other outside activity not compatible with the full and proper discharge of the duties and responsibilities of his or her Government employment whether or not in violation of any specific provision of law. Incompatible activities include, but are not limited to:

(1) Acceptance of a fee, compensation, gift, payment of expense, or any other thing of monetary value in any circumstances in which acceptance may result in, or create the appearance of, conflicts of interest;

(2) Outside employment which tends to impair the employee's mental or physical capacity to perform Government duties and responsibilities in an acceptable manner;

(3) Work which identifies the Department or any employee in his or her official capacity with any organization

commercializing products relating to work conducted by the Department, or with any commercial advertising matter, or work performed under such circumstances as to give the impression that it is an official act of the Department or represents an official point of view;

(4) Outside work or activity that takes the employee's time and attention during his official work hours.

(c) An employee shall not receive any salary or anything of monetary value from a private source as compensation for services to the Government. For example, a Department employee may be called upon, as a part of his or her official duties, to participate in a professional meeting sponsored by a non-Government organization, or to contribute a paper or other writing prepared on official time for publication under non-Government auspices. The employee must not accept an honorarium or fee for such services, even though the organization accepting the service customarily makes such a payment to those who participate. Nor may the employee accept a contribution to some charity, educational institution, or the like, in appreciation of the services furnished by the Department employee who cannot accept the usual payment. All offers to make such a contribution must be refused. Any employee with whom such a question is raised shall explain that the service involved was provided as an official action of the Department and is authorized by law. Under these circumstances, it is inappropriate for any payment to be made, even indirectly and to a third party, for services which are furnished without charge by the Government.

(d) Other than as provided in paragraph (c) of this section, employees may receive compensation or other things of monetary value for any lecture, discussion, writing or appearance the subject matter of which is in part devoted to the responsibility, programs or operations of the Department so long as the activity is undertaken in a personal capacity, is not performed as

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official duty, is not done while on official time, and does not create a conflict of interest or appearance of conflict of interest. However, such activities are considered outside employment and may be undertaken only as provided in this subpart.

(e) This section does not restrict the acceptance of compensation or other things of monetary value for any lecture, discussion, writing or appearance, the subject matter of which is not devoted to the responsibilities, programs, or operations of the Department and which are undertaken in a private capacity and in accordance with § 73.735–704, § 73.735–705, or § 73.735–706.

(f) Federal law limits the amount of honorarium that may be paid any employee for any one speech, writing or appearance to \$2,000.00 (not to include amounts for actual travel and subsistence expenses for the employee and his or her spouse) and an aggregate of \$25,000.00 in any calendar year. This limitation applies to such activities whether or not the subject matter is related to the responsibilities, programs or operations of the Department. (2 U.S.C. 441i) The term “honorarium” means payment of money or other thing of value whether made gratuitously or as a fee for an appearance, speech or article but does not include salary or compensation made for services rendered on a continuing basis, such as for teaching, or as proceeds from the sale of a book or similar undertaking.

(g) An employee who is a Presidential appointee covered by section 401(a) of Executive Order 11222 shall not receive compensation or anything of monetary value for any consultation, lecture, discussion, writing or appearance, the subject matter of which is devoted substantially to the responsibilities, programs, or operations of his or her component, or which draws substantially on official data or ideas which have not or will not on request become public information.

(h) Application of these general provisions to some specific activities is discussed below.

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§ 73.735–702 Criminal prohibitions on outside activities.

(a) An employee may not, with or without compensation, represent another before any Government agency, court or commission in connection with any proceeding, application, request for a ruling, contract, claim or other particular matter in which the United States is a party or has a direct and substantial interest. (18 U.S.C. 203 and 205)

(b) An employee may not act as agent or attorney for anyone else in prosecuting any claim against the United States (18 U.S.C. 205).

(c) As an exception to the above, if it is not inconsistent with the performance of his or her duties, an employee may act without compensation as an agent or attorney for another employee, or a person under active consideration for Federal employment, who is the subject of disciplinary, loyalty, or other personnel administration proceedings in connection with those proceedings at the administrative level. For example, an employee may represent another employee who is the subject of disciplinary action, or the complainant in a discrimination proceeding, at all stages within the Department and before the Merit Systems Protection Board or Equal Employment Opportunity Commission but not in Federal Court. It would be inconsistent with the performance of official duties for a supervisor to represent subordinate employees.

(d) The law and these regulations do not prohibit an employee from acting, with or without compensation, as agent or attorney for his or her parents, spouse, child or any person for whom, or estate for which, he or she is acting as fiduciary provided that the head of the principal operating component or his or her designee approve. Such approval, if granted, must be granted in accordance with the procedures for approval of outside activity. However, the employee may not do so if the particular matter is one in which he or she has participated personally and substantially or which is his or her official responsibility. (18 U.S.C. 205).

Dept. of Health and Human Services

§ 73.735-705

§ 73.735-703 Statutory prohibitions related to employment by a foreign government.

Employees, including officers in the Public Health Service (PHS) Commissioned Corps and retired officers of the Regular Commissioned Corps of the PHS, may not, without the consent of Congress, be employed by a foreign government or agency of a foreign government (Art. I, Sec. 9, U.S. Const.). Congress has consented to such employment by Reserve Commissioned Officers of the PHS not on active duty and by Retired Regular Commissioned Officers (37 U.S.C. 801, note) if approved under regulations of the Department of State. 22 CFR part 3a.

§ 73.735-704 Professional and consultative services.

(a) Employees may engage in outside professional or consultative work only after meeting certain conditions. Except as provided in §§ 73.735-705 and 73.735-706 for activities discussed in those sections, the conditions which must be met are:

(1) The work is not to be rendered, with or without compensation, to organizations, institutions, or state or local governments with which the official duties of the employee are directly related, or indirectly related if the indirect relationship is significant enough to cause the existence of conflict or apparent conflict of interest; or

(2) The work is not to be rendered for compensation to help a person, institution, or government unit prepare or aid in the preparation of grant applications, contract proposals, program reports, and other material which are designed to become the subject of dealings between the institutions or government units and the Federal Government. All requests to perform consultative services, either compensated or uncompensated, for institutions or government units which have recently negotiated or may in the near future seek a contract or grant from this Department must be carefully appraised to avoid any conflict or apparent conflict of interest.

(b) Advance administrative approval in accordance with § 73.735-708 of this subpart must be obtained. Such approval is required whether or not the

services are for compensation, and whether or not related to the employee's official duties.

(c) For the purpose of this section, "professional and consultative work" is performance of work requiring knowledge of an advanced type in a field of science or learning customarily acquired by a course of specialized instruction and study in an institution of higher education, or hospital which requires the exercise of judgment and discretion in its performance and is primarily intellectual in nature as opposed to manual, mechanical or physical work.

(d) Membership on a Board of Directors, Board of Regents, Board of Trustees, Planning Commission, Advisory Council or Committee, or on any similar body which provides advice, counsel, or consultation, shall be considered outside consultative services for which advance administrative approval is required.

§ 73.735-705 Writing and editing.

(a) Employees are encouraged to engage in outside writing and editing whether or not done for compensation, when such activity is not otherwise prohibited. Such writing and editing, though not a part of official duties, may be on a directly related subject or entirely unrelated. Certain conditions must be met in either case, however, and certain clearances or approvals are prescribed according to the content of the material as set forth in paragraphs (b) through (e) of this section.

(b) Conditions applying to writing and editing done not as a part of official duties.

(1) The following conditions shall apply to all writing and editing whether related or unrelated to the employee's official duties:

(i) Government-financed time or supplies shall not be used by the author or by other Government employees in connection with the activity; and

(ii) Official support must not be expressed or implied in the material itself or advertising or promotional material, including book jackets and covers, relating to the employee and his or her contribution to the publication.

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(2) If the writing or editing activity is unrelated to the employee's official duties or other responsibilities and programs of the Federal government, the employee must:

(i) Make no mention of his or her official title or affiliation with the Department, or

(ii) Use his or her official title or affiliation with the Department in a way that will not suggest or convey official endorsement of the work.

(3) If the writing or editing activity is related to the employee's official duties or other responsibilities and programs of the Federal government, the employee must:

(i) Make no mention of his or her official title or affiliation with the Department, or

(ii) Use his or her official title or affiliation with the Department and a disclaimer as provided in paragraph (c) of this section, or

(iii) Submit the material for clearance within the operating component, under procedures established by the component. When clearance is denied at any lower level, the employee shall have recourse for review up to the head of the principal operating component. This clearance will show there are no official objections to the activity and the employee may then use his or her official title or affiliation with the Department usually without a disclaimer.

(c) *Disclaimers.* (1) Except where the requirement for disclaimer is waived as a result of official clearance, disclaimers shall be used in all writing and editing related to the employee's official duties or other responsibilities and programs of the Federal government:

(i) In which the employee identifies himself or herself by official title or affiliation with the Department, or

(ii) When the prominence of the employee or the employee's position might lead the public to associate him or her with the Department, even without identification other than name.

(2) Disclaimers shall read as follows unless a different wording is approved by the Assistant General Counsel, Business and Administrative Law Division, Office of the General Counsel: "This (article, book, etc.) was (written, edited) by (employee's name) in (his or

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her) private capacity. No official support or endorsement by (name of operating component or of Department) is intended or should be inferred."

(d) *Advance approval.* Advance approval is required in accordance with § 73.735–708 of this subpart when one or more of the following conditions apply:

(1) Any Government information is used which is not available on request to persons outside the Government;

(2) Material is written or edited which pertains to subject matter directly related to an employee's official duties; (This includes editing for scientific or professional journals which is related to his or her official duties.)

(3) Material is written or edited which pertains to any Government-sponsored research or other studies for which clinical case records or other material of a confidential nature are used or to which access is limited for persons outside the Government. Such use will not be permitted unless made under safeguards established by the operating component to retain the confidentiality of the material, and such use is determined to be in the public interest.

§ 73.735–706 Teaching, lecturing, and speechmaking.

(a) Employees are encouraged to engage in teaching and lecturing activities which are not part of their official duties when certain conditions are met. These conditions, which apply to outside teaching and lecturing (including giving single addresses such as commencement and Memorial Day speeches) whether or not done for compensation, are:

(1) No Government-financed time, or Government supplies not otherwise available to the public, are used in connection with such activity;

(2) Government travel or per diem funds are not used for the sole purpose of obtaining or performing such teaching or lecturing;

(3) Such teaching or lecturing is not dependent on specific information which would not otherwise be available to the public;

(4) Teaching, lecturing, or writing may not be for the purpose of the special preparation of a person or class of

persons for an examination of the Office of Personnel Management or Board of Examiners for the Foreign Service, that depends on information obtained as a result of the employee's Government employment, except when that information has been made available to the general public or will be made available on request;

(5) Such activities do not involve knowingly instructing persons on dealing with particular matters pending before Government organizations with which the employee is associated in an official capacity;

(6) Advance approval is obtained when required by paragraph (b) of this section.

(b) Advance approval. Advance approval must be obtained in accordance with § 73.735–708 of this subpart before an employee may:

(1) Teach or lecture for an institution which has or is likely to have official dealings with the bureau or comparable organizational unit in which he or she is employed;

(2) Use, for teaching or lecturing purposes, clinical case records or other material of a confidential nature or to which access is limited for persons outside the Government. Such use will not be permitted unless made under safeguards established by the operating component to retain the confidentiality of the material, and such use is determined to be in the public interest.

§ 73.735–707 Holding office in professional societies.

(a) Employees may be members of professional societies and be elected or appointed to office in such a society. Activity in professional associations is generally desirable from the point of view of both the Department and the employee. Employees shall avoid, however, any real or apparent conflict of interest in connection with such membership. For example, they must not:

(1) Directly or indirectly commit the Department or any portion of it on any matter unless such action is taken in an official capacity;

(2) Permit their names to be attached to documents the distribution of which would be likely to embarrass the Department; or

(3) Serve in capacities involving them as representatives of non-Government organizations in dealing with the Government.

(b) In undertaking any office or function beyond ordinary membership in a professional association, a Department employee must obtain advance approval in accordance with § 73.735–708 of this subpart in any situation in which his or her responsibilities as an officer would relate to his or her official duties or would create a real or apparent conflict of interest with responsibilities as a Department employee. For example, advance administrative approval must be obtained:

(1) Before an employee who is responsible for review and approval of grants or contracts, or is in a supervisory position over those who conduct review and approval, may hold office, or be a trustee or member of the governing board, or the chairman or member of a committee, in any organization which has or is seeking a grant or contract with the bureau or comparable organizational unit in which he or she is employed;

(2) Before an employee may hold office in an organization which customarily expresses publicly views on matters of legislative or administrative policy within the specific areas of concern to the Department.

§ 73.735–708 Administrative approval of certain outside activities.

(a) *Scope.* As specified in § 73.735–704 through 707, an employee is required to obtain advance administrative approval to engage in the following outside activities:

(1) Certain writing or editing activities;

(2) Certain types of teaching and lecturing;

(3) All professional and consultative services;

(4) Any other outside activity for which the head of a principal operating component or the head of a sub-unit of a principal operating component imposes internal requirements for administrative approval; and

(5) Certain office-holding activities in professional societies.

(b) *Requests for Administrative Approval.* An employee seeking to engage

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in any of the activities for which advance approval is required shall make a written request for administrative approval a reasonable time before beginning the activity. (See § 73.735–202(e)(1)). This request should be directed to the employee's supervisor who will forward it to the official authorized to approve outside work requests for the employee's component. The request should include the following information:

- (1) Employee's name, position title, grade or rank;
 - (2) Nature of the activity, fully describing the specific duties or services for which approval is requested;
 - (3) Name and business of person or organization for which work will be done, or statement that work will be self-employment. If self-employment, employee must state whether activity will be conducted alone or with partners;
 - (4) Place where work will be performed;
 - (5) Estimated total time to be devoted to activity. If on a continuing basis, indicate estimated time per year and the anticipated termination date;
 - (6) Whether services can be performed entirely outside of usual duty hours. If not, the estimated number of hours absent from work should be indicated;
 - (7) Method or basis of compensation if any (e.g., fee, per diem, per annum, or other).
 - (8) Where an employee seeks approval to provide consultative or professional services to organizations including governments which have been awarded or may apply for a Federal grant or contract, the request shall also include full details on any aspect of the professional and consultative services which could relate in any way, either directly or indirectly, to grant applications, contract proposals, program reports, and other material which are designed to become the subject of dealings between the grantee or contractor and the Government. (See § 73.735–704(a)(2))
- (c) The Department Ethics Counselor will review and approve outside work requests for Executive level officers, non-career executives, deputy ethics counselors, and Schedule C employees in the Office of the Secretary.

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(d) *Granting Approval of Certain Activities.* The approving official shall review each request submitted under paragraph (b) of this section, and appraise each request on the basis of the standards of this part and all other applicable laws, regulations or internal rules of the principal operating component or sub-unit thereof. He or she should consult with a deputy ethics counselor or the Department Ethics Counselor in all cases that raise a difficult or novel question of law or fact. The approving official shall approve or disapprove each request and communicate his or her decision in writing to the employee.

§ 73.735–709 Annual reporting of outside activities.

By September 10 of each year the approving official shall require a report from each person for whom outside work has been approved during the past year. The report shall show:

- (a) For the 12 months just past (ending August 31):
 - (1) Whether the anticipated work was actually performed for the person or organization named in the request for approval;
 - (2) Actual amount of time spent on the activity.
- (b) For the forthcoming 12 months (ending August 31):
 - (1) Whether it is anticipated that the outside work will continue;
 - (2) Whether any change is anticipated with respect to information supplied in accordance with the original request on which approval was based.

§ 73.735–710 Maintenance of records.

The official responsible for the administrative aspects of these regulations (§ 73.735–202) shall make provisions for the retention and filing of requests for approval of outside work (or copies of such requests), a copy of the notification of approval or disapproval, and the annual report.

Subpart H—Financial Interest**§ 73.735–801 Participation in matters affecting a personal financial interest.**

(a) An employee shall not participate personally and substantially as a Government employee in a matter in which any of the following individuals or organizations has a financial interest:

- (1) The employee;
- (2) The employee's spouse;
- (3) The employee's minor child;
- (4) An organization in which the employee serves as an officer, director, trustee, partner, or employee; or
- (5) A person or organization with which the employee is negotiating for prospective employment or has an arrangement for prospective employment. Criminal penalties may be imposed under 18 U.S.C. 208 for violations of the prohibition.

(b) Applying the provision of 18 U.S.C. 208:

(1) A “financial interest” is any interest of monetary value which may be directly and predictably affected by the official action of an employee. There is no minimum amount of value or control that constitutes a financial interest.

Example 1: An employee owns a single share of stock in a widely-held corporation. If the corporation is likely to be affected by a matter in which the employee participates as a Government official, the employee may violate 18 U.S.C. 208.

Example 2: An employee has a paid part-time position with a non-federal organization. If the organization is likely to be affected by a matter in which the employee participates as a Government official, the employee would violate 18 U.S.C. 208.

(2) The prohibition of 18 U.S.C. 208 applies to personal and substantial involvement by an employee in a matter, exercised through decision, approval, disapproval, recommendation, investigation, giving advice, or other significant effort regarding the matter.

Example 1: An employee is a member of a panel that evaluates proposals for contracts and makes recommendations as to their award. If the employee's spouse owns stock in a company which submits a proposal that is reviewed by the panel, the employee would violate 18 U.S.C. 208 even though the panel recommendation may be rejected by the contracting officer.

Example 2: An employee is on a leave of absence from a university. He or she would violate 18 U.S.C. 208 by participating in the drafting of regulations which would have a “direct and predictable effect” upon universities in general and, therefore, upon the employee's university.

(3) An employee must know that the financial interest exists in order to violate 18 U.S.C. 208.

Example: An employee inherited a beneficial interest in a trust. He or she does not, however, have actual knowledge of the specific property held by the trustee. If the trust contains stock in a corporation which may be affected by the employee's official actions, he or she would not violate 18 U.S.C. 208 in taking official action affecting the corporation.

(4) Negotiation for prospective employment includes both an indication of interest on the part of the employee in working for an organization and an affirmative action on the part of the organization to show consideration of the employee.

Example 1: An employee of the Department sends resumes and cover letters to fifty prospective employers, all of whom regularly have dealings with HHS. Forty employers do not respond; however, ten respond with cordial form letters stating that the employee's resume will be retained for future reference. For purposes of the 18 U.S.C. 208 prohibition, the employee is negotiating for prospective employment at the time he or she sends resumes.

Example 2: At a site visit to a grantee institution, an employee who is officially responsible for a grant to that institution informs an officer of the institution that he or she is seeking a new position outside HHS. The grantee subsequently makes a conditional offer of employment to the employee who promptly responds by asking for an opportunity to discuss salary and related matters. Under these circumstances, a negotiation for prospective employment is underway.

(c) An employee may obtain approval to participate in his or her official capacity in a matter in which he or she has a direct or indirect financial interest, if the interest is not so substantial as to affect the integrity of his or her official duties. An employee who believes that such participation is warranted should follow the procedures in § 73.735–804.

(d) An employee convicted of violating 18 U.S.C. 208 may be fined up to

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\$10,000, or imprisoned up to two years, or both.

§ 73.735–802 Executive order prohibitions.

(a) *Basic prohibition of Executive Order 11222.* (1) An employee shall not have a direct or indirect financial interest that conflicts substantially, or appears to conflict substantially, with his or her duties as a Federal employee.

(2) An employee need not have a financial interest that actually conflicts with his or her duties to violate the prohibition of E.O. 11222. Any financial interest that could reasonably be viewed as an interest which might compromise the employee's integrity, whether or not this is in fact true, is subject to this prohibition.

(3) Except as provided in § 73.735–802 (b) and (c), an employee who has an indirect financial interest in a business entity through the ownership of shares in a widely-held mutual fund or other regulated investment company will not violate E.O. 11222. Stocks in business entities held by an intermediary such as a mutual fund are generally too remote or inconsequential to affect the integrity of an employee's services.

(b) *Employees in regulatory activities.* (1) An employee who is working in a regulatory activity shall not have a financial interest in any company whose business activities are subject to the regulations of the particular activity with which the employee is associated, unless the regulated activities of the company are an insignificant part of its total business operations.

(2) An employee working in a regulatory activity may not hold shares in a mutual fund or other regulated investment company which specializes in holdings in industries that are regulated by the particular activity in which he or she is employed.

Example: An employee working for the Bureau of Laboratories, Centers for Disease Control, may not hold shares in a regulated investment company which specializes in holdings that include medical testing laboratories.

(c) *Employees having procurement or contracting responsibilities.* (1) An employee who serves as a procurement or contracting officer shall not have a financial interest in a company or com-

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panies with which he or she in the course of his or her official duties would be likely to have procurement or contracting relationships.

(2) A procurement or contracting officer may not hold shares in a mutual fund or other regulated investment company that specializes in holdings in industries with which such officer would be likely to have procurement or contracting relationships.

Example: A contracting officer in the Social Security Administration owns shares in the XYZ Mutual Fund which specializes in stock in firms manufacturing electronic data processing equipment. Ownership of XYZ Mutual Fund shares would be prohibited in this instance. On the other hand, a contracting officer for a Public Health Service hospital, who is not likely to have responsibility for major contracts relating to electronic data processing, could hold such shares.

§ 73.735–803 Prohibition against involvement in financial transactions based on information obtained through Federal employment.

An employee shall not engage in, directly or indirectly, a financial transaction as a result of, or in primary reliance upon, any information gained through his or her official duties. Information gained through official duties are those facts and other data that relate to the employee's official duties or to the functions of the employing component and would not be available to the employee were he or she not an officer of the Federal government.

Example 1: An employee working part-time for a consulting firm that does no business with the employee's principal operating component, in the area of health care planning advises it, based upon his or her knowledge of a new health care planning program about to be initiated by the Public Health Service. The employee's knowledge of the program was acquired solely through reading policy statements and other PHS literature available to the public under the Freedom of Information Act. In such case, the employee would not violate this regulation if the outside activity was otherwise approvable under Subpart G.

Example 2: A contracting officer with detailed knowledge of a negotiated procurement contract invests in a corporation that is likely to indirectly profit from the award of that contract. The officer's decision to invest is based upon technical details of the successful contract proposal that would not

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otherwise be available to a private citizen. The officer would violate this regulation in such a situation.

§ 73.735–804 Waiver of the prohibitions in this subpart.

(a) An employee may request approval to participate in his or her official capacity in a matter in which he or she has a direct or indirect financial interest if the employee believes the interest is so remote and inconsequential that it would not affect the integrity of his or her official duties. Also an employee who has a financial interest that would otherwise be prohibited under these regulations may request an exemption from the prohibition for the reason stated in the preceding sentence.

(b) The request shall be in writing and shall include the following information:

(1) Employee's name, occupational title, grade or rank and Federal salary;

(2) Full description of financial interest: including whether ownership, service as officer, partner, etc.;

(3) Business or activity in which financial interest exists;

(4) Description of official matter in which employee is requesting approval to participate;

(5) Basis for requesting determination that the interest is "not so substantial as to be deemed likely to affect the integrity of the services which the Government may expect." (If based on a small total value of investment, supply appropriate information on total value, such as total shares held and latest quoted market price. If other basis, explain fully.)

The request should be sent through usual administrative channels to the official responsible for reviewing financial disclosure reports or statements for the employee's organization (Subpart I). That official, after conferring with a deputy ethics counselor or with the Department Ethics Counselor as appropriate, will make a decision about the exemption or exception and inform the employee in writing.

§ 73.735–805 Advice and guidance on conflicts matters.

(a) Whenever an employee has a question about the appropriate course of

conduct to be followed in a matter that may involve an actual or apparent conflict of interest, he or she should immediately consult with his or her supervisor or a deputy ethics counselor, or both. If a supervisor who is consulted determines that the matter warrants further consideration, he or she may, in conjunction with the employee, submit the details of the matter, in writing, to the appropriate deputy ethics counselor. These details should include a description of:

(1) The activity, relationship, or interest giving rise to the question posed by the employee;

(2) The duties or official responsibilities of the employee(s) involved;

(3) The nature of the actual or apparent conflict of interest; and

(4) Any other information that may be helpful in reviewing the problem.

(b) Upon receiving the submission of an employee or a supervisor, the deputy ethics counselor will develop any additional information about the matter as necessary, and will confer with the Department Ethics Counselor as appropriate. The Department Ethics Counselor and the head of the principal operating component or his or her designee will be informed of any serious violation of the standards of this subpart or any other conflict of interest law. Questions of first impression or other unusual matters shall be brought to the attention of the Department Ethics Counselor and the head of the principal operating component or his or her designee.

(c) On the basis of all information gathered including, where appropriate, the advice of the Department Ethics Counselor, the deputy ethics counselor will:

(1) Decide that there is no violation or potential violation of the standards of this subpart or any other law and so notify the employee and his or her supervisor in writing; or

(2) Decide that a violation or potential violation of the standards of this subpart or other law has occurred or may occur, and that the employee involved shall take one or more of the steps set forth in § 731.735–904 to resolve the problem and notify the employee and his or her supervisor in writing; or

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(3) Decide that, although no violation of this subpart or other law has occurred, the nature of the matter is such that the employee should periodically report any additional information that would require reconsideration of the initial submission.

§ 73.735–806 Documentation and publication of opinions.

(a) The Department Ethics Counselor, deputy ethics counselors, and any other individuals required to be involved in the review and resolution of violations or potential violations of this subpart shall maintain full and accurate documentation of the formal advice and guidance given.

(b) From time to time, the Department Ethics Counselor shall publish summaries of advisory opinions issued by his or her office, deleting, as necessary, any personal identifiers or other information which may give rise to an unwarranted invasion of personal privacy. These summaries shall be distributed to all deputy ethics counselors, heads of principal operating components, and principal regional officials.

(c) From time to time, the Department Ethics Counselor shall publish an index of all summaries issued in accordance with paragraph (b) of this section, and shall distribute these indexes to all deputy ethics counselors and heads of principal operating components who shall in turn make them available for review by supervisors and interested employees.

Subpart I—Reporting Financial Interests

§ 73.735–901 Reporting requirement of the Ethics in Government Act of 1978.

(a) *Applicability.* The following employees and special Government employees shall submit public financial disclosure reports in accordance with the provisions of Title II of the Ethics in Government Act of 1978, Pub. L. 95–521, as amended:

(1) Officers and employees (including consultants who will work more than 60 days in a calendar year) whose positions are classified at GS–16 or above of the General Schedule, or whose basic

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rate of pay (excluding “step” increases) under other pay schedules is equal to, or greater than, the rate for GS–16 (step 1);

(2) Members of the uniformed services whose pay grade is 0–7 or above;

(3) Officers and employees in any other positions determined by the Director of the Office of Government Ethics to be of equal classification to GS–16;

(4) Administrative Law Judges;

(5) Employees in the excepted service in positions which are of a confidential or policy-making character, unless their position has been excluded by the Director of the Office of Government Ethics;

(6) Department Ethics Counselor; and

(7) Deputy Ethics Counselors.

An employee who thinks that his or her position has been improperly included under the reporting requirements of this part may obtain a review of that determination by writing to the Department Ethics Counselor.

(b) *Filing Dates.* Employees listed in § 73.735–901 (a) of this subpart shall file a financial disclosure report:

(1) Within 5 days after the transmittal by the President to the Senate of their nomination to a position requiring Senate confirmation, or

(2) Within 30 days after assuming a covered position not requiring Senate confirmation unless the employee has left another covered position listed in § 73.735–901 (a) of this subpart, or

(3) Within 30 days after terminating Federal employment or assuming a position which is not listed in § 73.735–901 (a) of this subpart; and

(4) By May 15 of each calendar year, unless the employee has in that calendar year already submitted a financial disclosure report covering the preceding calendar year.

(c) *Submission of reports.* (1) Executive level officers, non-career executives, deputy ethics counselors and Schedule C employees in the Office of the Secretary who are required to report in accordance with § 73.735–901 (a) of this subpart shall submit their reports to the Department Ethics Counselor.

(2) All other employees required to report in accordance with § 73.735–901 (a) of this subpart shall submit their reports to the reviewing official for

their organizational component under procedures described in the Department's Personnel Manual. Personnel offices will keep a list of reviewing officials and will give each covered employee the name of the official to whom his or her report should be sent.

(d) *Review and certification of reports.*

(1) Each report submitted in accordance with this section shall be reviewed by the appropriate reviewing official within 60 days of its receipt. Upon reviewing a report and finding that the information contained therein reveals no conflict of interest or other violation of any provision of this part or applicable law, the reviewing officer shall certify the report with his or her signature.

(2) The certification of a report filed in accordance with this section shall have the concurrence of the Office of the General Counsel.

(3) Action to be taken by the reviewing official if the individual is not in compliance with applicable laws and regulations is discussed in §§ 73.735-903 and 73.735-904.

§ 73.735-902 Reporting requirements for certain employees not covered by the Ethics in Government Act of 1978.

(a) *Applicability.* The following employees and special Government employees shall submit confidential statements of employment and financial interests in accordance with the provisions of this subpart, provided they are not required to submit financial disclosure reports under § 73.735-901. A list of the positions in this Department whose incumbents are required to file financial interest statements as prescribed by this subpart is available for review in all of the Departments servicing personnel offices.

(1) Officers and employees in positions classified at GS-13 or above (or comparable pay level) who have decision-making responsibility for the following matters:

- (i) Contracting or procurement,
- (ii) Administering or monitoring grants or subsidies,
- (iii) Regulating or auditing private or other non-Federal enterprises, or
- (iv) Other activities where the decision or action would have an economic

impact on the interest of any non-Federal enterprise.

(2) Incumbents of any other positions designated by the head of the principal operating component, or by the Assistant Secretary for Management and Budget for the Office of the Secretary, to report employment and financial interests in order to protect the integrity of the Government and to avoid possible conflicts of interest. The designation of any such positions below the GS-13 grade must be approved by the Office of Personnel Management.

(3) All experts, consultants, or advisory committee members who are not required to submit a public financial disclosure report in accordance with the Ethics in Government Act except:

(i) Doctors, dentists and allied medical specialists performing services for, or consulted as to the diagnosis or treatment of, individual patients; or

(ii) Veterinarians performing services for or consulted as to care and service to animals.

(b) *Filing dates.* (1) Experts, consultants, and advisory committee members shall file a confidential Statement of Employment and Financial Interest no later than the date employment commences and shall file supplemental statements as necessary to keep all information submitted current and accurate.

(2) Other individuals covered by § 73.735-902 (a) of this subpart shall:

(i) File a confidential statement no later than 30 days after assuming a covered position unless the employee, within 30 days before assuming the position, left another covered position in HHS that is included in § 73.735-901(a) or § 73.735-902(a) of this subpart; and

(ii) Report changes in or additions to the information in the statement as of June 30 of each calendar year, or a different date set by employee's component with authorization by the Office of Personnel Management.

(c) *Submission and review of financial statements.* (1) Heads of principal operating components, the Assistant Secretary for Management and Budget, and principal regional officials for employees under their appointing authority shall establish procedures to ensure that financial statements from covered employees are received and updated on

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a timely basis and are referred to the appropriate reviewing officials for review and certification. (See § 73.735–202 (e)(1)).

(2) The reviewing official shall review statements to determine whether conflicts of interest or apparent conflicts might arise from the activities reported thereon. If the review discloses no conflict or apparent conflict, the reviewing official shall certify the statement with his or her signature. Action to take if the individual is not in compliance with applicable laws and regulations is discussed in §§ 73.735–903 and 73.735–904.

§ 73.735–903 Action if conflicts of interest or possible conflicts are noted.

(a) If after reviewing a financial disclosure report or a financial interest statement, a reviewing official believes that additional information is needed, he or she shall tell the individual submitting such report what additional information is required and the time by which it must be submitted.

(b) If the reviewing official is of the opinion that, on the basis of information submitted, the reporting individual is not in compliance with applicable laws and regulations, he or she shall notify the individual, afford him or her a reasonable opportunity for a written or oral response, and after consideration of such response, determine whether or not the individual is in compliance.

(c) If the reviewing official determines that an individual is not in compliance with applicable laws and regulations, he or she shall notify the individual of that determination in writing and, after an opportunity for personal consultation, determine and notify the individual of the action, including those actions set forth in § 73.735–904, that would be appropriate to assure compliance with such laws and regulations, and the date by which such action should be taken. The action required and the date for taking it shall be determined by the nature of the financial interest or other relationship, the particular circumstances of the reporting individual (including his or her ability to resolve the problem), and other factors which the reviewing official deems relevant. In no case, how-

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ever, should the date be later than 90 days after the reporting individual is notified of the reviewing official's opinion.

(d) If steps for assuring compliance with applicable laws and regulations are not taken by the date set in paragraph (c) of this section, the matter shall be referred to the Department Ethics Counselor.

§ 73.735–904 Resolution of apparent or actual conflicts of interest.

(a) Disqualification from participating in a particular matter or category of matters is an appropriate method for resolving apparent or actual conflicts of interest when the interest or activity giving rise to the problem:

(1) Bears a direct or indirect relationship to particular, identifiable duties of the employee involved; and

(2) Is not so substantial as to affect or give the appearance of affecting the integrity of the services which the Government may expect of the employee. Whenever disqualification is employed to resolve an apparent or actual conflict of interest, the disqualified employee shall sign a written statement reflecting the scope of the disqualification and the precise nature of the conflicting interest or activity. The reviewing official shall keep a file of all such disqualification statements and shall monitor compliance with these statements on a regular basis.

(b) *Change of assignment* is an appropriate method for resolving apparent or actual conflicts of interest when the interest giving rise to the problem bears a direct or indirect relationship to particular, identifiable duties of the employee involved, and those duties constitute a significant portion of the employee's position.

(c) *Waiver* under 18 U.S.C. 208(b) is an appropriate method for resolving apparent or actual conflicts of interest when:

(1) The employee seeking the waiver reported the financial interest that bears some relationship to his or her official duties, and the reviewing official, in consultation with a deputy ethics counselor or the Department Ethics Counselor, determines that the financial interest is not so substantial as to

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be deemed likely to affect the integrity of the services which the Government may expect from such employee; or

(2) By general rule or regulation published in the FEDERAL REGISTER, the Department has exempted the financial interest from the requirements of 18 U.S.C. 208 and this part as being too remote or too inconsequential to affect the integrity of the Government officers' service.

(d) A *trust* containing a financial interest which may give rise to an apparent or actual conflict of interest is an appropriate method of resolving such conflicts when:

(1) The trust is qualified under section 202(f) of the Ethics in Government Act of 1978 (Pub. L. 95-521), as amended, and subject to the regulations of the Office of Government Ethics; or

(2) In the opinion of the Department's Ethics Counselor, it is sufficiently independent of the employee involved so that the integrity of the employee's services to the Government are not compromised.

(e) *Divestiture* is an appropriate method for resolving actual conflicts of interest when the nature of the financial interest is such that the conflict of interest cannot be adequately resolved by any of the methods set forth in paragraphs (a), (b), (c), and (d) of this section.

(f) *Terminating* an appointment as a method for resolving an actual conflict of interest should be used only when it is clear that no other remedy can be found which would be acceptable to both the Department and the employee. Generally, this method will be employed only in the most extreme cases. Such a termination would be subject to adverse action.

Subpart J—Provisions Relating to Experts, Consultants and Advisory Committee Members

§ 73.735-1001 Coverage.

(a) For purposes of this subpart the title "consultant" will be used to include those who are appointed to serve as experts, consultants or members of advisory committees. All persons who serve as an employee of the Government in the capacity of a consultant

are covered by the provisions of this subpart irrespective of:

(1) The title by which designated;

(2) The statutory authority under which services are obtained;

(3) The duration of the period for which services are obtained;

(4) Whether services are obtained by appointment or invitation and acceptance;

(5) Whether services are compensated or rendered without compensation;

(6) Whether or not services are obtained pursuant to a statute excepting employees or special Government employees from conflict of interest statutes.

(b) When the service is for less than 130 days in a service year, experts, consultants, and advisory committee members are included in the group of employees designated by law (18 U.S.C. 202) as "Special Government employees."

§ 73.735-1002 Ethical standards of conduct.

(a) Like other Federal employees, an individual serving in a consultant capacity must conduct himself or herself according to ethical behavior standards of the highest order. In particular, such an individual must:

(1) Refrain from any use of office which is, or appears to be, motivated by a private gain for himself or herself or other persons, particularly those with whom he or she has family, business, or financial ties. The fact that desired gain, if it materializes, will not take place at the expense of the Government makes his or her actions no less improper.

(2) Conduct himself or herself in a manner devoid of any suggestion that he or she is exploiting Government employment for private advantage. A consultant must not, on the basis of any inside information, enter into any speculation or recommend speculation to members of his or her family or business associates, in commodities, land, or the securities of any private company. This injunction applies even though the consultant's duties have no connection whatever with the Government programs or activities which may affect the value of such commodities, land, or securities. He or she should be

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careful in all personal financial activities to avoid any appearance of acting on the basis of information obtained in the course of his or her Government work.

(3) Refrain from using information not generally available to those outside the Government for the special benefit of a business or other entity by which the consultant is employed or retained or in which he or she has a financial interest. Information not available to private industry should remain confidential in the consultant's hands and not be divulged to his or her private employer or clients. In cases of doubt whether information is generally available to the public, the consultant should confer with the person for whom he or she provides services, with the office having functional responsibility for a specific type of information, or, as appropriate, with the officials designated in § 73.735–202 to give interpretive and advisory service.

(4) Where requested by a private enterprise to act for it in a consultant or advisory capacity and the request appears motivated by the desire for inside information, make a choice between acceptance of the tendered private employment and continuation of his or her Government consultancy. He or she may not engage in both.

(5) Not use his or her position in any way to coerce, or give the appearance of coercing, anyone to provide a financial benefit to him or her or another person, particularly one with whom the consultant has family, business, or financial ties.

(6) Not receive or solicit anything of value as a gift, gratuity, loan, entertainment, or favor for himself or herself or another person, particularly one with whom he or she has family, business, or financial ties if the acceptance would result in loss of complete independence or impartiality in serving the Government. All consultants are subject to the restrictions in § 73.735–506 of this part concerning gifts and decorations from foreign governments.

(b) Consultants may engage in other employment so long as there is no real or apparent conflict between the consultant's private employment and his or her official duties. See § 73.735 Subpart G. The regular employment of a

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consultant who is a special Government employee is not considered outside work for purposes of Subpart G. Also, the limitation in § 73.735–701(f) regarding the amount of an honorarium that may be received does not apply to special Government employees.

(c) A consultant who has questions about conflicts of interest or the application of the regulations in this part to him or her or to his or her assigned work should make inquiry of the person for whom services are provided. That person may direct the consultant to the Department Ethics Counselor or a deputy ethics counselor for interpretive and advisory services as provided in § 73.735–202.

§ 73.735–1003 Conflicts of interest statutes.

(a) Each consultant should acquaint himself or herself with sections 203, 205, 207 and 208 of title 18, United States Code, all of which carry criminal penalties related to conflicts of interest. The restraints imposed by the four criminal sections are summarized in paragraphs (b) and (c) of this section.

(b) 18 U.S.C. 203 and 205.

(1) These two sections in general operate to preclude a person who works for the Government, except in the discharge of his or her official duties, from representing anyone else before a court or Government agency in a matter in which the United States is a party or has a direct and substantial interest. The prohibition applies whether or not compensation is received for the representation. However, if the individual is a special Government employee, this restriction applies only if:

(i) The representation involves a matter in which the individual has at any time participated personally and substantially in the course of his or her Government employment; or

(ii) The individual has served the Department for more than 60 days in the immediately preceding period of 365 days, and the matter is one which is pending before the Department. This second restraint applies whether or not the matter is one in which the individual participated personally and substantially in his or her Government employment. These two provisions

apply to a special Government employee on days when he or she does not serve the Government as well as on the days when services are rendered, and they apply to both paid and unpaid representation.

(2) To a considerable extent the prohibitions of sections 203 and 205 are aimed at the sale of influence to gain special favors for private businesses and other organizations and at the misuse of governmental position or information. In accordance with these aims, a consultant, even when not compelled to do so by sections 203 and 205, should make every effort in his or her private work to avoid any personal contact with respect to negotiations for contracts or grants with the component of the department in which he or she is serving, if the subject matter is related to the subject matter of his or her consultancy or other service. This will not always be possible to achieve where, for example, a consultant has an executive position with his or her regular employer which requires him or her to participate personally in contract negotiations with the department or agency he or she is advising. Whenever this is the case, the consultant should participate in the negotiations for his or her employer only after advising the responsible Government official of his or her involvement in other matters in the Department. In other instances an occasional consultant may have technical knowledge which is indispensable to his or her regular employer in his efforts to formulate a research and development contract or a research grant, and for the same reason, it is in the interest of the Government that the consultant should take part in negotiations for his or her private employer. Again, the individual should participate only after advising the responsible Government official of the relevant facts.

(3) Section 205 permits both the Government and the private employer of a special Government employee to benefit, in certain cases, from his or her performance of work under a grant or contract for which he or she would otherwise be disqualified because of having participated in the matter for the Government or because it is pending in a component in which the consultant

had served more than 60 days in the past year. This provision gives the head of a department the authority, notwithstanding any prohibition in either section 203 or 205, to allow a special Government employee to represent before such department or agency either his or her regular employer or another person or organization in the performance of work under a grant or contract. As a basis for this action, the Secretary must first make a certification in writing, published in the FEDERAL REGISTER, that it is required by the national interest.

(4) Section 205 contains two other exemptive provisions, which apply to both special and regular Government employees. See § 73.735-702.

(c) 18 U.S.C. 207 applies to individuals who have left Government service. See Subpart N of these regulations.

(d) 18 U.S.C. 208 bears on the activities of Government personnel, including special Government employees, in the course of their official duties. In general, it prevents a Government employee from participating as such in a particular matter in which, to his or her knowledge, he or she, his or her spouse, minor child, partner, or a profit or non-profit enterprise with which he or she is connected has a financial interest. However, the section permits an employee's agency to grant him or her an ad hoc exemption if the interest is not so substantial as to affect the integrity of his or her services. Insignificant interests may also be waived by a general rule or regulation. The matters in which special Government employees are disqualified by section 208 are not limited to those involving a specific party or parties in which the United States is a party or has an interest, as in the case of sections 203, 205 and 207. Section 208 therefore extends to matters in addition to contracts, grants, judicial and quasi-judicial proceedings, and other matters of an adversary nature. Accordingly, a special Government employee, like all government employees, should in general be disqualified from participating as such in a matter of any type the outcome of which will have a direct and predictable effect upon the financial interests covered by the section.

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However, the power of exemption may be exercised in this situation if the special Government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization. The power of exemption may also be exercised where the financial interests involved are minimal in value.

§ 73.735–1004 Requesting waivers or exemptions.

(a) A consultant may present in writing to the official for whom he or she provides services requests for the waivers or exemptions specified in § 73.735–1003. That official will take, or refer the request for, action as appropriate, and will see that the employee receives advice or decision on his or her request.

(b) A file of all waivers or exemptions granted shall be maintained in such manner that information can be given promptly on individual cases or statistics provided upon request. Generally, these records, together with written advice given in connection with less formal requests concerning questions of ethical standards, are kept with the employee's statement of employment and financial interests or financial disclosure report (§ 73.735–1006).

(c)(1) *Waiver for reviewers from certain multi-campus institutions.* Applicability of the prohibitions of 18 U.S.C. 208(a) and this subpart are hereby waived pursuant to a determination that the interest involved is too remote or too inconsequential to affect the integrity of a special Government employee's review of a funding application or contract proposal from one campus of one of the following multi-campus institutions, where the interest consists solely of employment as a faculty member (including Department Chairman) at a separate campus of the same multi-campus institution:

The University of Alabama system consisting of the University of Alabama, the University of Alabama in Birmingham, and the University of Alabama in Huntsville.

The campuses of the University of California.

The system consisting of Colorado State University, the University of Southern Colorado, and Fort Lewis College.

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The Indiana University system consisting of eight universities on nine campuses, with the exception of the system-wide schools: the School of Business; the School of Dentistry; the School of Medicine; the School of Nursing; and the School of Public and Environmental Affairs.

The University of Nebraska system consisting of the University of Nebraska—Lincoln, the University of Nebraska at Omaha, and the University of Nebraska Medical Center.

The campuses of the State University of New York.

The Oregon system of higher education consisting of the University of Oregon, Oregon State University, Oregon Health Sciences University, Portland State University, Western Oregon State College, Southern Oregon State College, Eastern Oregon State College, and the Oregon Institute of Technology.

The campuses of the University of Tennessee.

The separate universities comprising the University of Texas System.

The separate universities comprising the University of Wisconsin System.

(2) *Institutions that are not subject to 18 U.S.C. 208(a) and the subpart, because they are not part of the same organization within the State.* The following State institutions and systems of higher education have been determined to be separate from each other to such a degree that no waiver is necessary in order to permit a faculty member (including Department Chairman) employed by one of the State institutions of higher education to review a funding application or contract proposal from another of the named institutions within that State:

The University of Alabama System and other Alabama State owned institutions of higher education.

The California Community Colleges, the California State Universities and Colleges, and the University of California.

The University of Colorado, Colorado State University, and other Colorado State owned institutions of higher education.

The University of Connecticut, Connecticut State University, the Connecticut Technical Colleges, and the Connecticut Community Colleges.

The University of Illinois, Illinois State University, Western Illinois University, Southern Illinois University, and the Illinois Community Colleges.

The Indiana University and the other Indiana State owned institutions of higher education.

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The University of Iowa, and Iowa State University.

The University of Kansas, Kansas State University, Wichita State University, Fort Hays State University, Pittsburg State University, and the Kansas Technological Institute.

Louisiana State University, and other Louisiana State owned institutions of higher education.

The University of Massachusetts, and other Massachusetts State owned institutions of higher education.

The University of Michigan, Michigan State University, and Wayne State University.

The University of Minnesota, the Minnesota State University System, and the Minnesota Community College System.

The University of Missouri, and other Missouri State owned institutions of higher education.

The University of Nebraska, and other Nebraska State owned institutions of higher education.

The State University of New York System, and the City University of New York System.

The University of North Carolina, North Carolina State, and other North Carolina State owned institutions of higher education.

Pennsylvania State University, the University of Pittsburgh, Temple University, Lincoln University, and the other State owned colleges and universities in Pennsylvania.

The University of Texas System, the Texas A&M System, the Texas State University System, the University System of South Texas, the Lamar University System, the University of Houston System, East Texas State University, Stephen F. Austin State University, West Texas State University, Midwestern University, North Texas State University, Texas Southern University, Texas Woman's University, Texas Tech University and Pan American University.

The University of Utah and Utah State University.

[46 FR 7369, Jan. 23, 1981, as amended at 51 FR 15627, Apr. 25, 1986]

§ 73.735-1005 Salary from two sources.

Special Government employees are not subject to 18 U.S.C. 209 which prohibits other employees from receiving any salary, or supplementation of Government salary, from a private source as a compensation for services to the Government. This Department will not knowingly pay per diem to a consultant who also receives per diem pay for the same day from another Government agency (in or outside the Depart-

ment). Erroneous payments in contravention of this provision will be subject to collection, and any consultant who willfully collects double payments may be barred from further employment.

§ 73.735-1006 Reporting financial interests.

(a) Consultants who will work more than 60 days in a calendar year are subject to the provisions of title II of the Ethics in Government Act of 1978 when their rate of pay is equal to or greater than the basic rate for GS-16, Step 1. Such consultants are covered by the reporting requirements of § 73.735-901 of these regulations.

(b) Consultants not subject to the Ethics in Government Act shall file statements of financial interests as provided by § 73.735-902 of these regulations.

§ 73.735-1007 Political activity.

Consultants who serve intermittently are subject to the political activity restrictions of Subchapter III of Chapter 73 of Title 5 U.S.C. and Civil Service Rule IV only on days on which service is rendered and then for the entire 24 hours of such service day. Other consultants are subject to these restrictions at all times.

Subpart K—Special Government Employees Other Than Consultants

§ 73.735-1101 General provision.

Individuals who are designated as special Government employees because of the nature of their services but who are not serving as a consultant, expert, or advisory committee member are subject to the provisions of Subparts B through I of these regulations. However, the provisions of 18 U.S.C. 205, 206, 207, and 208 apply to them only as described in Subpart J. Also, the limitation in § 73.735-701(f) on the amount of an honorarium that may be received does not apply.

Subpart L—Disciplinary Action

§ 73.735–1201 General provisions.

(a) Violations of the regulations contained in the part may be cause for disciplinary action which could be in addition to any penalty prescribed by law. (For a list of some offenses for which disciplinary action may be taken and “The Code of Ethics for Government Service,” the violation of which may also result in disciplinary action, see appendixes A and B of this part).

(b) The type of disciplinary action to be taken must be determined in relation to the specific violation. Those responsible for recommending and for taking disciplinary action must apply judgment to each case, taking into account the general objectives of meeting any requirements of law, deterring similar offenses by the employee and other employees, and maintaining high standards of employee conduct and public confidence. Some types of disciplinary action which may be considered are:

- (1) Admonishment
- (2) Written reprimand
- (3) Reassignment
- (4) Suspension
- (5) Demotion
- (6) Removal

(c) Suspension, demotion, and removal are adverse actions; and when such actions are taken, applicable laws, regulations, and policies must be followed.

[46 FR 7369, Jan. 23, 1981, as amended at 53 FR 4409, Feb. 16, 1988]

Subpart M—Reporting Violations

§ 73.735–1301 Responsibility for reporting possible criminal violations.

An employee who has information which he or she reasonably believes indicates a possible offense against the United States by an employee of the Department, or any other individual working on behalf of the Department, shall immediately report such information to his or her supervisor, any management official, or directly to the Office of the Inspector General. Offenses covered by the preceding sentence include, but are not limited to, bribery, fraud, perjury, conflict of interest, mis-

use of funds, equipment, or facilities, and other conduct by a government officer or employee, grantee, contractor or other person which is prohibited by title 18 of the United States Code. Employees and supervisors should refer to chapter 5–10 of the Department’s General Administration Manual for procedures regarding the reporting and handling of such information.

§ 73.735–1302 Responsibility for reporting allegations of misconduct.

An employee who has information which he or she reasonably believes indicates the existence of an activity constituting (a) a possible violation of a rule or regulation of the Department; or (b) mismanagement, a gross waste of funds, or abuse of authority; or (c) a substantial and specific danger to the public health and safety, shall immediately report such information to his or her supervisor, any management official of the Department, or directly to the Office of the Inspector General. Employees and supervisors should refer to chapter 5–10 of the Department’s General Administration Manual for procedures regarding the reporting and handling of such information. This subsection does not cover employee grievances, equal employment opportunity complaints, classification appeals, or other matters for which a formal government-wide review system has been established by the Federal government.

§ 73.735–1303 Prohibition of reprisals.

(a) Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority, take or threaten to take any action against any employee as a reprisal for making a complaint or providing any information pursuant to §§ 73.735–1301 and 73.735–1302. If the complaint was made or the information was disclosed with the knowledge that it was false, or with willful disregard of its truth or falsity, any personnel action taken against the employee based on those reasons would not constitute a reprisal action.

(b) An employee who believes that he or she has been threatened with a personnel action, any other action, or harassment or has been harmed by any action as a reprisal for having made a complaint or providing information pursuant to § 73.735-1301 or § 73.735-1302 may request the Office of the Inspector General to review his or her allegations. Whenever the Inspector General has reason to believe that the allegations may be true, he or she will refer the matter to the Assistant Secretary for Personnel Administration for appropriate action. The Assistant Secretary for Personnel Administration may order a stay of any personnel action if he or she determines that there are reasonable grounds to believe that the personnel action is being taken as a reprisal for making a complaint or providing information pursuant to § 73.735-1301 or § 73.735-1302.

§ 73.735-1304 Referral of matters arising under the standards of this part.

(a) The Department Ethics Counselor may refer to the Inspector General for investigation and/or further action any matter arising under the standards of this part.

(b) The Department Ethics Counselor may refer to the Office of Government Ethics, or the Inspector General may refer to the Department of Justice, suspected violations of the criminal laws regarding employee standards of conduct and conflicts of interest.

Subpart N—Conduct and Responsibilities of Former Employees

§ 73.735-1401 Prohibitions against post-employment conflicts of interest.

(a) The purpose of criminal prohibition in 18 U.S.C. 207 is to prevent the unfair use of inside knowledge or influence that results from Federal service. 18 U.S.C. 207 generally prohibits a former employee from acting as another person's representative to the Government in particular matters involving a specific party or parties in which the employee had been involved while in Federal service. This prohibition does not require a former employee to decline employment with any

organization regardless of his or her dealings with that organization while employed by the Government. It applies solely to activities, not the mere existence of an employment arrangement.

(b) The Office of Government Ethics, Office of Personnel Management, has issued Government-wide regulations covering post-employment conflict of interest (5 CFR part 737). Those regulations are incorporated herein by reference, and they are available for review in personnel offices throughout the Department.

APPENDIX A TO PART 73—LIST OF SOME OFFENSES FOR WHICH DISCIPLINARY ACTION MAY BE TAKEN

Following is a list of some offenses for which disciplinary action may be taken under this Part. When a statute applies specifically to a particular offense, either wholly or in part, the statute is cited. Neither the list of offenses nor the statutory citations are all-inclusive. The "Code of Ethics for Government Service" is not cited because of its general applicability but is published in its entirety in appendix B.

A. Concerning Efficiency of Operations in General. 1. Engaging in wasteful actions or behavior in the performance of assigned duties; conducting non-Government business during official work hours; or participating in a strike (18 U.S.C. 1918), work stoppage, slowdown, sickout, or other similar action.

2. Absence without leave, failure to adhere to the rules and regulations for requesting and obtaining leave, or improper use of sick leave.

3. Deliberate insubordination or refusal to carry out lawful orders or assignments given.

4. Disruptive behavior, such as:

a. Inflicting or threatening or attempting to inflict bodily injury on another (except for necessary defense of self or others) while on the job or on Federal premises.

b. Discourtesy, disreputable conduct, or use of insulting, abusive or obscene language to or about other individuals while on the job.

5. Sexual harassment of employees or members of the public.

6. Failure to observe precautions for safety, such as failure to use safety equipment when it is provided or ignoring signs, posted rules or regulations, or written or verbal safety instructions.

7. Unauthorized use, possession, or distribution of alcoholic beverages (5 U.S.C.

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7352) or controlled substances (e.g., hallucinogens, such as LSD; stimulants, such as cocaine and amphetamines; sedatives, such as barbiturates; narcotics and other drugs or substances, such as hashish and other cannabis substances).

8. Unauthorized gambling; or canvassing, soliciting, or peddling on Government premises.

9. Failure to carry or show proper identification or credentials as required by competent authority; misuse of identification cards or investigative or identification credentials or badges.

10. Failure to disclose (i.e., report) information, when such disclosure is not specifically prohibited by law or Executive Order, that involves (a) violation of law, rule, or regulation, (b) mismanagement or gross waste of funds or abuse of authority, or (c) posing a substantial and specific danger to public health or safety; failure to cooperate in an official Department inquiry.

11. Failure to pay just debts, including taxes to and loans from governmental sources.

12. Deceit or interference in a Civil Service examination (18 U.S.C. 1917) or in connection with a Government personnel action.

13. Fraud or false statements in a Government matter. (18 U.S.C. 1001 through 1003.)

14. Supervisory failure to initiate disciplinary or corrective action when the facts are known and disciplinary or corrective action is warranted.

15. Employment of a member of an organization that advocates the overthrow of our constitutional form of government. (5 U.S.C. 7311; 50 U.S.C. 784.)

B. Concerning Government Funds, Property, Documents, and Records. 1. Actual or attempted embezzlement or theft of Government or personal money or property either directly or through use of Government documents, automated equipment, or other means; actual or attempted embezzlement or theft of the money or property of another person in the possession of an employee by reason of his or her employment. (18 U.S.C. 641 and 654.)

2. Failure to account for public money. (18 U.S.C. 643.)

3. Deliberate falsifying of official time and attendance records; improper use of official travel or forging, counterfeiting, or otherwise falsifying official Government travel records or documents. (18 U.S.C. 508.)

4. False record entries or false reports of money or securities. (18 U.S.C. 2073.)

5. Loss or misuse of or damage to Government property or endangering persons or Government property through carelessness or by willful malicious conduct.

6. Mutilating, destroying, or concealing public records. (18 U.S.C. 2071.)

7. Misuse of penalty (postal) privilege. (18 U.S.C. 1719.)

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8. Failure to safeguard administratively confidential, financial, and trade secrets information.

9. Unauthorized use of documents presented or used to procure the payment of money from or by the Government. (18 U.S.C. 285.)

10. Unauthorized use of a Government vehicle; serious or repeated violations of traffic regulations while driving a Government vehicle or a vehicle rented or leased for official Government purposes; reckless driving or improper operation of any Government owned, rented, or leased motor vehicle. (31 U.S.C. 1349[b].)

11. Violations of the Privacy Act, including:

a. Willful prohibited disclosure of individually identifiable information in violation of 5 U.S.C. 552a.

b. Willfully maintaining a system of records without meeting the notice requirements of the Privacy Act as required by 5 U.S.C. 552a.

12. Violation of regulations concerning the release of classified information, confidential, or security and investigative information. (18 U.S.C. 798 and 1905; 21 U.S.C. 331j; and 50 U.S.C. 783.)

C. Concerning Conflicts of Interest and Related Unethical Conduct: 1. Violations of 18 U.S.C. Chapter 11: Bribery, Graft, and Conflicts of Interest, including:

a. Having a direct or indirect financial interest (includes employee ownership of stocks, bonds, or partnership interests in an entity or employment of the employee, his or her spouse, or dependent child) that conflicts with one's Government duties because such entity is either regulated by, has or seeks to do business with the agency, or has any other particular matter with or pending before the agency that may give rise to either an actual conflict or the appearance thereof. (18 U.S.C. 208.)

b. Bribery of a public official; soliciting or accepting directly or indirectly anything of monetary value, including gifts, gratuities, favors, entertainment, or loans either as compensation for governmental services or from individuals who are seeking contractual or other business or financial relations with the Department, are conducting operations or activities that are regulated by the Department, or have interests that may be substantially affected by the performance or nonperformance of the employee's official duties; receiving salary or any contribution to or supplementation of salary from a private source as compensation for services for the Government. (18 U.S.C. 201 and 209.)

c. Acting as the agent of a foreign principal registered under the Foreign Agents Registration Act. (18 U.S.C. 219.)

2. Engaging, directly or indirectly, in a financial transaction as a result of or primarily relying on information that is obtained through one's official duties and would not be available were the employee not an employee of the Federal Government.

3. Soliciting a contribution from another employee for a gift to an official superior, making a donation as a gift to an official superior, or accepting a gift from an employee receiving less pay than oneself. (5 U.S.C. 7351.)

4. Engaging, without required permission, in outside activities that result in or create the appearance of a conflict of interest.

5. Teaching, lecturing, or writing that depends on specific information obtained as a result of one's Government employment when that information is not otherwise available to the public.

6. Failure to obtain required clearance of an official speech or article.

7. Lobbying with appropriated funds. (18 U.S.C. 1913.)

8. Representation before a Federal agency (other than in the proper discharge of one's official duties) as an agent or attorney in a claim against the United States (or receiving any gratuity or share in any such claim in consideration for assistance given) or as an agent or attorney for anyone before any department, agency, court, or otherwise in connection with any proceeding, application, request for a ruling, or claim on any other particular matter in which the United States is a party or has a direct and substantial interest. (18 U.S.C. 205.) (Note: This section notwithstanding, an employee may, if not inconsistent with the performance of his or her official duties, act without compensation as an agent or attorney for another person who is the subject of any disciplinary or other administrative proceeding or as an agent or attorney for one's parent, spouse, child, or any person or estate for whom or which he or she serves as personal fiduciary except in those matters in which the employee has participated personally and substantially.)

D. *Concerning Prohibited Political and Election Activities.* 1. Activities prohibited by 5 U.S.C. Chapter 73, Subchapter III, including:

a. Section 7323, "Political contributions; prohibition."

b. Section 7324, "Influencing elections; taking part in political campaigns; prohibitions; exceptions."

2. Activities prohibited by 18 U.S.C. Chapter 29, including:

a. Section 594, "Intimidation of voters."

b. Section 597, "Expenditures to influence voting."

c. Section 598, "Coercion by means of relief appropriations."

d. Section 600, "Promise of employment or other benefit for political activity."

e. Section 601, "Deprivation of employment or other benefit for political contribution."

f. Section 602, "Solicitation of political contributions."

g. Section 604, "Solicitation from persons on relief."

h. Section 606, "Intimidation to secure political contributions."

E. *Concerning Prohibited Personnel Practices.*

1. Commission of a prohibited personnel practice (as defined in 5 U.S.C. 2302[b] [1-11]); that is, any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority, commit any of the following practices:

a. Discriminate for or against any employee or applicant for employment on the basis of race, color, religion, sex, national origin, age, handicapping condition, marital status, or political affiliation.

b. Solicit or consider any recommendation or statement, oral or written, with respect to any individual who requests or is under consideration for any personnel action unless such recommendation or statement is based on the personal knowledge or records of the person furnishing it and consists of (1) an evaluation of the work performance ability, aptitude, or general qualifications of such individual or (2) an evaluation of the character, loyalty, or suitability of such individual.

c. Coerce the political activity of any person (including the providing of any political contribution or service) or take any action against any employee or applicant for employment as a reprisal for the refusal of any person to engage in such political activity.

d. Deceive or willfully obstruct any person with respect to such person's right to compete for employment.

e. Influence any person to withdraw from competition for any position for the purpose of improving or injuring the prospects of any other person for employment.

f. Grant any preference or advantage not authorized by law, rule, or regulation to any employee or applicant for employment (including defining the scope or manner of competition or the requirements for any position) for the purpose of improving or injuring the prospects of any particular person for employment.

g. Appoint, employ, promote, advance, or advocate for appointment, employment, promotion, or advancement, in or to a civilian position any individual who is a relative (as defined in 5 U.S.C. 3110) when the civilian position is in the Department or under his or her jurisdiction or control.

h. Take or fail to take a personnel action with respect to any employee or applicant for employment as a reprisal for the lawful disclosure of information.

i. Take or fail to take any personnel action against an employee or applicant for employment as a reprisal for the exercise of any

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appeal right granted by any law, rule, or regulation (including HHS Instructions and issuances).

j. Discriminate for or against any employee or applicant for employment on the basis of conduct that does not adversely affect the performance of the employee or applicant or the performance of others (except criminal conviction in determining suitability or fitness).

k. Take or fail to take any personnel action when the taking of or failure to take such action violates any law, rule, or regulation implementing, or directly concerning the merit system principles (as set forth in 5 U.S.C. 2301).

[53 FR 4410, Feb. 16, 1988]

APPENDIX B TO PART 73—CODE OF ETHICS FOR GOVERNMENT SERVICE

Any person in Government service should:

I. Put loyalty to the highest moral principles and to country above loyalty to persons, party, or Government department.

II. Uphold the Constitution, laws, and regulations of the United States and all governments therein and never be a party to their evasion.

III. Give a full day's labor for a full day's pay, giving earnest effort and best thought to the performance of duties.

IV. Seek to find and employ more efficient and economical ways of getting tasks accomplished.

V. Never discriminate unfairly by the dispensing of special favors or privileges to anyone, whether for remuneration or not; and never accept, for himself or herself or family members, favors or benefits under circumstances which might be construed by reasonable persons as influencing the performance of governmental duties.

VI. Make no private promises of any kind binding upon the duties of office, since a Government employee has no private word which can be binding on public duty.

VII. Engage in no business with the Government, either directly or indirectly, which is inconsistent with the conscientious performance of governmental duties.

VIII. Never use any information gained confidentially in the performance of governmental duties as a means of making private profit.

IX. Expose corruption wherever discovered.

X. Uphold these principles, ever conscious that public office is a public trust.

[53 FR 4410, Feb. 16, 1988]

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PART 73a—STANDARDS OF CONDUCT: FOOD AND DRUG ADMINISTRATION SUPPLEMENT

Subpart A—General Provisions

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73a.735–502 Employees in regulatory activities.

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Subpart J—Statements of Employment and Financial Interests

73a.735–1004 Submission and review of statements.

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SOURCE: 43 FR 7619, Feb. 24, 1978, unless otherwise noted.

EFFECTIVE DATE NOTE: At 90 FR 40985, Aug. 22, 2025, part 73a was removed, effective Oct. 21, 2025.

Subpart A—General Provisions

§ 73a.735–101 Principles and purpose.

(a) To assure that the business of the Food and Drug Administration (FDA) is conducted effectively, objectively, and without improper influence or appearance thereof, all employees must be persons of integrity and observe the highest standards of conduct. Because of FDA's special regulatory responsibilities to the consumer and industry, its employees must be especially alert to avoid any real or appearance of conflict of their private interests with their public duties. Their actions must be unquestionable and free from suspicion of partiality, favoritism, or any

hint of conflicting interests. This supplement recognizes FDA's public obligation to set reasonable and fair safeguards for the prevention of employee conflicts of interest. It is necessary to meet FDA's regulatory responsibilities and to otherwise assure full protection of the public confidence in the integrity of its employees.

(b) Since FDA is a unique consumer protection and regulatory agency within the Department, the DHHS Standards of Conduct need further supplementation to reflect this role. Therefore, for purposes of implementing the DHHS Standards of Conduct regulations within the FDA, this supplement provides interpretive definitions and additional requirements. As further guidance to its employees and supervisory officials, FDA will issue internal procedural instructions in accordance with this supplement.

§ 73a.735–103 Responsibilities.

(a) A "control activity" employee shall be personally responsible for assuring that he does not hold an interest in any organization whose FDA-regulated activities constitute more than an insignificant part of its business as defined in § 73a.735–502(b)(2). The Associate Commissioner for Administration (or his designee) is available to assist such employees in obtaining corporate data necessary to make such a determination.

(b) Other employees are similarly responsible for observing the financial interest retention requirements in §§ 73a.735–501(b) and 73a.735–502(a)(2).

§ 73a.735–104 Advice and guidance.

(a) The Associate Commissioner for Administration (or his designee) shall provide day-to-day guidance and assistance to employees and supervisors on matters covered by regulations in part 73 and this part of this chapter.

(b) The FDA Conflict of Interest Review Board shall review and make recommendations to the Commissioner on requests for exceptions to conflict of interest policies and procedures in regulations in this part and part 73 of this chapter.

Subpart B—Miscellaneous Provisions

§ 73a.735–201 Control activity employees formerly associated with organizations subject to FDA regulation.

(a) For a period of 1 year after FDA appointment, or appointment to the Food and Drug Division, Office of the General Counsel, a control activity employee who was employed in a regulated organization within 1 year before FDA employment shall not participate in any regulatory action before FDA that involves the former employer organization. Exceptions may be authorized only under paragraph (e) of this section.

(b) A control activity employee who was previously employed in a regulated organization shall not participate in any regulatory action before FDA in which the employee had participated personally and substantially in behalf of the former employer organization, e.g., drug investigations/applications, food additive petitions, matters dealing with compliance in areas of radiation-producing products or medical devices. Exceptions may be authorized only under paragraph (e) of this section.

(c) Employment in a regulated organization includes contractual relationships, e.g., attorneys who may have represented an FDA-regulated firm or industry or an association of such firms and individuals who may have served a firm, industry or association in a consultant capacity.

(d) Within 30 days after assignment to a control activity position, an employee shall submit to his supervisor detailed information concerning former industry employers, and dates and substance of involvement in such regulatory matters as may be subject to the prohibition in paragraph (b) of this action.

(e) The Commissioner may grant individual exceptions to paragraphs (a) and (b) of this section whenever he determines that strict application would not be in the best interests of the United States. A memorandum of any exception granted shall be filed for public inspection in the Public Records and Documents Center, Food and Drug

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Administration, Room 4-68, 5600 Fishers Lane, Rockville, Md. 20857, within 10 days after the Commissioner's decision. The memorandum shall include the employee's name, title, grade, summary of official duties, prior pertinent industry involvement, a brief description of the specific regulatory action in which the employee has been permitted to participate, and a statement explaining why such strict application of the subpart would not be in the best interests of the United States.

Subpart C [Reserved]

Subpart D—Outside Employment

§ 73a.735–401 General provisions.

(a) Employees of the Food and Drug Administration shall obtain advance approval for all outside employment, whether paid or unpaid. Employment, as used in this section, does not include:

(1) Memberships in charitable, religious, social, fraternal, recreational, public service, civic, or similar non-business organizations.

(2) Memberships in professional organizations. (Officeholding, however, requires advance approval.)

(3) Performance of duties in the Armed Forces Reserve or National Guard.

(b) Control activity employees (defined in § 73a.735–502) will not generally be granted approval to:

(1) Manage or direct an organization whose activities are subject to FDA regulation, or

(2) Be employed in an organization whose business activities are subject to FDA regulation unless:

(i) The regulated activities of the organization are an insignificant part of its total operations, i.e., the regulated products of the organization constitute no more than 10 percent of its annual gross sales, and

(ii) The outside employment is in nonregulated activities of the organization.

(c) All other employees will generally be granted approval to engage in outside employment which is compatible with the full performance of their FDA duties and responsibilities and which will not give rise to a real or apparent

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conflict of interest. Permissible employment includes but is not limited to:

(1) Employment where the sale of FDA-regulated products is incidental to the purpose of the establishment, e.g., hotels, theaters, bowling alleys, and sports arenas.

(2) Sales and clerical occupations relating to regulated products, e.g., supermarkets, drugstores, department stores, liquor stores.

(3) Trade, industrial, and service occupations relating to regulated products, e.g., gasoline service station attendant, line production or assembly work, cook, waiter, waitress, hospital attendant, snack bar vendor, warehouseman.

(d) All employees will generally be granted approval to engage in paid or unpaid outside employment which contributes to their technical or professional development, e.g.,

(1) Medical, dental, and veterinary practices.

(2) Pharmacy practice after meeting the following conditions which will serve to protect against possible conflicts or apparent conflicts of interest and to avoid other problems resulting in embarrassment to the employee or FDA:

(i) The primary purpose of the part-time employment is to contribute to the overall professional development of the employee and generally enhance his capability to better perform his current FDA duties.

(ii) The part-time duties will be confined generally to dispensing Rx drugs and related professional pharmacy duties.

(iii) The employee will avoid unrelated nonprofessional duties such as supervision or management of store operations, contractual or purchasing responsibilities (except normal “out-of-stock” requisitioning) and repacking and relabeling of bulk items.

(iv) The employee will demonstrate a high degree of discretion and judgment in his contacts with customers and representatives of regulated industry and competitor firms so as to avoid giving the impression that:

(a) His part-time actions, recommendations, opinions, or remarks are official points of view;

(b) He is using his FDA position for private gain by oral misrepresentations and false claims of the company's products;

(c) He is making a Government decision outside official channels, e.g., to customers, prescribing physicians, buyers, distributors;

(d) He or other FDA representatives will give preferential treatment to any regulated organization or representatives of such organizations, or that FDA employees have not exercised complete independence or impartiality in carrying out their regulatory and consumer protection responsibilities; or

(e) His part-time work is creating an adverse effect on the image of FDA or discrediting the integrity of official FDA regulatory decisions.

Subpart E—Financial Interests

§ 73a.735–501 General provisions.

(a) No restrictions are placed on ownership of diversified mutual funds.

(b) An FDA employee, other than a control activity employee (defined in § 73a.735–502), may have financial interests:

(1) In an organization whose FDA-regulated activities are an insignificant part of its total operations, i.e., no more than 10 percent of the organization's annual gross sales are in products regulated by FDA; or

(2) In an organization whose FDA-regulated business activities are a significant part of its total business operations: *Provided, That:*

(i) The holding is less than \$5,000 (value or cost at time of initial reporting),

(ii) The holding represents less than 1 percent of the total outstanding stock shares of that organization, and

(iii) No more than 50 percent of the employee's total investment value is concentrated in organizations whose FDA-regulated business activities are a significant part of their business operations.

(c) Notwithstanding the provisions of this part permitting employees to hold financial interests in organizations subject to FDA regulation, an employee holding such an interest shall not participate in an official matter

whose outcome would have a direct and predictable effect on his financial interest. However, this prohibition is not applicable to:

(1) Diversified mutual funds, which are exempted from 18 U.S.C. 208 by § 73.735–501(a) of this chapter.

(2) Financial interests for which the Commissioner has in advance granted a written exception on the ground that the public interest would be served if a particular employee is allowed to participate in an official matter whose outcome may have a direct and predictable effect on the employee's financial interest. Such exemptions will be granted only in exceptional circumstances. Any determination to authorize such exceptions shall be made in accordance with 18 U.S.C. 208(b)(1) and documented for public inspection in accordance with § 73a.735–504.

§ 73a.735–502 Employees in regulatory activities.

(a) An employee in regulatory activities ("control activity" employee) may hold financial interests in an FDA-regulated organization only if either of the following conditions are met:

(1) The regulated activities of the organization are an "insignificant" part of its total business operations, or

(2) Written approval for an individual exception is granted by the Commissioner in accordance with § 73a.735–504; however, such approval will not be considered unless all of the following conditions are met:

(i) Retention of the financial interest does not give rise to an actual conflict of interest;

(ii) Acquisition of the financial interest occurred by marriage or inheritance, or the interest was held prior to an FDA reorganization, change in regulations, or similar circumstances beyond the control of the employee that resulted in the interest becoming prohibited;

(iii) No direct relationship exists between the employee's official duties and the regulated activities of the organization in which the financial interest is held;

(iv) The employee occupies a position below that of Bureau/Deputy Bureau Director (or Assistant/Deputy General

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Counsel, Food and Drug Division, Office of the General Counsel); and

(v) The employee agrees to refrain from engaging, either directly or indirectly, in transactions that are designed to increase the value of his “expected” financial interest.

(b) To administer provisions within this part, the following interpretations apply:

(1) A “control activity” employee (“control activity” positions are identified in appendix C to part 73 of this chapter), means one who:

(i) Occupies an FDA position classified at GS-11 or above, or PHS Commissioned Officer 0-3 or above, or equivalent;

(ii) Occupies an FDA position below GS-11 with duties of a nature that the employee could in the discharge of his official duties and responsibilities cause an economic advantage for or impose a handicap on a non-Federal enterprise (includes investigators, inspectors, regulatory analysts);

(iii) Occupies a position at GS-11 or above in the Office of the Assistant General Counsel, Food and Drug Division.

(2) “Insignificant” (part of an organization’s total business operations) means that the FDA-regulated products constitute no more than 10 percent of the organization’s annual gross sales.

§ 73a.735-504 Exceptions.

(a) A control activity employee who can satisfy all of the conditions specified in § 73a.735-502(a)(2) may submit a request to retain a prohibited financial interest. Any such request must be submitted no later than 30 days after the event that results in the employee holding the prohibited financial interest. Such requests for exception should be forwarded in writing through supervisory channels to the Associate Commissioner for Administration for review by the FDA Conflict of Interest Review Board and subsequent recommendation to the Commissioner. All decisions on requests for exceptions shall be in writing and a copy furnished to the employee involved.

(b) A memorandum of each approved exception shall be filed in the Public Records and Documents Center for pub-

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lic inspection. Such public disclosure shall be made within 10 days after the Commissioner’s decision. The following is an example of the format of such memorandum (in a hypothetical employee situation):

(1) Employee: Joe Doe.

(2) Title: Research Chemist.

(3) Grade/Salary: GS-14.

(4) Organization: Bureau of Biologics, Food and Drug Administration, Bethesda, Md.

(5) Date of employee’s request for exception: _____.

(6) Date of Commissioner’s approval: _____.

(7) Basis for exception: Employee owns financial interest in the ABC Foods Corporation, and permanent retention is normally prohibited under FDA/HHS conflict of interest regulations for such an employee. The employee, however, acquired this financial interest prior to his reassignment to FDA on _____, which was part of a major Department reorganization transferring certain functions from NIH to the FDA (i.e., FDA’s Bureau of Biologics). At the time of acquisition and immediately prior to the reorganization, the employee’s financial interest was allowable under Department regulations. The employee’s official duties are fully confined to the matters under the jurisdiction of the Bureau of Biologics, and his official duties do not involve any contact with the food industry. The Commissioner has determined that an exception is warranted under the following criteria:

(i) Acquisition occurred prior to Department reorganization;

(ii) Financial interest retention will not give rise to an actual conflict of interest situation;

(iii) There is no direct relationship between the employee’s official duties and the regulated activities of ABC Foods;

(iv) The employee occupies a position below that of Bureau or Deputy Bureau Director (or equivalent position in the Office of the Commissioner); and

(v) The employee agrees to refrain from engaging in any direct or indirect transactions that are designed to increase the value/shares of the “expected” ABC Foods interests.

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This exception is considered equitable to the employee involved, and retention of the ABC Foods interest will not in any way impair the interests of the Government or of the public.

(c) In interpreting the requirement of § 73a.735–502(a)(2)(v), events not involving employee discretion (e.g., accepting dividends in the form of cash or additional shares) do not constitute transactions designed to increase the value/shares of an “excepted” financial interest. A transaction involving discretion, e.g., exercise of stock options, may be made only if proposed to the Associate Commissioner for Administration and approved by the Conflict of Interest Review Board as an amendment to the original exception. A memorandum recording such approval shall be made public in accordance with paragraph (b) of this section.

(d) An employee may temporarily retain a prohibited financial interest pending review of a written request for an exception submitted in accordance with this section.

(e) Except as provided in § 73a.735–501(c), no employee may participate in an official matter whose outcome will have a direct and predictable effect on a financial interest held by him. This prohibition applies to official matters handled before and after approval of an exception under this section.

Subparts F–I [Reserved]

Subpart J—Statements of Employment and Financial Interests

§ 73a.735–1004 Submission and review of statements.

(a) Employees occupying control activity positions shall file Form HHS–473 “Confidential Statement of Employment and Financial Interests” with the Associate Commissioner for Administration within 30 days after entrance in this category and annually thereafter as of June 30, or such other dates as the Secretary, with the concurrence of the Civil Service Commission, may approve. Prior to the due date, the Associate Commissioner for Administration shall advise “control activity” employees of the annual filing requirement through normal administrative channels. The annual re-

porting requirement shall commence as of June 30, 1977.

(b) The Associate Commissioner for Administration (or his designee) shall serve as the principal reviewing official for Outside Activity Forms, HHS–520 and 521, and shall make final determinations on matters arising from activities reported on Form HHS–473.

PART 73b—DEBARMENT OR SUSPENSION OF FORMER EMPLOYEES

Issued at 90 FR 40985, Aug. 22, 2025.

Sec.

73b.1 Scope.

73b.2 Rules and regulations.

73b.3 Reports of violations.

73b.4 Proceedings.

73b.5 Hearings.

AUTHORITY: 18 U.S.C. 207(j).

SOURCE: 47 FR 17505, Apr. 23, 1982, unless otherwise noted.

EFFECTIVE DATE NOTE: At 90 FR 40985, Aug. 22, 2025, part 73b was removed, effective Oct. 21, 2025.

§ 73b.1 Scope.

This part contains rules governing debarment or disqualification action against a former officer or employee of the Department, including former and retired officers of the commissioned corps of the Public Health Service, because of violation of the post-employment restrictions of the conflict of interest laws and regulations.

§ 73b.2 Rules and regulations.

This part will be applied in conformance with the standards established by the Office of Government Ethics in its regulations, 5 CFR part 737, and interpretations thereof. Former officers and employees of the Department may request advice and assistance in compliance with those regulations from the Assistant General Counsel, Business and Administrative Law Division, Department of Health and Human Services.

§ 73b.3 Reports of violations.

(a) If an officer or employee of the Department has reason to believe that

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a former officer or employee of the Department has violated any provision of 18 U.S.C. 207 (a), (b) or (c) or if any such officer or employee receives information to that effect, he/she shall promptly make a written report thereof which shall be forwarded to the Inspector General. If any other person has information of such violations, he/she may make a report thereof to the Inspector General or to any officer or employee of the Department.

(b) The Inspector General shall coordinate proceedings under this part with the Department of Justice in cases where it appears criminal prosecution is warranted.

§ 73b.4 Proceedings.

(a) Upon a determination by the Assistant General Counsel, Business and Administrative Law Division, or his/her designee, after investigation by the Inspector General, that there is reasonable cause to believe that a former officer or employee, including a former special Government employee, of the Department of Health and Human Services (former departmental employee) has violated 18 U.S.C. 207 (a), (b) or (c), the Assistant General Counsel, or his/her designee, shall cause a copy of written charges of the violation(s) to be served upon such individual, either personally or by registered mail. The charges shall be accompanied by a notice to the former departmental employee to show cause within a specified time of not less than 30 days after receipt of the notice why he/she should not be prohibited from engaging in representational activities in relation to matters pending in the Department, as authorized by 18 U.S.C. 207(j), or subjected to other appropriate debarment or disqualification action under that statute. The notice to show cause shall include:

(1) A statement of allegations, and their bases, sufficiently detailed to enable the former departmental employee to prepare an adequate defense;

(2) Notification of the right to a hearing, and that failure to answer shall constitute a waiver of defense; and

(3) An explanation of the method by which a hearing may be requested.

(b) If a former departmental employee who submits an answer to the

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notice to show cause does not request a hearing or if the Assistant General Counsel does not receive an answer within the time prescribed by the notice, the Assistant General Counsel shall forward the record, including the report(s) of investigation, to the Assistant Secretary for Personnel Administration (Assistant Secretary). In the case of a failure to answer, such failure shall constitute a waiver of defense.

(c) Upon receipt of a former departmental employee's request for a hearing, the Assistant General Counsel shall notify him/her of the time and place thereof, giving due regard both to such person's need for an adequate period to prepare a suitable defense and an expeditious resolution of allegations that may be damaging to his or her reputation.

(d) The presiding officer at the hearing and any related proceedings shall be a federal administrative law judge. He/she shall insure that the former departmental employee has the following rights:

(1) To self-representation or representation by counsel,

(2) To introduce and examine witnesses and submit physical evidence,

(3) To confront and cross-examine adverse witnesses,

(4) To present oral argument, and

(5) To a transcript or recording of the proceedings, upon request.

(e) The Assistant General Counsel shall designate one or more officers or employees of the Department to present the evidence against the former departmental employee and perform other functions incident to the proceedings.

(f) A decision adverse to the former departmental employee must be sustained by substantial evidence that he/she violated 18 U.S.C. 207 (a), (b) or (c). If a judgment of conviction has been entered by a Federal district court against the former departmental employee for violation of 18 U.S.C. 207 (a), (b) or (c), regardless of whether the judgment is based upon a verdict or a plea of guilty, such judgment of conviction shall be conclusive evidence of a violation of 18 U.S.C. 207 (a), (b) or (c), unless and until the judgment is vacated or reversed on appeal.

(g) The administrative law judge shall issue an initial decision based exclusively on the transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, and shall set forth in the decision findings and conclusions, supported by reasons, on the material issues of fact and law presented on the record.

(h) Within 30 days after issuance of the initial decision, either party may appeal in writing to the Assistant Secretary who in that event shall issue the final decision based on the record of the proceedings or those portions thereof cited by the parties to limit the issues. If the final decision modifies or reverses the initial decision, the Assistant Secretary shall specify the findings of fact and conclusions of law that vary from those of the presiding officer.

(i) If a former departmental employee fails to appeal from an adverse initial decision within the prescribed period of time, the administrative law judge shall forward the record of the proceedings to the Assistant Secretary.

(j) In the case of a former departmental employee who filed an answer to the notice to show cause but did not request a hearing, the Assistant Secretary shall make the final decision on the record submitted to him by the Assistant General Counsel pursuant to paragraph (b) of this section.

(k) In a case where:

(1) The defense has been waived,

(2) The former departmental employee has failed to appeal from an adverse initial decision, or

(3) The Assistant Secretary has issued a final decision that the former departmental employee violated 18 U.S.C. 207 (a), (b) or (c),

The Assistant Secretary may issue an order:

(i) Prohibiting the former departmental employee from making, on behalf of any other person (except the United States), any informal or formal appearance before, or, with the intent to influence, any oral or written communication to, the Department on a pending matter of business for a period not to exceed five years, or

(ii) Prescribing other appropriate debarment or disqualification action,

such as limiting the action to a particular organization or organizations within the Department.

(l) An order issued under either paragraph (k)(i) or (k)(ii) of this section shall be supplemented by a directive to officers and employees of the Department not to engage in conduct in relation to the former departmental employee that would contravene such order.

§ 73b.5 Hearings.

(a) Hearings shall be stenographically recorded and transcribed and the testimony of witnesses shall be taken under oath or affirmation. Hearings will be closed unless an open hearing is requested by the respondent, except that if classified information or protected information of third parties is likely to be adduced at the hearing, it will remain closed. If either party to the proceeding fails to appear at the hearing, after due notice thereof has been sent to him/her, he/she shall be deemed to have waived the right to a hearing and the administrative law judge may make a decision on the basis of the record before him/her at that time.

(b) The rules of evidence prevailing in courts of law and equity are not controlling in hearings under this part. However, the administrative law judge shall exclude evidence which is irrelevant, immaterial, or unduly repetitious.

(c) Depositions for use at a hearing may, with the consent of the parties in writing or the written approval of the administrative law judge be taken by either the Assistant General Counsel or the respondent or their duly authorized representatives. Depositions may be taken upon oral or written interrogatories. There shall be at least 10 days written notice to the other party. The requirement of a 10-day written notice may be waived by the parties in writing. When a deposition is taken upon written interrogatories, any cross-examination shall be upon written interrogatories. Copies of such written interrogatories shall be served upon the other party with the notice, and copies of any written cross-interrogation shall be mailed or delivered to the opposing party at least 5 days before the

date of taking the depositions, unless the parties mutually agree otherwise. Expenses in the reporting of depositions shall be borne by the party at whose instance the deposition is taken.

PARTS 74–75 [RESERVED]

PART 77—REMEDIAL ACTIONS APPLICABLE TO LETTER OF CREDIT ADMINISTRATION

Sec.

77.1 Purpose.

77.2 Scope.

77.3 Conditions that may give rise to remedial actions.

77.4 Remedial actions.

77.5 Remedial action procedures.

77.6 Emergency procedures.

AUTHORITY: 5 U.S.C. 301.

SOURCE: 50 FR 781, Jan. 7, 1985, unless otherwise noted.

§ 77.1 Purpose.

Letters of credit with the United States Treasury, issued by the Department to States or other grantees and contractors, are a convenient means for disbursing Federal funds to recipients of grant awards or contracts (recipient organizations) under the programs of this and other Executive Departments. The sound and efficient operation of the letter-of-credit system is dependent in large part upon the honesty, good faith, and responsible financial management of recipient organizations that receive funds pursuant to letters of credit. This part sets forth conditions that may prompt the Department to seek remedial action against a recipient organization operating under a letter of credit and the procedures that will be used to reach a final decision regarding the taking of remedial actions against a recipient organization.

§ 77.2 Scope.

The regulations in this part apply to all recipient organizations under any program administered by the Department through which the organization receives Federal funds under a letter of credit.

§ 77.3 Conditions that may give rise to remedial actions.

If the Department determines that any of the following conditions is present in a recipient organization's administration of a letter of credit, it may take remedial actions against the organization:

(a) A recipient organization draws Federal funds through its letter of credit in excess of the aggregate grant award or contract authority currently available to it.

(b) A recipient organization draws Federal funds for a particular program in excess of currently available grant award or contract authority for that program, even though the organization may not have exceeded its aggregate grant award or contract authority.

(c) A recipient organization fails to file timely all reports and other data required by the Department in connection with its grant awards, contracts, or letter of credit.

(d) A recipient organization accumulates, through its letter of credit or otherwise, excess amounts of Federal funds relative to its actual and immediate disbursement requirements.

(e) A recipient organization's cash management system fails to comply with generally accepted accounting principles or Departmental regulations or demonstrates irregularities, misrepresentations, fraud, or abuse in its operation.

§ 77.4 Remedial actions.

If, after the conclusion of the procedures set forth in § 77.5 or § 77.6 the Department finds that one or more of the conditions set forth in § 77.3 is or has been present, the Department may take the following remedial actions against a recipient organization's use of its letter of credit:

(a) The Department may place special limits, restrictions, or controls upon the recipient organization's use of its letter of credit.

(b) The Department may require more frequent or more detailed financial reporting from the recipient organization.

(c) The Department may suspend, reduce, or terminate the recipient organization's use of its letter of credit.

§ 77.5 Remedial action procedures.

Except as provided in § 77.6, the Department will use the following procedures whenever it seeks the remedial action specified in § 77.4.

(a) *Notice.* Prior to taking remedial action, the Department will provide the recipient organization written notice of its intended action setting forth both the legal and factual reasons therefor. Notice may be provided by certified or express mail, TWX, telegram, delivery, or similar means.

(b) *Opportunity to respond.* (1) The recipient organization has 30 days after receipt of the notice in which to submit to the Department a written statement setting forth any legal and factual reasons why it believes the proposed remedial action would be inappropriate. If no response is received by the Department within the 30-day period, the Department may make the proposed remedial action effective immediately. If a response opposing the taking of remedial action is received from the recipient organization within the 30-day period, no remedial action will be taken until a final decision has been reached under paragraph (c) of this section. (2) The Department may prepare a written reply to the recipient organization's response. Any such reply will be forwarded to the deciding official together with the notice sent to the recipient organization and the organization's response, and a copy of the reply will be served on the recipient organization.

(c) *Departmental decision.* The Department's decision to take remedial action under this part will be made by an official of the Department who had no involvement with the initial determination to seek remedial action. The deciding official may affirm, reverse, or modify the initial determination. In making the decision, the official will consider only the notice provided by the Department, the recipient organization's statement, the Department's reply, together with any other documents attached to them, and statements at any informal conference held pursuant to paragraph (d) of this section. The official's decision will be provided to the recipient organization in writing and will constitute the Department's

final administrative action on the matter.

(d) *Informal conference.* If, in the judgment of the official designated to make a final decision, it would materially enhance his ability to resolve the matters in dispute, he may convene an informal conference to question or hear an oral presentation by the parties. If an informal conference is convened it will be transcribed.

(e) *Effect of decision.* The decision in a proceeding under this section affects only the recipient organization's obligations related to its letter of credit and does not determine the organization's ultimate liability with respect to improperly spent funds or other misconduct.

§ 77.6 Emergency procedures.

(a) Should the Department determine that it cannot adequately protect assets of the Federal government available to a recipient organization under its letter of credit without taking remedial action prior to the procedures specified in § 77.5, it may immediately take remedial action subject to the subsequent completion of those procedures.

(b) Where the Department has taken remedial action as described in paragraph (a) of this section, it will notify the recipient organization orally of the remedial action within one business day of its imposition and in writing within seven business days of its imposition. The written notice will conform to that described in § 77.5(a).

(c) After receipt of the written notice, the recipient organization will have the same opportunity to respond as described in § 77.5(b)(1).

(d) The Department will issue a final decision in writing no later than twenty days following receipt of any response submitted by the recipient organization.

PART 78—CONDITIONS FOR WAIVER OF DENIAL OF FEDERAL BENEFITS

Sec.

78.1 Applicability.

78.2 Definitions.

78.3 Benefits not denied to rehabilitated offenders.

§ 78.1

AUTHORITY: Section 5301 of Pub. L. 100-690, the Anti-Drug Abuse Act of 1988, 102 Stat. 4310, 21 U.S.C. 853a.

SOURCE: 56 FR 29592, June 28, 1991, unless otherwise noted.

§ 78.1 Applicability.

This part is applicable to any decision to deny Federal benefits, under authority of 21 U.S.C. 853a, to an individual convicted of a Federal or State offense involving distribution or possession of a controlled substance as defined by the Controlled Substances Act, 21 U.S.C. 802.

§ 78.2 Definitions.

For the purposes of denying Federal benefits under 21 U.S.C. 853a:

(a) *Deemed to be rehabilitated* means that an individual has abstained from the illicit use of a controlled substance for the period of at least 180 days immediately prior to and including the date of sentencing provided that such abstinence is documented by the results of periodic urine drug testing conducted during that period; and provided further that such drug testing is conducted using an immunoassay test approved by the Food and Drug Administration for commercial distribution or, in the case of a State offense, either using an immunoassay test approved by the Food and Drug Administration for commercial distribution or pursuant to standards approved by the State.

(b) *Long-term treatment program or long-term drug treatment program* means any drug abuse treatment program of 180 days or more where the provider has been accredited by the Joint Commission on Accreditation of Health Organizations, the Commission on Accreditation of Rehabilitation Facilities, or the Council on Accreditation of Services for Families and Children, or licensed or otherwise approved by the State to provide drug abuse treatment.

§ 78.3 Benefits not denied to rehabilitated offenders.

(a) No individual convicted of any Federal or State offense involving the distribution of controlled substances shall be denied Federal benefits relating to long-term drug treatment pro-

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grams for addiction under 21 U.S.C. 853a(a)(2) if:

(1) The individual declares himself or herself to be an addict and submits to a long-term treatment program for addiction as defined by § 78.2(b), provided that in the determination of the sentencing court there is a reasonable body of evidence to substantiate the individual's declaration that such individual is an addict; or

(2) The individual is, in the determination of the sentencing court, deemed to be rehabilitated as defined by § 78.2(a).

(b) No individual convicted of any Federal or State offense involving the possession of controlled substances shall be denied any Federal benefit, or otherwise subject to penalties and conditions, under 21 U.S.C. 853a(b)(2) if:

(1) The individual declares himself or herself to be an addict and submits to a long-term treatment program for addiction as defined by § 78.2(b), provided that in the determination of the sentencing court there is a reasonable body of evidence to substantiate the individual's declaration that such individual is an addict; or

(2) The individual is, in the determination of the sentencing court, deemed to be rehabilitated as defined by § 78.2(a).

PART 79—PROGRAM FRAUD CIVIL REMEDIES

Sec.

79.1 Basis and purpose.

79.2 Definitions.

79.3 Basis for civil penalties and assessments.

79.4 Investigation.

79.5 Review by the reviewing official.

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79.7 Complaint.

79.8 Service of complaint.

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79.10 Default upon failure to file an answer.

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- 79.21 Discovery.
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- 79.42 Judicial review.
- 79.43 Collection of civil penalties and assessments.
- 79.44 Right to administrative offset.
- 79.45 Deposit in Treasury of United States.
- 79.46 Compromise or settlement.
- 79.47 Limitations.

AUTHORITY: 31 U.S.C. 3801-3812.

SOURCE: 53 FR 11659, Apr. 8, 1988, unless otherwise noted.

§ 79.1 Basis and purpose.

(a) *Basis.* This part implements the Program Fraud Civil Remedies Act of 1986, Pub. L. 99-509, §§6101-6104, 100 Stat. 1874 (October 21, 1986), to be codified at 31 U.S.C. 3801-3812, 31 U.S.C. 3809 of the statute requires each authority head to promulgate regulations necessary to implement the provisions of the statute.

(b) *Purpose.* This part (1) establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to authorities or to their agents, and (2) specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments.

§ 79.2 Definitions.

ALJ means an Administrative Law Judge in the authority appointed pur-

suant to 5 U.S.C. 3105 or detailed to the authority pursuant to 5 U.S.C. 3344.

Authority means the Department of Health and Human Services.

Authority head means the Departmental Grant Appeals Board of the Department of Health and Human Services.

Benefit means, in the context of *statement*, anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status, or loan guarantee.

Claim means any request, demand, or submission—

(a) Made to the authority for property, services, or money (including money representing grants, loans, insurance, or benefits);

(b) Made to a recipient of property, services, or money from the authority or to a party to a contract with the authority—

(1) For property or services if the United States—

(i) Provided such property or services;

(ii) Provided any portion of the funds for the purchase of such property or services; or

(iii) Will reimburse such recipient or party for the purchase of such property or services; or

(2) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States—

(i) Provided any portion of the money requested or demanded; or

(ii) Will reimburse such recipient or party for any portion of the money paid on such request or demand; or

(c) Made to the authority which has the effect of decreasing an obligation to pay or account for property, services, or money.

Complaint means the administrative complaint served by the reviewing official on the defendant under § 79.7.

Defendant means any person alleged in a complaint under § 79.7 to be liable for a civil penalty or assessment under § 79.3.

Department means the Department of Health and Human Services.

Government means the United States Government.

Individual means a natural person.

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Initial decision means the written decision of the ALJ required by § 79.10 or § 79.37, and includes a revised initial decision issued following a remand or a motion for reconsideration.

Investigating official means the Inspector General of the Department of Health and Human Services or an officer or employee of the Office of the Inspector General designated by the Inspector General and serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

Knows or has reason to know, means that a person, with respect to a claim or statement—

(a) Has actual knowledge that the claim or statement is false, fictitious, or fraudulent;

(b) Acts in deliberate ignorance of the truth or falsity of the claim or statement; or

(c) Acts in reckless disregard of the truth or falsity of the claim or statement.

Makes, wherever it appears, shall include the terms presents, submits, and causes to be made, presented, or submitted. As the context requires, *making* or *made*, shall likewise include the corresponding forms of such terms.

Person means any individual, partnership, corporation, association or private organization, and includes the plural of that term.

Representative means an attorney who is a member in good standing of the bar of any State, Territory, or possession of the United States or of the District of Columbia or the Commonwealth of Puerto Rico.

Reviewing official means the General Counsel of the Department or his or her designee who is—

(a) Not subject to supervision by, or required to report to, the investigating official;

(b) Not employed in the organizational unit of the authority in which the investigating official is employed; and

(c) Serving in a position for which the rate of basic pay is not less than the minimum rate of basic pay for grade GS-16 under the General Schedule.

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Statement means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made—

(a) With respect to a claim or to obtain the approval or payment of a claim (including relating to eligibility to make a claim); or

(b) With respect to (including relating to eligibility for)—

(1) A contract with, or a bid or proposal for a contract with; or

(2) A grant, loan, or benefit from, the authority, or any State, political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the Government will reimburse such State, political subdivision, or party for any portion of the money or property under such contract or for such grant, loan, or benefit,

§ 79.3 Basis for civil penalties and assessments.

(a) *Claims.* (1) Except as provided in paragraph (c) of this section, any person who makes a claim that the person knows or has reason to know—

(i) Is false, fictitious, or fraudulent;

(ii) Includes, or is supported by, any written statement which asserts a material fact which is false, fictitious, or fraudulent;

(iii) Includes, or is supported by, any written statement that—

(A) Omits a material fact;

(B) Is false, fictitious, or fraudulent as a result of such omission; and

(C) Is a statement in which the person making such statement has a duty to include such material fact; or

(iv) Is for payment for the provision of property or services which the person has not provided as claimed, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,500¹ for each such claim.

¹The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-

(2) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.

(3) A claim shall be considered made to the authority, recipient, or party when such claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of the authority, recipient, or party.

(4) Each claim for property, services, or money is subject to a civil penalty regardless of whether such property, services, or money is actually delivered or paid.

(5) If the Government has made any payment (including transferred property or provided services) on a claim, a person subject to a civil penalty under paragraph (a)(1) of this section shall also be subject to an assessment of not more than twice the amount of such claim or that portion thereof that is determined to be in violation of paragraph (a)(1). Such assessment shall be in lieu of damages sustained by the Government because of such claim.

(b) *Statements.* (1) Except as provided in paragraph (c) of this section, any person who makes a written statement that—

(i) The person knows or has reason to know—

(A) Asserts a material fact which is false, factitious, or fraudulent; or

(B) Is false, factitious, or fraudulent because it omits a material fact that the person making the statement has a duty to include in such statement; and

(ii) Contains, or is accompanied by, an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,500² for each such statement.

74). Annually adjusted amounts are published at 45 CFR part 102.

²The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-

(2) Each representation, certification, or affirmation constitutes a separate statement.

(3) A statement shall be considered made to the authority when such statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of the authority.

(c) *Applications for certain benefits.* (1) In the case of any claim or statement made by any individual relating to any of the benefits listed in paragraph (c)(2) of this section received by such individual, such individual may be held liable for penalties and assessments under this section only if such claim or statement is made by such individual in making application for such benefits with respect to such individual's eligibility to receive such benefits.

(2) For purposes of paragraph (c) of this section, the term *benefits* means—

(i) Benefits under the supplemental security income program under title XVI of the Social Security Act;

(ii) Old age, survivors, and disability insurance benefits under title II of the Social Security Act;

(iii) Benefits under title XVIII of the Social Security Act;

(iv) Aid to families with dependent children under a State plan approved under section 402(a) of the Social Security Act;

(v) Medical assistance under a State plan approved under section 1902(a) of the Social Security Act;

(vi) Benefits under title XX of the Social Security Act;

(vii) Benefits under section 336 of the Older Americans Act; or,

(viii) Benefits under the Low-Income Home Energy Assistance Act of 1981, which are intended for the personal use of the individual who receives the benefits or for a member of the individual's family.

(d) No proof of specific intent to defraud is required to establish liability under this section.

(e) In any case in which it is determined that more than one person is liable for making a claim or statement

74). Annually adjusted amounts are published at 45 CFR part 102.

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under this section, each such person may be held liable for a civil penalty.

(f) In any case in which it is determined that more than one person is liable for making a claim under this section on which the Government has made payment (including transferred property or provided services), an assessment may be imposed against any such person or jointly and severally against any combination of such persons.

[53 FR 11659, Apr. 8, 1988, as amended at 61 FR 52301, Oct. 7, 1996; 81 FR 61565, Sept. 6, 2016]

§ 79.4 Investigation.

(a) If an investigating official concludes that a subpoena pursuant to the authority conferred by 31 U.S.C. 3804(a) is warranted—

(1) The subpoena so issued shall notify the person to whom it is addressed of the authority under which the subpoena is issued and shall identify the records or documents sought;

(2) The investigating official may designate a person to act on his or her behalf to receive the documents sought; and

(3) The person receiving such subpoena shall be required to tender to the investigating official, or the person designated to receive the documents, a certification that—

(i) The documents sought have been produced;

(ii) Such documents are not available and the reasons therefor; or

(iii) Such documents suitably identified, have been withheld based upon the assertion of an identified privilege.

(b) If the investigating official concludes that an action under the Program Fraud Civil Remedies Act may be warranted, the investigating official shall submit a report containing the findings and conclusions of such investigation to the reviewing official.

(c) Nothing in this section shall preclude or limit an investigating official's discretion to refer allegations directly to the Department of Justice for suit under the False Claims Act or other civil relief, or to defer or postpone a report or referral to the reviewing official to avoid interference with a criminal investigation or prosecution.

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(d) Nothing in this section modifies any responsibility of an investigating official to report violations of criminal law to the Attorney General.

§ 79.5 Review by the reviewing official.

(a) If, based on the report of the investigating official under § 79.4(b), the reviewing official determines that there is adequate evidence to believe that a person is liable under § 79.3, the reviewing official shall transmit to the Attorney General a written notice of the reviewing official's attention to issue a complaint under § 79.7.

(b) Such notice shall include—

(1) A statement of the reviewing official's reasons for issuing a complaint;

(2) A statement specifying the evidence that supports the allegations of liability;

(3) A description of the claims or statements upon which the allegations of liability are based;

(4) An estimate of the amount of money, or the value of property, services, or other benefits, requested or demanded in violation of § 79.3 of this part;

(5) A statement of any exculpatory or mitigating circumstances that may relate to the claims or statements known by the reviewing official or the investigating official; and

(6) A statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments.

§ 79.6 Prerequisites for issuing a complaint.

(a) The reviewing official may issue a complaint under § 79.7 only if—

(1) The Department of Justice approves the issuance of a complaint in a written statement described in 31 U.S.C. 3803(b)(1), and

(2) In the case of allegations of liability under § 79.3(a) with respect to a claim, the reviewing official determines that, with respect to such claim or a group of related claims submitted at the same time such claim is submitted (as defined in paragraph (b) of this section), the amount of money, or the value of property or services, demanded or requested in violation of § 79.3(a) does not exceed \$150,000.

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(b) For the purposes of this section, a related group of claims submitted at the same time shall include only those claims arising from the same transaction (e.g., grant, loan, application, or contract) that are submitted simultaneously as part of a single request, demand, or submission.

(c) Nothing in this section shall be construed to limit the reviewing official's authority to join in a single complaint against a person claims that are unrelated or were not submitted simultaneously, regardless of the amount of money, or the value of property or services, demanded or requested.

§ 79.7 Complaint.

(a) On or after the date the Department of Justice approves the issuance of a complaint in accordance with 31 U.S.C. 3803(b)(1), the reviewing official may serve a complaint on the defendant, as provided in § 79.8.

(b) The complaint shall state—

(1) The allegations of liability against the defendant, including the statutory basis for liability, an identification of the claims or statements that are the basis for the alleged liability, and the reasons why liability allegedly arises from such claims or statements;

(2) The maximum amount of penalties and assessments for which the defendant may be held liable;

(3) Instructions for filing an answer to request a hearing, including a specific statement of the defendant's right to request a hearing by filing an answer and to be represented by a representative; and

(4) That failure to file an answer as set forth in § 79.9 will result in the imposition of the maximum amount of penalties and assessments without right to appeal, as provided in § 79.10.

(c) At the same time the reviewing official serves the complaint, he or she shall serve the defendant with a copy of these regulations.

§ 79.8 Service of complaint.

(a) Service of a complaint must be made by certified or registered mail or by delivery in any manner authorized by Rule 4(d) of the Federal Rules of Civil Procedure. Service is complete upon receipt.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by—

(1) Affidavit of the individual serving the complaint by delivery;

(2) A United States Postal Service return receipt card acknowledging receipt; or

(3) Written acknowledgment of receipt by the defendant or his or her representative.

§ 79.9 Answer.

(a) The defendant may request a hearing by filing an answer with the reviewing official within 30 days of service of the complaint. An answer shall be deemed to be a request for hearing.

(b) In the answer, the defendant—

(1) Shall admit or deny each of the allegations of liability made in the complaint;

(2) Shall state any defense on which the defendant intends to rely;

(3) May state any reasons why the defendant contends that the penalties and assessments should be less than the statutory maximum; and

(4) Shall state the name, address, and telephone number of the person authorized by the defendant to act as defendant's representative, if any.

(c) If the defendant is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the defendant, before that time expires, may file with the reviewing official a general answer denying liability and requesting a hearing, and a request for an extension of time within which to file an answer meeting the requirements of paragraph (b) of this section. As provided in § 79.11, the reviewing official shall file promptly with the ALJ the complaint, the general answer denying liability, and the request for an extension of time. For good cause shown, the ALJ may grant the defendant up to 30 additional days within which to file an answer meeting the requirements of paragraph (b) of this section.

§ 79.10 Default upon failure to file an answer.

(a) If the defendant does not file an answer within the time prescribed in

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§ 79.9(a), the reviewing official may refer the complaint to the ALJ.

(b) Upon the referral of the complaint, the ALJ shall promptly serve on the defendant in the manner prescribed in § 79.8, a notice that an initial decision will be issued under this section.

(c) The ALJ shall assume the facts alleged in the complaint to be true and, if such facts establish liability under § 79.3, the ALJ shall issue an initial decision imposing the maximum amount of penalties and assessments allowed under the statute.

(d) Except as otherwise provided in this section, by failing to file a timely answer, the defendant waives any right to further review of the penalties and assessments imposed under paragraph (c) of this section, and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(e) If, before such an initial decision becomes final, the defendant files a motion with the ALJ seeking to reopen on the grounds that extraordinary circumstances prevented the defendant from filing an answer, the initial decision shall be stayed pending the ALJ's decision on the motion.

(f) If, on such motion, the defendant can demonstrate extraordinary circumstances excusing the failure to file a timely answer, the ALJ shall withdraw the initial decision in paragraph (c) of this section, if such a decision has been issued, and shall grant the defendant an opportunity to answer the complaint.

(g) A decision of the ALJ denying a defendant's motion under paragraph (e) of this section is not subject to reconsideration under § 79.38.

(h) The defendant may appeal to the authority head the decision denying a motion to reopen by filing a notice of appeal with the authority head within 15 days after the ALJ denies the motion. The timely filing of a notice of appeal shall stay the initial decision until the authority head decides the issue.

(i) If the defendant files a timely notice of appeal with the authority head, the ALJ shall forward the record of the proceeding to the authority head.

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(j) The authority head shall decide expeditiously whether extraordinary circumstances excuse the defendant's failure to file a timely answer based solely on the record before the ALJ.

(k) If the authority head decides that extraordinary circumstances excuse the defendant's failure to file a timely answer, the authority head shall remand the case to the ALJ with instructions to grant the defendant an opportunity to answer.

(l) If the authority head decides that the defendant's failure to file a timely answer is not excused, the authority head shall reinstate the initial decision of the ALJ, which shall become final and binding upon the parties 30 days after the authority head issues such decision.

§ 79.11 Referral of complaint and answer to the ALJ.

Upon receipt of an answer, the reviewing official shall file the complaint and answer with the ALJ.

§ 79.12 Notice of hearing.

(a) When the ALJ receives the complaint and answer, the ALJ shall promptly serve a notice of hearing upon the defendant in the manner prescribed by § 79.8. At the same time, the ALJ shall send a copy of such notice to the representative for the Government.

(b) Such notice shall include—

(1) The tentative time and place, and the nature of the hearing;

(2) The legal authority and jurisdiction under which the hearing is to be held;

(3) The matters of fact and law to be asserted;

(4) A description of the procedures for the conduct of the hearing;

(5) The name, address, and telephone number of the representative of the Government and of the defendant, if any; and

(6) Such other matters as the ALJ deems appropriate.

§ 79.13 Parties to the hearing.

(a) The parties to the hearing shall be the defendant and the authority.

(b) Pursuant to 31 U.S.C. 3730(c)(5), a private plaintiff under the False Claims Act may participate in these

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proceedings to the extent authorized by the provisions of that Act.

§ 79.14 Separation of functions.

(a) The investigating official, the reviewing official, and any employee or agent of the authority who takes part in investigating, preparing, or presenting a particular case may not, in such case or a factually related case—

(1) Participate in the hearing as the ALJ;

(2) Participate or advise in the initial decision or the review of the initial decision by the authority head, except as a witness or a representative in public proceedings; or

(3) Make the collection of penalties and assessments under 31 U.S.C. 3806.

(b) The ALJ shall not be responsible to, or subject to the supervision or direction of, the investigating official or the reviewing official.

(c) Except as provided in paragraph (a) of this section, the representative for the Government may be employed anywhere in the authority, including in the offices of either the investigating official or the reviewing official.

§ 79.15 Ex parte contacts.

No party or person (except employees of the ALJ's office) shall 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.

§ 79.16 Disqualification of reviewing official or ALJ.

(a) A reviewing official or ALJ in a particular case may disqualify himself or herself at any time.

(b) A party may file with the ALJ a motion for disqualification of a reviewing official or an ALJ. Such motion shall be accompanied by an affidavit alleging personal bias or other reason for disqualification.

(c) Such motion and affidavit shall be filed promptly upon the party's discovery of reasons requiring disqualification, or such objections shall be deemed waived.

(d) Such affidavit shall state specific facts that support the party's belief that personal bias or other reason for disqualification exists and the time and circumstances of the party's discovery of such facts. It shall be accompanied by a certificate of the representative of record that it is made in good faith.

(e) Upon the filing of such a motion and affidavit, the ALJ shall proceed no further in the case until he or she resolves the matter of disqualification in accordance with paragraph (f) of this section.

(f)(1) If the ALJ determines that a reviewing official is disqualified, the ALJ shall dismiss the complaint without prejudice.

(2) If the ALJ disqualifies himself or herself, the case shall be reassigned promptly to another ALJ.

(3) If the ALJ denies a motion to disqualify, the authority head may determine the matter only as part of his or her review of the initial decision upon appeal, if any.

§ 79.17 Rights of parties.

Except as otherwise limited by this part, all parties may—

(a) Be accompanied, represented, and advised by a representative;

(b) Participate in any conference held by the ALJ;

(c) Conduct discovery;

(d) Agree to stipulations of fact or law, which shall be made part of the record;

(e) Present evidence relevant to the issues at the hearing;

(f) Present and cross-examine witnesses;

(g) Present oral arguments at the hearing as permitted by the ALJ; and

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

§ 79.18 Authority of the ALJ.

(a) The ALJ shall 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;

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(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 and the production of documents at depositions or at hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery;

(8) Regulate the course of the hearing and the conduct of representatives and parties;

(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;

(13) Conduct any conference, argument, or hearing on motions in person or by telephone; and

(14) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.

(c) The ALJ does not have the authority to find Federal statutes or regulations invalid.

§ 79.19 Prehearing conferences.

(a) The ALJ may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the ALJ shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) 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;

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(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;

(9) The time and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The ALJ may issue an order containing all matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 79.20 Disclosure of documents.

(a) Upon written request to the reviewing official, the defendant may review any relevant and material documents, transcripts, records, and other materials that relate to the allegations set out in the complaint and upon which the findings and conclusions of the investigating official under § 79.4(b) are based, unless such documents are subject to a privilege under Federal law. Upon payment of fees for duplication, the defendant may obtain copies of such documents.

(b) Upon written request to the reviewing official, the defendant also may obtain a copy of all exculpatory information in the possession of the reviewing official or investigating official relating to the allegations in the complaint, even if it is contained in a document that would otherwise be privileged. If the document would otherwise be privileged, only that portion containing exculpatory information must be disclosed.

(c) The notice sent to the Attorney General from the reviewing official as described in § 79.5 is not discoverable under any circumstances.

(d) The defendant may file a motion to compel disclosure of the documents subject to the provisions of this section. Such a motion may only be filed with the ALJ following the filing of an answer pursuant to § 79.9.

§ 79.21 Discovery.

(a) The following types of discovery are authorized:

- (1) Requests for production of documents for inspection and copying;
- (2) Requests for admission of the contents or authenticity of any relevant document or of the truth of any relevant fact;
- (3) Written interrogatories; and
- (4) Depositions.

(b) For the purpose of this section and §§ 79.22 and 79.23, the term *documents* includes information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.

(c) Unless mutually agreed to by the parties, discovery is available only as ordered by the ALJ. The ALJ shall regulate the timing of discovery.

(d) *Motions for discovery.* (1) A party seeking discovery may file a motion with the ALJ. Such a motion shall be accompanied by a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition.

(2) Within ten days of service, a party may file an opposition to the motion and/or a motion for protective order as provided in § 79.24.

(3) The ALJ may grant a motion for discovery only if he or she finds that the discovery sought—

- (i) Is necessary for the expeditious, fair, and reasonable consideration of the issues;
- (ii) Is not unduly costly or burdensome;
- (iii) Will not unduly delay the proceeding; and
- (iv) Does not seek privileged information.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

(5) The ALJ may grant discovery subject to a protective order under § 79.24.

(e) *Depositions.* (1) If a motion for deposition is granted, the ALJ shall issue a subpoena for the deponent, which may require the deponent to produce documents. The subpoena shall specify the time and place at which the deposition will be held.

(2) The party seeking to depose shall serve the subpoena in the manner prescribed in § 79.8.

(3) The deponent may file with the ALJ a motion to quash the subpoena or a motion for a protective order within ten days of service.

(4) The party seeking to depose shall provide for the taking of a verbatim transcript of the deposition, which it shall make available to all other parties for inspection and copying.

(f) Each party shall bear its own costs of discovery.

§ 79.22 Exchange of witness lists, statements and exhibits.

(a) At least 15 days before the hearing or at such other time as may be ordered by the ALJ, the parties shall exchange witness lists, copies of prior 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 § 79.33(b). At the time the above documents are exchanged, any party that intends to rely on the transcript of deposition testimony in lieu of live testimony at the hearing, if permitted by the ALJ, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.

(b) If a party objects, the ALJ shall not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above unless the ALJ finds good cause for the failure or that there is no prejudice to the objecting party.

(c) Unless another party objects within the time set by the ALJ, documents exchanged in accordance with paragraph (a) of this section shall be deemed to be authentic for the purpose of admissibility at the hearing.

§ 79.23 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any individual at the hearing may request that the ALJ issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual

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may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 15 days before the date fixed for the hearing unless otherwise allowed by the ALJ for good cause shown. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed in § 79.8, except that a subpoena on a party or upon an individual under the control of a party may be served as prescribed in § 79.26(b).

(f) A party or the individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within ten days after service or on or before the time specified in the subpoena for compliance if it is less than ten days after service.

§ 79.24 Protective order.

(a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by an opposing party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) In issuing a protective order, the ALJ may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) That the discovery not be had;

(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;

(3) That the discovery may be had only through a method of discovery other than that requested;

(4) That certain matters not be inquired into, or that the scope of discovery be limited to certain matters;

(5) That discovery be conducted with no one present except persons designated by the ALJ;

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(6) That the contents of discovery or evidence be sealed;

(7) That a deposition after being sealed be opened only by order of the ALJ;

(8) That a trade secret or other confidential research, development, commercial information, or facts pertaining to any criminal investigation, proceeding, or other administrative investigation not be disclosed or be disclosed only in a designated way; or

(9) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the ALJ.

§ 79.25 Fees.

The party requesting a subpoena shall 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 shall accompany the subpoena when served, except that when a subpoena is issued on behalf of the authority, a check for witness fees and mileage need not accompany the subpoena.

§ 79.26 Form, filing and service of papers.

(a) *Form.* (1) Documents filed with the ALJ shall include an original and two copies.

(2) Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the ALJ, and a designation of the paper (*e.g.*, motion to quash subpoena).

(3) Every pleading and paper shall be signed by, and shall 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. Date of mailing may be established by a certificate from the party or its representative or by proof that the document was sent by certified or registered mail.

(b) *Service.* A party filing a document with the ALJ shall, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document other than

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those required to be served as prescribed in § 79.8 shall be made by delivering a copy or by placing a copy of the document in the United States mail, postage prepaid, and addressed to the party's last known address. When a party is represented by a representative, service shall be made upon such representative in lieu of the actual 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, shall be proof of service.

§ 79.27 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) Except as provided in paragraph (c) of this section, when the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government shall be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional five calendar days will be added to the time permitted for any response.

§ 79.28 Motions.

(a) Any application to the ALJ for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall 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 shall be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 15 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 thereto has expired, except upon consent of the parties or fol-

lowing a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ shall make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

§ 79.29 Sanctions.

(a) The ALJ may sanction a person, including any party or representative, for—

(1) Failing to comply with an order, rule, or procedure governing the proceeding;

(2) Failing to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the hearing.

(b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition, the production of evidence within the party's control, or a request for admission, the ALJ may—

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, deem each matter of which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) If a party fails to prosecute or defend an action under this part commenced by service of a notice of hearing, the ALJ may dismiss the action or may issue an initial decision imposing penalties and assessments.

(e) The ALJ may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

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§ 79.30 The hearing and burden of proof.

(a) The ALJ shall conduct a hearing on the record in order to determine whether the defendant is liable for a civil penalty or assessment under § 79.3 and, if so, the appropriate amount of any such civil penalty or assessment considering any aggravating or mitigating factors.

(b) The authority shall prove defendant's liability and any aggravating factors by a preponderance of the evidence.

(c) The defendant shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise ordered by the ALJ for good cause shown.

§ 79.31 Determining the amount of penalties and assessments.

(a) In determining an appropriate amount of civil penalties and assessments, the ALJ and the authority head, upon appeal, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose. Because of the intangible costs of fraud, the expense of investigating such conduct, and the need to deter others who might be similarly tempted, ordinarily double damages and a significant civil penalty should be imposed.

(b) Although not exhaustive, the following factors are among those that may influence the ALJ and the authority head in determining the amount of penalties and assessments to impose with respect to the misconduct (i.e., the false, fictitious, or fraudulent claims or statements) charged in the complaint:

(1) The number of false, fictitious, or fraudulent claims or statements;

(2) The time period over which such claims or statements were made;

(3) The degree of the defendant's culpability with respect to the misconduct;

(4) The amount of money or the value of the property, services, or benefit falsely claimed;

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(5) The value of the Government's actual loss as a result of the misconduct, including foreseeable consequential damages and the costs of investigation;

(6) The relationship of the amount imposed as civil penalties to the amount of the Government's loss;

(7) The potential or actual impact of the misconduct upon national defense, public health or safety, or public confidence in the management of Government programs and operations, including particularly the impact on the intended beneficiaries of such programs;

(8) Whether the defendant has engaged in a pattern of the same or similar misconduct;

(9) Whether the defendant attempted to conceal the misconduct;

(10) The degree to which the defendant has involved others in the misconduct or in concealing it;

(11) Where the misconduct of employees or agents is imputed to the defendant, the extent to which the defendant's practices fostered or attempted to preclude such misconduct;

(12) Whether the defendant cooperated in or obstructed an investigation of the misconduct;

(13) Whether the defendant assisted in identifying and prosecuting other wrongdoers;

(14) The complexity of the program or transaction, and the degree of the defendant's sophistication with respect to it, including the extent of the defendant's prior participation in the program or in similar transactions;

(15) Whether the defendant has been found, in any criminal, civil, or administrative proceeding, to have engaged in similar misconduct or to have dealt dishonestly with the Government of the United States or of a State, directly or indirectly; and

(16) The need to deter the defendant and others from engaging in the same or similar misconduct.

(c) Nothing in this section shall be construed to limit the ALJ or the authority head from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

§ 79.32 Location of hearing.

(a) The hearing may be held—

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(1) In any judicial district of the United States in which the defendant resides or transacts business;

(2) In any judicial district of the United States in which the claim or statement in issue was made; or

(3) In such other place as may be agreed upon by the defendant and the ALJ.

(b) Each party shall have the opportunity to present argument with respect to the location of the hearing.

(c) The hearing shall be held at the place and at the time ordered by the ALJ.

§ 79.33 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner which 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 and deposition transcripts shall be exchanged as provided in § 79.22(a).

(c) The ALJ shall 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 needless consumption of time, and (3) protect witnesses from harassment or undue embarrassment.

(d) The ALJ shall permit the parties to conduct such cross-examination as may be required for a full and true disclosure of the facts.

(e) At the discretion of the ALJ, a witness may be cross-examined on matters relevant to the proceeding without regard to the scope of his or her direct examination. To the extent permitted by the ALJ, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse

party, or a witness identified with an adverse party.

(f) Upon motion of any party, the ALJ shall order witnesses excluded so that they cannot hear the testimony of other witnesses. This rule 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 by 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 employed by the Government engaged in assisting the representative for the Government.

§ 79.34 Evidence.

(a) The ALJ shall determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ shall not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, *e.g.*, to exclude unreliable evidence.

(c) The ALJ shall exclude irrelevant and 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 may be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The ALJ shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the ALJ pursuant to § 79.24.

§ 79.35 The record.

(a) The hearing will be recorded and transcribed. Transcripts may be obtained following the hearing from the

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ALJ at a cost not to exceed the actual cost of duplication.

(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 authority head.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the ALJ pursuant to § 79.24.

§ 79.36 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 shall fix the time for filing such briefs, not to exceed 60 days from the date the party receives 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.

§ 79.37 Initial decision.

(a) The ALJ shall issue an initial decision based only on the record, which shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the claims or statements identified in the complaint, or any portions thereof, violate § 79.3;

(2) If the person is liable for penalties or assessments, the appropriate amount of any such penalties or assessments considering any mitigating or aggravating factors that he or she finds in the case, such as those described in § 79.31.

(c) The ALJ shall promptly serve the initial decision on all parties within 90 days after the time for submission of post-hearing briefs and reply briefs (if permitted) has expired. The ALJ shall at the same time serve all parties with a statement describing the right of any defendant determined to be liable for a civil penalty or assessment to file a motion for reconsideration with the ALJ or a notice of appeal with the authority head. If the ALJ fails to meet the deadline contained in this para-

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graph, he or she shall notify the parties of the reason for the delay and shall set a new deadline.

(d) Unless the initial decision of the ALJ is timely appealed to the authority head, or a motion for reconsideration of the initial decision is timely filed, the initial decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after it is issued by the ALJ.

§ 79.38 Reconsideration of initial decision.

(a) Except as provided in paragraph (d) of this section, any party may file a motion for reconsideration of the initial decision within 20 days of receipt of the initial decision. If service was made by mail, receipt will be presumed to be five days from the date of mailing in the absence of contrary proof.

(b) Every such motion must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such motion shall be accompanied by a supporting brief.

(c) Responses to such motions shall be allowed only upon request of the ALJ.

(d) No party may file a motion for reconsideration of an initial decision that has been revised in response to a previous motion for reconsideration.

(e) The ALJ may dispose of a motion for reconsideration by denying it or by issuing a revised initial decision.

(f) If the ALJ denies a motion for reconsideration, the initial decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after the ALJ denies the motion, unless the initial decision is timely appealed to the authority head in accordance with § 79.39.

(g) If the ALJ issues a revised initial decision, that decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after it is issued, unless it is timely appealed to the authority head in accordance with § 79.39.

§ 79.39 Appeal to authority head.

(a) Any defendant who has filed a timely answer and who is determined in an initial decision to be liable for a

civil penalty or assessment may appeal such decision to the authority head by filing a notice of appeal with the authority head in accordance with this section.

(b)(1) A notice of appeal may be filed at any time within 30 days after the ALJ issues an initial decision. However, if another party files a motion for reconsideration under § 79.38, consideration of the appeal shall be stayed automatically pending resolution of the motion for reconsideration.

(2) If a motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ denies the motion or issues a revised initial decision, whichever applies.

(3) If no motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ issues the initial decision.

(4) The authority head may extend the initial 30-day period for an additional 30-days if the defendant files with the authority head a request for an extension within the initial 30 day period and shows good cause.

(c) If the defendant files a timely notice of appeal with the authority head, and the time for filing motions for reconsideration under § 79.38 has expired, the ALJ shall forward the record of the proceeding to the authority head.

(d) A notice of appeal shall be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions.

(e) The representative for the Government may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief.

(f) There is no right to appear personally before the authority head.

(g) There is no right to appeal any interlocutory ruling by the ALJ.

(h) In reviewing the initial decision, the authority head shall not consider any objection that was not raised before the ALJ unless a demonstration is made of extraordinary circumstances causing the failure to raise the objection.

(i) If any party demonstrates to the satisfaction of the authority head that additional evidence not presented at such hearing is material and that there were reasonable grounds for the failure

to present such evidence at such hearing, the authority head shall remand the matter to the ALJ for consideration of such additional evidence.

(j) The authority head may affirm, reduce, reverse, compromise, remand, or settle any penalty or assessment determined by the ALJ in any initial decision.

(k) The authority head shall promptly serve each party to the appeal with a copy of the decision of the authority head and a statement describing the right of any person determined to be liable for a penalty or assessment to seek judicial review.

(l) Unless a petition for review is filed as provided in 31 U.S.C. 3805 after a defendant has exhausted all administrative remedies under this part and within 60 days after the date on which the authority head serves the defendant with a copy of the authority head's decision, a determination that a defendant is liable under § 79.3 is final and is not subject to judicial review.

§ 79.40 Stays ordered by the Department of Justice.

If at any time the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the authority head a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the authority head shall stay the process immediately. The authority head may order the process resumed only upon receipt of the written authorization of the Attorney General.

§ 79.41 Stay pending appeal.

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the authority head.

(b) No administrative stay is available following a final decision of the authority head.

§ 79.42 Judicial review.

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District

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Court of a final decision of the authority head imposing penalties or assessments under this part and specifies the procedures for such review.

§ 79.43 Collection of civil penalties and assessments.

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

§ 79.44 Right to administrative offset.

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under § 79.42 or § 79.43, or any amount agreed upon in a compromise or settlement under § 79.46, may be collected by administrative offset under 31 U.S.C. 3716, except that an administrative offset may not be made under this subsection against a refund of an overpayment of Federal taxes, then or later owing by the United States to the defendant.

§ 79.45 Deposit in Treasury of United States.

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in 31 U.S.C. 3806(g).

§ 79.46 Compromise or settlement.

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.

(c) The authority head has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during the pendency of any review under § 79.42 or during the pendency of any action to collect penalties and assessments under § 79.43.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under § 79.42 or of

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any action to recover penalties and assessments under 31 U.S.C. 3806.

(e) The investigating official may recommend settlement terms to the reviewing official, the authority head, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the authority head, or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

§ 79.47 Limitations.

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in § 79.8 within 6 years after the date on which such claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under § 79.10(b) shall be deemed a notice of hearing for purposes of this section.

(c) The statute of limitations may be extended by agreement of the parties.

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

Sec.

- 80.1 Purpose.
- 80.2 Application of this regulation.
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APPENDIX A TO PART 80—FEDERAL FINANCIAL ASSISTANCE TO WHICH THESE REGULATIONS APPLY

APPENDIX B TO PART 80—GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS

AUTHORITY: Sec. 602, 78 Stat. 252; 42 U.S.C. 2000d–1.

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§ 80.1 Purpose.

The purpose of this part is to effectuate the provisions of title VI of the Civil Rights Act of 1964 (hereafter referred to as the "Act") to the end 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 otherwise subjected to discrimination under any program or activity receiving Federal financial assistance from the Department of Health and Human Services.

(Sec. 601, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d))

[29 FR 16298, Dec. 4, 1964, as amended at 38 FR 17982, July 5, 1973]

§ 80.2 Application of this regulation.

This regulation applies to any program to which Federal financial assistance is authorized to be extended to a recipient under a law administered by the Department, including the Federal financial assistance listed in appendix A to this part. It applies to money paid, property transferred, or other Federal financial assistance extended after the effective date of the regulation pursuant to an application approved prior to such effective date. This regulation does not apply to (a) any Federal financial assistance by way of insurance or guaranty contracts, (b) money paid, property transferred, or other assistance extended before the effective date of this regulation, (c) the use of any assistance by any individual who is the ultimate beneficiary under any such program, or (d) any employment practice, under any such program, or any employer, employment agency, or labor organization, except to the extent described in § 80.3. The fact that a type of Federal assistance is not listed in appendix A to this part shall not mean, if title VI of the Act is otherwise applicable, that a program is not covered. Federal financial assistance under statutes now in force or hereinafter enacted may be added to this list by notice published in the FEDERAL REGISTER.

(Secs. 602, 604, Civil Rights Act of 1964, 78 Stat. 252, 253 (42 U.S.C. 2000d-1, 2000d-3))

[38 FR 17979, July 5, 1973, as amended at 70 FR 24318, May 9, 2005]

§ 80.3 Discrimination prohibited.

(a) *General.* 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 otherwise subjected to discrimination under any program to which this part applies.

(b) *Specific discriminatory actions prohibited.* (1) A recipient under any program to which this part applies may not, directly or through contractual or other arrangements, on ground of race, color, or national origin:

(i) Deny an individual any service, financial aid, or other benefit provided under the program;

(ii) Provide any service, financial aid, or other benefit to an individual which is different, or is provided in a different manner, from that provided to others under the program;

(iii) Subject an individual to segregation or separate treatment in any matter related to his receipt of any service, financial aid, or other benefit under the program;

(iv) Restrict an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program;

(v) Treat an individual differently from others in determining whether he satisfies any admission, enrollment, quota, eligibility, membership or other requirement or condition which individuals must meet in order to be provided any service, financial aid, or other benefit provided under the program;

(vi) Deny an individual an opportunity to participate in the program through the provision of services or otherwise or afford him an opportunity to do so which is different from that afforded others under the program (including the opportunity to participate in the program as an employee but only to the extent set forth in paragraph (c) of this section).

(vii) Deny a person the opportunity to participate as a member of a planning or advisory body which is an integral part of the program.

(2) A recipient, in determining the types of services, financial aid, or other benefits, or facilities which will be provided under any such program, or the

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class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, or the class of individuals to be afforded an opportunity to participate in any such program, may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin.

(3) In determining the site or location of a facilities, an applicant or recipient may not make selections with the effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination under any programs to which this regulation applies, on the ground of race, color, or national origin; or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the Act or this regulation.

(4) As used in this section, the services, financial aid, or other benefits provided under a program receiving Federal financial assistance shall be deemed to include any service, financial aid, or other benefits provided in or through a facility provided with the aid of Federal financial assistance.

(5) The enumeration of specific forms of prohibited discrimination in this paragraph and paragraph (c) of this section does not limit the generality of the prohibition in paragraph (a) of this section.

(6)(i) In administering a program regarding which the recipient has previously discriminated against persons on the ground of race, color, or national origin, the recipient must take affirmative action to overcome the effects of prior discrimination.

(ii) Even in the absence of such prior discrimination, a recipient in administering a program may take affirmative action to overcome the effects of conditions which resulted in limiting participation by persons of a particular race, color, or national origin.

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(c) *Employment practices.* (1) Where a primary objective of the Federal financial assistance to a program to which this regulation applies is to provide employment, a recipient may not (directly or through contractual or other arrangements) subject an individual to discrimination on the ground of race, color, or national origin in its employment practices under such program (including recruitment or recruitment advertising, employment, layoff or termination, upgrading, demotion, or transfer, rates of pay or other forms of compensation, and use of facilities), including programs where a primary objective of the Federal financial assistance is (i) to reduce the employment of such individuals or to help them through employment to meet subsistence needs, (ii) to assist such individuals through employment to meet expenses incident to the commencement or continuation of their education or training, (iii) to provide work experience which contributes to the education or training of such individuals, or (iv) to provide remunerative activity to such individuals who because of handicaps cannot be readily absorbed in the competitive labor market. The following, under existing laws, have one of the above objectives as a primary objective:

(a) Projects under the Public Works Acceleration Act, Pub. L. 87-658, 42 U.S.C. 2641-2643.

(b) Work-study under the Vocational Education Act of 1963, as amended, 20 U.S.C. 1371-1374.

(c) Programs assisted under laws listed in appendix A to this part as respects employment opportunities provided thereunder, or in facilities provided thereunder, which are limited, or for which preference is given, to students, fellows, or other persons in training for the same or related employments.

(d) Assistance to rehabilitation facilities under the Vocational Rehabilitation Act, 29 U.S.C. 32-34, 41a and 41b.

(2) The requirements applicable to construction employment under any such program shall be those specified in or pursuant to Part III of Executive Order 11246 or any Executive order which supersedes it.

(3) Where a primary objective of the Federal financial assistance is not to

provide employment, but discrimination on the ground of race, color, or national origin in the employment practices of the recipient or other persons subject to the regulation tends, on the ground of race, color, or national origin, to exclude individuals from participation in, to deny them the benefits of, or to subject them to discrimination under any program to which this regulation applies, the foregoing provisions of this paragraph (c) shall apply to the employment practices of the recipient or other persons subject to the regulation, to the extent necessary to assure equality of opportunity to, and nondiscriminatory treatment of, beneficiaries.

(d) *Indian Health and Cuban Refugee Services.* An individual shall not be deemed subjected to discrimination by reason of his exclusion from benefits limited by Federal law to individuals of a particular race, color, or national origin different from his.

(e) *Medical emergencies.* Notwithstanding the foregoing provisions of this section, a recipient of Federal financial assistance shall not be deemed to have failed to comply with paragraph (a) of this section if immediate provision of a service or other benefit to an individual is necessary to prevent his death or serious impairment of his health, and such service or other benefit cannot be provided except by or through a medical institution which refuses or fails to comply with paragraph (a) of this section.

(Secs. 601, 602, 604, Civil Rights Act of 1964, 78 Stat. 252, 253 (42 U.S.C. 2000d, 2000d-1, 2000d-3))

[29 FR 16298, Dec. 4, 1964, as amended at 38 FR 17979, 17982, July 5, 1973; 70 FR 24318, May 9, 2005]

§ 80.4 Assurances required.

(a) *General.* (1) Every application for Federal financial assistance to which this part applies, except an application to which paragraph (b) of this section applies, and every application for Federal financial assistance to provide a facility shall, as a condition to its approval and the extension of any Federal financial assistance pursuant to the application, contain or be accompanied by an assurance that the program will be conducted or the facility

operated in compliance with all requirements imposed by or pursuant to this part. In the case of an application for Federal financial assistance to provide real property or structures thereon, the assurance shall obligate the recipient, or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. In the case of personal property the assurance shall obligate the recipient for the period during which he retains ownership or possession of the property. In all other cases the assurance shall obligate the recipient for the period during which Federal financial assistance is extended pursuant to the application. The responsible Department official shall specify the form of the foregoing assurances in the program, and the extent to which like assurances will be required of subgrantees, contractors and subcontractors, transferees, successors in interest, and other participants in the program. Any such assurance shall include provisions which give the United States a right to seek its judicial enforcement.

(2) Where Federal financial assistance is provided in the form of a transfer of real property or interest therein from the Federal Government the instrument effecting or recording the transfer shall contain a covenant running with the land to assure nondiscrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. Where no transfer of property is involved but property is improved with Federal financial assistance, the recipient shall agree to include such a covenant to any subsequent transfer of the property. Where the property is obtained from the Federal Government, such covenant may also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant where, in the discretion of the responsible Department official,

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such a condition and right of reverter is appropriate to the statute under which the real property is obtained and to the nature of the grant and the grantee. In the event a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on such property for the purposes for which the property was transferred, the responsible Department official may agree, upon request of the transferee and if necessary to accomplish such financing, and upon such conditions as he deems appropriate, to forbear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

(b) *Continuing Federal financial assistance.* Every application by a State or a State agency for continuing Federal financial assistance to which this regulation applies (including the Federal financial assistance listed in part 2 of appendix A to this part) shall as a condition to its approval and the extension of any Federal financial assistance pursuant to the application (1) contain or be accompanied by a statement that the program is (or, in the case of a new program, will be) conducted in compliance with all requirements imposed by or pursuant to this regulation, and (2) provide or be accompanied by provision for such methods of administration for the program as are found by the responsible Department official to give reasonable assurance that the applicant and all recipients of Federal financial assistance under such program will comply with all requirements imposed by or pursuant to this regulation.

(c) *Elementary and secondary schools.* The requirements of paragraph (a) or (b) of this section with respect to any elementary or secondary school or school system shall be deemed to be satisfied if such school or school system (1) is subject to a final order of a court of the United States for the desegregation of such school or school system, and provides an assurance that it will comply with such order, including any future modification of such order, or (2) submits a plan for the desegregation of such school or school

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system which the responsible Department official determines is adequate to accomplish the purposes of the Act and this part, at the earliest practicable time, and provides reasonable assurance that it will carry out such plan; in any case of continuing Federal financial assistance the responsible Department official may reserve the right to redetermine, after such period as may be specified by him, the adequacy of the plan to accomplish the purposes of the Act and the regulations in this part. In any case in which a final order of a court of the United States for the desegregation of such school or school system is entered after submission of such a plan, such plan shall be revised to conform to such final order, including any future modification of such order.

(d) *Assurance from institutions.* (1) In the case of any application for Federal financial assistance to an institution of higher education (including assistance for construction, for research, for special training project, for student loans or for any other purpose), the assurance required by this section shall extend to admission practices and to all other practices relating to the treatment of students.

(2) The assurance required with respect to an institution of higher education, hospital, or any other institution, insofar as the assurance relates to the institution's practices with respect to admission or other treatment of individuals as students, patients, or clients of the institution or to the opportunity to participate in the provision of services or other benefits to such individuals, shall be applicable to the entire institution.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1); sec. 182, 80 Stat. 1209 (42 U.S.C. 2000d-5))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17980, 17982, July 5, 1973; 70 FR 24318, May 9, 2005]

§ 80.5 Illustrative application.

The following examples will illustrate the programs aided by Federal financial assistance of the Department. (In all cases the discrimination prohibited is discrimination on the ground of

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race, color, or national origin prohibited by Title VI of the Act and this regulation, as a condition of the receipt of Federal financial assistance).

(a) In federally assisted programs for the provision of health or welfare services, discrimination in the selection or eligibility of individuals to receive the services, and segregation or other discriminatory practices in the manner of providing them, are prohibited. This prohibition extends to all facilities and services provided by the grantee or, if the grantee is a State, by a political subdivision of the State. It extends also to services purchased or otherwise obtained by the grantee (or political subdivision) from hospitals, nursing homes, schools, and similar institutions for beneficiaries of the program, and to the facilities in which such services are provided, subject, however, to the provisions of § 80.3(e).

(b) In federally-affected area assistance (Pub. L. 815 and Pub. L. 874) for construction aid and for general support of the operation of elementary or secondary schools, or in more limited support to such schools such as for the acquisition of equipment, the provision of vocational education, or the provision of guidance and counseling services, discrimination by the recipient school district in any of its elementary or secondary schools in the admission of students, or in the treatment of its students in any aspect of the educational process, is prohibited. In this and the following illustrations the prohibition of discrimination in the treatment of students or other trainees includes the prohibition of discrimination among the students or trainees in the availability or use of any academic, dormitory, eating, recreational, or other facilities of the grantee or other recipient.

(c) In a research, training, demonstration, or other grant to a university for activities to be conducted in a graduate school, discrimination in the admission and treatment of students in the graduate school is prohibited, and the prohibition extends to the entire university.

(d) In a training grant to a hospital or other nonacademic institution, discrimination is prohibited in the selection of individuals to be trained and in

their treatment by the grantee during their training. In a research or demonstration grant to such an institution discrimination is prohibited with respect to any educational activity and any provision of medical or other services and any financial aid to individuals incident to the program.

(e) In grants to assist in the construction of facilities for the provision of health, educational or welfare services, assurances will be required that services will be provided without discrimination, to the same extent that discrimination would be prohibited as a condition of Federal operating grants for the support of such services. Thus, as a condition of grants for the construction of academic, research, or other facilities at institutions of higher education, assurances will be required that there will be no discrimination in the admission or treatment of students. In case of hospital construction grants the assurance will apply to patients, to interns, residents, student nurses, and other trainees, and to the privilege of physicians, dentists, and other professionally qualified persons to practice in the hospital, and will apply to the entire facility for which, or for a part of which, the grant is made, and to facilities operated in connection therewith.

(f) Upon transfers of real or personal surplus property for health or educational uses, discrimination is prohibited to the same extent as in the case of grants for the construction of facilities or the provision of equipment for like purposes.

(g) Each applicant for a grant for the construction of educational television facilities is required to provide an assurance that it will, in its broadcast services, give due consideration to the interests of all significant racial or ethnic groups within the population to be served by the applicant.

(h) A recipient may not take action that is calculated to bring about indirectly what this regulation forbids it to accomplish directly. Thus, a State, in selecting or approving projects or sites for the construction of public libraries which will receive Federal financial assistance, may not base its selections or approvals on criteria which

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have the effect of defeating or of substantially impairing accomplishments of the objectives of the Federal assistance as respects individuals of a particular race, color or national origin.

(i) In some situations, even though past discriminatory practices attributable to a recipient or applicant have been abandoned, the consequences of such practices continue to impede the full availability of a benefit. If the efforts required of the applicant or recipient under § 80.6(d), to provide information as to the availability of the program or activity and the rights of beneficiaries under this regulation, have failed to overcome these consequences, it will become necessary under the requirement stated in (i) of § 80.3(b) (6) for such applicant or recipient to take additional steps to make the benefits fully available to racial and nationality groups previously subject to discrimination. This action might take the form, for example, of special arrangements for obtaining referrals or making selections which will insure that groups previously subjected to discrimination are adequately served.

(j) Even though an applicant or recipient has never used discriminatory policies, the services and benefits of the program or activity it administers may not in fact be equally available to some racial or nationality groups. In such circumstances, an applicant or recipient may properly give special consideration to race, color, or national origin to make the benefits of its program more widely available to such groups, not then being adequately served. For example, where a university is not adequately serving members of a particular racial or nationality group, it may establish special recruitment policies to make its program better known and more readily available to such group, and take other steps to provide that group with more adequate service.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1))

[29 FR 16298, Dec. 4, 1964; 29 FR 16988, Dec. 11, 1964, as amended at 38 FR 17980, 17982, July 5, 1973; 70 FR 24318, May 9, 2005]

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§ 80.6 Compliance information.

(a) *Cooperation and assistance.* The responsible Department official shall to the fullest extent practicable seek the cooperation of recipients in obtaining compliance with this part and shall provide assistance and guidance to recipients to help them comply voluntarily with this part.

(b) *Compliance reports.* Each recipient shall keep such records and submit to the responsible Department official or his designee timely, complete and accurate compliance reports at such times, and in such form and containing such information, as the responsible Department official or his designee may determine to be necessary to enable him to ascertain whether the recipient has complied or is complying with this part. For example, recipients should have available for the Department racial and ethnic data showing the extent to which members of minority groups are beneficiaries of and participants in federally-assisted programs. In the case in which a primary recipient extends Federal financial assistance to any other recipient, such other recipient shall also submit such compliance reports to the primary recipient as may be necessary to enable the primary recipient to carry out its obligations under this part.

(c) *Access to sources of information.* Each recipient shall permit access by the responsible Department official or his designee during normal business hours to such of its books, records, accounts, and other sources of information, and its facilities as may be pertinent to ascertain compliance with this part. Where any information required of a recipient is in the exclusive possession of any other agency, institution or person and this agency, institution or person shall fail or refuse to furnish this information the recipient shall so certify in its report and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar the Department from evaluating or seeking to enforce compliance with this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary in formal enforcement

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proceedings or where otherwise required by law.

(d) *Information to beneficiaries and participants.* Each recipient shall make available to participants, beneficiaries, and other interested persons such information regarding the provisions of this regulation and its applicability to the program for which the recipient receives Federal financial assistance, and make such information available to them in such manner, as the responsible Department official finds necessary to apprise such persons of the protections against discrimination assured them by the Act and this regulation.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17981, 17982, July 5, 1973; 70 FR 24318, May 9, 2005]

§ 80.7 Conduct of investigations.

(a) *Periodic compliance reviews.* The responsible Department official or his designee shall from time to time review the practices of recipients to determine whether they are complying with this part.

(b) *Complaints.* Any person who believes himself or any specific class of individuals to be subjected to discrimination prohibited by this part may by himself or by a representative file with the responsible Department official or his designee a written complaint. A complaint must be filed not later than 180 days from the date of the alleged discrimination, unless the time for filing is extended by the responsible Department official or his designee.

(c) *Investigations.* The responsible Department official or his designee will make a prompt investigation whenever a compliance review, report, complaint, or any other information indicates a possible failure to comply with this part. The investigation should include, where appropriate, a review of the pertinent practices and policies of the recipient, the circumstances under which the possible noncompliance with this part occurred, and other factors relevant to a determination as to whether the recipient has failed to comply with this part.

(d) *Resolution of matters.* (1) If an investigation pursuant to paragraph (c)

of this section indicates a failure to comply with this part, the responsible Department official or his designee will so inform the recipient and the matter will be resolved by informal means whenever possible. If it has been determined that the matter cannot be resolved by informal means, action will be taken as provided for in § 80.8.

(2) If an investigation does not warrant action pursuant to paragraph (d)(1) of this section the responsible Department official or his designee will so inform the recipient and the complainant, if any, in writing.

(e) *Intimidatory or retaliatory acts prohibited.* No recipient or other person shall intimidate, threaten, coerce, or discriminate against any individual for the purpose of interfering with any right or privilege secured by section 601 of the Act or this part, or because he has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under this part. The identity of complainants shall be kept confidential except to the extent necessary to carry out the purposes of this part, including the conduct of any investigation, hearing, or judicial proceeding arising thereunder.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d, 2000d-1))

[29 FR 16298, Dec. 4, 1964, as amended at 38 FR 17981, 17982, July 5, 1973]

§ 80.8 Procedure for effecting compliance.

(a) *General.* If there appears to be a failure or threatened failure to comply with this regulation, and if the noncompliance or threatened noncompliance cannot be corrected by informal means, compliance with this part may be effected by the suspension or termination of or refusal to grant or to continue Federal financial assistance or by any other means authorized by law. Such other means may include, but are not limited to, (1) a reference to the Department of Justice with a recommendation that appropriate proceedings be brought to enforce any rights of the United States under any law of the United States (including other titles of the Act), or any assurance or other contractual undertaking,

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and (2) any applicable proceeding under State or local law.

(b) *Noncompliance with § 80.4.* If an applicant fails or refuses to furnish an assurance required under § 80.4 or otherwise fails or refuses to comply with a requirement imposed by or pursuant to that section Federal financial assistance may be refused in accordance with the procedures of paragraph (c) of this section. The Department shall not be required to provide assistance in such a case during the pendency of the administrative proceedings under such paragraph except that the Department shall continue assistance during the pendency of such proceedings where such assistance is due and payable pursuant to an application therefor approved prior to the effective date of this part.

(c) *Termination of or refusal to grant or to continue Federal financial assistance.* No order suspending, terminating or refusing to grant or continue Federal financial assistance shall become effective until (1) the responsible Department official has advised the applicant or recipient of his failure to comply and has determined that compliance cannot be secured by voluntary means, (2) there has been an express finding on the record, after opportunity for hearing, of a failure by the applicant or recipient to comply with a requirement imposed by or pursuant to this part, (3) the expiration of 30 days after the Secretary has filed with the committee of the House and the committee of the Senate having legislative jurisdiction over the program involved, a full written report of the circumstances and the grounds for such action. Any action to suspend or terminate or to refuse to grant or to continue Federal financial assistance shall be limited to the particular political entity, or part thereof, or other applicant or recipient as to whom such a finding has been made and shall be limited in its effect to the particular program, or part thereof, in which such noncompliance has been so found.

(d) *Other means authorized by law.* No action to effect compliance by any other means authorized by law shall be taken until (1) the responsible Department official has determined that compliance cannot be secured by voluntary

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means, (2) the recipient or other person has been notified of its failure to comply and of the action to be taken to effect compliance, and (3) the expiration of at least 10 days from the mailing of such notice to the recipient or other person. During this period of at least 10 days additional efforts shall be made to persuade the recipient or other person to comply with the regulation and to take such corrective action as may be appropriate.

(Secs. 601, 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d-1; sec. 182, 80 Stat. 1209; (42 U.S.C. 2000d-5))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14556, Oct. 19, 1967; 38 FR 17982, July 5, 1973]

§ 80.9 Hearings.

(a) *Opportunity for hearing.* Whenever an opportunity for a hearing is required by § 80.8(c), reasonable notice shall be given by registered or certified mail, return receipt requested, to the affected applicant or recipient. This notice shall advise the applicant or recipient of the action proposed to be taken, the specific provision under which the proposed action against it is to be taken, and the matters of fact or law asserted as the basis for this action, and either (1) fix a date not less than 20 days after the date of such notice within which the applicant or recipient may request of the responsible Department official that the matter be scheduled for hearing or (2) advise the applicant or recipient that the matter in question has been set down for hearing at a stated place and time. The time and place so fixed shall be reasonable and shall be subject to change for cause. The complainant, if any, shall be advised of the time and place of the hearing. An applicant or recipient may waive a hearing and submit written information and argument for the record. The failure of an applicant or recipient to request a hearing for which a date has been set shall be deemed to be a waiver of the right to a hearing under section 602 of the Act and § 80.8(c) of this regulation and consent to the making of a decision on the basis of such information as may be filed as the record.

(b) *Time and place of hearing.* Hearings shall be held at the offices of the

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Department in Washington, DC, at a time fixed by the responsible Department official unless he determines that the convenience of the applicant or recipient or of the Department requires that another place be selected. Hearings shall be held before a hearing examiner designated in accordance with 5 U.S.C. 3105 and 3344 (section 11 of the Administrative Procedure Act).

(c) *Right to counsel.* In all proceedings under this section, the applicant or recipient and the Department shall have the right to be represented by counsel.

(d) *Procedures, evidence, and record.* (1) The hearing, decision, and any administrative review thereof shall be conducted in conformity with sections 5-8 of the Administrative Procedure Act, and in accordance with such rules of procedure as are proper (and not inconsistent with this section) relating to the conduct of the hearing, giving of notices subsequent to those provided for in paragraph (a) of this section, taking of testimony, exhibits, arguments and briefs, requests for findings, and other related matters. Both the Department and the applicant or recipient shall be entitled to introduce all relevant evidence on the issues as stated in the notice for hearing or as determined by the officer conducting the hearing at the outset of or during the hearing. Any person (other than a Government employee considered to be on official business) who, having been invited or requested to appear and testify as a witness on the Government's behalf, attends at a time and place scheduled for a hearing provided for by this part, may be reimbursed for his travel and actual expenses of attendance in an amount not to exceed the amount payable under the standardized travel regulations to a Government employee traveling on official business.

(2) Technical rules of evidence shall not apply to hearings conducted pursuant to this part, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied where reasonably necessary by the officer conducting the hearing. The hearing officer may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered

or taken for the record shall be open to examination by the parties and opportunity shall be given to refute facts and arguments advanced on either side of the issues. A transcript shall be made of the oral evidence except to the extent the substance thereof is stipulated for the record. All decisions shall be based upon the hearing record and written findings shall be made.

(e) *Consolidated or Joint Hearings.* In cases in which the same or related facts are asserted to constitute noncompliance with this regulation with respect to two or more Federal statutes, authorities, or other means by which Federal financial assistance is extended, to which this part applies, or noncompliance with this part and the regulations of one or more other Federal departments or agencies issued under Title VI of the Act, the responsible Department official may, by agreement with such other departments or agencies where applicable, provide for the conduct of consolidated or joint hearings, and for the application to such hearings of rules of procedures not inconsistent with this part. Final decisions in such cases, insofar as this regulation is concerned, shall be made in accordance with § 80.10.

(Sec. 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d-1))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17981, 17982, July 5, 1973; 70 FR 24318, May 9, 2005]

§ 80.10 Decisions and notices.

(a) *Decisions by hearing examiners.* After a hearing is held by a hearing examiner such hearing examiner shall either make an initial decision, if so authorized, or certify the entire record including his recommended findings and proposed decision to the reviewing authority for a final decision, and a copy of such initial decision or certification shall be mailed to the applicant or recipient and to the complainant, if any. Where the initial decision referred to in this paragraph or in paragraph (c) of this section is made by the hearing examiner, the applicant or recipient or the counsel for the Department may, within the period provided for in the rules of procedure issued by the responsible Department official, file with the reviewing authority exceptions to the

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initial decision, with his reasons therefor. Upon the filing of such exceptions the reviewing authority shall review the initial decision and issue its own decision thereof including the reasons therefor. In the absence of exceptions the initial decision shall constitute the final decision, subject to the provisions of paragraph (e) of this section.

(b) *Decisions on record or review by the reviewing authority.* Whenever a record is certified to the reviewing authority for decision or it reviews the decision of a hearing examiner pursuant to paragraph (a) or (c) of this section, the applicant or recipient shall be given reasonable opportunity to file with it briefs or other written statements of its contentions, and a copy of the final decision of the reviewing authority shall be given in writing to the applicant or recipient and to the complainant, if any.

(c) *Decisions on record where a hearing is waived.* Whenever a hearing is waived pursuant to § 80.9(a) the reviewing authority shall make its final decision on the record or refer the matter to a hearing examiner for an initial decision to be made on the record. A copy of such decision shall be given in writing to the applicant or recipient, and to the complainant, if any.

(d) *Rulings required.* Each decision of a hearing examiner or reviewing authority shall set forth a ruling on each finding, conclusion, or exception presented, and shall identify the requirement or requirements imposed by or pursuant to this part with which it is found that the applicant or recipient has failed to comply.

(e) *Review in certain cases by the Secretary.* If the Secretary has not personally made the final decision referred to in paragraph (a), (b), or (c) of this section, a recipient or applicant or the counsel for the Department may request the Secretary to review a decision of the Reviewing Authority in accordance with rules of procedure issued by the responsible Department official. Such review is not a matter of right and shall be granted only where the Secretary determines there are special and important reasons therefor. The Secretary may grant or deny such request, in whole or in part. He may also review such a decision upon his own

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motion in accordance with rules of procedure issued by the responsible Department official. In the absence of a review under this paragraph, a final decision referred to in paragraphs (a), (b), and (c) of this section shall become the final decision of the Department when the Secretary transmits it as such to Congressional committees with the report required under section 602 of the Act. Failure of an applicant or recipient to file an exception with the Reviewing Authority or to request review under this paragraph shall not be deemed a failure to exhaust administrative remedies for the purpose of obtaining judicial review.

(f) *Content of orders.* The final decision may provide for suspension or termination of, or refusal to grant or continue Federal financial assistance, in whole or in part, to which this regulation applies, and may contain such terms, conditions, and other provisions as are consistent with and will effectuate the purposes of the Act and this regulation, including provisions designed to assure that no Federal financial assistance to which this regulation applies will thereafter be extended under such law or laws to the applicant or recipient determined by such decision to be in default in its performance of an assurance given by it pursuant to this regulation, or to have otherwise failed to comply with this regulation unless and until it corrects its non-compliance and satisfies the responsible Department official that it will fully comply with this regulation.

(g) *Post-termination proceedings.* (1) An applicant or recipient adversely affected by an order issued under paragraph (f) of this section shall be restored to full eligibility to receive Federal financial assistance if it satisfies the terms and conditions of that order for such eligibility or if it brings itself into compliance with this part and provides reasonable assurance that it will fully comply with this part. An elementary or secondary school or school system which is unable to file an assurance of compliance with § 80.3 shall be restored to full eligibility to receive Federal financial assistance, if it files a court order or a plan for desegregation which meets the requirements of

§ 80.4(c), and provides reasonable assurance that it will comply with the court order or plan.

(2) Any applicant or recipient adversely affected by an order entered pursuant to paragraph (f) of this section may at any time request the responsible Department official to restore fully its eligibility to receive Federal financial assistance. Any such request shall be supported by information showing that the applicant or recipient has met the requirements of paragraph (g)(1) of this section. If the responsible Department official determines that those requirements have been satisfied, he shall restore such eligibility.

(3) If the responsible Department official denies any such request, the applicant or recipient may submit a request for a hearing in writing, specifying why it believes such official to have been in error. It shall thereupon be given an expeditious hearing, with a decision on the record, in accordance with rules of procedure issued by the responsible Department official. The applicant or recipient will be restored to such eligibility if it proves at such hearing that it satisfied the requirements of paragraph (g)(1) of this section. While proceedings under this paragraph are pending, the sanctions imposed by the order issued under paragraph (f) of this section shall remain in effect.

(Sec. 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d-1))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17981, 17982, July 5, 1973]

§ 80.11 Judicial review.

Action taken pursuant to section 602 of the Act is subject to judicial review as provided in section 603 of the Act.

(Sec. 603, 78 Stat. 253, (42 U.S.C. 2000d-2))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14556, Oct. 19, 1967]

§ 80.12 Effect on other regulations; forms and instructions.

(a) *Effect on other regulations.* All regulations, orders, or like directions heretofore issued by any officer of the Department which impose requirements designed to prohibit any dis-

crimination against individuals on the ground of race, color, or national origin under any program to which this regulation applies, and which authorize the suspension or termination of or refusal to grant or to continue Federal financial assistance to any applicant for or recipient of assistance for failure to comply with such requirements, are hereby superseded to the extent that such discrimination is prohibited by this regulation, except that nothing in this regulation shall be deemed to relieve any person of any obligation assumed or imposed under any such superseded regulation, order, instruction, or like direction prior to the effective date of this regulation. Nothing in this regulation, however, shall be deemed to supersede any of the following (including future amendments thereof): (1) The "Standards for a Merit System of Personnel Administration," issued jointly by the Secretaries of Defense, of Health and Human Services, and of Labor, 45 CFR part 70; (2) Executive Order 11063 and regulations issued thereunder, or any other regulations or instructions, insofar as such Order, regulations, or instructions prohibit discrimination on the ground of race, color, or national origin in any program or situation to which this regulation is inapplicable, or prohibit discrimination on any other ground; or (3) requirements for Emergency School Assistance as published in 35 FR 13442 and codified as 45 CFR part 181.

(b) *Forms and instructions.* The responsible Department official shall issue and promptly make available to interested persons forms and detailed instructions and procedures for effectuating this part.

(c) *Supervision and coordination.* The responsible Department official may from time to time assign to officials of the Department, or to officials of other departments or agencies of the Government with the consent of such departments or agencies, responsibilities in connection with the effectuation of the purposes of Title VI of the Act and this regulation (other than responsibility for review as provided in § 80.10(e)), including the achievements of effective coordination and maximum uniformity within the Department and within the Executive Branch of the Government

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in the application of Title VI and this regulation to similar programs and in similar situations. Any action taken, determination made, or requirement imposed by an official of another Department or Agency acting pursuant to an assignment of responsibility under this subsection shall have the same effect as though such action had been taken by the responsible official of this Department.

(Sec. 602, Civil Rights Act of 1964, 78 Stat. 252 (42 U.S.C. 2000d-10))

[29 FR 16298, Dec. 4, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17981, 17982, July 5, 1973]

§ 80.13 Definitions.

As used in this part—

(a) The term *Department* means the Department of Health and Human Services, and includes each of its operating agencies and other organizational units.

(b) The term *Secretary* means the Secretary of Health and Human Services.

(c) The term *responsible Department official* means the Secretary or, to the extent of any delegation by the Secretary of authority to act in his stead under any one or more provisions of this part, any person or persons to whom the Secretary has heretofore delegated, or to whom the Secretary may hereafter delegate such authority.

(d) The term *reviewing authority* means the Secretary, or any person or persons (including a board or other body specially created for that purpose and also including the responsible Department official) acting pursuant to authority delegated by the Secretary to carry out responsibilities under § 80.10 (a) through (d).

(e) The term *United States* means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, and the territories and possessions of the United States, and the term *State* means any one of the foregoing.

(f) The term *Federal financial assistance* includes (1) grants and loans of Federal funds, (2) the grant or donation of Federal property and interests in property, (3) the detail of Federal personnel, (4) the sale and lease of, and the permission to use (on other than a cas-

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ual or transient basis), Federal property or any interest in such property without consideration or at a nominal consideration, or at a consideration which is reduced for the purpose of assisting the recipient, or in recognition of the public interest to be served by such sale or lease to the recipient, and (5) any Federal agreement, arrangement, or other contract which has as one of its purposes the provision of assistance.

(g) The term *program or activity* and the term *program* mean all of the operations of—

(1)(i) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(ii) The entity of such State or local government that distributes Federal financial assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(2)(i) A college, university, or other postsecondary institution, or a public system of higher education; or

(ii) A local educational agency (as defined in 20 U.S.C. 7801), system of vocational education, or other school system;

(3)(i) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(A) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(B) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(ii) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(4) Any other entity which is established by two or more of the entities described in paragraph (g)(1), (g)(2), or (g)(3) of this section; any part of which is extended Federal financial assistance.

(h) The term *facility* includes all or any portion of structures, equipment,

or other real or personal property or interests therein, and the provision of facilities includes the construction, expansion, renovation, remodeling, alteration or acquisition of facilities.

(i) The term *recipient* means any State, political subdivision of any State, or instrumentality of any State or political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, in any State, to whom Federal financial assistance is extended, directly or through another recipient, including any successor, assign, or transferee thereof, but such term does not include any ultimate beneficiary.

(j) The term *primary recipient* means any recipient which is authorized or required to extend Federal financial assistance to another recipient.

(k) The term *applicant* means one who submits an application, request, or plan required to be approved by a Department official, or by a primary recipient, as a condition to eligibility for Federal financial assistance, and the term *application* means such an application, request, or plan.

(Secs. 602, 606, Civil Rights Act of 1964, (42 U.S.C. 2000d-1, 2000d-4a))

[29 FR 16298, Dec. 4, 1964; 29 FR 16988, Dec. 11, 1964, as amended at 32 FR 14555, Oct. 19, 1967; 38 FR 17982, July 5, 1973; 70 FR 24318, May 9, 2005]

APPENDIX A TO PART 80—FEDERAL FINANCIAL ASSISTANCE TO WHICH THESE REGULATIONS APPLY

Part 1. Assistance other than Continuing Assistance to States

1. Loans for acquisition of equipment for academic subjects, and for minor remodeling (20 U.S.C. 445).

2. Construction of facilities for institutions of higher education (20 U.S.C. 701-758).

3. School Construction in federally-affected and in major disaster areas (20 U.S.C. 631-647).

4. Construction of educational broadcast facilities (47 U.S.C. 390-399).

5. Loan service of captioned films and educational media; research on, and production and distribution of, educational media for the handicapped, and training of persons in the use of such media for the handicapped (20 U.S.C. 1452).

6. Demonstration residential vocational education schools (20 U.S.C. 1321).

7. Research and related activities in education of handicapped children (20 U.S.C. 1441).

8. Educational research, dissemination and demonstration projects; research training; and construction under the Cooperation Research Act (20 U.S.C. 331-332(b)).

9. Research in teaching modern foreign languages (20 U.S.C. 512).

10. Training projects for manpower development and training (42 U.S.C. 2601, 2602, 2610a-2610c).

11. Research and training projects in Vocational Education (20 U.S.C. 1281(a), 1282-1284).

12. Allowances to institutions training NDEA graduate fellows (20 U.S.C. 461-465).

13. Grants for training in librarianship (20 U.S.C. 1031-1033).

14. Grants for training personnel for the education of handicapped children (20 U.S.C. 1431).

15. Allowances for institutions training teachers and related educational personnel in elementary and secondary education, or post-secondary vocational education (20 U.S.C. 1111-1118).

16. Recruitment, enrollment, training and assignment of Teacher Corps personnel (20 U.S.C. 1101-1107a).

17. Operation and maintenance of schools in Federally-affected and in major disaster areas (20 U.S.C. 236-241; 241-1; 242-244).

18. Grants or contracts for the operation of training institutes for elementary or secondary school personnel to deal with special educational problems occasioned by desegregation (42 U.S.C. 2000c-3).

19. Grants for in-service training of teachers and other schools personnel and employment of specialists in desegregation problems (42 U.S.C. 2000c-4).

20. Higher education students loan program (Title II, National Defense Education Act, 20 U.S.C. 421-429).

21. Educational Opportunity grants and assistance for State and private programs of low-interest insured loans and State loans to students in institutions of higher education (Title IV, Higher Education Act of 1965, 20 U.S.C. 1061-1087).

22. Grants and contracts for the conduct of Talent Search, Upward Bound, and Special Services Programs (20 U.S.C. 1068).

23. Land-grant college aid (7 U.S.C. 301-308; 321-326; 328-331).

24. Language and area centers (Title VI, National Defense Education Act, 20 U.S.C. 511).

25. American Printing House for the Blind (20 U.S.C. 101-105).

26. Future Farmers of America (36 U.S.C. 271-391) and similar programs.

27. Science clubs (Pub. L. 85-875, 20 U.S.C. 2, note).

28. Howard University (20 U.S.C. 121-129).

29. Gallaudet College (31 D.C. Code, Ch. 10).

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30. Establishment and operation of a model secondary school for the deaf by Gallaudet College (31 D.C. Code 1051-1053; 80 Stat. 1027-1028).

31. Faculty development programs, workshops and institutes (20 U.S.C. 1131-1132).

32. National Technical Institute for the Deaf (20 U.S.C. 681-685).

33. Institutes and other programs for training educational personnel (Parts D, E, and F, Title V, Higher Education Act of 1965) (20 U.S.C. 1119-1119c-4).

34. Grants and contracts for research and demonstration projects in librarianship (20 U.S.C. 1034).

35. Acquisition of college library resources (20 U.S.C. 1021-1028).

36. Grants for strengthening developing institutions of higher education (20 U.S.C. 1051-1054); National Fellowships for teaching at developing institutions (20 U.S.C. 1055), and grants to retired professors to teach at developing institutions (20 U.S.C. 1056).

37. College Work-Study Program (42 U.S.C. 2751-2757).

38. Financial assistance for acquisition of higher education equipment, and minor remodeling (20 U.S.C. 1121-1129).

39. Grants for special experimental demonstration projects and teacher training in adult education (20 U.S.C. 1208).

40. Grant programs for advanced and undergraduate international studies (20 U.S.C. 1171-1176; 22 U.S.C. 2452(b)).

41. Experimental projects for developing State leadership or establishment of special services (20 U.S.C. 865).

42. Grants to and arrangements with State educational and other agencies to meet special educational needs of migratory children of migratory agricultural workers (20 U.S.C. 241e(c)).

43. Grants by the Commissioner of Education to local educational agencies for supplementary educational centers and services; guidance, counseling, and testing (20 U.S.C. 841-844; 844b).

44. Resource centers for improvement of education of handicapped children (20 U.S.C. 1421) and centers and services for deaf-blind children (20 U.S.C. 1422).

45. Recruitment of personnel and dissemination of information on education of handicapped (20 U.S.C. 1433).

46. Grants for research and demonstrations relating to physical education or recreation for handicapped children (20 U.S.C. 1442) and training of physical educators and recreation personnel (20 U.S.C. 1434).

47. Dropout prevention projects (20 U.S.C. 887).

48. Bilingual education programs (20 U.S.C. 880b-880b-6).

49. Grants to agencies and organizations for Cuban refugees (22 U.S.C. 2601(b)(4)).

50. Grants and contracts for special programs for children with specific learning dis-

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abilities including research and related activities, training and operating model centers (20 U.S.C. 1461).

51. Curriculum development in vocational and technical education (20 U.S.C. 1391).

52. Establishment, including construction, and operation of a National Center on Educational Media and Materials for the Handicapped (20 U.S.C. 1453).

53. Grants and contracts for the development and operation of experimental preschool and early education programs for handicapped (20 U.S.C. 1423).

54. Grants to public or private non-profit agencies to carry on the Follow Through Program in kindergarten and elementary schools (42 U.S.C. 2809 (a)(2)).

55. Grants for programs of cooperative education and grants and contracts for training and research in cooperative education (20 U.S.C. 1087a-1087c).

56. Grants and contracts to encourage the sharing of college facilities and resources (network for knowledge) (20 U.S.C. 1133-1133b).

57. Grants, contracts, and fellowships to improve programs preparing persons for public service and to attract students to public service (20 U.S.C. 1134-1134b).

58. Grants for the improvement of graduate programs (20 U.S.C. 1135-1135c).

59. Contracts for expanding and improving law school clinical experience programs (20 U.S.C. 1136-1136b).

60. Exemplary programs and projects in vocational education (20 U.S.C. 1301-1305).

61. Grants to reduce borrowing cost for construction of residential schools and dormitories (20 U.S.C. 1323).

62. Project grants and contracts for research and demonstration relating to new or improved health facilities and services (section 304, PHS Act, 42 U.S.C. 242b).

63. Grants for construction or modernization of emergency rooms of general hospitals (Title VI, Part C, PHS Act, 42 U.S.C. 291j).

64. Institutional and special projects grants to schools of nursing (sections 805-808, PHS Act, 42 U.S.C. 296d-296g).

65. Grants for construction and initial staffing of facilities for prevention and treatment of alcoholism (section 241-2, Community Mental Health Centers Act (42 U.S.C. 2688 f and g)).

66. Grants for construction and initial staffing of specialized facilities for the treatment of alcoholics requiring care in such facilities (section 243, Community Mental Health Centers Act, 42 U.S.C. 2688h).

67. Special project grants for training programs, evaluation of existing treatment programs, and conduct of significant programs relating to treatment of alcoholics (section 246, Community Mental Health Centers Act, 42 U.S.C. 2688j-1).

68. Grants for construction and initial staff of treatment facilities for narcotic addicts

(section 251, Community Mental Health Centers Act, 42 U.S.C. 2688m).

69. Special project grants for training programs, evaluation of existing treatment programs, and conduct of significant programs relating to treatment of narcotics addicts (section 252, Community Mental Health Centers Act, 42 U.S.C. 2688n-1).

70. Grants for consultation services for Community Mental Health Centers, alcoholism prevention and treatment facilities for narcotic addicts, and facilities for mental health of children (section 264, Community Mental Health Centers Act, 42 U.S.C. 2688r).

71. Grants for construction and initial staff of facilities for mental health of children (section 271, Community Mental Health Centers Act, 42 U.S.C. 2688u).

72. Special project grants for training programs and evaluation of existing treatment program relating to mental health of children (section 272, Community Mental Health Centers Act, 42 U.S.C. 2688x).

73. Grants and loans for construction and modernization of medical facilities in the District of Columbia (Pub. L. 90-457; 82 Stat. 631-3).

74. Teaching facilities for nurse training (sections. 801-804, Public Health Service Act, 42 U.S.C. 296-296c).

75. Teaching facilities for allied health professions personnel (section 791, Public Health Service Act, 42 U.S.C. 295h).

76. Mental retardation research facilities (Title VI, Part D, Public Health Service Act, 42 U.S.C. 295-395e).

77. George Washington University Hospital construction (76 Stat. 83, Pub. L. 87-460, May 31, 1962).

78. Research projects, including conferences, communication activities and prime or other center grants (sections 301, 303, 304, and 308, Public Health Service Act, 42 U.S.C. 241, 242a, 242b, and 242f).

79. General research support (section 301(d), Public Health Service Act, 42 U.S.C. 241).

80. Mental Health demonstrations and administrative studies (section 303(a)(2), Public Health Service Act, 42 U.S.C. 242a).

81. Migratory workers health services (section 310, Public Health Service Act, 42 U.S.C. 242h).

82. Immunization programs (section 317, Public Health Service Act, 42 U.S.C. 247b).

83. Health research training projects and fellowship grants (sections 301, 433, Public Health Service Act, 42 U.S.C. 242, 289c).

84. Categorical (heart, cancer, etc.) grants for training, traineeships or fellowships (sections 303, 433, etc., Public Health Service Act, 42 U.S.C. 242a, 289c, etc.).

85. Advanced professional nurse traineeships (section 821, Public Health Service Act, 42 U.S.C. 297).

86. Department projects under Appalachian Regional Development Act (40 U.S.C. App. A).

87. Grants to institutions for traineeships for professional public health personnel (section 306, Public Health Service Act, 42 U.S.C. 242d).

88. Grants for graduate or specialized training in public health (section 309, Public Health Service Act, 42 U.S.C. 242g).

89. Health professions school student loan program (Title VII, Part C, Public Health Service Act, 42 U.S.C. 294-294(k)).

90. Grants for provision in schools of public health of training, consultation and technical assistance in the field of public health and in the administration of state or local public health programs (section 309(c), Public Health Service Act, 42 U.S.C. 242(g)(c)).

91. Project grants for training, studies, or demonstrations looking metropolitan area, or other local area plans for health services (section 314(c), Public Health Service Act, 42 U.S.C. 246(c)).

92. Project grants for training, studies, or demonstrations looking toward the development of improved comprehensive health planning (section 314(c), Public Health Service Act, 42 U.S.C. 246(c)).

93. Project grants for health services development (section 314(e), Public Health Service Act, 42 U.S.C. 246(e)).

94. Institutional and special grants to health professions schools (Title VII, Part E, Public Health Service Act, 42 U.S.C. 295f-295f-4).

95. Improvement grants to centers for allied health professions (section 792, Public Health Service Act, 42 U.S.C. 295h-1).

96. Scholarship grants to health professions schools (Title VII, Part F, Public Health Service Act, 42 U.S.C. 295h-1).

97. Scholarship grants to schools of nursing (Title VIII, Part D, Public Health Service Act, 42 U.S.C. 198c-298c-6).

98. Traineeships for advanced training of allied health professions personnel (section 793, Public Health Service Act, 42 U.S.C. 295h-2).

99. Contracts to encourage full utilization of nursing educational talent (section 868, Public Health Service Act, 42 U.S.C. 298c-7).

100. Grants to community mental health centers for the compensation of professional and technical personnel for the initial operation of new centers or of new services in centers (Community Mental Health Centers Act, Part B, 42 U.S.C. 2688-2688d).

101. Grants for the planning, construction, equipment and operation of multicounty demonstration health projects in the Appalachian region (section 202 of Appalachian Regional Development Act, Pub. L. 89-4, as amended, Pub. L. 90-103 40 U.S.C. App. 202).

102. Education, research, training, and demonstrations in the fields of heart disease, cancer, stroke and related diseases (sections

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900–110, Public Health Service Act, 42 U.S.C. 299a–j).

103. Assistance to medical libraries (sections 390–399, Public Health Service Act, 42 U.S.C. 280b–280b–9).

104. Nursing student loans (sections 822–828, Public Health Service Act, 42 U.S.C. 297a–g).

105. Hawaii leprosy payments (section 331, Public Health Service Act, 42 U.S.C. 255).

106. Heart disease laboratories and related facilities for patient care (section 412(d), Public Health Service Act, 42 U.S.C. 287a(d)).

107. Grants for construction of hospitals serving Indians (Pub. L. 85–151, 42 U.S.C. 2005).

108. Indian Sanitation Facilities (Pub. L. 86–121, 42 U.S.C. 2004a).

109. Research projects relating to maternal and child health services and crippled children's services (42 U.S.C. 712).

110. Maternal and child health special project grants to State agencies and institutions of higher learning (42 U.S.C. 703(s)).

111. Maternity and infant care and family planning services; special project grants to local health agencies and other organizations (42 U.S.C. 708).

112. Special project grants to State agencies and institutions of higher learning for crippled children's services (42 U.S.C. 704(2)).

113. Special project grants for health of school and preschool children (42 U.S.C. 709) and for dental health of children (42 U.S.C. 710).

114. Grants to institutions of higher learning for training personnel for health care and related services for mothers and children (42 U.S.C. 711).

115. Grants and contracts for the conduct of research, experiments, or demonstrations relating to the developments, utilization, quality, organization, and financing of services, facilities, and resources of hospitals, long-term care facilities, for other medical facilities (section 304, Public Health Service Act, as amended by Pub. L. 90–174, 42 U.S.C. 242b).

116. Health research facilities (Title VII Part A, Public Health Service Act, 42 U.S.C. 292–292j).

117. Teaching facilities for health professions personnel (Title VII, Part B, Public Health Service Act, 42 U.S.C. 293–293h).

118. Project grants and contracts for research, development, training, and studies in the field of electronic product radiation (section 356, Public Health Service Act, 42 U.S.C. 263d).

119. Project grants and contracts for research, studies, demonstrations, training, and education relating to coal mine health (section 501, Federal Coal Mine Health and Safety Act of 1969, Public Law 91–173).

120. Surplus real and related personal property disposal (40 U.S.C. 484(k)).

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121. Supplementary medical insurance benefits for the aged (Title XVIII, Part A, Social Security Act, 42 U.S.C. 1395c–1395i–2).

122. Issuance of rent-free permits for vending stands, credit unions, employee associations, etc. (20 U.S.C. 107–107f; 45 CFR Part 20; section 25, 12 U.S.C. 1170).

123. Grants for special vocational rehabilitation projects (29 U.S.C. 34(a)(1)).

124. Experimental, pilot or demonstration projects to promote the objectives of Title I, X, XIV, XVI, or XIX or Part A of Title IV of the Social Security Act (42 U.S.C. 1315).

125. Social Security and welfare cooperative research or demonstration projects (42 U.S.C. 1310).

126. Child welfare research, training, or demonstration projects (42 U.S.C. 626).

127. Training projects (Title VI, Older Americans Act, 42 U.S.C. 3041–3042).

128. Grants for expansion of vocational rehabilitation services (29 U.S.C. 34(a)(2)(A)).

129. Grants for construction of rehabilitation facilities (29 U.S.C. 41a(a)–(e)) and for initial staffing of rehabilitation facilities (29 U.S.C. 41a(f)).

130. Project development grants for rehabilitation facilities (29 U.S.C. 41a(g)(2)).

131. Rehabilitation Facility improvement grants (29 U.S.C. 41b(b)).

132. Agreement for the establishment and operation of a national center for deaf-blind youths and adults (29 U.S.C. 42a).

133. Project grants for services for migratory agricultural workers (29 U.S.C. 42b).

134. Grants for initial staffing of community mental retardation facilities (42 U.S.C. 2678–2678d).

135. Grants for training welfare personnel and for expansion and development of undergraduate and graduate social work programs (42 U.S.C. 906, 908).

136. Research and development projects concerning older Americans (42 U.S.C. 3031–3032).

137. Grants to States for training of nursing home administrators (42 U.S.C. 1396g (e)).

138. Contracts or jointly financed cooperative arrangements with industry (29 U.S.C. 34(a)(2)(B)).

139. Project grants for new careers in rehabilitation (29 U.S.C. 34(a)(2)(C)).

140. Children of low-income families (20 U.S.C. 241a–241m).

141. Grants for training (29 U.S.C. 37(a)(2)).

142. Grants for projects for training services (29 U.S.C. 41b(a)).

143. Grants for comprehensive juvenile delinquency planning (42 U.S.C. 3811).

144. Grants for project planning in juvenile delinquency (42 U.S.C. 3812).

145. Grants for juvenile delinquency rehabilitative services projects (42 U.S.C. 3822, 3842).

146. Grants for juvenile delinquency preventive service projects (42 U.S.C. 3861).

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147. Grants for training projects in juvenile delinquency fields (42 U.S.C. 3861).

148. Grants for development of improved techniques and practices in juvenile delinquency services (42 U.S.C. 3871).

149. Grants for technical assistance in juvenile delinquency services (42 U.S.C. 3872).

150. Grants for State technical assistance to local units in juvenile delinquency services (42 U.S.C. 3873).

151. Grants for public service centers projects (42 U.S.C. 2744).

152. Grants to public or private non-profit agencies to carry on the Project Headstart Program (42 U.S.C. 2809(a)(1)).

153. Project grants for new careers for the handicapped (29 U.S.C. 34(a)(2)(D)).

154. Construction, demonstration, and training grants for university-affiliated facilities for persons with developmental disabilities (42 U.S.C. 2661-2666).

155. Supplementary medical insurance benefits for the aged (Title XVIII, Part B, Social Security Act, 42 U.S.C. 1395j-1395w-6).

Part 2. Continuing Assistance to State

1. Grants to States for public library services and construction, interlibrary cooperation and specialized State library services for certain State institutions and the physically handicapped (20 U.S.C. 351-355).

2. Grants to States for strengthening instruction in academic subjects (20 U.S.C. 441-444).

3. Grants to States for vocational education (20 U.S.C. 1241-1264).

4. Arrangements with State education agencies for training under the Manpower Development and Training Act (42 U.S.C. 2601-2602, 2610a).

5. Grants to States to assist in the elementary and secondary education of children of low-income families (20 U.S.C. 241a-241m).

6. Grants to States to provide for school library resources, textbooks and other instructional materials for pupils and teachers in elementary and secondary schools (20 U.S.C. 821-827).

7. Grants to States to strengthen State departments of education (20 U.S.C. 861-870).

8. Grants to States for community service programs (20 U.S.C. 1001-1011).

9. Grants to States for adult basic education and related research, teacher training and special projects (20 U.S.C. 1201-1211).

10. Grants to State educational agencies for supplementary educational centers and services, and guidance, counseling and testing (20 U.S.C. 841-847).

11. Grants to States for research and training in vocational education (20 U.S.C. 1281(b)).

12. Grants to States for exemplary programs and projects in vocational education (20 U.S.C. 1301-1305).

13. Grants to States for residential vocational education schools (20 U.S.C. 1321).

14. Grants to States for consumer and homemaking education (20 U.S.C. 1341).

15. Grants to States for cooperative vocational educational program (20 U.S.C. 1351-1355).

16. Grants to States for vocational workstudy programs (20 U.S.C. 1371-1374).

17. Grants to States to attract and qualify teachers to meet critical teaching shortages (20 U.S.C. 1108-1110c).

18. Grants to States for education of handicapped children (20 U.S.C. 1411-1414).

19. Grants for administration of State plans and for comprehensive planning to determine construction needs of institutions of higher education (20 U.S.C. 715(b)).

20. Grants to States for comprehensive health planning (section 314(a), Public Health Service Act, 42 U.S.C. 246(a)).

21. Grants to States for establishing and maintaining adequate public health services (section 314(d), Public Health Service Act, 42 U.S.C. 246(d)).

22. Grants, loans, and loan guarantees with interest subsidies for hospital and medical facilities (Title VI, Public Health Service Act, 42 U.S.C. 291 *et seq.*).

23. Grants to States for community mental health centers construction (Community Mental Health Centers Act, Part A, 42 U.S.C. 2681-2687).

24. Cost of rehabilitation services (Title II, Social Security Act section 222(d); 42 U.S.C. 422(d)).

25. Surplus personal property disposal donations for health and educational purposes through State agencies (40 U.S.C. 484(j)).

26. Grants for State and community programs on aging (Title III, Older Americans Act, 42 U.S.C. 3021-3025).

27. Grants to States for planning, provision of services, and construction and operation of facilities for persons with developmental disabilities (42 U.S.C. 2670-2677c).

28. Grants to States for vocational rehabilitation services (29 U.S.C. 32); for innovation of vocational rehabilitation services (29 U.S.C. 33); and for rehabilitation facilities planning (29 U.S.C. 41a(g)(1)).

29. Designation of State licensing agency for blind operators of vending stands (20 U.S.C. 107-107f).

30. Grants to States for old-age assistance (42 U.S.C. 301 *et seq.*); aid to families with dependent children (42 U.S.C. 601 *et seq.*); child-welfare services (42 U.S.C. 620 *et seq.*); aid to the blind (42 U.S.C. 1201 *et seq.*); aid to the permanently and totally disabled (42 U.S.C. 1351 *et seq.*); aid to the aged, blind, or disabled (42 U.S.C. 1381 *et seq.*); medical assistance (42 U.S.C. 1396 *et seq.*).

31. Grants to States for maternal and child health and crippled children's services (42 U.S.C. 701-707); for special projects for maternal and infant care (42 U.S.C. 708).

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32. Grants to States for juvenile delinquency preventive and rehabilitative services (42 U.S.C. 3841).

[38 FR 17982, July 5, 1973; 40 FR 18173, Apr. 25, 1975, as amended at 70 FR 24319, May 9, 2005; 89 FR 37692, May 6, 2024]

APPENDIX B TO PART 80—GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS

I. SCOPE AND COVERAGE

A. APPLICATION OF GUIDELINES

These Guidelines apply to recipients of any Federal financial assistance from the Department of Health and Human Services that offer or administer programs of vocational education or training. This includes State agency recipients.

B. DEFINITION OF RECIPIENT

The definition of *recipient* of Federal financial assistance is established by Department regulations implementing title VI, title IX, and section 504 (45 CFR 80.13(i), 86.2(h), 84.3(f)).

For the purposes of title VI:

The term *recipient* means any State, political subdivision of any State, or instrumentality of any State or political subdivision, any public or private agency, institution, or organization, or other entity, or any individual, in any State, to whom Federal financial assistance is extended, directly or through another recipient, for any program, including any successor, assignee, or transferee thereof, but such term does not include any ultimate beneficiary [e.g., students] under any such program. (45 CFR 80.13(i)).

For the purpose of title IX:

Recipient means any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person to whom Federal financial assistance is extended directly or through another recipient and which operates an education program or activity which receives or benefits from such assistance, including any subunit, successor, assignee, or transferee thereof. (45 CFR 86.2(h)).

For the purposes of section 504:

Recipient means any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipi-

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ent, but excluding the ultimate beneficiary of the assistance. (45 CFR 84.3(f)).

C. EXAMPLES OF RECIPIENTS COVERED BY THESE GUIDELINES

The following education agencies, when they provide vocational education, are examples of recipients covered by these Guidelines:

1. The board of education of a public school district and its administrative agency.
2. The administrative board of a specialized vocational high school serving students from more than one school district.
3. The administrative board of a technical or vocation school that is used exclusively or principally for the provision of vocational education to persons who have completed or left high school (including persons seeking a certificate or an associate degree through a vocational program offered by the school) and who are available for study in preparation for entering the labor market.
4. The administrative board of a postsecondary institution, such as a technical institute, skill center, junior college, community college, or four year college that has a department or division that provides vocational education to students seeking immediate employment, a certificate or an associate degree.
5. The administrative board of a proprietary (private) vocational education school.
6. A State agency recipient itself operating a vocational education facility.

D. EXAMPLES OF SCHOOLS TO WHICH THESE GUIDELINES APPLY

The following are examples of the types of schools to which these Guidelines apply.

1. A junior high school, middle school, or those grades of a comprehensive high school that offers instruction to inform, orient, or prepare students for vocational education at the secondary level.
2. A vocational education facility operated by a State agency.
3. A comprehensive high school that has a department exclusively or principally used for providing vocational education; or that offers at least one vocational program to secondary level students who are available for study in preparation for entering the labor market; or that offers adult vocational education to persons who have completed or left high school and who are available for study in preparation for entering the labor market.
4. A comprehensive high school, offering the activities described above, that receives students on a contract basis from other school districts for the purpose of providing vocational education.
5. A specialized high school used exclusively or principally for the provision of vocational education, that enrolls students

from one or more school districts for the purpose of providing vocational education.

6. A technical or vocational school that primarily provides vocational education to persons who have completed or left high school and who are available for study in preparation for entering the labor market, including students seeking an associate degree or certificate through a course of vocational instruction offered by the school.

7. A junior college, a community college, or four-year college that has a department or division that provides vocational education to students seeking immediate employment, an associate degree or a certificate through a course of vocational instruction offered by the school.

8. A proprietary school, licensed by the State, that offers vocational education.

NOTE: Subsequent sections of these Guidelines may use the term *secondary vocational education center* in referring to the institutions described in paragraphs 3, 4 and 5 above or the term *postsecondary vocational education center* in referring to institutions described in paragraphs 6 and 7 above or the term *vocational education center* in referring to any or all institutions described above.

II. RESPONSIBILITIES ASSIGNED ONLY TO STATE AGENCY RECIPIENTS

A. RESPONSIBILITIES OF ALL STATE AGENCY RECIPIENTS

State agency recipients, in addition to complying with all other provisions of the Guidelines relevant to them, may not require, approve of, or engage in any discrimination or denial of services on the basis of race, color, national origin, sex, or handicap in performing any of the following activities:

1. Establishment of criteria or formulas for distribution of Federal or State funds to vocational education programs in the State;
2. Establishment of requirements for admission to or requirements for the administration of vocational education programs;
3. Approval of action by local entities providing vocational education. (For example, a State agency must ensure compliance with section IV of these Guidelines if and when it reviews a vocational education agency decision to create or change a geographic service area.);
4. Conducting its own programs. (For example, in employing its staff it may not discriminate on the basis of sex or handicap.)

B. STATE AGENCIES PERFORMING OVERSIGHT RESPONSIBILITIES

The State agency responsible for the administration of vocational education programs must adopt a compliance program to prevent, identify and remedy discrimination on the basis of race, color, national origin, sex or handicap by its subrecipients. (A *sub-*

recipient, in this context, is a local agency or vocational education center that receives financial assistance through a State agency.) This compliance program must include:

1. Collecting and analyzing civil rights related data and information that subrecipients compile for their own purposes or that are submitted to State and Federal officials under existing authorities;
2. Conducting periodic compliance reviews of selected subrecipients (i.e., an investigation of a subrecipient to determine whether it engages in unlawful discrimination in any aspect of its program); upon finding unlawful discrimination, notifying the subrecipient of steps it must take to attain compliance and attempting to obtain voluntary compliance;
3. Providing technical assistance upon request to subrecipients. This will include assisting subrecipients identify unlawful discrimination and instructing them in remedies for and prevention of such discrimination;
4. Periodically reporting its activities and findings under the foregoing paragraphs, including findings of unlawful discrimination under paragraph 2, immediately above, to the Office for Civil Rights.

State agencies are not required to terminate or defer assistance to any subrecipient. Nor are they required to conduct hearings. The responsibilities of the Office for Civil Rights to collect and analyze data, to conduct compliance reviews, to investigate complaints and to provide technical assistance are not diminished or attenuated by the requirements of Section II of the Guidelines.

C. STATEMENT OF PROCEDURES AND PRACTICES

Within one year from the publication of these Guidelines in final form, each State agency recipient performing oversight responsibilities must submit to the Office for Civil Rights the methods of administration and related procedures it will follow to comply with the requirements described in paragraphs A and B immediately above. The Department will review each submission and will promptly either approve it, or return it to State officials for revision.

III. DISTRIBUTION OF FEDERAL FINANCIAL ASSISTANCE AND OTHER FUNDS FOR VOCATIONAL EDUCATION

A. AGENCY RESPONSIBILITIES

Recipients that administer grants for vocational education must distribute Federal, State, or local vocational education funds so that no student or group of students is unlawfully denied an equal opportunity to benefit from vocational education on the basis of race, color, national origin, sex, or handicap.

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B. DISTRIBUTION OF FUNDS

Recipients may not adopt a formula or other method for the allocation of Federal, State, or local vocational education funds that has the effect of discriminating on the basis of race, color, national origin, sex, or handicap. However, a recipient may adopt a formula or other method of allocation that uses as a factor race, color, national origin, sex, or handicap [or an index or proxy for race, color, national origin, sex, or handicap e.g., number of persons receiving Aid to Families with Dependent Children or with limited English speaking ability] if the factor is included to compensate for past discrimination or to comply with those provisions of the Vocational Education Amendments of 1976 designed to assist specified protected groups.

C. EXAMPLE OF A PATTERN SUGGESTING UNLAWFUL DISCRIMINATION

In each State it is likely that some local recipients will enroll greater proportions of minority students in vocational education than the State-wide proportion of minority students in vocational education. A funding formula or other method of allocation that results in such local recipients receiving per-pupil allocations of Federal or State vocational education funds lower than the State-wide average per-pupil allocation will be presumed unlawfully discriminatory.

D. DISTRIBUTION THROUGH COMPETITIVE GRANTS OR CONTRACTS

Each State agency that establishes criteria for awarding competitive vocational education grants or contracts must establish and apply the criteria without regard to the race, color, national origin, sex, or handicap of any or all of a recipient's students, except to compensate for past discrimination.

E. APPLICATION PROCESSES FOR COMPETITIVE OR DISCRETIONARY GRANTS

State agencies must disseminate information needed to satisfy the requirements of any application process for competitive or discretionary grants so that all recipients, including those having a high percentage of minority or handicapped students, are informed of and able to seek funds. State agencies that provide technical assistance for the completion of the application process must provide such assistance without discrimination against any one recipient or class of recipients.

F. ALTERATION OF FUND DISTRIBUTION TO PROVIDE EQUAL OPPORTUNITY

If the Office for Civil Rights finds that a recipient's system for distributing vocational education funds unlawfully discriminates on the basis of race, color, national or

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igin, sex, or handicap, it will require the recipient to adopt an alternative nondiscriminatory method of distribution. The Office for Civil Rights may also require the recipient to compensate for the effects of its past unlawful discrimination in the distribution of funds.

IV. ACCESS AND ADMISSION OF STUDENTS TO VOCATIONAL EDUCATION PROGRAMS

A. RECIPIENT RESPONSIBILITIES

Criteria controlling student eligibility for admission to vocational education schools, facilities and programs may not unlawfully discriminate on the basis of race, color, national origin, sex, or handicap. A recipient may not develop, impose, maintain, approve, or implement such discriminatory admissions criteria.

B. SITE SELECTION FOR VOCATIONAL SCHOOLS

State and local recipients may not select or approve a site for a vocational education facility for the purpose or with the effect of excluding, segregating, or otherwise discriminating against students on the basis of race, color, or national origin. Recipients must locate vocational education facilities at sites that are readily accessible to both nonminority and minority communities, and that do not tend to identify the facility or program as intended for nonminority or minority students.

C. ELIGIBILITY FOR ADMISSION TO VOCATIONAL EDUCATION CENTERS BASED ON RESIDENCE

Recipients may not establish, approve or maintain geographic boundaries for a vocational education center service area or attendance zone, (hereinafter *service area*), that unlawfully exclude students on the basis of race, color, or national origin. The Office for Civil Rights will presume, subject to rebuttal, that any one or combination of the following circumstances indicates that the boundaries of a given service area are unlawfully constituted:

1. A school system or service area contiguous to the given service area, contains minority or nonminority students in substantially greater proportion than the given service area;

2. A substantial number of minority students who reside outside the given vocational education center service area, and who are not eligible for the center reside, nonetheless, as close to the center as a substantial number of non-minority students who are eligible for the center;

3. The over-all vocational education program of the given service area in comparison to the over-all vocational education program of a contiguous school system or service area enrolling a substantially greater proportion

of minority students: (a) Provides its students with a broader range of curricular offerings, facilities and equipment; or (b) provides its graduates greater opportunity for employment in jobs: (i) For which there is a demonstrated need in the community or region; (ii) that pay higher entry level salaries or wages; or (iii) that are generally acknowledged to offer greater prestige or status.

D. ADDITIONS AND RENOVATIONS TO EXISTING VOCATIONAL EDUCATION FACILITIES

A recipient may not add to, modify, or renovate the physical plant of a vocational education facility in a manner that creates, maintains, or increases student segregation on the basis of race, color, national origin, sex, or handicap.

E. REMEDIES FOR VIOLATIONS OF SITE SELECTION AND GEOGRAPHIC SERVICE AREA REQUIREMENTS

If the conditions specified in paragraphs IV, A, B, C, or D, immediately above, are found and not rebutted by proof of non-discrimination, the Office for Civil rights will require the recipient(s) to submit a plan to remedy the discrimination. The following are examples of steps that may be included in the plan, where necessary to overcome the discrimination: (1) Redrawing of the boundaries of the vocational education center's service area to include areas unlawfully excluded and/or to exclude areas unlawfully included; (2) provision of transportation to students residing in areas unlawfully excluded; (3) provision of additional programs and services to students who would have been eligible for attendance at the vocational education center but for the discriminatory service area or site selection; (4) reassignment of students; and (5) construction of new facilities or expansion of existing facilities.

F. ELIGIBILITY FOR ADMISSION TO SECONDARY VOCATIONAL EDUCATION CENTERS BASED ON NUMERICAL LIMITS IMPOSED ON SENDING SCHOOLS

A recipient may not adopt or maintain a system for admission to a secondary vocational education center or program that limits admission to a fixed number of students from each sending school included in the center's service area if such a system disproportionately excludes students from the center on the basis of race, sex, national origin or handicap. (Example: Assume 25 percent of a school district's high school students are black and that most of those black students are enrolled in one high school; the white students, 75 percent of the district's total enrollment, are generally enrolled in the five remaining high schools. This paragraph prohibits a system of admission to the secondary vocational education center that limits eligibility to a fixed and equal number

of students from each of the district's six high schools.)

G. REMEDIES FOR VIOLATION OF ELIGIBILITY BASED ON NUMERICAL LIMITS REQUIREMENTS

If the Office for Civil Rights finds a violation of paragraph F, above, the recipient must implement an alternative system of admissions that does not disproportionately exclude students on the basis of race, color, national origin, sex, or handicap.

H. ELIGIBILITY FOR ADMISSION TO VOCATIONAL EDUCATION CENTERS, BRANCHES OR ANNEXES BASED UPON STUDENT OPTION

A vocational education center, branch or annex, open to all students in a service area and predominantly enrolling minority students or students of one race, national origin or sex, will be presumed unlawfully segregated if: (1) It was established by a recipient for members of one race, national origin or sex; or (2) it has since its construction been attended primarily by members of one race, national origin or sex; or (3) most of its program offerings have traditionally been selected predominantly by members of one race, national origin or sex.

I. REMEDIES FOR FACILITY SEGREGATION UNDER STUDENT OPTION PLANS

If the conditions specified in paragraph IV-H are found and not rebutted by proof of non-discrimination, the Office for Civil Rights will require the recipient(s) to submit a plan to remedy the segregation. The following are examples of steps that may be included in the plan, where necessary to overcome the discrimination:

(1) elimination of program duplication in the segregated facility and other proximate vocational facilities; (2) relocation or "clustering" of programs or courses; (3) adding programs and courses that traditionally have been identified as intended for members of a particular race, national origin or sex to schools that have traditionally served members of the other sex or traditionally served persons of a different race or national origin; (4) merger of programs into one facility through school closings or new construction; (5) intensive outreach recruitment and counseling; (6) providing free transportation to students whose enrollment would promote desegregation.

[Paragraph J omitted]

K. ELIGIBILITY BASED ON EVALUATION OF EACH APPLICANT UNDER ADMISSIONS CRITERIA

Recipients may not judge candidates for admission to vocational education programs on the basis of criteria that have the effect of disproportionately excluding persons of a particular race, color, national origin, sex,

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or handicap. However, if a recipient can demonstrate that such criteria have been validated as essential to participation in a given program and that alternative equally valid criteria that do not have such a disproportionate adverse effect are unavailable, the criteria will be judged nondiscriminatory. Examples of admissions criteria that must meet this test are past academic performance, record of disciplinary infractions, counselors' approval, teachers' recommendations, interest inventories, high school diplomas and standardized tests, such as the Test of Adult Basic Education (TABE).

An introductory, preliminary, or exploratory course may not be established as a prerequisite for admission to a program unless the course has been and is available without regard to race, color, national origin, sex, and handicap. However, a course that was formerly only available on a discriminatory basis may be made a prerequisite for admission to a program if the recipient can demonstrate that: (a) the course is essential to participation in the program; and (b) the course is presently available to those seeking enrollment for the first time and to those formerly excluded.

L. ELIGIBILITY OF NATIONAL ORIGIN MINORITY PERSONS WITH LIMITED ENGLISH LANGUAGE SKILLS

Recipients may not restrict an applicant's admission to vocational education programs because the applicant, as a member of a national origin minority with limited English language skills, cannot participate in and benefit from vocational instruction to the same extent as a student whose primary language is English. It is the responsibility of the recipient to identify such applicants and assess their ability to participate in vocational instruction.

Acceptable methods of identification include: (1) Identification by administrative staff, teachers, or parents of secondary level students; (2) identification by the student in postsecondary or adult programs; and (3) appropriate diagnostic procedures, if necessary.

Recipients must take steps to open all vocational programs to these national origin minority students. A recipient must demonstrate that a concentration of students with limited English language skills in one or a few programs is not the result of discriminatory limitations upon the opportunities available to such students.

M. REMEDIAL ACTION IN BEHALF OF PERSONS WITH LIMITED ENGLISH LANGUAGE SKILLS

If the Office for Civil Rights finds that a recipient has denied national origin minority persons admission to a vocational school or program because of their limited English language skills or has assigned students to

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vocational programs solely on the basis of their limited English language skills, the recipient will be required to submit a remedial plan that insures national origin minority students equal access to vocational education programs.

N. EQUAL ACCESS FOR HANDICAPPED STUDENTS

Recipients may not deny handicapped students access to vocational education programs or courses because of architectural or equipment barriers, or because of the need for related aids and services or auxiliary aids. If necessary, recipients must: (1) Modify instructional equipment; (2) modify or adapt the manner in which the courses are offered; (3) house the program in facilities that are readily accessible to mobility impaired students or alter facilities to make them readily accessible to mobility impaired students; and (4) provide auxiliary aids that effectively make lectures and necessary materials available to postsecondary handicapped students; (5) provide related aids or services that assure secondary students an appropriate education.

Academic requirements that the recipient can demonstrate are essential to a program of instruction or to any directly related licensing requirement will not be regarded as discriminatory. However, where possible, a recipient must adjust those requirements to the needs of individual handicapped students.

Access to vocational programs or courses may not be denied handicapped students on the ground that employment opportunities in any occupation or profession may be more limited for handicapped persons than for non-handicapped persons.

O. PUBLIC NOTIFICATION

Prior to the beginning of each school year, recipients must advise students, parents, employees and the general public that all vocational opportunities will be offered without regard to race, color, national origin, sex, or handicap. Announcement of this policy of non-discrimination may be made, for example, in local newspapers, recipient publications and/or other media that reach the general public, program beneficiaries, minorities (including national origin minorities with limited English language skills), women, and handicapped persons. A brief summary of program offerings and admission criteria should be included in the announcement; also the name, address and telephone number of the person designated to coordinate Title IX and Section 504 compliance activity.

If a recipient's service area contains a community of national origin minority persons with limited English language skills,

public notification materials must be disseminated to that community in its language and must state that recipients will take steps to assure that the lack of English language skills will not be a barrier to admission and participation in vocational education programs.

V. COUNSELING AND PREVOCATIONAL PROGRAMS

A. RECIPIENT RESPONSIBILITIES

Recipients must insure that their counseling materials and activities (including student program selection and career/employment selection), promotional, and recruitment efforts do not discriminate on the basis of race, color, national origin, sex, or handicap.

B. COUNSELING AND PROSPECTS FOR SUCCESS

Recipients that operate vocational education programs must insure that counselors do not direct or urge any student to enroll in a particular career or program, or measure or predict a student's prospects for success in any career or program based upon the student's race, color, national origin, sex, or handicap. Recipients may not counsel handicapped students toward more restrictive career objectives than nonhandicapped students with similar abilities and interests. If a vocational program disproportionately enrolls male or female students, minority or nonminority students, or handicapped students, recipients must take steps to insure that the disproportion does not result from unlawful discrimination in counseling activities.

C. STUDENT RECRUITMENT ACTIVITIES

Recipients must conduct their student recruitment activities so as not to exclude or limit opportunities on the basis of race, color, national origin, sex, or handicap. Where recruitment activities involve the presentation or portrayal of vocational and career opportunities, the curricula and programs described should cover a broad range of occupational opportunities and not be limited on the basis of the race, color, national origin, sex, or handicap of the students or potential students to whom the presentation is made. Also, to the extent possible, recruiting teams should include persons of different races, national origins, sexes, and handicaps.

D. COUNSELING OF STUDENTS WITH LIMITED ENGLISH-SPEAKING ABILITY OR HEARING IMPAIRMENTS

Recipients must insure that counselors can effectively communicate with national origin minority students with limited English language skills and with students who have

hearing impairments. This requirement may be satisfied by having interpreters available.

E. PROMOTIONAL ACTIVITIES

Recipients may not undertake promotional efforts (including activities of school officials, counselors, and vocational staff) in a manner that creates or perpetuates stereotypes or limitations based on race, color, national origin, sex or handicap. Examples of promotional efforts are career days, parents' night, shop demonstrations, visitations by groups of prospective students and by representatives from business and industry. Materials that are part of promotional efforts may not create or perpetuate stereotypes through text or illustration. To the extent possible they should portray males or females, minorities or handicapped persons in programs and occupations in which these groups traditionally have not been represented. If a recipient's service area contains a community of national origin minority persons with limited English language skills, promotional literature must be distributed to that community in its language.

VI. EQUAL OPPORTUNITY IN THE VOCATIONAL EDUCATION INSTRUCTIONAL SETTING

A. ACCOMMODATIONS FOR HANDICAPPED STUDENTS

Recipients must place secondary level handicapped students in the regular educational environment of any vocational education program to the maximum extent appropriate to the needs of the student unless it can be demonstrated that the education of the handicapped person in the regular environment with the use of supplementary aids and services cannot be achieved satisfactorily. Handicapped students may be placed in a program only after the recipient satisfies the provisions of the Department's Regulation, 45 CFR part 84, relating to evaluation, placement, and procedural safeguards. If a separate class or facility is identifiable as being for handicapped persons, the facility, the programs, and the services must be comparable to the facilities, programs, and services offered to nonhandicapped students.

B. STUDENT FINANCIAL ASSISTANCE

Recipients may not award financial assistance in the form of loans, grants, scholarships, special funds, subsidies, compensation for work, or prizes to vocational education students on the basis of race, color, national origin, sex, or handicap, except to overcome the effects of past discrimination. Recipients may administer sex restricted financial assistance where the assistance and restriction are established by will, trust, bequest, or any similar legal instrument, if the overall effect of all financial assistance awarded does not discriminate on the basis of sex. Materials

and information used to notify students of opportunities for financial assistance may not contain language or examples that would lead applicants to believe the assistance is provided on a discriminatory basis. If a recipient's service area contains a community of national origin minority persons with limited English language skills, such information must be disseminated to that community in its language.

C. HOUSING IN RESIDENTIAL POSTSECONDARY VOCATIONAL EDUCATION CENTERS

Recipients must extend housing opportunities without discrimination based on race, color, national origin, sex, or handicap. This obligation extends to recipients that provide on-campus housing and/or that have agreements with providers of off-campus housing. In particular, a recipient postsecondary vocational education program that provides on-campus or off-campus housing to its non-handicapped students must provide, at the same cost and under the same conditions, comparable convenient and accessible housing to handicapped students.

D. COMPARABLE FACILITIES

Recipients must provide changing rooms, showers, and other facilities for students of one sex that are comparable to those provided to students of the other sex. This may be accomplished by alternating use of the same facilities or by providing separate, comparable facilities.

Such facilities must be adapted or modified to the extent necessary to make the vocational education program readily accessible to handicapped persons.

VII. WORK STUDY, COOPERATIVE VOCATIONAL EDUCATION, JOB PLACEMENT, AND APPRENTICE TRAINING

A. RESPONSIBILITIES IN COOPERATIVE VOCATIONAL EDUCATION PROGRAMS, WORK-STUDY PROGRAMS, AND JOB PLACEMENT PROGRAMS

A recipient must insure that: (a) It does not discriminate against its students on the basis of race, color, national origin, sex, or handicap in making available opportunities in cooperative education, work study and job placement programs; and (b) students participating in cooperative education, work study and job placement programs are not discriminated against by employers or prospective employers on the basis of race, color, national origin, sex, or handicap in recruitment, hiring, placement, assignment to work tasks, hours of employment, levels of responsibility, and in pay.

If a recipient enters into a written agreement for the referral or assignment of students to an employer, the agreement must contain an assurance from the employer that students will be accepted and assigned to

jobs and otherwise treated without regard to race, color, national origin, sex, or handicap.

Recipients may not honor any employer's request for students who are free of handicaps or for students of a particular race, color, national origin, or sex. In the event an employer or prospective employer is or has been subject to court action involving discrimination in employment, school officials should rely on the court's findings if the decision resolves the issue of whether the employer has engaged in unlawful discrimination.

B. APPRENTICE TRAINING PROGRAMS

A recipient may not enter into any agreement for the provision or support of apprentice training for students or union members with any labor union or other sponsor that discriminates against its members or applicants for membership on the basis of race, color, national origin, sex, or handicap. If a recipient enters into a written agreement with a labor union or other sponsor providing for apprentice training, the agreement must contain an assurance from the union or other sponsor: (1) That it does not engage in such discrimination against its membership or applicants for membership; and (2) that apprentice training will be offered and conducted for its membership free of such discrimination.

VIII. EMPLOYMENT OF FACULTY AND STAFF

A. EMPLOYMENT GENERALLY

Recipients may not engage in any employment practice that discriminates against any employee or applicant for employment on the basis of sex or handicap. Recipients may not engage in any employment practice that discriminates on the basis of race, color, or national origin if such discrimination tends to result in segregation, exclusion or other discrimination against students.

B. RECRUITMENT

Recipients may not limit their recruitment for employees to schools, communities, or companies disproportionately composed of persons of a particular race, color, national origin, sex, or handicap except for the purpose of overcoming the effects of past discrimination. Every source of faculty must be notified that the recipient does not discriminate in employment on the basis of race, color, national origin, sex, or handicap.

C. PATTERNS OF DISCRIMINATION

Whenever the Office for Civil Rights finds that in light of the representation of protected groups in the relevant labor market there is a significant underrepresentation or overrepresentation of protected group persons on the staff of a vocational education school or program, it will presume that the

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disproportion results from unlawful discrimination. This presumption can be overcome by proof that qualified persons of the particular race, color, national origin, or sex, or that qualified handicapped persons are not in fact available in the relevant labor market.

D. SALARY POLICIES

Recipients must establish and maintain faculty salary scales and policy based upon the conditions and responsibilities of employment, without regard to race, color, national origin, sex or handicap.

E. EMPLOYMENT OPPORTUNITIES FOR HANDICAPPED APPLICANTS

Recipients must provide equal employment opportunities for teaching and administrative positions to handicapped applicants who can perform the essential functions of the position in question. Recipients must make reasonable accommodation for the physical or mental limitations of handicapped applicants who are otherwise qualified unless recipients can demonstrate that the accommodation would impose an undue hardship.

F. THE EFFECTS OF PAST DISCRIMINATION

Recipients must take steps to overcome the effects of past discrimination in the recruitment, hiring, and assignment of faculty. Such steps may include the recruitment or reassignment of qualified persons of a particular race, national origin, or sex, or who are handicapped.

G. STAFF OF STATE ADVISORY COUNCILS OF VOCATIONAL EDUCATION

State Advisory Councils of Vocational Education are recipients of Federal financial assistance and therefore must comply with Section VIII of the Guidelines.

H. EMPLOYMENT AT STATE OPERATED VOCATIONAL EDUCATION CENTERS THROUGH STATE CIVIL-SERVICE AUTHORITIES

Where recruitment and hiring of staff for State operated vocational education centers is conducted by a State civil service employment authority, the State education agency operating the program must insure that recruitment and hiring of staff for the vocational education center is conducted in accordance with the requirements of these Guidelines.

IX. PROPRIETARY VOCATIONAL EDUCATION SCHOOLS

A. RECIPIENT RESPONSIBILITIES

Proprietary vocational education schools that are recipients of Federal financial assistance through Federal student assistance programs or otherwise are subject to all of

the requirements of the Department's regulations and these Guidelines.

B. ENFORCEMENT AUTHORITY

Enforcement of the provisions of Title IX of the Education Amendments of 1972 and section 504 of the Rehabilitation Act of 1973 is the responsibility of the Department of Health and Human Services. However, authority to enforce Title VI of the Civil Rights Act of 1964 for proprietary vocational education schools has been delegated to the Veterans Administration.

When the Office for Civil Rights receives a Title VI complaint alleging discrimination by a proprietary vocational education school it will forward the complaint to the Veterans Administration and cite the applicable requirements of the Department's regulations and these Guidelines. The complainant will be notified of such action.

[44 FR 17164, Mar. 21, 1979]

PART 81—PRACTICE AND PROCEDURE FOR HEARINGS UNDER PART 80 OF THIS TITLE

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AUTHORITY: 5 U.S.C. 301 and 45 CFR 80.9(d).

SOURCE: 32 FR 15156, Nov. 2, 1967, unless otherwise noted.

Subpart A—General Information

§ 81.1 Scope of rules.

The rules of procedure in this part supplement §§ 80.9 and 80.10 of this subtitle and govern the practice for hearings, decisions, and administrative review conducted by the Department of Health and Human Services, pursuant to Title VI of the Civil Rights Act of 1964 (section 602, 78 Stat. 252) and part 80 of this subtitle.

§ 81.2 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 Civil Rights hearing clerk. Inquiries may be made at the Central Information Center, Department of Health and Human Services, 330 Independence Avenue SW., Washington, DC 20201.

§ 81.3 Use of gender and number.

As used in this part, words importing the singular number may extend and be applied to several persons or things, and vice versa. Words importing the masculine gender may be applied to females or organizations.

§ 81.4 Suspension of rules.

Upon notice to all parties, the reviewing authority or the presiding officer, with respect to matters pending before them, may modify or waive any rule in this part upon determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

Subpart B—Appearance and Practice**§ 81.11 Appearance.**

A party may appear in person or by counsel and participate fully in any proceeding. A State agency or a corporation may appear by any of its officers or by any employee it authorizes to appear on its behalf. Counsel must be members in good standing of the bar of a State, Territory, or possession of the United States or of the District of Columbia or the Commonwealth of Puerto Rico.

§ 81.12 Authority for representation.

Any individual acting in a representative capacity in any proceeding may be required to show his authority to act in such capacity.

§ 81.13 Exclusion from hearing for misconduct.

Disrespectful, disorderly, or contemptuous language or contemptuous conduct, refusal to comply with directions, or continued use of dilatory tactics by any person at any hearing before a presiding officer shall constitute grounds for immediate exclusion of such person from the hearing by the presiding officer.

Subpart C—Parties**§ 81.21 Parties; General Counsel deemed a party.**

(a) The term party shall include an applicant or recipient or other person to whom a notice of hearing or opportunity for hearing has been mailed naming him a respondent.

(b) The General Counsel of the Department of Health and Human Services shall be deemed a party to all proceedings.

§ 81.22 Amici curiae.

(a) Any interested person or organization may file a petition to participate in a proceeding as an amicus curiae. Such petition shall be filed prior to the prehearing conference, or if none is held, before the commencement of the hearing, unless the petitioner shows good cause for filing the petition later. The presiding officer may grant

the petition if he 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 thereof. An amicus curiae is not a party and may not introduce evidence at a hearing.

(b) An amicus curiae may submit a statement of position to the presiding officer prior to the beginning of a hearing, and shall serve a copy on each party. The amicus curiae may submit a brief on each occasion a decision is to be made or a prior decision is subject to review. His brief shall be filed and served on each party within the time limits applicable to the party whose position he deems himself to support; or if he does not deem himself to support the position of any party, within the longest time limit applicable to any party at that particular stage of the proceedings.

(c) When all parties have completed their initial examination of a witness, any amicus curiae may request the presiding officer to propound specific questions to the witness. The presiding officer, in his discretion, may grant any such request if he believes the proposed additional testimony may assist materially in elucidating factual matters at issue between the parties and will not expand the issues.

§ 81.23 Complainants not parties.

A person submitting a complaint pursuant to § 80.7(b) of this title is not a party to the proceedings governed by this part, but may petition, after proceedings are initiated, to become an amicus curiae.

Subpart D—Form, Execution, Service and Filing of Documents**§ 81.31 Form of documents to be filed.**

Documents to be filed under the rules in this part shall be dated, the original signed in ink, shall show the docket description and title of the proceeding, and shall show the title, if any, and address of the signatory. Copies need not be signed but the name of the person signing the original shall be reproduced. Documents shall be legible and shall not be more than 8½ inches wide and 12 inches long.

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§ 81.32 Signature of documents.

The signature of a party, authorized officer, employee or attorney constitutes a certificate that he has read the document, that to the best of his knowledge, information, and belief there is good ground to support it, and that it is not interposed for delay. If a document is not signed or is signed with intent to defeat the purpose of this section, it may be stricken as sham and false and the proceeding may proceed as though the document had not been filed. Similar action may be taken if scandalous or indecent matter is inserted.

§ 81.33 Filing and service.

All notices by a Department official, and all written motions, requests, petitions, memoranda, pleadings, exceptions, briefs, decisions, and correspondence to a Department official from a party, or vice versa, relating to a proceeding after its commencement shall be filed and served on all parties. Parties shall supply the original and two copies of documents submitted for filing. Filings shall be made with the Civil Rights hearing clerk at the address stated in the notice of hearing or notice of opportunity for hearing, during regular business hours. Regular business hours are every Monday through Friday (legal holidays in the District of Columbia excepted) from 9 a.m. to 5:30 p.m., eastern standard or daylight saving time, whichever is effective in the District of Columbia at the time. Originals only on exhibits and transcripts of testimony need be filed. For requirements of service on amici curiae, see § 81.107.

§ 81.34 Service—how made.

Service shall be made by personal delivery of one copy to each person to be served or by mailing by first-class mail, properly addressed with postage prepaid. When a party or amicus has appeared by attorney or other representative, service upon such attorney or representative will be deemed service upon the party or amicus. Documents served by mail preferably should be mailed in sufficient time to reach the addressee by the date on which the original is due to be filed, and should

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be air mailed if the addressee is more than 300 miles distant.

§ 81.35 Date of service.

The date of service shall be the day when the matter is deposited in the U.S. mail or is delivered in person, except that the date of service of the initial notice of hearing or opportunity for hearing shall be the date of its delivery, or of its attempted delivery if refused.

§ 81.36 Certificate of service.

The original of every document filed and required to be served upon parties to a proceeding shall be endorsed with a certificate of service signed by the party making service or by his attorney or representative, stating that such service has been made, the date of service, and the manner of service, whether by mail or personal delivery.

Subpart E—Time

§ 81.41 Computation.

In computing any period of time under the rules in this part or in an order issued hereunder, 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 in the District of Columbia, in which event it includes the next following business day. When the period of time prescribed or allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays shall be excluded from the computation.

§ 81.42 Extension of time or postponement.

Requests for extension of time should be served on all parties and should set forth the reasons for the application. Applications may be granted upon a showing of good cause by the applicant. From the designation of a presiding officer until the issuance of his decision such requests should be addressed to him. Answers to such requests are permitted, if made promptly.

§ 81.43 Reduction of time to file documents.

For good cause, the reviewing authority or the presiding officer, with

respect to matters pending before them, may reduce any time limit prescribed by the rules in this part, except as provided by law or in part 80 of this title.

Subpart F—Proceedings Prior to Hearing

§ 81.51 Notice of hearing or opportunity for hearing.

Proceedings are commenced by mailing a notice of hearing or opportunity for hearing to an affected applicant or recipient, pursuant to § 80.9 of this title.

§ 81.52 Answer to notice.

The respondent, applicant or recipient may file an answer to the notice within 20 days after service thereof. Answers shall admit or deny specifically and in detail each allegation of the notice, unless the respondent party is without knowledge, in which case his answer should so state, and the statement will be deemed a denial. Allegations of fact in the notice not denied or controverted by answer shall be deemed admitted. Matters alleged as affirmative defenses shall be separately stated and numbered. Failure of the respondent to file an answer within the 20-day period following service of the notice may be deemed an admission of all matters of fact recited in the notice.

§ 81.53 Amendment of notice or answer.

The General Counsel may amend the notice of hearing or opportunity for hearing once as a matter of course before an answer thereto is served, and each respondent may amend his answer once as a matter of course not later than 10 days before the date fixed for hearing but in no event later than 20 days from the date of service of his original answer. Otherwise a notice or answer may be amended only by leave of the presiding officer. A respondent shall file his answer to an amended notice within the time remaining for filing the answer to the original notice or within 10 days after service of the amended notice, whichever period may be the longer, unless the presiding officer otherwise orders.

§ 81.54 Request for hearing.

Within 20 days after service of a notice of opportunity for hearing which does not fix a date for hearing the respondent, either in his answer or in a separate document, may request a hearing. Failure of the respondent to request a hearing shall be deemed a waiver of the right to a hearing and to constitute his consent to the making of a decision on the basis of such information as is available.

§ 81.55 Consolidation.

The responsible Department official may provide for proceedings in the Department to be joined or consolidated for hearing with proceedings in other Federal departments or agencies, by agreement with such other departments or agencies. All parties to any proceeding consolidated subsequently to service of the notice of hearing or opportunity for hearing shall be promptly served with notice of such consolidation.

§ 81.56 Motions.

Motions and petitions shall state the relief sought, the authority relied upon, and the facts alleged. If made before or after the hearing, these matters shall be in writing. If made at the hearing, they may be stated orally; but the presiding officer may require that they be reduced to writing and filed and served on all parties in the same manner as a formal motion. Motions, answers, and replies shall be addressed to the presiding officer, if the case is pending before him. A repetitious motion will not be entertained.

§ 81.57 Responses to motions and petitions.

Within 8 days after a written motion or petition is served, or such other period as the reviewing authority or the presiding officer may fix, any party may file a response thereto. An immediate oral response may be made to an oral motion.

§ 81.58 Disposition of motions and petitions.

The reviewing authority or the presiding officer may not sustain or grant a written motion or petition prior to

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expiration of the time for filing responses thereto, but may overrule or deny such motion or petition without awaiting response: *Provided, however,* That prehearing conferences, hearings and decisions need not be delayed pending disposition of motions or petitions. Oral motions and petitions may be ruled on immediately. Motions and petitions submitted to the reviewing authority or the presiding officer, respectively, and not disposed of in separate rulings or in their respective decisions will be deemed denied. Oral arguments shall not be held or written motions or petitions unless the presiding officer in his discretion expressly so orders.

Subpart G—Responsibilities and Duties of Presiding Officer

§ 81.61 Who presides.

A hearing examiner assigned under 5 U.S.C. 3105 or 3344 (formerly section 11 of the Administrative Procedure Act) shall preside over the taking of evidence in any hearing to which these rules of procedure apply.

§ 81.62 Designation of hearing examiner.

The designation of the hearing examiner as presiding officer shall be in writing, and shall specify whether the examiner is to make an initial decision or to certify the entire record including his recommended findings and proposed decision to the reviewing authority, and may also fix the time and place of hearing. A copy of such order shall be served on all parties. After service of an order designating a hearing examiner to preside, and until such examiner makes his decision, motions and petitions shall be submitted to him. In the case of the death, illness, disqualification or unavailability of the designated hearing examiner, another hearing examiner may be designated to take his place.

§ 81.63 Authority of presiding officer.

The presiding officer shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He shall have all powers necessary to these ends, including (but not limited to) the power to:

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(a) Arrange and issue notice of the date, time, and place of hearings, or, upon due notice to the parties, to change the date, time, and place of hearings previously set.

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

(c) Require parties and amici curiae to state their position with respect to the various issues in the proceeding.

(d) Administer oaths and affirmations.

(e) Rule on motions, and other procedural items on matters pending before him.

(f) Regulate the course of the hearing and conduct of counsel therein.

(g) Examine witnesses and direct witnesses to testify.

(h) Receive, rule on, exclude or limit evidence.

(i) Fix the time for filing motions, petitions, briefs, or other items in matters pending before him.

(j) Issue initial or recommended decisions.

(k) Take any action authorized by the rules in this part or in conformance with the provisions of 5 U.S.C. 551–559 (the Administrative Procedure Act).

Subpart H—Hearing Procedures

§ 81.71 Statement of position and trial briefs.

The presiding officer may require parties and amici curiae to file written statements of position prior to the beginning of a hearing. The presiding officer may also require the parties to submit trial briefs.

§ 81.72 Evidentiary purpose.

(a) The hearing is directed to receiving factual evidence and expert opinion testimony related to the issues in the proceeding. Argument will not be received in evidence; rather it should be presented in statements, memoranda, or briefs, as determined by the presiding officer. Brief opening statements, which shall be limited to statement of the party's position and what he intends to prove, may be made at hearings.

(b) Hearings for the reception of evidence will be held only in cases where issues of fact must be resolved in order to determine whether the respondent has failed to comply with one or more applicable requirements of part 80 of this title. In any case where it appears from the respondent's answer to the notice of hearing or opportunity for hearing, from his failure timely to answer, or from his admissions or stipulations in the record, that there are no matters of material fact in dispute, the reviewing authority or presiding officer may enter an order so finding, vacating the hearing date if one has been set, and fixing the time for filing briefs under §81.101. Thereafter the proceedings shall go to conclusion in accordance with subpart J of this part. The presiding officer may allow an appeal from such order in accordance with §81.86.

§81.73 Testimony.

Testimony shall be given orally under oath or affirmation by witnesses at the hearing; but the presiding officer, in his discretion, may require or permit that the direct testimony of any witness be prepared in writing and served on all parties in advance of the hearing. Such testimony may be adopted by the witness at the hearing, and filed as part of the record thereof. Unless authorized by the presiding officer, witnesses will not be permitted to read prepared testimony into the record. Except as provided in §§81.75 and 81.76, witnesses shall be available at the hearing for cross-examination.

§81.74 Exhibits.

Proposed exhibits shall be exchanged at the prehearing conference, or otherwise prior to the hearing if the presiding officer so requires. Proposed exhibits not so exchanged may be denied admission as evidence. The authenticity of all proposed exhibits exchanged prior to hearing will be deemed admitted unless written objection thereto is filed prior to the hearing or unless good cause is shown at the hearing for failure to file such written objection.

§81.75 Affidavits.

An affidavit is; not inadmissible as such. Unless the presiding officer fixes other time periods affidavits shall be filed and served on the parties not later than 15 days prior to the hearing; and not less than 7 days prior to hearing a party may file and serve written objection to any affidavit on the ground that he believes it necessary to test the truth of assertions therein at hearing. In such event the assertions objected to will not be received in evidence unless the affiant is made available for cross-examination, or the presiding officer determines that cross-examination is not necessary for the full and true disclosure of facts referred to in such assertions. Notwithstanding any objection, however, affidavits may be considered in the case of any respondent who waives a hearing.

§81.76 Depositions.

Upon such terms as may be just, for the convenience of the parties or of the Department, the presiding officer may authorize or direct the testimony of any witness to be taken by deposition.

§81.77 Admissions as to facts and documents.

Not later than 15 days prior to the scheduled date of the hearing except for good cause shown, or prior to such earlier date as the presiding officer may order, any party may serve upon an opposing party a written request for the admission of the genuineness and authenticity of any relevant documents described in and exhibited with the request, or for the admission of the truth of any relevant matters of fact stated in the request. Each of the matters of which an admission is requested shall be deemed admitted, unless within a period designated in the request (not less than 10 days after service thereof, or within such further time as the presiding officer or the reviewing authority if no presiding officer has yet been designated may allow upon motion and notice) the party to whom the request is directed serves upon the requesting party a sworn statement either denying specifically the matters of which an admission is requested or setting forth in detail the reasons why he cannot truthfully either admit or

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deny such matters. Copies of requests for admission and answers thereto shall be served on all parties. Any admission made by a party to such request is only for the purposes of the pending proceeding, or any proceeding or action instituted for the enforcement of any order entered therein, and shall not constitute and admission by him for any other purpose or be used against him in any other proceeding or action.

§ 81.78 Evidence.

Irrelevant, immaterial, unreliable, and unduly repetitious evidence will be excluded.

§ 81.79 Cross-examination.

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

§ 81.80 Unsponsored written material.

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

§ 81.81 Objections.

Objections to evidence shall be timely and briefly state the ground relied upon.

§ 81.82 Exceptions to rulings of presiding officer unnecessary.

Exceptions to rulings of the presiding officer are unnecessary. It is sufficient that a party, at the time the ruling of the presiding officer is sought, makes known the action which he desires the presiding officer to take, or his objection to an action taken, and his grounds therefor.

§ 81.83 Official notice.

Where official notice is taken or is to be taken of a material fact not appearing in the evidence of record, any party, on timely request, shall be afforded an opportunity to show the contrary.

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§ 81.84 Public document items.

Whenever there is offered (in whole or in part) a public document, such as an official report, decision, opinion, or published scientific or economic statistical data issued by any of the executive departments (or their subdivisions), legislative agencies or committees, or administrative agencies of the Federal Government (including Government-owned corporations), or a similar document issued by a State or its agencies, and such document (or part thereof) has been shown by the offeror to be reasonably available to the public, such document need not be produced or marked for identification, but may be offered for official notice, as a public document item by specifying the document or relevant part thereof.

§ 81.85 Offer of proof.

An offer of proof made in connection with an objection taken to any ruling of the presiding officer rejecting or excluding proffered oral testimony shall consist of a statement of the substance of the evidence which counsel contends would be adduced by such testimony; and, if the excluded evidence consists of evidence in documentary or written form or of reference to documents or records, a copy of such evidence shall be marked for identification and shall accompany the record as the offer of proof.

§ 81.86 Appeals from ruling of presiding officer.

Rulings of the presiding officer may not be appealed to the reviewing authority prior to his consideration of the entire proceeding except with the consent of the presiding officer and where he certifies on the record or in writing that the allowance of an interlocutory appeal is clearly necessary to prevent exceptional delay, expense, or prejudice to any party, or substantial detriment to the public interest. If an appeal is allowed, any party may file a brief with the reviewing authority within such period as the presiding officer directs. No oral argument will be heard unless the reviewing authority directs otherwise. At any time prior to submission of the proceeding to it for decisions, the reviewing authority may direct the presiding officer to certify

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any question or the entire record to it for decision. Where the entire record is so certified, the presiding officer shall recommend a decision.

Subpart I—The Record

§ 81.91 Official transcript.

The Department will designate the official reporter for all hearings. The official transcripts of testimony taken, together with any exhibits, briefs, or memoranda of law filed therewith shall be filed with the Department. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not to exceed the maximum rates fixed by the contract between the Department and the reporter. Upon notice to all parties, the presiding officer may authorize corrections to the transcript which involve matters of substance.

§ 81.92 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 shall constitute the exclusive record for decision.

Subpart J—Posthearing Procedures, Decisions

§ 81.101 Posthearing briefs: Proposed findings and conclusions.

(a) The presiding officer shall fix the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law, and, if permitted, reply briefs.

(b) Briefs should include a summary of the evidence relied upon together with references to exhibit numbers and pages of the transcript, with citations of the authorities relied upon.

§ 81.102 Decisions following hearing.

When the time for submission of posthearing briefs has expired, the presiding officer shall certify the entire record, including his recommended findings and proposed decision, to the responsible Department official; or if so authorized he shall make an initial decision. A copy of the recommended

findings and proposed decision, or of the initial decision, shall be served upon all parties, and amici, if any.

§ 81.103 Exceptions to initial or recommended decisions.

Within 20 days after the mailing of an initial or recommended decision, any party may file exceptions to the decision, stating reasons therefor, with the reviewing authority. Any other party may file a response thereto within 30 days after the mailing of the decision. Upon the filing of such exceptions, the reviewing authority shall review the decision and issue its own decision thereon.

§ 81.104 Final decisions.

(a) Where the hearing is conducted by a hearing examiner who makes an initial decision, if no exceptions thereto are filed within the 20-day period specified in § 81.103, such decision shall become the final decision of the Department, and shall constitute “final agency action” within the meaning of 5 U.S.C. 704 (formerly section 10(c) of the Administrative Procedure Act), subject to the provisions of § 81.106.

(b) Where the hearing is conducted by a hearing examiner who makes a recommended decision, or upon the filing of exceptions to a hearing examiner's initial decision, the reviewing authority shall review the recommended or initial decision and shall issue its own decision thereon, which shall become the final decision of the Department, and shall constitute “final agency action” within the meaning of 5 U.S.C. 704 (formerly section 10(c) of the Administrative Procedure Act), subject to the provisions of § 81.106.

(c) All final decisions shall be promptly served on all parties, and amici, if any.

§ 81.105 Oral argument to the reviewing authority.

(a) If any party desires to argue a case orally on exceptions or replies to exceptions to an initial or recommended decision, he shall make such request in writing. The reviewing authority may grant or deny such requests in its discretion. If granted, it will serve notice of oral argument on all parties. The notice will set forth

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the order of presentation, the amount of time allotted, and the time and place for argument. The names of persons who will argue should be filed with the Department hearing clerk not later than 7 days before the date set for oral argument.

(b) The purpose of oral argument is to emphasize and clarify the written argument in the briefs. Reading at length from the brief or other texts is not favored. Participants should confine their arguments to points of controlling importance and to points upon which exceptions have been filed. Consolidations of appearances at oral argument by parties taking the same side will permit the parties' interests to be presented more effectively in the time allotted.

(c) Pamphlets, charts, and other written material may be presented at oral argument only if such material is limited to facts already in the record and is served on all parties and filed with the Department hearing clerk at least 7 days before the argument.

§ 81.106 Review by the Secretary.

Within 20 days after an initial decision becomes a final decision pursuant to § 81.104(a) or within 20 days of the mailing of a final decision referred to in § 81.104(b), as the case may be, a party may request the Secretary to review the final decision. The Secretary may grant or deny such request, in whole or in part, or serve notice of his intent to review the decision in whole or in part upon his own motion. If the Secretary grants the requested review, or if he serves notice of intent to review upon his own motion, each party to the decision shall have 20 days following notice of the Secretary's proposed action within which to file exceptions to the decision and supporting briefs and memoranda, or briefs and memoranda in support of the decision. Failure of a party to request review under this paragraph shall not be deemed a failure to exhaust administrative remedies for the purpose of obtaining judicial review.

§ 81.107 Service on amici curiae.

All briefs, exceptions, memoranda, requests, and decisions referred to in this Subpart J shall be served upon

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amici curiae at the same times and in the same manner required for service on parties. Any written statements of position and trial briefs required of parties under § 81.71 shall be served on amici.

Subpart K—Judicial Standards of Practice

§ 81.111 Conduct.

Parties and their representatives are expected to conduct themselves with honor and dignity and observe judicial standards of practice and ethics in all proceedings. They should not indulge in offensive personalities, unseemly wrangling, or intemperate accusations or characterizations. A representative of any party whether or not a lawyer shall observe the traditional responsibilities of lawyers as officers of the court and use his best efforts to restrain his client from improprieties in connection with a proceeding.

§ 81.112 Improper conduct.

With respect to any proceeding it is improper for any interested person to attempt to sway the judgment of the reviewing authority by undertaking to bring pressure or influence to bear upon any officer having a responsibility for a decision in the proceeding, or his decisional staff. It is improper that such interested persons or any members of the Department's staff or the presiding officer give statements to communications media, by paid advertisement or otherwise, designed to influence the judgment of any officer having a responsibility for a decision in the proceeding, or his decisional staff. It is improper for any person to solicit communications to any such officer, or his decisional staff, other than proper communications by parties or amici curiae.

§ 81.113 Ex parte communications.

Only persons employed by or assigned to work with the reviewing authority who perform no investigative or prosecuting function in connection with a proceeding shall communicate ex parte with the reviewing authority, or the presiding officer, or any employee or person involved in the decisional process in such proceedings

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with respect to the merits of that or a factually related proceeding. The reviewing authority, the presiding officer, or any employee or person involved in the decisional process of a proceeding shall communicate *ex parte* with respect to the merits of that or a factually related proceeding only with persons employed by or assigned to work with them and who perform no investigative or prosecuting function in connection with the proceeding.

§ 81.114 Expeditious treatment.

Requests for expeditious treatment of matters pending before the responsible Department official or the presiding officer are deemed communications on the merits, and are improper except when forwarded from parties to a proceeding and served upon all other parties thereto. Such communications should be in the form of a motion.

§ 81.115 Matters not prohibited.

A request for information which merely inquires about the status of a proceeding without discussing issues or expressing points of view is not deemed an *ex parte* communication. Such requests should be directed to the Civil Rights hearing clerk. Communications with respect to minor procedural matters or inquiries or emergency requests for extensions of time are not deemed *ex parte* communications prohibited by § 81.113. Where feasible, however, such communications should be by letter with copies to all parties. *Ex parte* communications between a respondent and the responsible Department official or the Secretary with respect to securing such respondent's voluntary compliance with any requirement of part 80 of this title are not prohibited.

§ 81.116 Filing of *ex parte* communications.

A prohibited communication in writing received by the Secretary, the reviewing authority, or by the presiding officer, shall be made public by placing it in the correspondence file of the docket in the case and will not be considered as part of the record for decision. If the prohibited communication is received orally a memorandum setting forth its substance shall be made and filed in the correspondence section

of the docket in the case. A person referred to in such memorandum may file a comment for inclusion in the docket if he considers the memorandum to be incorrect.

Subpart L—Posttermination Proceedings

§ 81.121 Posttermination proceedings.

(a) An applicant or recipient adversely affected by the order terminating, discontinuing, or refusing Federal financial assistance in consequence of proceedings pursuant to this title may request the responsible Department official for an order authorizing payment, or permitting resumption, of Federal financial assistance. Such request shall be in writing and shall affirmatively show that since entry of the order, it has brought its program or activity into compliance with the requirements of the Act, and with the Regulation thereunder, and shall set forth specifically, and in detail, the steps which it has taken to achieve such compliance. If the responsible Department official denies such request the applicant or recipient shall be given an expeditious hearing if it so requests in writing and specifies why it believes the responsible Department official to have been in error. The request for such a hearing shall be addressed to the responsible Department official and shall be made within 30 days after the applicant or recipient is informed that the responsible Department official has refused to authorize payment or permit resumption of Federal financial assistance.

(b) In the event that a hearing shall be requested pursuant to paragraph (a) of this section, the hearing procedures established by this part shall be applicable to the proceedings, except as otherwise provided in this section.

Subpart M—Definitions

§ 81.131 Definitions.

The definitions contained in § 80.13 of this subtitle apply to this part, unless the context otherwise requires, and the term *reviewing authority* as used herein includes the Secretary of Health and

Human Services, with respect to action by that official under § 81.106.

Transition provisions: (a) The amendments herein shall become effective upon publication in the FEDERAL REGISTER.

(b) These rules shall apply to any proceeding or part thereof to which part 80 of this title as amended effective October 19, 1967 (published in the FEDERAL REGISTER for October 19, 1967), and as the same may be hereafter amended, applies. In the case of any proceeding or part thereof governed by the provisions of part 80 as that part existed prior to such amendment, and rules in this part 81 shall apply as if these amendments were not in effect.

PART 83—REGULATION FOR THE ADMINISTRATION AND ENFORCEMENT OF SECTIONS 799A AND 845 OF THE PUBLIC HEALTH SERVICE ACT

Subpart A—Purposes; Definitions; Coverage

Sec.

83.1 Purposes.

83.2 Definitions.

83.3 Remedial and affirmative actions.

83.4 Coverage.

83.5 Effect of title IX of the Education Amendments of 1972.

83.6–83.9 [Reserved]

Subpart B—Discrimination in Admissions Prohibited

83.10 General obligations.

83.11 Discriminatory acts prohibited.

83.12 Recruitment.

83.13 State law and licensure requirements.

83.14 Development and dissemination of nondiscrimination policy.

83.15 Designation by entity of responsible employee and adoption of grievance procedures.

83.16–83.19 [Reserved]

Subpart C—Procedures [Interim]

83.20 Interim procedures.

AUTHORITY: Sec. 215(b), Public Health Service Act (42 U.S.C. 216(b)).

SOURCE: 40 FR 28573, July 7, 1975, unless otherwise noted.

Subpart A—Purposes; Definitions; Coverage

§ 83.1 Purposes.

(a) The purposes of this part are (1) to effectuate the provisions of sections 799A and 845 of the Public Health Service Act, which forbid the extension of Federal support under title VII or VIII of that Act to any entity of the types described in those sections unless that entity submits to the Secretary of Health and Human Services an assurance satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs, and (2) to implement the policy of the Secretary that no Federal support will be extended under those titles to any other entity unless that entity submits to the Secretary an assurance satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs.

(b) The objective of this part is to abolish use of sex as a criterion in the admission of individuals to all training programs operated by an entity which receives support under title VII or VIII of the Act, and thereby to foster maximum use of all available human resources in meeting the Nation's needs for qualified health personnel.

§ 83.2 Definitions.

As used in this part the term—

(a) *Act* means the Public Health Service Act.

(b) *Administrative law judge* means a person appointed by the Reviewing Authority to preside over a hearing held under this part.

(c) *Assurance commitment clause* means a clause in an invitation for a contract offer extended by the Federal Government under title VII or VIII of the Act which, when executed by an entity as part of such offer, becomes, upon acceptance of such offer by the Federal Government, a contractual obligation of such entity to comply with its assurance submitted to the Director under this part.

(d) *Department* means the Department of Health and Human Services.

(e) *Director* means the Director of the Office for Civil Rights of the Department.

(f) *Entity* means (1) a school of medicine, school of dentistry, school of osteopathy, school of pharmacy, school of optometry, school of podiatry, school of veterinary medicine, or school of public health, as defined by section 724 of the Act;

(2) A school of nursing, as defined by section 843 of the Act;

(3) A school or college of a training center for an allied health profession, as defined by section 795 of the Act, or of another institution of undergraduate education which school or college can provide a training program;

(4) An affiliated hospital, as defined by section 724 or 795 of the Act; and

(5) Any other institution, organization, consortium, or agency which is eligible to receive Federal support.

(g) *Federal support* means assistance extended after November 18, 1971, under title VII or VIII of the Act to an entity by means of a grant to, a contract with, or a loan guarantee or interest subsidy payment made on behalf of, such entity.

(h) *Federally supported entity* means an entity which receives Federal support.

(i) *Reviewing authority* means that component of the Department to which the Secretary delegates authority to review the decision of an administrative law judge in a proceeding arising under this part.

(j) *Secretary* means the Secretary of Health and Human Services.

(k) *Training program* means a program of training described by section 724(4) of the Act, a program of education described by, or specified by regulations pursuant to, section 795(1) of the Act, a program of education described by section 843(c), 843(d), or 843(e) of the Act, and a program leading to any license or certification requisite to the practice of a health profession for which a degree specified in any such section is granted.

§ 83.3 Remedial and affirmative actions.

(a) *Remedial action*. If the Director finds that an entity has discriminated against persons on the basis of sex in any of its training programs, such entity shall take such remedial action as the Director deems necessary to over-

come the effects of such discrimination.

(b) *Affirmative action*. In the absence of a finding of discrimination on the basis of sex in a training program, an entity may take affirmative action to overcome the effects of conditions which resulted in limited participation therein by persons of a particular sex.

§ 83.4 Coverage.

(a) If an entity receives Federal support for any of its training programs, all of its training programs thereby become subject to this part.

(b) The obligation imposed by this part on a federally supported entity not to discriminate on the basis of sex in the admission of individuals to a training program includes not only the obligation not to discriminate on such basis in the selection of individuals for such program, but also the obligation not to discriminate on such basis against individuals after their selection for such program.

(c) The obligation imposed by this part on a federally supported entity not to discriminate on the basis of sex against an individual who is an applicant for, or is enrolled in, a training program is applicable to the same extent to the actions of such entity with respect to an applicant for, or a student enrolled in, an undergraduate program of education of such entity if individuals enrolled in such program must complete all or a part of such programs to be eligible for admission to an undergraduate training program of such entity.

(d) An entity shall not discriminate on the basis of sex in violation of this part for as long as such entity receives or benefits from Federal support. For purposes of the preceding sentence, an entity shall be deemed to continue to receive or benefit from Federal support for as long as it retains ownership, possession, or use of either real or personal property and which was acquired in whole or in part with Federal support. If an entity receives value for property which was acquired in whole or in part with Federal support and such value is applied toward the acquisition of other property, such entity shall be deemed to continue to receive or benefit from such support for as long

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as such entity retains ownership, use, or possession of such other property.

(e) An entity shall not transfer property which was acquired, constructed, altered, repaired, expanded, or renovated in whole or in part with Federal support unless the agency, organization, or individual to whom such property is to be transferred has submitted to the Director, and he or she has found satisfactory, an assurance of compliance with this part. The preceding sentence shall not apply with respect to any real or personal property for which payments have been recaptured by the United States under title VII or VIII of the Act, with respect to any other property for which the transferring entity has refunded to the Federal Government the Federal share of the fair market value of such property, or with respect to any personal property which has only scrap value to both the entity and the agency, organization or individual to which the property is to be transferred.

§ 83.5 Effect of title IX of the Education Amendments of 1972.

The obligations imposed by this part are independent of obligations imposed by or pursuant to title IX of the Education Amendments of 1972.

§§ 83.6–83.9 [Reserved]

Subpart B—Discrimination in Admissions Prohibited

§ 83.10 General obligations.

(a) *Eligibility for support.* No entity will be provided Federal support unless such entity has furnished the Director assurances satisfactory to him or her that it will not discriminate on the basis of sex, in violation of this part, in the admission of individuals to each of its training programs.

(b) *Eliminating the effects of discrimination.* An assurance of compliance with this part will not be satisfactory to the Director if the entity submitting such assurance fails to take whatever remedial action in accordance with § 83.3(a) that is necessary for such entity to eliminate the effects of any discrimination on the basis of sex in the admission of individuals to its training programs that such entity practiced

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prior to the submission to the Director of such assurance, or practices at the time of or subsequent to such submission. The Director may require such entity, as a condition to determining that its assurance is, or remains, satisfactory, to take specific actions, or to submit to him or her specific information, bearing upon compliance with this part.

§ 83.11 Discriminatory acts prohibited.

(a) *General.* No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any academic, extracurricular, research, occupational training, or other training program or activity operated by an entity.

(b) *Discrimination in selection.* In determining whether an individual satisfies any enrollment, eligibility, or other condition for selection for a training program, a federally supported entity shall not:

(1) On the basis of sex, given preference to one individual over another by ranking applicants on such basis, or otherwise give such preference; or

(2) Apply numerical limitations upon the number or proportion of persons of either sex who may be admitted; or

(3) Otherwise treat one individual differently from another on the basis of sex.

(c) *Testing.* A federally supported entity shall not administer or operate any test or use any criterion for admission which has a disproportionately adverse effect on persons on the basis of sex unless the use of such test or criterion is shown validly to predict success in the training program or activity in question and alternative tests or criteria which do not have such a disproportionately adverse effect are shown to be unavailable.

(d) *Prohibitions relating to marital or parental status.* In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, in providing financial aid or any other benefit, an entity to which this subpart applies:

(1) Shall not apply any rule concerning the actual or potential parental, family, or marital status of a student or applicant which treats persons differently on the basis of sex;

(2) Shall not discriminate against or exclude any person on the basis of pregnancy, childbirth, termination of pregnancy or recovery therefrom, or establish or follow any rule or practice which so discriminates or excludes;

(3) Shall treat pregnancy, childbirth, termination of pregnancy and any temporary disabilities related to or resulting from pregnancy, childbirth, termination of pregnancy or recovery therefrom in the same manner and under the same policies as any other temporary disability or physical condition; and

(4) Shall not make pre-admission inquiry as to the marital status of an applicant for admission, including whether such applicant is "Miss," or "Mrs." A recipient may make pre-admission inquiry as to the sex of an applicant for admission, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by this part.

(e) *Preference to students from other institutions in admission.* An entity shall not give preference to applicants for admission, on the basis of attendance at any educational institution or other school or entity which admits as students only or predominantly members of one sex, if the giving of such preference has the effect of discriminating on the basis of sex in violation of this part.

(f) *Discrimination in the provision of benefits and services—(1) General.* Except as otherwise provided in this part in providing financial aid or any other benefit, or in providing any service, to an applicant for a training program or to a student enrolled in such program, no federally supported entity shall on the basis of sex:

(i) Treat one individual differently from another in determining whether such individual satisfies any requirement or condition for the provision of such benefit or service;

(ii) Provide a different benefit or service or provide a benefit or a service in a different manner;

(iii) Deny an individual any such benefit or service;

(iv) Subject an individual to separate treatment or rules of behavior;

(v) Discriminate against any individual by assisting an agency, organization, or individual in providing, in a manner which discriminates on the basis of sex, a benefit or service to applicants for or students enrolled in a training program; or

(vi) Otherwise limit any individual in the enjoyment of any right, privilege, advantage, or opportunity.

(2) *Financial aid established by certain legal instruments.* (i) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established pursuant to domestic or foreign wills, trusts, bequests, or similar legal instruments or by acts of a foreign government which requires that awards be made to members of a particular sex specified therein: *Provided*, That the overall effect of the award of such sex-restricted scholarships, fellowships, and other forms of financial assistance does not discriminate on the basis of sex.

(ii) To ensure nondiscriminatory awards of assistance as required in paragraph (f)(2)(i) of this section, recipients shall develop and use procedures under which:

(A) Students are selected for award of financial assistance on the basis of non-discriminatory criteria and not on the basis of availability of funds restricted to members of a particular sex;

(B) An appropriate sex-restricted scholarship, fellowship, or other form of financial assistance is allocated to each student selected under paragraph (f)(2)(ii) (A) of this section; and

(C) No student is denied the award for which he or she was selected under paragraph (f)(2)(ii)(A) of this section because of the absence of a scholarship, fellowship, or other form of financial assistance designated for a member of that student's sex.

(g) *Housing.* (1) An entity shall not, on the basis of sex, apply different rules or regulations, impose different fees or requirements, or offer different services or benefits related to housing, except as provided in this subsection

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(including housing provided only to married students).

(2) An entity may provide separate housing on the basis of sex.

(3) Housing provided by an entity to students of one sex, when compared to that provided to students of the other sex, shall be as a whole: (i) Proportionate in quantity to the number of students of that sex applying for such housing; and (ii) comparable in quality and cost to the student.

(4) An entity shall not on the basis of sex, administer different policies or practices concerning occupancy by its students of housing other than that provided by such recipient.

(5) An entity which, through solicitation, listing, approval of housing, or otherwise, assists any agency, organization, or person in making housing available to any of its students, shall take reasonable action to ensure that such housing is provided to students of one sex, when compared to that provided to students of the other sex, is as a whole: (i) Proportionate in quantity and (ii) comparable in quality and cost to the student. An entity may render such assistance to any agency, organization, or person which provides all or part of such housing to students only of one sex.

(h) *Inter-institutional programs.* If a federally supported entity aids participation, by any applicant for or student enrolled in any of its training programs, in any program or activity of another organization or agency, such entity shall:

(1) Develop and implement a procedure to assure itself that such organization or agency takes no action with respect to such applicants or students which this part would prohibit such entity from taking; and

(2) Not aid such participation if such organization or agency takes such action.

(i) *Discrimination in employment prohibited.* A federally supported entity shall not discriminate on the basis of sex in employment practices relating to its professional and other staff who work directly with applicants for or students enrolled in any of its training programs. The provisions of this subpart apply to:

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(1) Recruitment, advertising, and the process of application for employment;

(2) Hiring, upgrading, promotion, consideration for and award of tenure, demotion, transfer, layoff, termination, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation, and changes in compensation;

(4) Job assignments, classifications and structure, including position descriptions, lines of progression, and seniority lists;

(5) The terms of any collective bargaining agreement;

(6) Granting and return from leaves of absence, pregnancy leave, leave for persons of either sex to care for children or dependents, or any other leave;

(7) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(8) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, selection for tuition assistance, selection for sabbaticals and leaves of absence to pursue training;

(9) Employer-sponsored activities, including social or recreational programs; and

(10) Any other term, condition, or privilege of employment.

§ 83.12 Recruitment.

(a) *Comparable recruitment.* A federally supported entity shall, with respect to each of its training programs, make comparable efforts to recruit members of each sex in the geographic area from which such entity attracts its students. A federally supported entity shall not recruit for any of its training programs exclusively or primarily at organizations or agencies which admit as members or students, or which provide a service for, only members of one sex unless such entity can demonstrate that such action is part of a recruitment program which does not have the effect of discriminating on the basis of sex in selection for a training program.

(b) *Recruitment practices.* A federally supported entity shall:

(1) Prominently include a statement of its policy of nondiscrimination on

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the basis of sex in each announcement, bulletin, catalogue, or application form which describes the training program of such entity or is used in connection with the recruitment of employees who will work directly with applicants for or students enrolled in a training program;

(2) Distribute without discrimination on the basis of sex any announcements, bulletins, catalogues, or other materials used in connection with the recruitment of students for a training program or employees who will work directly with applicants for such program or such students; and

(3) Apprise each of its recruitment representatives of its policy of non-discrimination on the basis of sex, and require such representatives to adhere to such policy.

§ 83.13 State law and licensure requirements.

The obligation of an entity to comply with this part is not obviated or alleviated by any State or local law which would render an applicant for or student enrolled in a training program ineligible on the basis of sex for any license or certificate requisite to the practice of the health profession for which such applicant seeks, or student pursues, training.

§ 83.14 Development and dissemination of nondiscrimination policy.

(a) A federally supported entity shall develop a written policy statement of nondiscrimination on the basis of sex, in accordance with this part, and shall implement specific and continuing steps to publicize such statement to applicants for admission or employment, students, employees, and sources of referral of applicants for admission or employment.

(b) Each federally supported entity shall prominently include a statement of the policy described in paragraph (a) of this section in each announcement, bulletin, catalogue, and application form which it makes available to any person of a type described in paragraph (a) of this section, or which is otherwise used in connection with the recruitment of students or employees who work directly with students and applicants for admission.

(c) A federally supported entity shall not use or distribute a publication of the type described in this section which suggests, by text or illustration, that such recipient treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by this part.

§ 83.15 Designation by entity of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A federally supported entity shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under this part, including any investigation of any complaint communicated to such entity alleging its noncompliance with this part or alleging any action which would be prohibited by this part. The entity shall notify all of its students and employees who work directly with students and applicants for admission of the name, office address and telephone number of the employee or employees appointed pursuant to this paragraph.

(b) *Complaint procedure of entity.* A federally supported entity shall adopt and publish grievance procedures providing for prompt and equitable resolution of student and employee complaints alleging any action which would be prohibited by this part. Such procedures shall be in writing and available to all present and prospective students and employees.

§§ 83.16–83.19 [Reserved]

Subpart C—Procedures [Interim]

§ 83.20 Interim procedures.

For the purposes of implementing this part during the period between its effective date and the final issuance by the Department of a consolidated procedural regulation applicable to sections 704 and 845 of the Act and other civil rights authorities administered by the Department, the procedural provisions applicable to title VI of the Civil Rights Act of 1964 are hereby adopted and incorporated herein by reference. These procedures may be found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

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**PART 84—NONDISCRIMINATION
ON THE BASIS OF DISABILITY IN
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CEIVING FEDERAL FINANCIAL
ASSISTANCE**

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APPENDIX C TO PART 84—GUIDELINES RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

AUTHORITY: 29 U.S.C. 794.

Subpart G also issued under 21 U.S.C. 1174; 42 U.S.C. 4581.

SOURCE: 42 FR 22677, May 4, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 84.1 Purpose and broad coverage.

(a) *Purpose.* The purpose of this part is to implement section 504 of the Rehabilitation Act of 1973, as amended, which prohibits discrimination on the basis of disability in any program or activity receiving Federal financial assistance.

(b) *Broad coverage.* The definition of “disability” in this part shall be construed broadly in favor of expansive coverage to the maximum extent permitted by the terms of section 504. The primary object of attention in cases brought under section 504 should be whether entities receiving Federal financial assistance have complied with their obligations and whether discrimination has occurred, not whether the individual meets the definition of “disability.” The question of whether an individual meets the definition of “disability” under this part should not demand extensive analysis.

[89 FR 40179, May 9, 2024]

§ 84.2 Application.

(a) This part applies to each recipient of Federal financial assistance from the Department and to the recipient’s programs or activities that involve individuals with disabilities in the United States. This part does not apply to the recipient’s programs or activities outside the United States that do not involve individuals with disabilities in the United States.

(b) The requirements of this part do not apply to the ultimate beneficiaries of any program or activity operated by a recipient of Federal financial assistance.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to

the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

[89 FR 40180, May 9, 2024]

§ 84.3 Relationship to other laws.

This part does not invalidate or limit the remedies, rights, and procedures of any other Federal laws, or State or local laws (including State common law) that provide greater or equal protection for the rights of individuals with disabilities, or individuals associated with them.

[89 FR 40180, May 9, 2024]

§ 84.4 Disability.

(a) *Definition*—(1) *Disability.* *Disability* means, with respect to an individual:

(i) A physical or mental impairment that substantially limits one or more of the major life activities of such individual;

(ii) A record of such an impairment; or

(iii) Being regarded as having such an impairment as described in paragraph (f) of this section.

(2) *Rules of construction.* (i) The definition of “disability” shall be construed broadly in favor of expansive coverage, to the maximum extent permitted by the terms of section 504.

(ii) An individual may establish coverage under any one or more of the three prongs of the definition of “disability” in paragraph (a)(1) of this section, the “actual disability” prong in paragraph (a)(1)(i) of this section, the “record of” prong in paragraph (a)(1)(ii) of this section, or the “regarded as” prong in paragraph (a)(1)(iii) of this section.

(iii) Where an individual is not challenging a recipient’s failure to provide reasonable modifications, it is generally unnecessary to proceed under the “actual disability” (paragraph (a)(1)(i) of this section) or “record of” (paragraph (a)(1)(ii) of this section) prongs, which require a showing of an impairment that substantially limits a

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major life activity or a record of such an impairment. In these cases, the evaluation of coverage can be made solely under the “regarded as” (this paragraph (a)(1)(iii)) prong of the definition of disability, which does not require a showing of an impairment that substantially limits a major life activity or a record of such an impairment. An individual may choose, however, to proceed under the “actual disability” or “record of” prong regardless of whether the individual is challenging a recipient’s failure to provide reasonable modifications.

(b) *Physical or mental impairment*—(1)(i) *Physical or mental impairment* is defined as any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more body systems, such as: neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, immune, circulatory, hemic, lymphatic, skin, and endocrine; or

(ii) Any mental or psychological disorder such as intellectual disability, organic brain syndrome, mental health condition, and specific learning disability.

(2) *Physical or mental impairment* includes, but is not limited to, contagious and noncontagious diseases and conditions such as the following: orthopedic, visual, speech and hearing impairments, and cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, intellectual disability, mental health condition, dyslexia and other specific learning disabilities, Attention Deficit Hyperactivity Disorder, Human Immunodeficiency Virus infection (whether symptomatic or asymptomatic), tuberculosis, substance use disorder, alcohol use disorder, and long COVID.

(3) *Physical or mental impairment* does not include homosexuality or bisexuality.

(c) *Major life activities*—(1) *Definition*. Major life activities include, but are not limited to:

(i) Caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, sitting, reaching, lifting, bending, speaking, breathing, learning, reading, concen-

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trating, thinking, writing, communicating, interacting with others, and working; and

(ii) The operation of a major bodily function, such as the functions of the immune system, special sense organs and skin, normal cell growth, and digestive, genitourinary, bowel, bladder, neurological, brain, respiratory, circulatory, cardiovascular, endocrine, hemic, lymphatic, musculoskeletal, and reproductive systems. The operation of a major bodily function includes the operation of an individual organ within a body system.

(2) *Rules of construction*. (i) In determining whether an impairment substantially limits a major life activity, the term major shall not be interpreted strictly to create a demanding standard.

(ii) Whether an activity is a major life activity is not determined by reference to whether it is of central importance to daily life.

(d) *Substantially limits*—(1) *Rules of construction*. The following rules of construction apply when determining whether an impairment substantially limits an individual in a major life activity.

(i) The term “substantially limits” shall be construed broadly in favor of expansive coverage, to the maximum extent permitted by the terms of section 504. “Substantially limits” is not meant to be a demanding standard.

(ii) The primary object of attention in cases brought under section 504 should be whether recipients have complied with their obligations and whether discrimination has occurred, not the extent to which an individual’s impairment substantially limits a major life activity. Accordingly, the threshold issue of whether an impairment substantially limits a major life activity should not demand extensive analysis.

(iii) An impairment that substantially limits one major life activity does not need to limit other major life activities to be considered a substantially limiting impairment.

(iv) An impairment that is episodic or in remission is a disability if it would substantially limit a major life activity when active.

(v) An impairment is a disability within the meaning of this part if it

substantially limits the ability of an individual to perform a major life activity as compared to most people in the general population. An impairment does not need to prevent, or significantly or severely restrict, the individual from performing a major life activity to be considered substantially limiting. Nonetheless, not every impairment will constitute a disability within the meaning of this section.

(vi) The determination of whether an impairment substantially limits a major life activity requires an individualized assessment. However, in making this assessment, the term “substantially limits” shall be interpreted and applied to require a degree of functional limitation that is lower than the standard for substantially limits applied prior to the ADA Amendments Act of 2008 (ADAAA).

(vii) The comparison of an individual’s performance of a major life activity to the performance of the same major life activity by most people in the general population usually will not require scientific, medical, or statistical evidence. Nothing in this paragraph (d)(1) is intended, however, to prohibit or limit the presentation of scientific, medical, or statistical evidence in making such a comparison where appropriate.

(viii) The determination of whether an impairment substantially limits a major life activity shall be made without regard to the ameliorative effects of mitigating measures. However, the ameliorative effects of ordinary eyeglasses or contact lenses shall be considered in determining whether an impairment substantially limits a major life activity. Ordinary eyeglasses or contact lenses are lenses that are intended to fully correct visual acuity or to eliminate refractive error.

(ix) The six-month “transitory” part of the “transitory and minor” exception in paragraph (f)(2) of this section does not apply to the “actual disability” (paragraph (a)(1)(i) of this section) or “record of” (paragraph (a)(1)(ii) of this section) prongs of the definition of “disability.” The effects of an impairment lasting or expected to last less than six months can be substantially limiting within the meaning of this section for establishing an ac-

tual disability or a record of a disability.

(2) *Predictable assessments.* (i) The principles set forth in the rules of construction in this section are intended to provide for generous coverage and application of section 504’s prohibition on discrimination through a framework that is predictable, consistent, and workable for all individuals and entities with rights and responsibilities under section 504.

(ii) Applying the principles in this section, the individualized assessment of some types of impairments as set forth in paragraph (d)(2)(iii) of this section will, in virtually all cases, result in a determination of coverage under paragraph (a)(1)(i) of this section (the “actual disability” prong) or paragraph (a)(1)(ii) of this section (the “record of” prong). Given their inherent nature, these types of impairments will, as a factual matter, virtually always be found to impose a substantial limitation on a major life activity. Therefore, with respect to these types of impairments, the necessary individualized assessment should be particularly simple and straightforward.

(iii) For example, applying the principles of this section it should easily be concluded that the types of impairments set forth in paragraphs (d)(2)(iii)(A) through (K) of this section will, at a minimum, substantially limit the major life activities indicated. The types of impairments described in this paragraph (d)(2) may substantially limit additional major life activities (including major bodily functions) not explicitly listed in paragraphs (d)(2)(iii)(A) through (K).

(A) Deafness substantially limits hearing;

(B) Blindness substantially limits seeing;

(C) Intellectual disability substantially limits brain function;

(D) Partially or completely missing limbs or mobility impairments requiring the use of a wheelchair substantially limit musculoskeletal function;

(E) Autism Spectrum Disorder substantially limits brain function;

(F) Cancer substantially limits normal cell growth;

(G) Cerebral palsy substantially limits brain function;

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(H) Diabetes substantially limits endocrine function;

(I) Epilepsy, muscular dystrophy, and multiple sclerosis each substantially limits neurological function;

(J) Human Immunodeficiency Virus (HIV) infection substantially limits immune function; and

(K) Major depressive disorder, bipolar disorder, post-traumatic stress disorder, traumatic brain injury, obsessive compulsive disorder, and schizophrenia each substantially limits brain function.

(3) *Condition, manner, or duration.* (i) At all times taking into account the principles set forth in the rules of construction in this section, in determining whether an individual is substantially limited in a major life activity, it may be useful in appropriate cases to consider, as compared to most people in the general population, the conditions under which the individual performs the major life activity; the manner in which the individual performs the major life activity; or the duration of time it takes the individual to perform the major life activity, or for which the individual can perform the major life activity.

(ii) Consideration of facts such as condition, manner, or duration may include, among other things, consideration of the difficulty, effort or time required to perform a major life activity; pain experienced when performing a major life activity; the length of time a major life activity can be performed; or the way an impairment affects the operation of a major bodily function. In addition, the non-ameliorative effects of mitigating measures, such as negative side effects of medication or burdens associated with following a particular treatment regimen, may be considered when determining whether an individual's impairment substantially limits a major life activity.

(iii) In determining whether an individual has a disability under the "actual disability" (paragraph (a)(1)(i) of this section) or "record of" (paragraph (a)(1)(ii) of this section) prongs of the definition of "disability," the focus is on how a major life activity is substantially limited, and not on what outcomes an individual can achieve. For

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example, someone with a learning disability may achieve a high level of academic success, but may nevertheless be substantially limited in one or more major life activities, including, but not limited to, reading, writing, speaking, or learning because of the additional time or effort he or she must spend to read, write, speak, or learn compared to most people in the general population.

(iv) Given the rules of construction set forth in this section, it may often be unnecessary to conduct an analysis involving most or all of the facts related to condition, manner, or duration. This is particularly true with respect to impairments such as those described in paragraph (d)(2)(iii) of this section, which by their inherent nature should be easily found to impose a substantial limitation on a major life activity, and for which the individualized assessment should be particularly simple and straightforward.

(4) *Mitigating measures.* Mitigating measures include, but are not limited to:

(i) Medication, medical supplies, equipment, appliances, low-vision devices (defined as devices that magnify, enhance, or otherwise augment a visual image, but not including ordinary eyeglasses or contact lenses), prosthetics including limbs and devices, hearing aid(s) and cochlear implant(s) or other implantable hearing devices, mobility devices, and oxygen therapy equipment and supplies;

(ii) Use of assistive technology;

(iii) Reasonable modifications or auxiliary aids or services as defined in this part;

(iv) Learned behavioral or adaptive neurological modifications; or

(v) Psychotherapy, behavioral therapy, or physical therapy.

(e) *Has a record of such an impairment*—(1) *General.* An individual has a record of such an impairment if the individual has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(2) *Broad construction.* Whether an individual has a record of an impairment that substantially limited a major life activity shall be construed broadly to

the maximum extent permitted by section 504 and should not demand extensive analysis. An individual will be considered to fall within the prong in this paragraph (e) of the definition of “disability” if the individual has a history of an impairment that substantially limited one or more major life activities when compared to most people in the general population or was misclassified as having had such an impairment. In determining whether an impairment substantially limited a major life activity, the principles articulated in paragraph (d)(1) of this section apply.

(3) *Reasonable modification.* An individual with a record of a substantially limiting impairment may be entitled to a reasonable modification if needed and related to the past disability.

(f) *Is regarded as having such an impairment.* The following principles apply under the “regarded” as prong of the definition of “disability” in paragraph (a)(1)(iii) of this section:

(1) Except as set forth in paragraph (f)(2) of this section, an individual is “regarded as having such an impairment” if the individual is subjected to a prohibited action because of an actual or perceived physical or mental impairment, whether or not that impairment substantially limits, or is perceived to substantially limit, a major life activity, even if the recipient asserts, or may or does ultimately establish, a defense to the action prohibited by section 504.

(2) An individual is not “regarded as having such an impairment” if the recipient demonstrates that the impairment is, objectively, both “transitory” and “minor.” A recipient may not defeat “regarded as” coverage of an individual simply by demonstrating that it subjectively believed the impairment was transitory and minor; rather, the recipient must demonstrate that the impairment is (in the case of an actual impairment) or would be (in the case of a perceived impairment), objectively, both “transitory” and “minor.” For purposes of this section, “transitory” is defined as lasting or expected to last six months or less.

(3) Establishing that an individual is “regarded as having such an impairment” does not, by itself, establish li-

ability. Liability is established under section 504 only when an individual proves that a recipient discriminated on the basis of disability within the meaning of section 504.

(g) *Exclusions.* The term “disability” does not include the terms set forth at 29 U.S.C. 705(20)(F).

[89 FR 40180, May 9, 2024]

§ 84.5 Assurances required.

(a) *Assurances.* An applicant for Federal financial assistance to which this part applies shall submit an assurance, on a form specified by the Director, that the program or activity will be operated in compliance with this part. An applicant may incorporate these assurances by reference in subsequent applications to the Department.

(b) *Duration of obligation.* (1) In the case of Federal financial assistance extended in the form of real property or to provide real property or structures on the property, the assurance will obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used for the purpose for which Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) In the case of Federal financial assistance extended to provide personal property, the assurance will obligate the recipient for the period during which it retains ownership or possession of the property.

(3) In all other cases the assurance will obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Covenants.* (1) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the instrument effecting or recording this transfer shall contain a covenant running with the land to assure non-discrimination for the period during which the real property is used for a purpose for which the Federal financial assistance is extended or for another purpose involving the provision of similar services or benefits.

(2) Where no transfer of property is involved but property is purchased or

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improved with Federal financial assistance, the recipient shall agree to include the covenant described in paragraph (b)(2) of this section in the instrument effecting or recording any subsequent transfer of the property.

(3) Where Federal financial assistance is provided in the form of real property or interest in the property from the Department, the covenant shall also include a condition coupled with a right to be reserved by the Department to revert title to the property in the event of a breach of the covenant. If a transferee of real property proposes to mortgage or otherwise encumber the real property as security for financing construction of new, or improvement of existing, facilities on the property for the purposes for which the property was transferred, the Director may, upon request of the transferee and if necessary to accomplish such financing and upon such conditions as he or she deems appropriate, agree to forbear the exercise of such right to revert title for so long as the lien of such mortgage or other encumbrance remains effective.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.6 Remedial action, voluntary action, and self-evaluation.

(a) *Remedial action.* (1) If the Director finds that a recipient has discriminated against persons on the basis of disability in violation of section 504 or this part, the recipient shall take such remedial action as the Director deems necessary to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against persons on the basis of disability in violation of section 504 or this part and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both recipients to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of section 504 or this part, require a recipient to take remedial action (i) with respect to persons with disabilities who are no longer participants in the recipient's program or activity but who were participants

in the program or activity when such discrimination occurred or (ii) with respect to persons with disabilities who would have been participants in the program or activity had the discrimination not occurred.

(b) *Voluntary action.* A recipient may take steps, in addition to any action that is required by this part, to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity by qualified persons with disabilities.

(c) *Self-evaluation.* (1) A recipient shall, within one year of the effective date of this part:

(i) Evaluate, with the assistance of interested persons, including persons with disabilities or organizations representing persons with disabilities, its current policies and practices and the effects thereof that do not or may not meet the requirements of this part;

(ii) Modify, after consultation with interested persons, including persons with disabilities or organizations representing persons with disabilities, any policies and practices that do not meet the requirements of this part; and

(iii) Take, after consultation with interested persons, including persons with disabilities or organizations representing persons with disabilities, appropriate remedial steps to eliminate the effects of any discrimination that resulted from adherence to these policies and practices.

(2) A recipient that employs fifteen or more persons shall, for at least three years following completion of the evaluation required under paragraph (c)(1) of this section, maintain on file, make available for public inspection, and provide to the Director upon request: (i) A list of the interested persons consulted (ii) a description of areas examined and any problems identified, and (iii) a description of any modifications made and of any remedial steps taken.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005; 89 FR 40182, May 9, 2024]

§ 84.7 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* A recipient that employs fifteen or more persons shall designate at least

one person to coordinate its efforts to comply with this part.

(b) *Adoption of grievance procedures.* A recipient that employs fifteen or more persons shall adopt grievance procedures that incorporate appropriate due process standards and that provide for the prompt and equitable resolution of complaints alleging any action prohibited by this part. Such procedures need not be established with respect to complaints from applicants for employment or from applicants for admission to postsecondary educational institutions.

§ 84.8 Notice.

A recipient shall make available to employees, applicants, participants, beneficiaries, and other interested persons information regarding the provisions of this part and its applicability to the programs or activities of the recipient, and make such information available to them in such manner as the head of the recipient or their designee finds necessary to apprise such persons of the protections against discrimination assured them by section 504 and this part.

[89 FR 40182, May 9, 2024]

§ 84.9 Administrative requirements for small recipients.

The Director may require any recipient with fewer than fifteen employees, or any class of such recipients, to comply with §§ 84.7 and 84.8, in whole or in part, when the Director finds a violation of this part or finds that such compliance will not significantly impair the ability of the recipient or class of recipients to provide benefits or services.

§ 84.10 Definitions.

As used in this part, the term:

2004 ADA Accessibility Guidelines (ADAAG) means the requirements set forth in appendices B and D to 36 CFR part 1191 (2009).

2010 Standards means the 2010 ADA Standards for Accessible Design, which consist of the 2004 ADAAG and the requirements contained in 28 CFR 35.151.

ADA means the Americans with Disabilities Act (Pub. L. 101-336, 104 Stat. 327, 42 U.S.C. 12101-12213 and 47 U.S.C. 225 and 611), including changes made by

the ADA Amendments Act of 2008 (Pub. L. 110-325), which became effective on January 1, 2009.

Applicant means one who submits an application, request, or plan required to be approved by the designated Department official or by a primary recipient, as a condition of eligibility for Federal financial assistance.

Architectural Barriers Act means the Architectural Barriers Act (42 U.S.C. 4151-4157), including the Architectural Barriers Act Accessibility Standards at 41 CFR 102-76.60 through 102-76.95.

Archived web content means web content that—

(1) Was created before the date the recipient is required to comply with § 84.84, reproduces paper documents created before the date the recipient is required to comply with § 84.84, or reproduces the contents of other physical media created before the date the recipient is required to comply with § 84.84;

(2) Is retained exclusively for reference, research, or recordkeeping;

(3) Is not altered or updated after the date of archiving; and

(4) Is organized and stored in a dedicated area or areas clearly identified as being archived.

Auxiliary aids and services include:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services; notetakers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible electronic and information technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers;

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secondary auditory programs (SAP); large print materials; accessible electronic and information technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision;

(3) Acquisition or modification of equipment or devices; and

(4) Other similar services and actions.

Companion means a family member, friend, or associate of an individual seeking access to a program or activity of a recipient, who, along with such individual, is an appropriate person with whom the recipient should communicate.

Conventional electronic documents means web content or content in mobile apps that is in the following electronic file formats: portable document formats (PDF), word processor file formats, presentation file formats, and spreadsheet file formats.

Current illegal use of drugs means illegal use of drugs that occurred recently enough to justify a reasonable belief that a person's drug use is current or that continuing use is a real and ongoing problem.

Department means the Department of Health and Human Services.

Direct threat means:

(1) Except as provided in paragraph (2) of this definition, a significant risk to the health or safety of others that cannot be eliminated by a modification of policies, practices, or procedures, or by the provision of auxiliary aids or services as provided in § 84.75.

(2) With respect to employment as provided in § 84.12, the term as defined by the Equal Employment Opportunity Commission's regulation implementing title I of the Americans with Disabilities Act of 1990, at 29 CFR 1630.2(r).

Director means the Director of the Office for Civil Rights.

Disability means:

(1) Except as provided in paragraph (2) of this definition, the definition of *disability* found at § 84.4.

(2) With respect to employment, the definition of *disability* found at 29 CFR 1630.2.

Drug means a controlled substance, as defined in schedules I through V of

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section 202 of the Controlled Substances Act (21 U.S.C. 812).

Existing facility means a facility in existence on any given date, without regard to whether the facility may also be considered newly constructed or altered under this part.

Facility means all or any portion of buildings, structures, sites, complexes, equipment, rolling stock or other conveyances, roads, walks, passageways, parking lots, or other real or personal property, including the site where the building, property, structure, or equipment is located.

Federal financial assistance means any grant, cooperative agreement, loan, contract (other than a direct Federal procurement contract or a contract of insurance or guaranty), subgrant, contract under a grant or any other arrangement by which the Department provides or otherwise makes available assistance in the form of:

(1) Funds;

(2) Services of Federal personnel;

(3) Real and personal property or any interest in or use of such property, including:

(i) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(ii) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government; and

(4) Any other thing of value by way of grant, loan, contract, or cooperative agreement.

Foster care means 24-hour substitute care for children placed away from their parents or guardians and for whom the State agency has placement and care responsibility. This includes, but is not limited to, placements in foster family homes, foster homes of relatives, group homes, emergency shelters, residential facilities, childcare institutions, and pre-adoptive homes. A child is in foster care in accordance with this definition regardless of whether the foster care facility is licensed and payments are made by the State or local agency for the care of the child, whether adoption subsidy payments are being made prior to the finalization of an adoption, or whether

there is Federal matching of any payments that are made.

Illegal use of drugs means the use of one or more drugs, the possession or distribution of which is unlawful under the Controlled Substances Act (21 U.S.C. 812). The term illegal use of drugs does not include the use of a drug taken under supervision by a licensed health care professional, or other uses authorized by the Controlled Substances Act or other provisions of Federal law.

Individual with a disability means a person who has a disability. The term *individual with a disability* does not include an individual who is currently engaging in illegal use of drugs when a recipient acts on the basis of such use.

Kiosks means self-service transaction machines made available by recipients at set physical locations for the independent use of patients or program participants in health and human service programs or activities. They often consist of a screen and an input device—either a keyboard, touch screen, or similar device—onto which the program participant independently types in or otherwise enters information. In health and human service programs, recipients often make kiosks available so that patients or program participants can check in, provide information for the receipt of services, procure services, have their vital signs taken, or perform other similar actions.

Medical diagnostic equipment (MDE) means equipment used in, or in conjunction with, medical settings by health care providers for diagnostic purposes. MDE includes, for example, examination tables, examination chairs (including chairs used for eye examinations or procedures), and dental examinations or procedures), weight scales, mammography equipment, x-ray machines, and other radiological equipment commonly used for diagnostic purposes by health professionals.

Mobile applications (apps) means software applications that are downloaded and designed to run on mobile devices, such as smartphones and tablets.

Most integrated setting means a setting that provides individuals with disabilities the opportunity to interact with nondisabled persons to the fullest

extent possible. These settings provide opportunities to live, work, and receive services in the greater community, like individuals without disabilities; are located in mainstream society; offer access to community activities and opportunities at times, frequencies and with persons of an individual's choosing; and afford individuals choice in their daily life activities.

Other power-driven mobility device means any mobility device powered by batteries, fuel, or other engines—whether or not designed primarily for use by individuals with mobility disabilities—that is used by individuals with mobility disabilities for the purpose of locomotion, including golf cars, electronic personal assistance mobility devices (EPAMDs), such as the Segway® PT, or any mobility device designed to operate in areas without defined pedestrian routes, but that is not a wheelchair within the meaning of this section. This definition does not apply to Federal wilderness areas; wheelchairs in such areas are defined in section 508(c)(2) of the ADA, 42 U.S.C. 12207(c)(2).

Parents means biological or adoptive parents or legal guardians, as determined by applicable State law.

Program or activity means all of the operations of any entity described in paragraphs (1) through (4) of this definition, any part of which is extended Federal financial assistance:

(1)(i) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(ii) The entity of such State or local government that distributes such assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(2)(i) A college, university, or other postsecondary institution, a public system of higher education; or

(ii) A local educational agency (as defined in 20 U.S.C. 7801), system of career and technical education, or other school system;

(3)(i) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

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(A) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(B) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(ii) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(4) Any other entity which is established by two or more of the entities described in paragraph (1), (2), or (3) of this definition.

Prospective parents means individuals who are seeking to become foster or adoptive parents.

Qualified individual with a disability means:

(1) Except as provided in paragraphs (2) through (4) of this definition, an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by a recipient; and

(2) With respect to employment, an individual with a disability who meets the definition of “qualified” in the Equal Employment Opportunity Commission’s regulation implementing title I of the Americans with Disabilities Act of 1990, 29 CFR 1630.2(m).

(3) With respect to childcare, pre-school, elementary, secondary, or adult educational services, a person with a disability—

(i) Of an age during which non-disabled persons are provided such services;

(ii) Of any age during which it is mandatory under State law to provide such services to persons with a disability; or

(iii) To whom a State is required to provide a free appropriate public education under the Individuals with Disabilities Education Act; and

(4) With respect to postsecondary and career and technical education serv-

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ices, an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in the recipient’s program or activity.

Qualified interpreter means an interpreter who, via an on-site appearance or through a video remote interpreting (VRI) service, is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary. Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.

Recipient means any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended directly or through another recipient, including any successor, assignee, or transferee of a recipient, but excluding the ultimate beneficiary of the assistance.

Section 504 means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794)), as amended.

Section 508 Standards means the standards for Information and Communications Technologies (ICT) promulgated at 36 CFR part 1194 by the U.S. Access Board per section 508 of the Rehabilitation Act (29 U.S.C. 794d as amended).

Service animal means any dog that is individually trained to do work or perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability. Other species of animals, whether wild or domestic, trained or untrained, are not service animals for the purposes of this

definition. The work or tasks performed by a service animal must be directly related to the individual's disability. Examples of work or tasks include, but are not limited to, assisting individuals who are blind or have low vision with navigation and other tasks, alerting individuals who are deaf or hard of hearing to the presence of people or sounds, providing non-violent protection or rescue work, pulling a wheelchair, assisting an individual during a seizure, alerting individuals to the presence of allergens, retrieving items such as medicine or the telephone, providing physical support and assistance with balance and stability to individuals with mobility disabilities, and helping persons with mental and neurological disabilities by preventing or interrupting impulsive or harmful behaviors. The crime deterrent effects of an animal's presence and the provision of emotional support, well-being, comfort, or companionship do not constitute work or tasks for the purposes of this definition.

Standards for Accessible Medical Diagnostic Equipment ("Standards for Accessible MDE") means the standards promulgated by the Architectural and Transportation Barriers Compliance Board (Access Board) under section 510 of the Rehabilitation Act of 1973, as amended, found at 36 CFR part 1195 (as of Jan. 9, 2017), with the exception of M301.2.2 and M302.2.2.

State includes, in addition to each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Ultimate beneficiary means one among a class of persons who are entitled to benefit from, or otherwise participate in, a program or activity receiving Federal financial assistance and to whom the protections of this part extend. The ultimate beneficiary class may be the general public or some narrower group of persons.

User agent means any software that retrieves and presents web content for users.

Video remote interpreting (VRI) service means an interpreting service that uses video conference technology over dedi-

cated lines or wireless technology offering high-speed, wide-bandwidth video connection that delivers high-quality video images as provided in § 84.77(d).

WCAG 2.1 means the Web Content Accessibility Guidelines (WCAG) 2.1, W3C Recommendation 05 June 2018, <https://www.w3.org/TR/2018/REC-WCAG21-20180605/> and <https://perma.cc/UB8A-GG2F>. WCAG 2.1 is incorporated by reference elsewhere in this part (see §§ 84.84 and 84.86).

Web content means the information and sensory experience to be communicated to the user by means of a user agent, including code or markup that defines the content's structure, presentation, and interactions. Examples of web content include text, images, sounds, videos, controls, animations, and conventional electronic documents.

Wheelchair means a manually-operated or power-driven device designed primarily for use by an individual with a mobility disability for the main purpose of indoor, or of both indoor and outdoor locomotion. This definition does not apply to Federal wilderness areas; wheelchairs in such areas are defined in section 508(c)(2) of the ADA, 42 U.S.C. 12207(c)(2).

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005. Redesignated and revised and republished at 89 FR 40180, 40182, May 9, 2024]

Subpart B—Employment Practices

SOURCE: 89 FR 40185, May 9, 2024, unless otherwise noted.

§ 84.16 Discrimination prohibited.

(a) No qualified individual with a disability shall, on the basis of disability, be subjected to discrimination in employment under any program or activity receiving Federal financial assistance from the Department.

(b) The standards used to determine whether paragraph (a) of this section has been violated shall be the standards applied under title I of the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. 12111 *et seq.*, and, as such sections relate to employment, the provisions of sections 501 through 504 and 511 of the ADA of 1990, as

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amended (codified at 42 U.S.C. 12201–12204, 12210), as implemented in the Equal Employment Opportunity Commission’s regulation at 29 CFR part 1630.

§§ 84.17–84.20 [Reserved]

Subpart C—Accessibility

§ 84.21 Discrimination prohibited.

Except as otherwise provided in § 84.22, no qualified individual with a disability shall, because a recipient’s facilities are inaccessible to or unusable by individuals with disabilities, be excluded from participation in, or be denied the benefits of the programs or activities of a recipient, or be subjected to discrimination by any recipient.

[89 FR 40185, May 9, 2024]

§ 84.22 Existing facilities.

(a) *General.* A recipient shall operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by individuals with disabilities. This paragraph (a) does not—

(1) Necessarily require a recipient to make each of its existing facilities accessible to and usable by individuals with disabilities; or

(2) Require a recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where a recipient’s personnel believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the recipient has the burden of proving that compliance with this paragraph (a) would result in such an alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of the recipient or their designee after considering all the recipient’s resources available for use in the funding and operation of the program or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, the recipient shall

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take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with disabilities receive the benefits or services provided by the recipient.

(b) *Methods.* A recipient may comply with the requirements of this section through such means as redesign or acquisition of equipment, reassignment of services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities, use of accessible rolling stock or other conveyances, or any other methods that result in making its programs or activities readily accessible to and usable by individuals with disabilities. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with this section. A recipient, in making alterations to existing buildings, shall meet the accessibility requirements of § 84.23. In choosing among available methods for meeting the requirements of this section, a recipient shall give priority to those methods that offer programs and activities to qualified individuals with disabilities in the most integrated setting appropriate.

(c) *Small health, welfare, or other social service providers.* If a recipient with fewer than fifteen employees that provides health, welfare, or other social services finds, after consultation with a person with a disability seeking its services, that there is no method of complying with paragraph (a) of this section other than making a significant alteration in its existing facilities, the recipient may, as an alternative, refer the person with a disability to other providers of those services that are accessible.

(d) *Time period.* A recipient shall comply with the requirement of paragraph (a) of this section within sixty days of the effective date of this part except that where structural changes in facilities are necessary, such changes shall be made within three years of the effective date of this part, but in any event as expeditiously as possible.

(e) *Transition plan.* In the event that structural changes to facilities are necessary to meet the requirement of paragraph (a) of this section, a recipient shall develop, within six months of the effective date of this part, a transition plan setting forth the steps necessary to complete such changes. The plan shall be developed with the assistance of interested persons, including persons with disabilities or organizations representing persons with disabilities. A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum:

(1) Identify physical obstacles in the recipient's facilities that limit the accessibility of its program or activity to persons with disabilities;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve full accessibility under paragraph (a) and, if the time period of the transition plan is longer than one year, identify the steps that will be taken during each year of the transition period; and

(4) Indicate the person responsible for implementation of the plan.

(f) *Notice.* The recipient shall adopt and implement procedures to ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of services, activities, and facilities that are accessible to and usable by persons with disabilities.

(g) *Safe harbor.* Elements that have not been altered in existing facilities on or after July 8, 2024, and that comply with the corresponding technical and scoping specifications for those elements in the American National Standard Specification (ANSI) (ANSI A117.1-1961(R1971)) for facilities constructed between June 3, 1977, and January 18, 1991 or for those elements in the Uniform Federal Accessibility Standards (UFAS), appendix A to 41 CFR part 101-19, subpart 101-19.6 (revised as of July 1, 2002), for those facilities constructed between January 18, 1991, and July 8, 2024, are not required to be modified to comply with the re-

quirements set forth in the 2010 Standards.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005; 89 FR 40185, May 9, 2024]

§ 84.23 New construction and alterations.

(a) *Design and construction.* Each facility or part of a facility constructed by, on behalf of, or for the use of a recipient shall be designed and constructed in such manner that the facility or part of the facility is readily accessible to and usable by individuals with disabilities, if the construction was commenced after June 3, 1977.

(b) *Alterations.* Each facility or part of a facility altered by, on behalf of, or for the use of a recipient in a manner that affects or could affect the usability of the facility or part of the facility shall, to the maximum extent feasible, be altered in such manner that the altered portion of the facility is readily accessible to and usable by individuals with disabilities, if the alteration was commenced after June 3, 1977.

(c) *Accessibility standards and compliance dates for recipients that are public entities.* (1) The accessibility standards and compliance dates in this paragraph (c) apply to recipients that are public entities. Public entities are any State or local government; any department, agency, special purpose district, or other instrumentality of a State or States or local government; and the National Railroad Passenger Corporation, and any commuter authority (as defined in section 103(8) of the Rail Passenger Service Act). (45 U.S.C. 541)

(2) If physical construction or alterations commenced after June 3, 1977, but before January 18, 1991, then construction and alterations subject to this section shall be deemed in compliance with this section if they meet the requirements of the ANSI Standards (ANSI A117.1-1961(R1971)) (ANSI). Departures from particular requirements of ANSI by the use of other methods are permitted when it is clearly evident that equivalent access to the facility or part of the facility is provided.

(3) If physical construction or alterations commence on or after January 18, 1991, but before July 8, 2024, then

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new construction and alterations subject to this section shall be deemed in compliance with this section if they meet the requirements of the Uniform Federal Accessibility Standards (UFAS), appendix A to 41 CFR part 101-19, subpart 101-19.6 (revised as of July 1, 2002). Departures from particular requirements of UFAS by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

(4) For physical construction or alterations that commence on or after July 8, 2024, but before May 9, 2025, then new construction and alterations subject to this section may comply with either UFAS or the 2010 Standards. Departures from particular requirements of either standard by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

(5) If physical construction or alterations commence on or after May 9, 2025, then new construction and alterations subject to this section shall comply with the 2010 Standards.

(6) For the purposes of this section, ceremonial groundbreaking or razing of structures prior to site preparation do not commence physical construction or alterations.

(d) *Accessibility standards and compliance dates for recipients that are private entities.* (1) The accessibility standards and compliance dates in this paragraph (d) apply to recipients that are private entities. Private entities are any person or entity other than a public entity.

(2) New construction and alterations subject to this section where the date when the last application for a building permit or permit extension is certified to be complete by a State, county, or local government or, in those jurisdictions where the government does not certify completion of applications, if the date when the last application for a building permit or permit extension is received by the State, county, or local government between June 3, 1977, and January 18, 1991, or if no permit is required, if the start of physical construction or alterations occurs between June 3, 1977, and January 18, 1991, shall

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be deemed in compliance with this section if they meet the requirements of ANSI. Departures from particular requirements of ANSI by the use of other methods are permitted when it is clearly evident that equivalent access to the facility or part of the facility is provided.

(3) New construction and alterations subject to this section shall comply with UFAS if the date when the last application for a building permit or permit extension is certified to be complete by a State, county, or local government (or, in those jurisdictions where the government does not certify completion of applications, if the date when the last application for a building permit or permit extension is received by the State, county, or local government) is on or after January 18, 1991, and before July 8, 2024, or if no permit is required, if the start of physical construction or alterations occurs on or after January 18, 1991, and before July 8, 2024. Departures from particular requirements of UFAS by the use of other methods are permitted when it is clearly evident that equivalent access to the facility or part of the facility is provided.

(4) New construction and alterations subject to this section shall comply either with UFAS or the 2010 Standards if the date when the last application for a building permit or permit extension is certified to be complete by a State, county, or local government (or, in those jurisdictions where the government does not certify completion of applications, if the date when the last application for a building permit or permit extension is received by the State, county, or local government) is on or after July 8, 2024, and before May 9, 2025, or if no permit is required, if the start of physical construction or alterations occurs on or after July 8, 2024, and before May 9, 2025. Departures from particular requirements of either standard by the use of other methods shall be permitted when it is clearly evident that equivalent access to the facility or part of the facility is thereby provided.

(5) New construction and alterations subject to this section shall comply with the 2010 Standards if the date when the last application for a building

permit or permit extension is certified to be complete by a State, county, or local government (or, in those jurisdictions where the government does not certify completion of applications, if the date when the last application for a building permit or permit extension is received by the State, county, or local government) is on or after May 9, 2025, or if no permit is required, if the start of physical construction or alterations occurs on or after May 9, 2025.

(6) For the purposes of this section, ceremonial groundbreaking or razing of structures prior to site preparation do not commence physical construction or alterations.

(e) *Noncomplying new construction and alterations.* (1) Newly constructed or altered facilities or elements covered by paragraph (a) or (b) of this section that were constructed or altered between June 3, 1977, and January 18, 1991, and that do not comply with ANSI shall be made accessible in accordance with the 2010 Standards.

(2) Newly constructed or altered facilities or elements covered by paragraph (a) or (b) of this section that were constructed or altered on or after January 18, 1991, and before May 9, 2025, and that do not comply with UFAS shall before May 9, 2025, be made accessible in accordance with either UFAS or the 2010 Standards.

(3) Newly constructed or altered facilities or elements covered by paragraph (a) or (b) of this section that were constructed or altered before May 9, 2025, and that do not comply with ANSI (for facilities constructed or altered between June 3, 1977, and January 18, 1991) or UFAS (for facilities constructed or altered on or after January 18, 1991) shall, on or after May 9, 2025, be made accessible in accordance with the 2010 Standards.

(f) *Public buildings or facilities requirements.* New construction and alterations of buildings or facilities undertaken in compliance with the 2010 Standards will comply with the scoping and technical requirements for a “public building or facility” regardless of whether the recipient is a public entity as defined in 28 CFR 35.104 or a private entity.

(g) *Compliance with the Architectural Barriers Act of 1968.* Nothing in this sec-

tion relieves recipients whose facilities are covered by the Architectural Barriers Act, from their responsibility of complying with the requirements of the Architectural Barriers Act and its implementing regulations, 41 CFR 102–76.60 through 102–76.95 (General Services Administration); 39 CFR part 255 (U.S. Postal Service); 24 CFR part 40 (U.S. Department of Housing and Urban Development); and the U.S. Department of Defense “Policy Memorandum for Secretaries of the Military Departments: Access for People with Disabilities” (October 31, 2008).

(h) *Mechanical rooms.* For purposes of this section, section 4.1.6(1)(g) of UFAS will be interpreted to exempt from the requirements of UFAS only mechanical rooms and other spaces that, because of their intended use, will not require accessibility to the public or beneficiaries or result in the employment or residence therein of individuals with physical disabilities.

[89 FR 40185, May 9, 2024]

§§ 84.24–84.30 [Reserved]

Subpart D—Childcare, Preschool, Elementary and Secondary, and Adult Education

§ 84.31 Application of this subpart.

This subpart applies to childcare, preschool, elementary and secondary, and adult education programs or activities that receive Federal financial assistance and to recipients that operate, or that receive Federal financial assistance for the operation of, such programs or activities.

[89 FR 40187, May 9, 2024]

§§ 84.32–84.37 [Reserved]

§ 84.38 Childcare, preschool, elementary and secondary, and adult education.

A recipient to which this subpart applies that provides childcare, preschool, elementary and secondary, or adult education may not, on the basis of disability, exclude qualified individuals with disabilities and shall take into account the needs of such persons

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in determining the aids, benefits, or services to be provided.

[89 FR 40187, May 9, 2024]

§§ 84.39–84.40 [Reserved]

Subpart E—Postsecondary Education

§ 84.41 Application of this subpart.

Subpart E applies to postsecondary education programs or activities, including postsecondary vocational education programs or activities, that receive Federal financial assistance and to recipients that operate, or that receive Federal financial assistance for the operation of, such programs or activities.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005]

§ 84.42 Admissions and recruitment.

(a) *General.* Qualified persons with disabilities may not, on the basis of disability, be denied admission or be subjected to discrimination in admission or recruitment by a recipient to which this subpart applies.

(b) *Admissions.* In administering its admission policies, a recipient to which this subpart applies:

(1) May not apply limitations upon the number or proportion of persons with disabilities who may be admitted;

(2) May not make use of any test or criterion for admission that has a disproportionate, adverse effect on persons with disabilities or any class of persons with disabilities unless (i) the test or criterion, as used by the recipient, has been validated as a predictor of success in the education program or activity in question and (ii) alternate tests or criteria that have a less disproportionate, adverse effect are not shown by the Director to be available.

(3) Shall assure itself that (i) admissions tests are selected and administered so as best to ensure that, when a test is administered to an applicant who has a disability that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the applicant's impaired sensory,

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manual, or speaking skills (except where those skills are the factors that the test purports to measure); (ii) admissions tests that are designed for persons with impaired sensory, manual, or speaking skills are offered as often and in as timely a manner as are other admissions tests; and (iii) admissions tests are administered in facilities that, on the whole, are accessible to persons with disabilities; and

(4) Except as provided in paragraph (c) of this section, may not make preadmission inquiry as to whether an applicant for admission is a person with a disability but, after admission, may make inquiries on a confidential basis as to disabilities that may require accommodation.

(c) *Preadmission inquiry exception.* When a recipient is taking remedial action to correct the effects of past discrimination pursuant to § 84.6(a) or when a recipient is taking voluntary action to overcome the effects of conditions that resulted in limited participation in its federally assisted program or activity pursuant to § 84.6(b), the recipient may invite applicants for admission to indicate whether and to what extent they are disabled, *Provided*, That:

(1) The recipient states clearly on any written questionnaire used for this purpose or makes clear orally if no written questionnaire is used that the information requested is intended for use solely in connection with its remedial action obligations or its voluntary action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential, that refusal to provide it will not subject the applicant to any adverse treatment, and that it will be used only in accordance with this part.

(d) *Validity studies.* For the purpose of paragraph (b)(2) of this section, a recipient may base prediction equations on first year grades, but shall conduct periodic validity studies against the criterion of overall success in the education program or activity in question in order to monitor the general validity of the test scores.

[42 FR 22677, May 4, 1977, as amended at 89 FR 40187, May 9, 2024]

§ 84.43 Treatment of students; general.

(a) No qualified student with a disability shall, on the basis of disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any academic, research, occupational training, housing, health insurance, counseling, financial aid, physical education, athletics, recreation, transportation, other extracurricular, or other postsecondary education aids, benefits, or services to which this subpart applies.

(b) A recipient to which this subpart applies that considers participation by students in education programs or activities not operated wholly by the recipient as part of, or equivalent to, and education program or activity operated by the recipient shall assure itself that the other education program or activity, as a whole, provides an equal opportunity for the participation of qualified persons with disabilities.

(c) A recipient to which this subpart applies may not, on the basis of disability, exclude any qualified student with a disability from any course, course of study, or other part of its education program or activity.

(d) A recipient to which this subpart applies shall operate its program or activity in the most integrated setting appropriate.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005; 89 FR 40187, May 9, 2024]

§ 84.44 Academic adjustments.

(a) *Academic requirements.* A recipient to which this subpart applies shall make such modifications to its academic requirements as are necessary to ensure that such requirements do not discriminate or have the effect of discriminating, on the basis of disability, against a qualified applicant or student with a disability. Academic requirements that the recipient can demonstrate are essential to the instruction being pursued by such student or to any directly related licensing requirement will not be regarded as discriminatory within the meaning of this section. Modifications may include changes in the length of time permitted for the completion of degree re-

quirements, substitution of specific courses required for the completion of degree requirements, and adaptation of the manner in which specific courses are conducted.

(b) *Other rules.* A recipient to which this subpart applies may not impose upon students with disabilities other rules, such as the prohibition of tape recorders in classrooms or of dog guides in campus buildings, that have the effect of limiting the participation of students with disabilities in the recipient's education program or activity.

(c) *Course examinations.* In its course examinations or other procedures for evaluating students' academic achievement, a recipient to which this subpart applies shall provide such methods for evaluating the achievement of students who have a disability that impairs sensory, manual, or speaking skills as will best ensure that the results of the evaluation represents the student's achievement in the course, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where such skills are the factors that the test purports to measure).

(d) *Auxiliary aids.* (1) A recipient to which this subpart applies shall take such steps as are necessary to ensure that no student with a disability is denied the benefits of, excluded from participation in, or otherwise subjected to discrimination because of the absence of educational auxiliary aids for students with impaired sensory, manual, or speaking skills.

(2) Auxiliary aids may include taped texts, interpreters or other effective methods of making orally delivered materials available to students with hearing impairments, readers in libraries for students with visual impairments, classroom equipment adapted for use by students with manual impairments, and other similar services and actions. Recipients need not provide attendants, individually prescribed devices, readers for personal use or study, or other devices or services of a personal nature.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005; 89 FR 40187, May 9, 2024]

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§ 84.45 Housing.

(a) *Housing provided by the recipient.* A recipient that provides housing to its students without disabilities shall provide comparable, convenient, and accessible housing to students with disabilities at the same cost as to others. At the end of the transition period provided for in subpart C of this part, such housing shall be available in sufficient quantity and variety so that the scope of students with disabilities' choice of living accommodations is, as a whole, comparable to that of students without disabilities.

(b) *Other housing.* A recipient that assists any agency, organization, or person in making housing available to any of its students shall take such action as may be necessary to assure itself that such housing is, as a whole, made available in a manner that does not result in discrimination on the basis of disability.

[42 FR 22677, May 4, 1977, as amended at 89 FR 40187, May 9, 2024]

§ 84.46 Financial and employment assistance to students.

(a) *Provision of financial assistance.* (1) In providing financial assistance to qualified persons with disabilities, a recipient to which this subpart applies may not (i), on the basis of disability, provide less assistance than is provided to persons without disabilities, limit eligibility for assistance, or otherwise discriminate or (ii) assist any entity or person that provides assistance to any of the recipient's students in a manner that discriminates against qualified persons with disabilities on the basis of disability.

(2) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established under wills, trusts, bequests, or similar legal instruments that require awards to be made on the basis of factors that discriminate or have the effect of discriminating on the basis of disability only if the overall effect of the award of scholarships, fellowships, and other forms of financial assistance is not discriminatory on the basis of disability.

(b) *Assistance in making available outside employment.* A recipient that as-

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sists any agency, organization, or person in providing employment opportunities to any of its students shall assure itself that such employment opportunities, as a whole, are made available in a manner that would not violate subpart B if they were provided by the recipient.

(c) *Employment of students by recipients.* A recipient that employs any of its students may not do so in a manner that violates subpart B.

[42 FR 22677, May 4, 1977, as amended at 89 FR 40187, May 9, 2024]

§ 84.47 Nonacademic services.

(a) *Physical education and athletics.* (1) In providing physical education courses and athletics and similar aids, benefits, or services to any of its students, a recipient to which this subpart applies may not discriminate on the basis of disability. A recipient that offers physical education courses or that operates or sponsors intercollegiate, club, or intramural athletics shall provide to qualified students with disabilities an equal opportunity for participation in these activities.

(2) A recipient may offer to students with disabilities physical education and athletic activities that are separate or different only if separation or differentiation is consistent with the requirements of § 84.43(d) and only if no qualified student with a disability is denied the opportunity to compete for teams or to participate in courses that are not separate or different.

(b) *Counseling and placement services.* A recipient to which this subpart applies that provides personal, academic, or vocational counseling, guidance, or placement services to its students shall provide these services without discrimination on the basis of disability. The recipient shall ensure that qualified students with disabilities are not counseled toward more restrictive career objectives than are students without disabilities with similar interests and abilities. This requirement does not preclude a recipient from providing factual information about licensing and certification requirements that may present obstacles to persons with disabilities in their pursuit of particular careers.

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(c) *Social organizations.* A recipient that provides significant assistance to fraternities, sororities, or similar organizations shall assure itself that the membership practices of such organizations do not permit discrimination otherwise prohibited by this subpart.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005; 89 FR 40187, May 9, 2024]

§§ 84.48–84.50 [Reserved]

Subpart F—Health, Welfare, and Social Services

§ 84.51 Application of this subpart.

Subpart F applies to health, welfare, and other social service programs or activities that receive Federal financial assistance and to recipients that operate, or that receive Federal financial assistance for the operation of, such programs or activities.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005]

§ 84.52 Health, welfare, and other social services.

(a) *General.* In providing health, welfare, or other social services or benefits, a recipient may not, on the basis of handicap:

(1) Deny a qualified person with a disability these benefits or services;

(2) Afford a qualified person with a disability an opportunity to receive benefits or services that is not equal to that offered persons without disabilities;

(3) Provide a qualified person with a disability with benefits or services that are not as effective (as defined in § 84.4(b)) as the benefits or services provided to others;

(4) Provide benefits or services in a manner that limits or has the effect of limiting the participation of qualified persons with disabilities; or

(5) Provide different or separate benefits or services to persons with disabilities except where necessary to provide qualified persons with disabilities with benefits and services that are as effective as those provided to others.

(b) *Notice.* A recipient that provides notice concerning benefits or services or written material concerning waivers

of rights or consent to treatment shall take such steps as are necessary to ensure that qualified persons with disabilities, including those with impaired sensory or speaking skills, are not denied effective notice because of their disability.

[42 FR 22677, May 4, 1977, as amended at 89 FR 40187, May 9, 2024]

§ 84.53 Individuals with substance and alcohol use disorders.

A recipient to which this subpart applies that operates a health care facility may not discriminate in admission or treatment against an individual with a substance or alcohol use disorder who has a medical condition, because of the person's substance or alcohol use disorder.

[89 FR 40188, May 9, 2024]

§ 84.54 Education of institutionalized persons.

A recipient to which this subpart applies and that provides aids, benefits, or services to persons who are institutionalized because of disability shall ensure that each qualified individual with disabilities, as defined in § 84.10, in its program or activity is provided an appropriate education, consistent with the Department of Education section 504 regulations at 34 CFR 104.33(b). Nothing in this section shall be interpreted as altering in any way the obligations of recipients under subpart D of this part.

[89 FR 40188, May 9, 2024]

§ 84.55 Procedures relating to health care for infants with disabilities.

(a) *Infant Care Review Committees.* The Department encourages each recipient health care provider that provides health care services to infants in programs or activities receiving Federal financial assistance to establish an Infant Care Review Committee (ICRC) to assist the provider in delivering health care and related services to infants and in complying with this part. The purpose of the committee is to assist the health care provider in the development of standards, policies and procedures for providing treatment to infants with disabilities and in making

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decisions concerning medically beneficial treatment in specific cases. While the Department recognizes the value of ICRC's in assuring appropriate medical care to infants, such committees are not required by this section. An ICRC should be composed of individuals representing a broad range of perspectives, and should include a practicing physician, a representative of a disability organization, a practicing nurse, and other individuals. A suggested model ICRC is set forth in paragraph (f) of this section.

(b)–(e) [Reserved]

(f) *Model Infant Care Review Committee.* Recipient health care providers wishing to establish Infant Care Review Committees should consider adoption of the following model. This model is advisory. Recipient health care providers are not required to establish a review committee or, if one is established, to adhere to this model. In seeking to determine compliance with this part, as it relates to health care for infants with disabilities, by health care providers that have an ICRC established and operated substantially in accordance with this model, the Department will, to the extent possible, consult with the ICRC.

(1) *Establishment and purpose.* (i) The hospital establishes an Infant Care Review Committee (ICRC) or joins with one or more other hospitals to create a joint ICRC. The establishing document will state that the ICRC is for the purpose of facilitating the development and implementation of standards, policies and procedures designed to assure that, while respecting reasonable medical judgments, treatment and nourishment not be withheld, solely on the basis of present or anticipated physical or mental impairments, from infants with disabilities who, in spite of such impairments, will benefit medically from the treatment or nourishment.

(ii) The activities of the ICRC will be guided by the following principles:

(A) The interpretative guidelines of the Department relating to the applicability of this part to health care for infants with disabilities.

(B) As stated in the “Principles of Treatment of Disabled Infants” of the coalition of major medical and disability organizations, including the

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American Academy of Pediatrics, National Association of Children's Hospitals and Related Institutions, Association for Retarded Citizens, Down's Syndrome Congress, Spina Bifida Association, and others:

When medical care is clearly beneficial, it should always be provided. When appropriate medical care is not available, arrangements should be made to transfer the infant to an appropriate medical facility. Consideration such as anticipated or actual limited potential of an individual and present or future lack of available community resources are irrelevant and must not determine the decisions concerning medical care. The individual's medical condition should be the sole focus of the decision. These are very strict standards.

It is ethically and legally justified to withhold medical or surgical procedures which are clearly futile and will only prolong the act of dying. However, supportive care should be provided, including sustenance as medically indicated and relief of pain and suffering. The needs of the dying person should be respected. The family also should be supported in its grieving.

In cases where it is uncertain whether medical treatment will be beneficial, a person's disability must not be the basis for a decision to withhold treatment. At all times during the process when decisions are being made about the benefit or futility of medical treatment, the person should be cared for in the medically most appropriate ways. When doubt exists at any time about whether to treat, a presumption always should be in favor of treatment.

(C) As stated by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research:

This [standard for providing medically beneficial treatment] is a very strict standard in that it excludes consideration of the negative effects of an impaired child's life on other persons, including parents, siblings, and society. Although abiding by this standard may be difficult in specific cases, it is all too easy to undervalue the lives of infants with disabilities; the Commission finds it imperative to counteract this by treating them no less vigorously than their healthy peers or than older children with similar disabilities would be treated.

(iii) The ICRC will carry out its purposes by:

(A) Recommending institutional policies concerning the withholding or withdrawal of medical or surgical

treatments to infants, including guidelines for ICRC action for specific categories of life-threatening conditions affecting infants;

(B) Providing advice in specific cases when decisions are being considered to withhold or withdraw from infant life-sustaining medical or surgical treatment; and

(C) Reviewing retrospectively on a regular basis infant medical records in situations in which life-sustaining medical or surgical treatment has been withheld or withdrawn.

(2) *Organization and staffing.* The ICRC will consist of at least 7 members and include the following:

(i) A practicing physician (e.g., a pediatrician, a neonatologist, or a pediatric surgeon),

(ii) A practicing nurse,

(iii) A hospital administrator,

(iv) A representative of the legal profession,

(v) A representative of a disability group, or a developmental disability expert,

(vi) A lay community member, and

(vii) A member of a facility's organized medical staff, who shall serve as chairperson.

In connection with review of specific cases, one member of the ICRC shall be designated to act as "special advocate" for the infant, as provided in paragraph (f)(3)(ii)(E) of the section. The hospital will provide staff support for the ICRC, including legal counsel. The ICRC will meet on a regular basis, or as required below in connection with review of specific cases. It shall adopt or recommend to the appropriate hospital official or body such administrative policies as terms of office and quorum requirements. The ICRC will recommend procedures to ensure that both hospital personnel and patient families are fully informed of the existence and functions of the ICRC and its availability on a 24-hour basis.

(3) *Operation of ICRC—(i) Prospective policy development.* (A) The ICRC will develop and recommend for adoption by the hospital institutional policies concerning the withholding or withdrawal of medical treatment for infants with life-threatening conditions. These will include guidelines for management of specific types of cases or di-

agnoses, for example, Down's syndrome and spina bifida, and procedures to be followed in such recurring circumstances as, for example, brain death and parental refusal to consent to life-saving treatment. The hospital, upon recommendation of the ICRC, may require attending physicians to notify the ICRC of the presence in the facility of an infant with a diagnosis specified by the ICRC, e.g., Down's syndrome and spina bifida.

(B) In recommending these policies and guidelines, the ICRC will consult with medical and other authorities on issues involving disabled individuals, e.g., neonatologists, pediatric surgeons, county and city agencies which provide services for the disabled, and disability advocacy organizations. It will also consult with appropriate committees of the medical staff, to ensure that the ICRC policies and guidelines build on existing staff by-laws, rules and regulations concerning consultations and staff membership requirements. The ICRC will also inform and educate hospital staff on the policies and guidelines it develops.

(ii) *Review of specific cases.* In addition to regularly scheduled meetings, interim ICRC meetings will take place under specified circumstances to permit review of individual cases. The hospital will, to the extent possible, require in each case that life-sustaining treatment be continued, until the ICRC can review the case and provide advice.

(A) Interim ICRC meetings will be convened within 24 hours (or less if indicated) when there is disagreement between the family of an infant and the infant's physician as to the withholding or withdrawal of treatment, when a preliminary decision to withhold or withdraw life-sustaining treatment has been made in certain categories of cases identified by the ICRC, when there is disagreement between members of the hospital's medical and/or nursing staffs, or when otherwise appropriate.

(B) Such interim ICRC meetings will take place upon the request of any member of the ICRC or hospital staff or parent or guardian of the infant. The ICRC will have procedures to preserve the confidentiality of the identity of persons making such requests, and

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such persons shall be protected from reprisal. When appropriate, the ICRC or a designated member will inform the requesting individual of the ICRC's recommendation.

(C) The ICRC may provide for telephone and other forms of review when the timing and nature of the case, as identified in policies developed by the ICRC, make the convening of an interim meeting impracticable.

(D) Interim meetings will be open to the affected parties. The ICRC will ensure that the interests of the parents, the physician, and the child are fully considered; that family members have been fully informed of the patient's condition and prognosis; that they have been provided with a listing which describes the services furnished by parent support groups and public and private agencies in the geographic vicinity to infants with conditions such as that before the ICRC; and that the ICRC will facilitate their access to such services and groups.

(E) To ensure a comprehensive evaluation of all options and factors pertinent to the committee's deliberations, the chairperson will designate one member of the ICRC to act, in connection with that specific case, as special advocate for the infant. The special advocate will seek to ensure that all considerations in favor of the provision of life-sustaining treatment are fully evaluated and considered by the ICRC.

(F) In cases in which there is disagreement on treatment between a physician and an infant's family, and the family wishes to continue life-sustaining treatment, the family's wishes will be carried out, for as long as the family wishes, unless such treatment is medically contraindicated. When there is physician/family disagreement and the family refuses consent to life-sustaining treatment, and the ICRC, after due deliberation, agrees with the family, the ICRC will recommend that the treatment be withheld. When there is physician/family disagreement and the family refuses consent, but the ICRC disagrees with the family, the ICRC will recommend to the hospital board or appropriate official that the case be referred immediately to an appropriate court or child protective agency, and every effort shall be made to continue

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treatment, preserve the status quo, and prevent worsening of the infant's condition until such time as the court or agency renders a decision or takes other appropriate action. The ICRC will also follow this procedure in cases in which the family and physician agree that life-sustaining treatment should be withheld or withdrawn, but the ICRC disagrees.

(iii) *Retrospective record review.* The ICRC, at its regularly-scheduled meeting, will review all records involving withholding or termination of medical or surgical treatment to infants consistent with hospital policies developed by the ICRC, unless the case was previously before the ICRC pursuant to paragraph (f)(3)(ii) of this section. If the ICRC finds that a deviation was made from the institutional policies in a given case, it shall conduct a review and report the findings to appropriate hospital personnel for appropriate action.

(4) *Records.* The ICRC will maintain records of all of its deliberations and summary descriptions of specific cases considered and the disposition of those cases. Such records will be kept in accordance with institutional policies on confidentiality of medical information. They will be made available to appropriate government agencies, or upon court order, or as otherwise required by law.

NOTE: The mandatory provisions set forth in paragraphs (b)–(e) inclusive of this section are subject to an injunction prohibiting their enforcement. In *Bowen v. American Hospital Association*, _____ U.S. ____, 106 S. Ct. 2101 (1986), the Supreme Court upheld the action of a United States District Court, 585 F. Supp. 541 (S.D.N.Y. 1984), declaring invalid and enjoining enforcement of provisions under this section, promulgated January 12, 1984.

(Information collection requirements contained in paragraph (c) have been approved by the Office of Management and Budget under control number 0990-0114)

[49 FR 1651, Jan. 12, 1984, as amended at 52 FR 3012, Jan. 30, 1987; 70 FR 24320, May 9, 2005; 89 FR 40188, May 9, 2024]

§ 84.56 Medical treatment.

(a) *Discrimination prohibited.* No qualified individual with a disability shall, on the basis of disability, be subjected to discrimination in medical treatment

under any program or activity that receives Federal financial assistance, including in the allocation or withdrawal of any good, benefit, or service.

(b) *Specific prohibitions.* The general prohibition in paragraph (a) of this section includes the following specific prohibitions:

(1) *Denial of medical treatment.* A recipient may not deny or limit medical treatment to a qualified individual with a disability when the denial is based on:

(i) Bias or stereotypes about a patient's disability;

(ii) Judgments that the individual will be a burden on others due to their disability, including, but not limited to caregivers, family, or society; or

(iii) A belief that the life of a person with a disability has lesser value than the life of a person without a disability, or that life with a disability is not worth living.

(2) *Denial of treatment for a separate symptom or condition.* Where a qualified individual with a disability or their authorized representative seeks or consents to treatment for a separately diagnosable symptom or medical condition (whether or not that symptom or condition is a disability under this part or is causally connected to the individual's underlying disability), a recipient may not deny or limit clinically appropriate treatment if it would be offered to a similarly situated individual without an underlying disability.

(3) *Provision of medical treatment.* A recipient may not, on the basis of disability, provide a medical treatment to an individual with a disability where it would not provide the same treatment to an individual without a disability, unless the disability impacts the effectiveness, or ease of administration of the treatment itself, or has a medical effect on the condition to which the treatment is directed.

(c) *Construction—(1) Professional judgment in treatment.* (i) Nothing in this section requires the provision of medical treatment where the recipient has a legitimate, nondiscriminatory reason for denying or limiting that service or where the disability renders the individual not qualified for the treatment.

(ii) Circumstances in which the recipient has a legitimate, nondiscriminatory

reason for denying or limiting a service or where the disability renders the individual not qualified for the treatment may include circumstances in which the recipient typically declines to provide the treatment to any individual, or reasonably determines based on current medical knowledge or the best available objective evidence that such medical treatment is not clinically appropriate for a particular individual. The criteria in paragraphs (b)(1)(i) through (iii) of this section are not a legitimate nondiscriminatory reason for denying or limiting medical treatment and may not be a basis for a determination that an individual is not qualified for the treatment, or that a treatment is not clinically appropriate for a particular individual.

(2) *Consent.* (i) Nothing in this section requires a recipient to provide medical treatment to an individual where the individual, or their authorized representative, does not consent to that treatment.

(ii) Nothing in this section allows a recipient to discriminate against a qualified individual with a disability on the basis of disability in seeking to obtain consent from an individual or their authorized representative for the recipient to provide, withhold, or withdraw treatment.

(3) *Providing information.* Nothing in this section precludes a provider from providing an individual with a disability or their authorized representative with information regarding the implications of different courses of treatment based on current medical knowledge or the best available objective evidence.

[89 FR 40188, May 9, 2024]

§ 84.57 Value assessment methods.

A recipient shall not, directly or through contractual, licensing, or other arrangements, use any measure, assessment, or tool that discounts the value of life extension on the basis of disability to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of any aid, benefit, or

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service, including the terms or conditions under which they are made available.

[89 FR 40188, May 9, 2024]

§§ 84.58–84.59 [Reserved]

§ 84.60 Children, parents, caregivers, foster parents, and prospective parents in the child welfare system.

(a) Discriminatory actions prohibited.

(1) No qualified individual with a disability shall, on the basis of disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any child welfare program or activity that receives Federal financial assistance.

(2) Under the prohibition set forth in paragraph (a)(1) of this section, discrimination includes:

(i) Decisions based on speculation, stereotypes, or generalizations that a parent, caregiver, foster parent, or prospective parent, because of a disability, cannot safely care for a child; and

(ii) Decisions based on speculation, stereotypes, or generalizations about a child with a disability.

(b) *Additional prohibitions.* The prohibitions in paragraph (a) of this section apply to actions by a recipient of Federal financial assistance made directly or through contracts, agreements, or other arrangements, including any action to:

(1) Deny a qualified parent with a disability custody or control of, or visitation to, a child;

(2) Deny a qualified parent with a disability an opportunity to participate in or benefit from any and all services provided by a child welfare agency, including but not limited to, family preservation and reunification services equal to that afforded to persons without disabilities;

(3) Terminate the parental rights or legal guardianship of a qualified individual with a disability;

(4) Deny a qualified caregiver, foster parent, companion, or prospective parent with a disability the opportunity to participate in or benefit from child welfare programs and activities; or

(5) Require children, on the basis of the disability, to be placed outside the family home through custody relinquishment, voluntary placement, or

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other forfeiture of parental rights in order to receive necessary services.

(c) *Parenting evaluation procedures.* A recipient to which this subpart applies shall establish procedures for referring to qualified professionals for evaluation those individuals, who, because of disability, need or are believed to need adapted services or reasonable modifications. A recipient shall also ensure that tests, assessments, and other evaluation tools and materials used for the purpose of assessing or evaluating parenting ability are based in evidence or research, are conducted by a qualified professional and are tailored to assess actual parenting ability and specific areas of disability-related needs. Parenting evaluations must be fully accessible to people with disabilities and shall not be based on a single general intelligence quotient or measure of the person's disability, rather than their parenting ability. Assessments of parents or children must be individualized and based on the best available objective evidence.

[89 FR 40188, May 9, 2024]

Subpart G—General Requirements

SOURCE: 89 FR 40189, May 9, 2024, unless otherwise noted.

§ 84.68 General prohibitions against discrimination.

(a) No qualified individual with a disability shall, solely on the basis of disability, be excluded from participation in or be denied the benefits of the programs or activities of a recipient, or be subjected to discrimination by any recipient.

(b)(1) A recipient, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of disability—

(i) Deny a qualified individual with a disability the opportunity to participate in or benefit from the aid, benefit, or service.

(ii) Afford a qualified individual with a disability an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others.

(iii) Provide a qualified individual with a disability an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the benefit or to reach the same level of achievement as that provided to others.

(iv) Provide different or separate aids, benefits, or services to individuals with disabilities or to any class of individuals with disabilities than is provided to others unless such action is necessary to provide qualified individuals with disabilities with aids, benefits, or services that are as effective as those provided to others.

(v) Aid or perpetuate discrimination against a qualified individual with a disability by providing significant assistance to an agency, organization, or person that discriminates on the basis of disability in providing any aid, benefit, or service to beneficiaries of the recipient's program.

(vi) Deny a qualified individual with a disability the opportunity to participate as a member of planning or advisory boards.

(vii) Otherwise limit a qualified individual with a disability in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(2) A recipient may not deny a qualified individual with a disability the opportunity to participate in programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) A recipient may not, directly or through contractual or other arrangements, utilize criteria or methods of administration—

(i) That have the effect of subjecting qualified individuals with disabilities to discrimination on the basis of disability;

(ii) That have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program with respect to individuals with disabilities; or

(iii) That perpetuate the discrimination of another recipient if both recipients are subject to common administrative control or are agencies of the same state.

(4) A recipient may not, in determining the site or location of a facility, make selections—

(i) That have the effect of excluding individuals with disabilities from, denying them the benefits of, or otherwise subjecting them to discrimination; or

(ii) That have the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program or activity with respect to individuals with disabilities.

(5) A recipient, in the selection of procurement contractors, may not use criteria that subject qualified individuals with disabilities to discrimination on the basis of disability.

(6) A recipient may not administer a licensing or certification program in a manner that subjects qualified individuals with disabilities to discrimination on the basis of disability, nor may a recipient establish requirements for the programs or activities of licensees or certified entities that subject qualified individuals with disabilities to discrimination on the basis of disability. The programs or activities of entities that are licensed or certified by the recipient are not, themselves, covered by this part.

(7)(i) A recipient shall make reasonable modifications in policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the recipient can demonstrate that making the modifications would fundamentally alter the nature of the program or activity.

(ii) A recipient is not required to provide a reasonable modification to an individual who meets the definition of "disability" solely under the "regarded as" prong of the definition of disability in § 84.4(a)(1)(iii).

(8) A recipient shall not impose or apply eligibility criteria that screen out or tend to screen out an individual with a disability or any class of individuals with disabilities from fully and equally enjoying any program or activity, unless such criteria can be shown to be necessary for the provision of the program or activity being offered.

(c) Nothing in this part prohibits a recipient from providing benefits, services, or advantages to individuals with

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disabilities, or to a particular class of individuals with disabilities beyond those required by this part.

(d) A recipient shall administer programs and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

(e)(1) Nothing in this part shall be construed to require an individual with a disability to accept a modification, aid, service, opportunity, or benefit provided under section 504 or this part which such individual chooses not to accept.

(2) Nothing in section 504 or this part authorizes the representative or guardian of an individual with a disability to decline food, water, medical treatment, or medical services for that individual.

(f) A recipient may not place a surcharge on a particular individual with a disability or any group of individuals with disabilities to cover the costs of measures, such as the provision of auxiliary aids or program accessibility, that are required to provide that individual or group with the nondiscriminatory treatment required by section 504 or this part.

(g) A recipient shall not exclude or otherwise deny equal programs or activities to an individual or entity because of the known disability of an individual with whom the individual or entity is known to have a relationship or association.

(h) A recipient may impose legitimate safety requirements necessary for the safe operation of its programs or activities. However, the recipient must ensure that its safety requirements are based on actual risks, not on mere speculation, stereotypes, or generalizations about individuals with disabilities.

(i) Nothing in this part shall provide the basis for a claim that an individual without a disability was subject to discrimination because of a lack of disability, including a claim that an individual with a disability was granted a reasonable modification that was denied to an individual without a disability.

§ 84.69 Illegal use of drugs.

(a) *General.* (1) Except as provided in paragraph (b) of this section, this part

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does not prohibit discrimination against an individual based on that individual's current illegal use of drugs.

(2) A recipient shall not discriminate on the basis of illegal use of drugs against an individual who is not engaging in current illegal use of drugs and who—

(i) Has successfully completed a supervised drug rehabilitation program or has otherwise been rehabilitated successfully;

(ii) Is participating in a supervised rehabilitation program; or

(iii) Is erroneously regarded as engaging in such use.

(b) *Services provided under the Rehabilitation Act.* (1) A recipient shall not exclude an individual on the basis of that individual's current illegal use of drugs from the benefits of programs and activities providing health services and services provided under subchapters I, II, and III of the Rehabilitation Act, if the individual is otherwise entitled to such services.

(2) A drug rehabilitation or treatment program may deny participation to individuals who engage in illegal use of drugs while they are in the program.

(c) *Drug testing.* (1) This part does not prohibit the recipient from adopting or administering reasonable policies or procedures, including but not limited to drug testing, designed to ensure that an individual who formerly engaged in the illegal use of drugs is not now engaging in current illegal use of drugs.

(2) Nothing in this paragraph (c) shall be construed to encourage, prohibit, restrict, or authorize the conduct of testing for the illegal use of drugs.

§ 84.70 Maintenance of accessible features.

(a) A recipient shall maintain in operable working condition those features of facilities and equipment that are required to be readily accessible to and usable by persons with disabilities by section 504 or this part.

(b) This section does not prohibit isolated or temporary interruptions in service or access due to maintenance or repairs.

(c) For a recipient, if the 2010 Standards reduce the technical requirements or the number of required accessible elements below the number required by

UFAS, the technical requirements or the number of accessible elements in a facility subject to this part may be reduced in accordance with the requirements of the 2010 Standards.

§ 84.71 Retaliation or coercion.

(a) A recipient shall not discriminate against any individual because that individual has opposed any act or practice made unlawful by this part, or because that individual made a charge, testified, assisted, or participated in any manner in an investigation, proceeding, or hearing under section 504 or this part.

(b) A recipient shall not coerce, intimidate, threaten, or interfere with any individual in the exercise or enjoyment of, or on account of their having exercised or enjoyed, or on account of their having aided or encouraged any other individual in the exercise or enjoyment of any right granted or protected by section 504 or this part.

§ 84.72 Personal devices and services.

This part does not require a recipient to provide to individuals with disabilities personal devices, such as wheelchairs; individually prescribed devices, such as prescription eyeglasses or hearing aids; readers for personal use or study; or services of a personal nature including assistance in eating, toileting, or dressing.

§ 84.73 Service animals.

(a) *General.* Generally, a recipient shall modify its policies, practices, or procedures to permit the use of a service animal by an individual with a disability.

(b) *Exceptions.* A recipient may ask an individual with a disability to remove a service animal from the premises if—

(1) The animal is out of control and the animal's handler does not take effective action to control it; or

(2) The animal is not housebroken.

(c) *If an animal is properly excluded.* If a recipient properly excludes a service animal under paragraph (b) of this section, it shall give the individual with a disability the opportunity to participate in the program or activity without having the service animal on the premises.

(d) *Animal under handler's control.* A service animal shall be under the control of its handler. A service animal shall have a harness, leash, or other tether, unless either the handler is unable because of a disability to use a harness, leash, or other tether, or the use of a harness, leash, or other tether would interfere with the service animal's safe, effective performance of work or tasks, in which case the service animal must be otherwise under the handler's control (*e.g.*, voice control, signals, or other effective means).

(e) *Care or supervision.* A recipient is not responsible for the care or supervision of a service animal.

(f) *Inquiries.* A recipient shall not ask about the nature or extent of a person's disability but may make two inquiries to determine whether an animal qualifies as a service animal. A recipient may ask if the animal is required because of a disability and what work or task the animal has been trained to perform. A recipient shall not require documentation, such as proof that the animal has been certified, trained, or licensed as a service animal. Generally, a recipient may not make these inquiries about a service animal when it is readily apparent that an animal is trained to do work or perform tasks for an individual with a disability (*e.g.*, the dog is observed guiding an individual who is blind or has low vision, pulling a person's wheelchair, or providing assistance with stability or balance to an individual with an observable mobility disability).

(g) *Access to areas of the recipient.* Individuals with disabilities shall be permitted to be accompanied by their service animals in all areas of the recipient's facilities where members of the public, participants in programs or activities, or invitees, as relevant, are allowed to go.

(h) *Surcharges.* A recipient shall not ask or require an individual with a disability to pay a surcharge, even if people accompanied by pets are required to pay fees, or to comply with other requirements generally not applicable to people without pets. If a recipient normally charges individuals for the damage they cause, an individual with a disability may be charged for damage caused by their service animal.

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(i) *Miniature horses*—(1) *Reasonable modifications*. A recipient shall make reasonable modifications in policies, practices, or procedures to permit the use of a miniature horse by an individual with a disability if the miniature horse has been individually trained to do work or perform tasks for the benefit of the individual with a disability.

(2) *Assessment factors*. In determining whether reasonable modifications in policies, practices, or procedures can be made to allow a miniature horse into a specific facility, a recipient shall consider—

(i) The type, size, and weight of the miniature horse and whether the facility can accommodate these features;

(ii) Whether the handler has sufficient control of the miniature horse;

(iii) Whether the miniature horse is housebroken; and

(iv) Whether the miniature horse's presence in a specific facility compromises legitimate safety requirements that are necessary for safe operation.

(3) *Other requirements*. Paragraphs (c) through (h) of this section, which apply to service animals, shall also apply to miniature horses.

§ 84.74 Mobility devices.

(a) *Use of wheelchairs and manually-powered mobility aids*. A recipient shall permit individuals with mobility disabilities to use wheelchairs and manually-powered mobility aids, such as walkers, crutches, canes, braces, or other similar devices designed for use by individuals with mobility disabilities in any areas open to pedestrian use.

(b) *Use of other power-driven mobility devices*—(1) *Requirement*. A recipient shall make reasonable modifications in its policies, practices, or procedures to permit the use of other power-driven mobility devices by individuals with mobility disabilities, unless a recipient can demonstrate that the class of other power-driven mobility devices cannot be operated in accordance with legitimate safety requirements that a recipient has adopted pursuant to § 84.68(h).

(2) *Assessment factors*. In determining whether a particular other power-driven mobility device can be allowed in a

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specific facility as a reasonable modification under paragraph (b)(1) of this section, a recipient shall consider—

(i) The type, size, weight, dimensions, and speed of the device;

(ii) The facility's volume of pedestrian traffic (which may vary at different times of the day, week, month, or year);

(iii) The facility's design and operational characteristics (*e.g.*, whether its program or activity is conducted indoors, its square footage, the density and placement of stationary devices, and the availability of storage for the device, if requested by the user);

(iv) Whether legitimate safety requirements can be established to permit the safe operation of the other power-driven mobility device in the specific facility; and

(v) Whether the use of the other power-driven mobility device creates a substantial risk of serious harm to the immediate environment or natural or cultural resources, or poses a conflict with Federal land management laws and regulations.

(c) *Inquiry about disability*—(1) *Requirement*. A recipient shall not ask an individual using a wheelchair or other power-driven mobility device questions about the nature and extent of the individual's disability.

(2) *Inquiry into use of other power-driven mobility device*. A recipient may ask a person using an other power-driven mobility device to provide a credible assurance that the mobility device is required because of the person's disability. A recipient in permitting the use of an other power-driven mobility device by an individual with a mobility disability shall accept the presentation of a valid, State-issued, disability parking placard or card, or other State-issued proof of disability as a credible assurance that the use of the other power-driven mobility device is for the individual's mobility disability. In lieu of a valid, State-issued disability parking placard or card, or State-issued proof of disability, a recipient shall accept as a credible assurance a verbal representation, not contradicted by observable fact, that the other power-driven mobility device is being used for a mobility disability. A "valid" disability placard or card is

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one that is presented by the individual to whom it was issued and is otherwise in compliance with the State of issuance's requirements for disability placards or cards.

§ 84.75 Direct threat.

(a) This part does not require a recipient to permit an individual to participate in or benefit from the programs or activities of that recipient when that individual poses a direct threat.

(b) Except as provided in paragraph (c) of this section, in determining whether an individual poses a direct threat, a recipient must make an individualized assessment, based on reasonable judgment that relies on current medical knowledge or on the best available objective evidence, to ascertain: the nature, duration, and severity of the risk; the probability that the potential injury will actually occur; and whether reasonable modifications of policies, practices, or procedures or the provision of auxiliary aids or services will mitigate the risk.

(c) In determining whether an individual poses a direct threat in employment, the recipient must make an individualized assessment according to the Equal Employment Opportunity Commission's regulation implementing title I of the Americans with Disabilities Act of 1990, at 29 CFR 1630.2(r).

§ 84.76 Integration.

(a) *Application.* This section applies to programs or activities that receive Federal financial assistance from the Department and to recipients that operate such programs or activities.

(b) *Discriminatory action prohibited.* A recipient shall administer a program or activity in the most integrated setting appropriate to the needs of a qualified person with a disability.

(c) *Segregated setting.* Segregated settings include but are not limited to congregate settings that are populated exclusively or primarily with individuals with disabilities and may be characterized by regimentation in daily activities; lack of privacy or autonomy; or policies or practices limiting visitors or limiting individuals' ability to engage freely in community activities

and to manage their own activities of daily living.

(d) *Specific prohibitions.* The general prohibition in paragraph (b) of this section includes but is not limited to the following specific prohibitions, to the extent that such action results in unnecessary segregation, or serious risk of such segregation, of persons with disabilities.

(1) Establishing or applying policies or practices that limit or condition individuals with disabilities' access to the most integrated setting appropriate to their needs;

(2) Providing greater benefits or benefits under more favorable terms in segregated settings than in integrated settings;

(3) Establishing or applying more restrictive rules and requirements for qualified individuals with disabilities in integrated settings than for individuals with disabilities in segregated settings; or

(4) Failure to provide community-based services that results in institutionalization or serious risk of institutionalization. This paragraph (d)(4) includes, but is not limited to planning, service system design, funding, or service implementation practices that result in institutionalization or serious risk of institutionalization. Qualified individuals with disabilities need not wait until the harm of institutionalization or segregation occurs to assert their right to avoid unnecessary segregation.

(e) *Fundamental alteration.* A recipient may establish a defense to the application of this section if it can demonstrate that a requested modification would fundamentally alter the nature of its program or activity.

Subpart H—Communications

SOURCE: 89 FR 40192, May 9, 2024, unless otherwise noted.

§ 84.77 General.

(a)(1) A recipient shall take appropriate steps to ensure that communications with applicants, participants, members of the public, and companions with disabilities are as effective as communications with others.

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(2) For purposes of this section, *companion* means a family member, friend, or associate of an individual seeking access to a program or activity of a recipient, who, along with such individual, is an appropriate person with whom the recipient should communicate.

(b)(1) The recipient shall furnish appropriate auxiliary aids and services where necessary to afford qualified individuals with disabilities, including applicants, participants, beneficiaries, companions, and members of the public, an equal opportunity to participate in, and enjoy the benefits of, a program or activity of a recipient.

(2) The type of auxiliary aid or service necessary to ensure effective communication will vary in accordance with the method of communication used by the individual; the nature, length, and complexity of the communication involved; and the context in which the communication is taking place. In determining what types of auxiliary aids and services are necessary, a recipient shall give primary consideration to the requests of individuals with disabilities. In order to be effective, auxiliary aids and services must be provided in accessible formats, in a timely manner, and in such a way as to protect the privacy and independence of the individual with a disability.

(c)(1) A recipient shall not require an individual with a disability to bring another individual to interpret for him or her.

(2) A recipient shall not rely on an adult accompanying an individual with a disability to interpret or facilitate communication except—

(i) In an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no interpreter available; or

(ii) When the individual with a disability specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances.

(3) A recipient shall not rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to

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the safety or welfare of an individual or the public when there is no interpreter available.

(d) When the recipient chooses to provide qualified interpreters via video remote interpreting services (VRI), it shall ensure that it provides—

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter's face, arms, hands, and fingers, and the participating individual's face, arms, hands, and fingers, regardless of their body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the VRI.

§ 84.78 Telecommunications.

(a) Where a recipient communicates by telephone with applicants and beneficiaries, text telephones (TTYs) or equally effective telecommunications systems shall be used to communicate with individuals who are deaf or hard of hearing or have speech impairments.

(b) When a recipient uses an automated-attendant system, including, but not limited to, voice mail and messaging, or an interactive voice response system, for receiving and directing incoming telephone calls, that system must provide effective real-time communication with individuals using auxiliary aids and services, including TTYs and all forms of Federal Communications Commission (FCC)-approved telecommunications relay systems, including internet-based relay systems.

(c) A recipient shall respond to telephone calls from a telecommunications relay service established under title IV of the ADA in the same manner that it responds to other telephone calls.

§ 84.79 Telephone emergency services.

Telephone emergency services, including 911 services, shall provide direct access to individuals who use TTYs and computer modems.

§ 84.80 Information and signage.

(a) A recipient shall ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of accessible services, activities, and facilities.

(b) A recipient shall provide signage at all inaccessible entrances to each of its facilities, directing users to an accessible entrance or to a location at which they can obtain information about accessible facilities. The international symbol for accessibility shall be used at each accessible entrance of a facility.

§ 84.81 Duties.

This subpart does not require a recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or undue financial and administrative burdens. In those circumstances where a recipient's personnel believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the recipient has the burden of proving that compliance with this subpart would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of the recipient or their designee after considering all the recipient's resources available for use in the funding and operation of the program or activity and must be accompanied by a written statement of reasons for reaching that conclusion. If an action required to comply with this part would result in such an alteration or such burdens, the recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with disabilities receive the benefits or services provided by the recipient.

Subpart I—Web, Mobile, and Kiosk Accessibility

SOURCE: 89 FR 40193, May 9, 2024, unless otherwise noted.

§ 84.82 Application.

This subpart applies to all programs or activities that receive Federal financial assistance from the Department.

§ 84.83 Accessibility of kiosks.

No qualified individual with a disability shall, on the basis of disability, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity of a recipient provided through kiosks.

§ 84.84 Requirements for web and mobile accessibility.

(a) *General.* A recipient shall ensure that the following are readily accessible to and usable by individuals with disabilities:

(1) Web content that a recipient provides or makes available, directly or through contractual, licensing, or other arrangements; and

(2) Mobile apps that a recipient provides or makes available, directly or through contractual, licensing, or other arrangements.

(b) *Requirements.* (1) Beginning May 11, 2026, a recipient with fifteen or more employees shall ensure that the web content and mobile apps that the recipient provides or makes available, directly or through contractual, licensing, or other arrangements, comply with Level A and Level AA success criteria and conformance requirements specified in WCAG 2.1, unless the recipient can demonstrate that compliance with this section would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens.

(2) Beginning May 10, 2027, a recipient with fewer than fifteen employees shall ensure that the web content and mobile apps that the recipient provides or makes available, directly or through contractual, licensing, or other arrangements, comply with Level A and Level AA success criteria and conformance requirements specified in WCAG

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2.1, unless the recipient can demonstrate that compliance with this section would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens.

(3) WCAG 2.1 is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All material approved for incorporation by reference (IBR) is available for inspection at HHS and at the National Archives and Records Administration (“NARA”). Contact HHS, OCR at: Office for Civil Rights, U.S. Department of Health and Human Services, 200 Independence Ave. SW, Room 509F, HHH Building, Washington, DC 20201; phone: (202) 545-4884; email: 504@hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the World Wide Web Consortium (W3C) Web Accessibility Initiative (“WAI”), 401 Edgewater Place, Suite 600, Wakefield, MA 01880; phone: (339) 273-2711; email: contact@w3.org; website: www.w3.org/TR/2018/REC-WCAG21-20180605/ and <https://perma.cc/UB8A-GG2F>.

§ 84.85 Exceptions.

The requirements of § 84.84 do not apply to the following:

(a) *Archived web content.* Archived web content as defined in § 84.10.

(b) *Preexisting conventional electronic documents.* Conventional electronic documents that are available as part of a recipient’s web content or mobile apps before the date the recipient is required to comply with § 84.84, unless such documents are currently used to apply for, gain access to, or participate in the recipient’s programs or activities.

(c) *Content posted by a third party.* Content posted by a third party, unless the third party is posting due to contractual, licensing, or other arrangements with the recipient.

(d) *Individualized, password-protected documents or otherwise secured conventional electronic documents.* Conventional electronic documents that are:

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(1) About a specific individual, their property, or their account; and

(2) Password-protected or otherwise secured.

(e) *Preexisting social media posts.* A recipient’s social media posts that were posted before the date the recipient is required to comply with § 84.84.

§ 84.86 Conforming alternate versions.

(a) A recipient may use conforming alternate versions of web content, as defined by WCAG 2.1, to comply with § 84.84 only where it is not possible to make web content directly accessible due to technical or legal limitations.

(b) WCAG 2.1 is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All material approved for incorporation by reference is available for inspection at HHS and at NARA. Contact HHS, OCR at: Office for Civil Rights, U.S. Department of Health and Human Services, 200 Independence Ave. SW, Room 509F, HHH Building, Washington, DC 20201; phone: (202) 545-4884; email: 504@hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the World Wide Web Consortium (W3C) Web Accessibility Initiative (“WAI”), 401 Edgewater Place, Suite 600, Wakefield, MA 01880; phone: (339) 273-2711; email: contact@w3.org; website: www.w3.org/TR/2018/REC-WCAG21-20180605/ and <https://perma.cc/UB8A-GG2F>.

§ 84.87 Equivalent facilitation.

Nothing in this subpart prevents the use of designs, methods, or techniques as alternatives to those prescribed, provided that the alternative designs, methods, or techniques result in substantially equivalent or greater accessibility and usability of the web content or mobile app.

§ 84.88 Duties.

Where a recipient can demonstrate that compliance with the requirements of § 84.84 would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens, compliance

with § 84.84 is required to the extent that it does not result in a fundamental alteration or undue financial and administrative burdens. In those circumstances where personnel of the recipient believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, a recipient has the burden of proving that compliance with § 84.84 would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of a recipient or their designee after considering all resources available for use in the funding and operation of the program or activity, and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, a recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with disabilities receive the benefits or services provided by the recipient to the maximum extent possible.

§ 84.89 Effect of noncompliance that has a minimal impact on access.

A recipient that is not in full compliance with the requirements of § 84.84(b) will be deemed to have met the requirements of § 84.84 in the limited circumstance in which the recipient can demonstrate that the noncompliance has such a minimal impact on access that it would not affect the ability of individuals with disabilities to use the recipient's web content or mobile app to do any of the following in a manner that provides substantially equivalent timeliness, privacy, independence, and ease of use:

- (a) Access the same information as individuals without disabilities;
- (b) Engage in the same interactions as individuals without disabilities;
- (c) Conduct the same transactions as individuals without disabilities; and
- (d) Otherwise participate in or benefit from the same programs and activities as individuals without disabilities.

Subpart J—Accessible Medical Equipment

SOURCE: 89 FR 40194, May 9, 2024, unless otherwise noted.

§ 84.90 Application.

This subpart applies to programs or activities that receive Federal financial assistance from the Department and to recipients that operate, or that receive Federal financial assistance for the operation of, such programs or activities.

§ 84.91 Requirements for medical diagnostic equipment.

No qualified individual with a disability shall, on the basis of disability, be excluded from participation in, be denied the benefits of the programs or activities of a recipient offered through or with the use of medical diagnostic equipment (MDE), or otherwise be subjected to discrimination under any program or activity that receives Federal financial assistance because the recipient's MDE is not readily accessible to or usable by persons with disabilities.

§ 84.92 Newly purchased, leased, or otherwise acquired medical diagnostic equipment.

(a) *Requirements for all newly purchased, leased, or otherwise acquired medical diagnostic equipment.* All MDE that recipients purchase, lease (including via lease renewals), or otherwise acquire more than July 8, 2024, subject to the requirements and limitations set forth in this section, meet the Standards for Accessible MDE, unless and until the recipient satisfies the scoping requirements set forth in paragraph (b) of this section.

(b) *Scoping requirements—(1) General requirement for medical diagnostic equipment.* Where a program or activity of a recipient, including physicians' offices, clinics, emergency rooms, hospitals, outpatient facilities, and multi-use facilities, utilizes MDE, at least 10 percent of the total number of units, but no fewer than one unit, of each type of equipment in use must meet the Standards for Accessible MDE.

(2) *Facilities that specialize in treating conditions that affect mobility.* In rehabilitation facilities that specialize in

§ 84.93

treating conditions that affect mobility, outpatient physical therapy facilities, and other programs or activities that specialize in treating conditions that affect mobility, at least 20 percent, but no fewer than one unit, of each type of equipment in use must meet the Standards for Accessible MDE.

(3) *Facilities with multiple departments.* In any facility or program with multiple departments, clinics, or specialties, where a program or activity uses MDE, the facility shall disperse the accessible MDE required by paragraphs (b)(1) and (2) of this section in a manner that is proportionate by department, clinic, or specialty using MDE.

(c) *Requirements for examination tables and weight scales.* Within 2 years after July 8, 2024, recipients shall, subject to the requirements and limitations set forth in this section, purchase, lease, or otherwise acquire the following, unless the recipient already has them in place:

(1) At least one examination table that meets the Standards for Accessible MDE, if the recipient uses at least one examination table; and

(2) At least one weight scale that meets the Standards for Accessible MDE, if the recipient uses at least one weight scale.

(d) *Equivalent facilitation.* Nothing in this section prevents the use of designs, products, or technologies as alternatives to those prescribed by the Standards for Accessible MDE, provided they result in substantially equivalent or greater accessibility and usability of the program or activity. The responsibility for demonstrating equivalent facilitation rests with the recipient.

(e) *Fundamental alteration and undue burdens.* This section does not require a recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity, or in undue financial and administrative burdens. In those circumstances where personnel of the recipient believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, a recipient has the burden of proving that compliance with para-

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graph (a) or (c) of this section would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of a recipient or their designee after considering all resources available for use in the funding and operation of the program or activity and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, a recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with disabilities receive the benefits or services provided by the recipient.

(f) *Diagnostically required structural or operational characteristics.* A recipient meets its burden of proving that compliance with paragraph (a) or (c) of this section would result in a fundamental alteration under paragraph (e) of this section if it demonstrates that compliance with paragraph (a) or (c) would alter diagnostically required structural or operational characteristics of the equipment, and prevent the use of the equipment for its intended diagnostic purpose. This paragraph (f) does not excuse compliance with other technical requirements where compliance with those requirements does not prevent the use of the equipment for its diagnostic purpose.

§ 84.93 Existing medical diagnostic equipment.

(a) *Accessibility.* A recipient shall operate each program or activity offered through or with the use of MDE so that the program or activity, in its entirety, is readily accessible to and usable by individuals with disabilities. This paragraph (a) does not—

(1) Necessarily require a recipient to make each of its existing pieces of medical diagnostic equipment accessible to and usable by individuals with disabilities; or

(2) Require a recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity, or in undue financial and administrative burdens. In those circumstances where personnel of the recipient believe that

the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, a recipient has the burden of proving that compliance with this paragraph (a) would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the head of the recipient or their designee after considering all resources available for use in the funding and operation of the program or activity and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, the recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with disabilities receive the benefits or services provided by the recipient.

(3) A recipient meets its burden of proving that compliance with this paragraph (a) would result in a fundamental alteration under paragraph (a)(2) of this section if it demonstrates that compliance with this paragraph (a) would alter diagnostically required structural or operational characteristics of the equipment, and prevent the use of the equipment for its intended diagnostic purpose.

(b) *Methods.* A recipient may comply with the requirements of this section through such means as reassignment of services to alternate accessible locations, home visits, delivery of services at alternate accessible sites, purchase, lease, or other acquisition of accessible MDE, or any other methods that result in making its programs or activities readily accessible to and usable by individuals with disabilities. A recipient is not required to purchase, lease, or otherwise acquire accessible medical diagnostic equipment where other methods are effective in achieving compliance with this section. In choosing among available methods for meeting the requirements of this section, a recipient shall give priority to those methods that offer programs and activities to qualified individuals with disabilities in the most integrated setting appropriate.

§ 84.94 Qualified staff.

Recipients must ensure their staff are able to successfully operate accessible MDE, assist with transfers and positioning of individuals with disabilities, and carry out the program access obligation regarding existing MDE.

§§ 84.95–84.97 [Reserved]

Subpart K—Procedures

§ 84.98 Procedures.

The procedural provisions applicable to title VI of the Civil Rights Act of 1964 apply to this part. These procedures are found in 45 CFR 80.6 through 80.10 and 45 CFR part 81.

[89 FR 40195, May 9, 2024]

APPENDIX A TO PART 84—ANALYSIS OF FINAL REGULATION

SUBPART A—GENERAL PROVISIONS

Definitions—1. “*Recipient*”. Section 84.23 contains definitions used throughout the regulation. Most of the comments concerning § 84.3(f), which contains the definition of “recipient,” commended the inclusion of recipient whose sole source of Federal financial assistance is Medicaid. The Secretary believes that such Medicaid providers should be regarded as recipients under the statute and the regulation and should be held individually responsible for administering services in a nondiscriminatory fashion. Accordingly, § 84.3(f) has not been changed. Small Medicaid providers, however, are exempt from some of the regulation’s administrative provisions (those that apply to recipients with fifteen or more employees). And such recipients will be permitted to refer patients to accessible facilities in certain limited circumstances under revised § 84.22(b). The Secretary recognizes the difficulties involved in Federal enforcement of this regulation with respect to thousands of individual Medicaid providers. As in the case of title VI of the Civil Rights Act of 1964, the Office for Civil Rights will concentrate its compliance efforts on the state Medicaid agencies and will look primarily to them to ensure compliance by individual providers.

One other comment requested that the regulation specify that nonpublic elementary and secondary schools that are not otherwise recipients do not become recipients by virtue of the fact their students participate in certain federally funded programs. The Secretary believes it unnecessary to amend the

regulation in this regard, because almost identical language in the Department's regulations implementing title VI and Title IX of the Education Amendments of 1972 has consistently been interpreted so as not to render such schools recipients. These schools, however, are indirectly subject to the substantive requirements of this regulation through the application of §84.4(b)(iv), which prohibits recipients from assisting agencies that discriminate on the basis of handicap in providing services to beneficiaries of the recipients' programs.

2. "*Federal financial assistance*". In §84.3(h), defining Federal financial assistance, a clarifying change has been made: procurement contracts are specifically excluded. They are covered, however, by the Department of Labor's regulation under section 503. The Department has never considered such contracts to be contracts of assistance; the explicit exemption has been added only to avoid possible confusion.

The proposed regulation's exemption of contracts of insurance or guaranty has been retained. A number of comments argued for its deletion on the ground that section 504, unlike title VI and title IX, contains no statutory exemption for such contracts. There is no indication, however, in the legislative history of the Rehabilitation Act of 1973 or of the amendments to that Act in 1974, that Congress intended section 504 to have a broader application, in terms of Federal financial assistance, than other civil rights statutes. Indeed, Congress directed that section 504 be implemented in the same manner as titles VI and IX. In view of the long established exemption of contracts of insurance or guaranty under title VI, we think it unlikely that Congress intended section 504 to apply to such contracts.

3. "*Handicapped person*". Section 84.3(j), which defines the class of persons protected under the regulation, has not been substantially changed. The definition of handicapped person in paragraph (j)(1) conforms to the statutory definition of handicapped person that is applicable to section 504, as set forth in section 111(a) of the Rehabilitation Act Amendments of 1974, Pub. L. 93-516.

The first of the three parts of the statutory and regulatory definition includes any person who has a physical or mental impairment that substantially limits one or more major life activities. Paragraph (j)(2)(i) further defines physical or mental impairments. The definition does not set forth a list of specific diseases and conditions that constitute physical or mental impairments because of the difficulty of ensuring the comprehensiveness of any such list. The term includes, however, such diseases and conditions as orthopedic, visual, speech, and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emo-

tional illness, and, as discussed below, drug addiction and alcoholism.

It should be emphasized that a physical or mental impairment does not constitute a handicap for purposes of section 504 unless its severity is such that it results in a substantial limitation of one or more major life activities. Several comments observed the lack of any definition in the proposed regulation of the phrase "substantially limits." The Department does not believe that a definition of this term is possible at this time.

A related issue raised by several comments is whether the definition of handicapped person is unreasonably broad. Comments suggested narrowing the definition in various ways. The most common recommendation was that only "traditional" handicaps be covered. The Department continues to believe, however, that it has no flexibility within the statutory definition to limit the term to persons who have those severe, permanent, or progressive conditions that are most commonly regarded as handicaps. The Department intends, however, to give particular attention in its enforcement of section 504 to eliminating discrimination against persons with the severe handicaps that were the focus of concern in the Rehabilitation Act of 1973.

The definition of handicapped person also includes specific limitations on what persons are classified as handicapped under the regulation. The first of the three parts of the definition specifies that only physical and mental handicaps are included. Thus, environmental, cultural, and economic disadvantage are not in themselves covered; nor are prison records, age, or homosexuality. Of course, if a person who has any of these characteristics also has a physical or mental handicap, the person is included within the definition of handicapped person.

In paragraph (j)(2)(i), physical or mental impairment is defined to include, among other impairments, specific learning disabilities. The Department will interpret the term as it is used in section 602 of the Education of the Handicapped Act, as amended. Paragraph (15) of section 602 uses the term "specific learning disabilities" to describe such conditions as perceptual handicaps, brain injury, minimal brain dysfunction, dyslexia, and developmental aphasia.

Paragraph (j)(2)(i) has been shortened, but not substantively changed, by the deletion of clause (C), which made explicit the inclusion of any condition which is mental or physical but whose precise nature is not at present known. Clauses (A) and (B) clearly comprehend such conditions.

The second part of the statutory and regulatory definition of handicapped person includes any person who has a record of a physical or mental impairment that substantially limits a major life activity. Under the definition of "record" in paragraph (j)(2)(iii),

persons who have a history of a handicapping condition but no longer have the condition, as well as persons who have been incorrectly classified as having such a condition, are protected from discrimination under section 504. Frequently occurring examples of the first group are persons with histories of mental or emotional illness, heart disease, or cancer; of the second group, persons who have been misclassified as mentally retarded.

The third part of the statutory and regulatory definition of handicapped person includes any person who is regarded as having a physical or mental impairment that substantially limits one or more major life activities. It includes many persons who are ordinarily considered to be handicapped but who do not technically fall within the first two parts of the statutory definition, such as persons with a limp. This part of the definition also includes some persons who might not ordinarily be considered handicapped, such as persons with disfiguring scars, as well as persons who have no physical or mental impairment but are treated by a recipient as if they were handicapped.

4. *Drug addicts and alcoholics.* As was the case during the first comment period, the issue of whether to include drug addicts and alcoholics within the definition of handicapped person was of major concern to many commenters. The arguments presented on each side of the issue were similar during the two comment periods, as was the preference of commenters for exclusion of this group of persons. While some comments reflected misconceptions about the implications of including alcoholics and drug addicts within the scope of the regulation, the Secretary understands the concerns that underlie the comments on this question and recognizes that application of section 504 to active alcoholics and drug addicts presents sensitive and difficult questions that must be taken into account in interpretation and enforcement.

The Secretary has carefully examined the issue and has obtained a legal opinion from the Attorney General. That opinion concludes that drug addiction and alcoholism are "physical or mental impairments" within the meaning of section 7(6) of the Rehabilitation Act of 1973, as amended, and that drug addicts and alcoholics are therefore handicapped for purposes of section 504 if their impairment substantially limits one of their major life activities. The Secretary therefore believes that he is without authority to exclude these conditions from the definition. There is a medical and legal consensus that alcoholism and drug addiction are diseases, although there is disagreement as to whether they are primarily mental or physical. In addition, while Congress did not focus specifically on the problems of drug addiction and alcoholism in enacting section

504, the committees that considered the Rehabilitation Act of 1973 were made aware of the Department's long-standing practice of treating addicts and alcoholics as handicapped individuals eligible for rehabilitation services under the Vocational Rehabilitation Act.

The Secretary wishes to reassure recipients that inclusion of addicts and alcoholics within the scope of the regulation will not lead to the consequences feared by many commenters. It cannot be emphasized too strongly that the statute and the regulation apply only to discrimination against qualified handicapped persons solely by reason of their handicap. The fact that drug addiction and alcoholism may be handicaps does not mean that these conditions must be ignored in determining whether an individual is qualified for services or employment opportunities. On the contrary, a recipient may hold a drug addict or alcoholic to the same standard of performance and behavior to which it holds others, even if any unsatisfactory performance or behavior is related to the person's drug addiction or alcoholism. In other words, while an alcoholic or drug addict may not be denied services or disqualified from employment solely because of his or her condition, the behavioral manifestations of the condition may be taken into account in determining whether he or she is qualified.

With respect to the employment of a drug addict or alcoholic, if it can be shown that the addiction or alcoholism prevents successful performance of the job, the person need not be provided the employment opportunity in question. For example, in making employment decisions, a recipient may judge addicts and alcoholics on the same basis it judges all other applicants and employees. Thus, a recipient may consider—for all applicants including drug addicts and alcoholics—past personnel records, absenteeism, disruptive, abusive, or dangerous behavior, violations of rules and unsatisfactory work performance. Moreover, employers may enforce rules prohibiting the possession or use of alcohol or drugs in the work-place, provided that such rules are enforced against all employees.

With respect to services, there is evidence that drug addicts and alcoholics are often denied treatment at hospitals for conditions unrelated to their addiction or alcoholism. In addition, some addicts and alcoholics have been denied emergency treatment. These practices have been specifically prohibited by section 407 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1174) and section 321 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (42 U.S.C. 4581), as amended. These statutory

provisions are also administered by the Department's Office for Civil Rights and are implemented in §84.53 of this regulation.

With respect to other services, the implications of coverage, of alcoholics and drug addicts are two-fold: first, no person may be excluded from services solely by reason of the presence or history of these conditions; second, to the extent that the manifestations of the condition prevent the person from meeting the basic eligibility requirements of the program or cause substantial interference with the operation of the program, the condition may be taken into consideration. Thus, a college may not exclude an addict or alcoholic as a student, on the basis of addiction or alcoholism, if the person can successfully participate in the education program and complies with the rules of the college and if his or her behavior does not impede the performance of other students.

Of great concern to many commenters was the question of what effect the inclusion of drug addicts and alcoholics as handicapped persons would have on school disciplinary rules prohibiting the use or possession of drugs or alcohol by students. Neither such rules nor their application to drug addicts or alcoholics is prohibited by this regulation, provided that the rules are enforced evenly with respect to all students.

5. *"Qualified handicapped person."* Paragraph (k) of §84.3 defines the term "qualified handicapped person." Throughout the regulation, this term is used instead of the statutory term "otherwise qualified handicapped person." The Department believes that the omission of the word "otherwise" is necessary in order to comport with the intent of the statute because, read literally, "otherwise" qualified handicapped persons include persons who are qualified except for their handicap, rather than in spite of their handicap. Under such a literal reading, a blind person possessing all the qualifications for driving a bus except sight could be said to be "otherwise qualified" for the job of driving. Clearly, such a result was not intended by Congress. In all other respects, the terms "qualified" and "otherwise qualified" are intended to be interchangeable.

Section 84.3(k)(1) defines a qualified handicapped person with respect to employment as a handicapped person who can, with reasonable accommodation, perform the essential functions of the job in question. The term "essential functions" does not appear in the corresponding provision of the Department of Labor's section 503 regulation, and a few commenters objected to its inclusion on the ground that a handicapped person should be able to perform all job tasks. However, the Department believes that inclusion of the phrase is useful in emphasizing that handicapped persons should not be disqualified simply because they may have difficulty in performing tasks that bear only a mar-

ginal relationship to a particular job. Further, we are convinced that inclusion of the phrase is not inconsistent with the Department of Labor's application of its definition.

Certain commenters urged that the definition of qualified handicapped person be amended so as explicitly to place upon the employer the burden of showing that a particular mental or physical characteristic is essential. Because the same result is achieved by the requirement contained in paragraph (a) of §84.13, which requires an employer to establish that any selection criterion that tends to screen out handicapped persons is job-related, that recommendation has not been followed.

Section 84.3(k)(2) (formerly §84.3(k)(3)) defines qualified handicapped person, with respect to preschool, elementary, and secondary programs, in terms of age. Several commenters recommended that eligibility for the services be based upon the standard of substantial benefit, rather than age, because of the need of many handicapped children for early or extended services if they are to have an equal opportunity to benefit from education programs. No change has been made in this provision, again because of the extreme difficulties in administration that would result from the choice of the former standard. Under the remedial action provisions of §84.6(a)(3), however, persons beyond the age limits prescribed in §84.3(k)(2) may in appropriate cases be required to be provided services that they were formerly denied because of a recipient's violation of section 504.

Section 84.3(k)(2) states that a handicapped person is qualified for preschool, elementary, or secondary services if the person is of an age at which nonhandicapped persons are eligible for such services or at which state law mandates the provision of educational services to handicapped persons. In addition, the extended age ranges for which recipients must provide full educational opportunity to all handicapped persons in order to be eligible for assistance under the Education of the Handicapped Act—generally, 3-18 as of September 1978, and 3-21 as of September 1980 are incorporated by reference in this paragraph.

Section 84.3(k)(3) formerly §84.3(k)(2) defines qualified handicapped person with respect to postsecondary educational programs. As revised, the paragraph means that both academic and technical standards must be met by applicants to these programs. The term "technical standards" refers to all non-academic admissions criteria that are essential to participation in the program in question.

6. *General prohibitions against discrimination.* Section 84.4 contains general prohibitions against discrimination applicable to all recipients of assistance from this Department.

Paragraph (b)(1)(i) prohibits the exclusion of qualified handicapped persons from aids, benefits, or services, and paragraph (ii) requires that equal opportunity to participate or benefit be provided. Paragraph (iii) requires that services provided to handicapped persons be as effective as those provided to the nonhandicapped. In paragraph (iv), different or separate services are prohibited except when necessary to provide equally effective benefits.

In this context, the term "equally effective," defined in paragraph (b)(2), is intended to encompass the concept of equivalent, as opposed to identical, services and to acknowledge the fact that in order to meet the individual needs of handicapped persons to the same extent that the corresponding needs of nonhandicapped persons are met, adjustments to regular programs or the provision of different programs may sometimes be necessary. For example, a welfare office that uses the telephone for communicating with its clients must provide alternative modes of communicating with its deaf clients. This standard parallels the one established under title VI of Civil Rights Act of 1964 with respect to the provision of educational services to students whose primary language is not English. See *Lau v. Nichols*, 414 U.S. 563 (1974). To be equally effective, however, an aid, benefit, or service need not produce equal results; it merely must afford an equal opportunity to achieve equal results.

It must be emphasized that, although separate services must be required in some instances, the provision of unnecessarily separate or different services is discriminatory. The addition to paragraph (b)(2) of the phrase "in the most integrated setting appropriate to the person's needs" is intended to reinforce this general concept. A new paragraph (b)(3) has also been added to §84.4, requiring recipients to give qualified handicapped persons the option of participating in regular programs despite the existence of permissibly separate or different programs. The requirement has been reiterated in §§84.38 and 84.47 in connection with physical education and athletics programs.

Section 84.4(b)(1)(v) prohibits a recipient from supporting another entity or person that subjects participants or employees in the recipient's program to discrimination on the basis of handicap. This section would, for example, prohibit financial support by a recipient to a community recreational group or to a professional or social organization that discriminates against handicapped persons. Among the criteria to be considered in each case are the substantiality of the relationship between the recipient and the other entity, including financial support by the recipient, and whether the other entity's activities relate so closely to the recipient's program or activity that they fairly should

be considered activities of the recipient itself. Paragraph (b)(1)(vi) was added in response to comment in order to make explicit the prohibition against denying qualified handicapped persons the opportunity to serve on planning and advisory boards responsible for guiding federally assisted programs or activities.

Several comments appeared to interpret §84.4(b)(5), which proscribes discriminatory site selection, to prohibit a recipient that is located on hilly terrain from erecting any new buildings at its present site. That, of course, is not the case. This paragraph is not intended to apply to construction of additional buildings at an existing site. Of course, any such facilities must be made accessible in accordance with the requirements of §84.23.

7. *Assurances of compliance.* Section 84.5(a) requires a recipient to submit to the Director an assurance that each of its programs and activities receiving or benefiting from Federal financial assistance from this Department will be conducted in compliance with this regulation. To facilitate the submission of assurances by thousands of Medicaid providers, the Department will follow the title VI procedures of accepting, in lieu of assurances, certification on Medicaid vouchers. Many commenters also sought relief from the paperwork requirements imposed by the Department's enforcement of its various civil rights responsibilities by requesting the Department to issue one form incorporating title VI, title IX, and section 504 assurances. The Secretary is sympathetic to this request. While it is not feasible to adopt a single civil rights assurance form at this time, the Office for Civil Rights will work toward that goal.

8. *Private rights of action.* Several comments urged that the regulation incorporate provision granting beneficiaries a private right of action against recipients under section 504. To confer such a right is beyond the authority of the executive branch of Government. There is, however, case law holding that such a right exists. *Lloyd v. Regional Transportation Authority*, 548 F. 2d 1277 (7th Cir. 1977); see *Hairston v. Drosick*, Civil No. 75-0691 (S.D. W. Va., Jan. 14, 1976); *Gurmankin v. Castanzo*, 411 F. Supp. 982 (E.D. Pa. 1976); cf. *Lau v. Nichols*, *supra*.

9. *Remedial action.* Where there has been a finding of discrimination, §84.6 requires a recipient to take remedial action to overcome the effects of the discrimination. Actions that might be required under paragraph (a)(1) include provision of services to persons previously discriminated against, reinstatement of employees and development of a remedial action plan. Should a recipient fail to take required remedial action, the ultimate sanctions of court action or termination of Federal financial assistance may be imposed.

Paragraph (a)(2) extends the responsibility for taking remedial action to a recipient that exercises control over a noncomplying recipient. Paragraph (a)(3) also makes clear that handicapped persons who are not in the program at the time that remedial action is required to be taken may also be the subject of such remedial action. This paragraph has been revised in response to comments in order to include persons who would have been in the program if discriminatory practices had not existed. Paragraphs (a) (1), (2), and (3) have also been amended in response to comments to make plain that, in appropriate cases, remedial action might be required to redress clear violations of the statute itself that occurred before the effective date of this regulation.

10. *Voluntary action.* In §84.6(b), the term “voluntary action” has been substituted for the term “affirmative action” because the use of the latter term led to some confusion. We believe the term “voluntary action” more accurately reflects the purpose of the paragraph. This provision allows action, beyond that required by the regulation, to overcome conditions that led to limited participation by handicapped persons, whether or not the limited participation was caused by any discriminatory actions on the part of the recipient. Several commenters urged that paragraphs (a) and (b) be revised to require remedial action to overcome effects of prior discriminatory practices regardless of whether there has been an express finding of discrimination. The self-evaluation requirement in paragraph (c) accomplishes much the same purpose.

11. *Self-evaluation.* Paragraph (c) requires recipients to conduct a self-evaluation in order to determine whether their policies or practices may discriminate against handicapped persons and to take steps to modify any discriminatory policies and practices and their effects. The Department received many comments approving of the addition to paragraph (c) of a requirement that recipients seek the assistance of handicapped persons in the self-evaluation process. This paragraph has been further amended to require consultation with handicapped persons or organizations representing them before recipients undertake the policy modifications and remedial steps prescribed in paragraphs (c)(1)(ii) and (iii).

Paragraph (c)(2), which sets forth the recordkeeping requirements concerning self-evaluation, now applies only to recipients with fifteen or more employees. This change was made as part of an effort to reduce unnecessary or counterproductive administrative obligations on small recipients. For those recipients required to keep records, the requirements have been made more specific; records must include a list of persons consulted and a description of areas examined, problems identified, and corrective steps

taken. Moreover, the records must be made available for public inspection.

12. *Grievance procedure.* Section 84.7 (formerly §84.8) requires recipients with fifteen or more employees to designate an individual responsible for coordinating its compliance efforts and to adopt a grievance procedure. Two changes were made in the section in response to comment. A general requirement that appropriate due process procedures be followed has been added. It was decided that the details of such procedures could not at this time be specified because of the varied nature of the persons and entities who must establish the procedures and of the programs to which they apply. A sentence was also added to make clear that grievance procedures are not required to be made available to unsuccessful applicants for employment or to applicants for admission to colleges and universities.

The regulation does not require that grievance procedures be exhausted before recourse is sought from the Department. However, the Secretary believes that it is desirable and efficient in many cases for complainants to seek resolution of their complaints and disputes at the local level and therefore encourages them to use available grievance procedures.

A number of comments asked whether compliance with this section or the notice requirements of §84.8 could be coordinated with comparable action required by the title IX regulation. The Department encourages such efforts.

13. *Notice.* Section 84.8 (formerly §84.9) sets forth requirements for dissemination of statements of nondiscrimination policy by recipients.

It is important that both handicapped persons and the public at large be aware of the obligations of recipients under section 504. Both the Department and recipients have responsibilities in this regard. Indeed the Department intends to undertake a major public information effort to inform persons of their rights under section 504 and this regulation. In §84.8 the Department has sought to impose a clear obligation on major recipients to notify beneficiaries and employees of the requirements of section 504, without dictating the precise way in which this notice must be given. At the same time, we have avoided imposing requirements on small recipients (those with fewer than fifteen employees) that would create unnecessary and counterproductive paper work burdens on them and unduly stretch the enforcement resources of the Department.

Section 84.8(a), as simplified, requires recipients with fifteen or more employees to take appropriate steps to notify beneficiaries and employees of the recipient's obligations under section 504. The last sentence of §84.8(a) has been revised to list possible, rather than required, means of notification.

Section 84.8(b) requires recipients to include a notification of their policy of non-discrimination in recruitment and other general information materials.

In response to a number of comments, §84.8 has been revised to delete the requirements of publication in local newspapers, which has proved to be both troublesome and ineffective. Several commenters suggested that notification on separate forms be allowed until present stocks of publications and forms are depleted. The final regulation explicitly allows this method of compliance. The separate form should, however, be included with each significant publication or form that is distributed.

Former §84.9(b)(2), which prohibited the use of materials that might give the impression that a recipient excludes qualified handicapped persons from its program, has been deleted. The Department is convinced by the comments that this provision is unnecessary and difficult to apply. The Department encourages recipients, however, to include in their recruitment and other general information materials photographs of handicapped persons and ramps and other features of accessible buildings.

Under new §84.9 the Director may, under certain circumstances, require recipients with fewer than fifteen employees to comply with one or more of these requirements. Thus, if experience shows a need for imposing notice or other requirements on particular recipients or classes of small recipients, the Department is prepared to expand the coverage of these sections.

14. *Inconsistent State laws.* Section 84.10(a) states that compliance with the regulation is not excused by state or local laws limiting the eligibility of qualified handicapped persons to receive services or to practice an occupation. The provision thus applies only with respect to state or local laws that unjustifiably differentiate on the basis of handicap.

Paragraph (b) further points out that the presence of limited employment opportunities in a particular profession, does not excuse a recipient from complying with the regulation. Thus, a law school could not deny admission to a blind applicant because blind lawyers may find it more difficult to find jobs that do nonhandicapped lawyers.

SUBPART B—EMPLOYMENT PRACTICES

Subpart B prescribes requirements for non-discrimination in the employment practices of recipients of Federal financial assistance administered by the Department. This subpart is consistent with the employment provisions of the Department's regulation implementing title IX of the Education Amendments of 1972 (45 CFR part 86) and the regulation of the Department of Labor under section 503 of the Rehabilitation Act, which requires certain Federal contractors to take

affirmative action in the employment and advancement of qualified handicapped persons. All recipients subject to title IX are also subject to this regulation. In addition, many recipients subject to this regulation receive Federal procurement contracts in excess of \$2,500 and are therefore also subject to section 503.

15. *Discriminatory practices.* Section 84.11 sets forth general provisions with respect to discrimination in employment. A new paragraph (a)(2) has been added to clarify the employment obligations of recipients that receive Federal funds under Part B of the Education of the Handicapped Act, as amended (EHA). Section 606 of the EHA obligates elementary or secondary school systems that receive EHA funds to take positive steps to employ and advance in employment qualified handicapped persons. This obligation is similar to the nondiscrimination requirement of section 504 but requires recipients to take additional steps to hire and promote handicapped persons. In enacting section 606 Congress chose the words "positive steps" instead of "affirmative action" advisedly and did not intend section 606 to incorporate the types of activities required under Executive Order 11246 (affirmative action on the basis of race, color, sex, or national origin) or under sections 501 and 503 of the Rehabilitation Act of 1973.

Paragraph (b) of §84.11 sets forth the specific aspects of employment covered by the regulation. Paragraph (c) provides that inconsistent provisions of collective bargaining agreements do not excuse non-compliance.

16. *Reasonable accommodation.* The reasonable accommodation requirement of §84.12 generated a substantial number of comments. The Department remains convinced that its approach is both fair and effective. Moreover, the Department of Labor reports that it has experienced little difficulty in administering the requirements of reasonable accommodation. The provision therefore remains basically unchanged from the proposed regulation.

Section 84.12 requires a recipient to make reasonable accommodation to the known physical or mental limitations of a handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program. Where a handicapped person is not qualified to perform a particular job, where reasonable accommodation does not overcome the effects of a person's handicap, or where reasonable accommodation causes undue hardship to the employer, failure to hire or promote the handicapped person will not be considered discrimination.

Section 84.12(b) lists some of the actions that constitute reasonable accommodation. The list is neither all-inclusive nor meant to

suggest that employers must follow all of the actions listed.

Reasonable accommodation includes modification of work schedules, including part-time employment, and job restructuring. Job restructuring may entail shifting non-essential duties to other employees. In other cases, reasonable accommodation may include physical modifications or relocation of particular offices or jobs so that they are in facilities or parts of facilities that are accessible to and usable by handicapped persons. If such accommodations would cause undue hardship to the employer, they need not be made.

Paragraph (c) of this section sets forth the factors that the Office for Civil Rights will consider in determining whether an accommodation necessary to enable an applicant or employee to perform the duties of a job would impose an undue hardship. The weight given to each of these factors in making the determination as to whether an accommodation constitutes undue hardship will vary depending on the facts of a particular situation. Thus, a small day-care center might not be required to expend more than a nominal sum, such as that necessary to equip a telephone for use by a secretary with impaired hearing, but a large school district might be required to make available a teacher's aide to a blind applicant for a teaching job. Further, it might be considered reasonable to require a state welfare agency to accommodate a deaf employee by providing an interpreter, while it would constitute an undue hardship to impose that requirement on a provider of foster home care services. The reasonable accommodation standard in §84.12 is similar to the obligation imposed upon Federal contractors in the regulation implementing section 503 of the Rehabilitation Act of 1973, administered by the Department of Labor. Although the wording of the reasonable accommodation provisions of the two regulations is not identical, the obligation that the two regulations impose is the same, and the Federal Government's policy in implementing the two sections will be uniform. The Department adopted the factors listed in paragraph (c) instead of the "business necessity" standard of the Labor regulation because that term seemed inappropriate to the nature of the programs operated by the majority of institutions subject to this regulation, e.g., public school systems, hospitals, colleges and universities, nursing homes, day-care centers, and welfare offices. The factors listed in paragraph (c) are intended to make the rationale underlying the business necessity standard applicable to an understandable by recipients of HHS funds.

17. *Tests and selection criteria.* Revised §84.13(a) prohibits employers from using test or other selection criteria that screen out or tend to screen out handicapped persons un-

less the test or criterion is shown to be job-related and alternative tests or criteria that do not screen out or tend to screen out as many handicapped persons are not shown by the Director to be available. This paragraph is an application of the principle established under title VII of the Civil Rights Act of 1964 in *Griggs v. Duke Power Company*, 401 U.S. 424 (1971).

Under the proposed section, a statistical showing of adverse impact on handicapped persons was required to trigger an employer's obligation to show that employment criteria and qualifications relating to handicap were necessary. This requirement was changed because the small number of handicapped persons taking tests would make statistical showings of "disproportionate, adverse effect" difficult and burdensome. Under the altered, more workable provision, once it is shown that an employment test substantially limits the opportunities of handicapped persons, the employer must show the test to be job-related. A recipient is no longer limited to using predictive validity studies as the method for demonstrating that a test or other selection criterion is in fact job-related. Nor, in all cases, are predictive validity studies sufficient to demonstrate that a test or criterion is job-related. In addition, §84.13(a) has been revised to place the burden on the Director, rather than the recipient, to identify alternate tests.

Section 84.13(b) requires that a recipient take into account that some tests and criteria depend upon sensory, manual, or speaking skills that may not themselves be necessary to the job in question but that may make the handicapped person unable to pass the test. The recipient must select and administer tests so as best to ensure that the test will measure the handicapped person's ability to perform on the job rather than the person's ability to see, hear, speak, or perform manual tasks, except, of course, where such skills are the factors that the test purports to measure. For example, a person with a speech impediment may be perfectly qualified for jobs that do not or need not, with reasonable accommodation, require ability to speak clearly. Yet, if given an oral test, the person will be unable to perform in a satisfactory manner. The test results will not, therefore, predict job performance but instead will reflect impaired speech.

18. *Preemployment inquiries.* Section 84.14, concerning preemployment inquiries, generated a large number of comments. Commenters representing handicapped persons strongly favored a ban on preemployment inquiries on the ground that such inquiries are often used to discriminate against handicapped persons and are not necessary to serve any legitimate interests of employers. Some recipients, on the other hand, argued that preemployment inquiries are necessary

to determine qualifications of the applicant, safety hazards caused by a particular handicapping condition, and accommodations that might be required.

The Secretary has concluded that a general prohibition of preemployment inquiries is appropriate. However, a sentence has been added to paragraph (a) to make clear that an employer may inquire into an applicant's ability to perform job-related tasks but may not ask if the person has a handicap. For example, an employer may not ask on an employment form if an applicant is visually impaired but may ask if the person has a current driver's license (if that is a necessary qualification for the position in question). Similarly, employers may make inquiries about an applicant's ability to perform a job safely. Thus, an employer may not ask if an applicant is an epileptic but may ask whether the person can perform a particular job without endangering other employees.

Section 84.14(B) allows preemployment inquiries only if they are made in conjunction with required remedial action to correct past discrimination, with voluntary action to overcome past conditions that have limited the participation of handicapped persons, or with obligations under section 503 of the Rehabilitation Act of 1973. In these instances, paragraph (b) specifies certain safeguards that must be followed by the employer.

Finally, the revised provision allows an employer to condition offers of employment to handicapped persons on the results of medical examinations, so long as the examinations are administered to all employees in a nondiscriminatory manner and the results are treated on a confidential basis.

19. *Specific acts of Discrimination.* Sections 84.15 (recruitment), 84.16 (compensation), 84.17 (job classification and structure) and 84.18 (fringe benefits) have been deleted from the regulation as unnecessarily duplicative of §84.11 (discrimination prohibited). The deletion of these sections in no way changes the substantive obligations of employers subject to this regulation from those set forth in the July 16 proposed regulation. These deletions bring the regulation closer in form to the Department of Labor's section 503 regulation.

Proposed §84.18, concerning fringe benefits, had allowed for differences in benefits or contributions between handicapped and non-handicapped persons in situations only where such differences could be justified on an actuarial basis. Section 84.11 simply bars discrimination in providing fringe benefits and does not address the issue of actuarial differences. The Department believes that currently available data and experience do not demonstrate a basis for promulgating a regulation specifically allowing for differences in benefits or contributions.

SUBPART C—PROGRAM ACCESSIBILITY

In general, subpart C prohibits the exclusion of qualified handicapped persons from federally assisted programs or activities because a recipient's facilities are inaccessible or unusable.

20. *Existing facilities.* Section 84.22 maintains the same standard for nondiscrimination in regard to existing facilities as was included in the proposed regulation. The section states that a recipient's program or activity, when viewed in its entirety, must be readily accessible to and usable by handicapped persons. Paragraphs (a) and (b) make clear that a recipient is not required to make each of its existing facilities accessible to handicapped persons if its program as a whole is accessible. Accessibility to the recipient's program or activity may be achieved by a number of means, including redesign of equipment, reassignment of classes or other services to accessible buildings, and making aides available to beneficiaries. In choosing among methods of compliance, recipients are required to give priority consideration to methods that will be consistent with provision of services in the most appropriate integrated setting. Structural changes in existing facilities are required only where there is no other feasible way to make the recipient's program accessible.

Under §84.22, a university does not have to make all of its existing classroom buildings accessible to handicapped students if some of its buildings are already accessible and if it is possible to reschedule or relocate enough classes so as to offer all required courses and a reasonable selection of elective courses in accessible facilities. If sufficient relocation of classes is not possible using existing facilities, enough alterations to ensure program accessibility are required. A university may not exclude a handicapped student from a specifically requested course offering because it is not offered in an accessible location, but it need not make every section of that course accessible.

Commenters representing several institutions of higher education have suggested that it would be appropriate for one postsecondary institution in a geographical area to be made accessible to handicapped persons and for other colleges and universities in that area to participate in that school's program, thereby developing an educational consortium for the postsecondary education of handicapped students. The Department believes that such a consortium, when developed and applied only to handicapped persons, would not constitute compliance with §84.22, but would discriminate against qualified handicapped persons by restricting their choice in selecting institutions of higher education and would, therefore, be inconsistent with the basic objectives of the statute.

Nothing in this regulation, however, should be read as prohibiting institutions from forming consortia for the benefit of all students. Thus, if three colleges decide that it would be cost-efficient for one college to offer biology, the second physics, and the third chemistry to all students at the three colleges, the arrangement would not violate section 504. On the other hand, it would violate the regulation if the same institutions set up a consortium under which one college undertook to make its biology lab accessible, another its physics lab, and a third its chemistry lab, and under which mobility-impaired handicapped students (but not other students) were required to attend the particular college that is accessible for the desired courses.

Similarly, while a public school district need not make each of its buildings completely accessible, it may not make only one facility or part of a facility accessible if the result is to segregate handicapped students in a single setting.

All recipients that provide health, welfare, or other social services may also comply with §84.22 by delivering services at alternate accessible sites or making home visits. Thus, for example, a pharmacist might arrange to make home deliveries of drugs. Under revised §84.22(c), small providers of health, welfare, and social services (those with fewer than fifteen employees) may refer a beneficiary to an accessible provider of the desired service, but only if no means of meeting the program accessibility requirement other than a significant alteration in existing facilities is available. The referring recipient has the responsibility of determining that the other provider is in fact accessible and willing to provide the service. The Secretary believes this “last resort” referral provision is appropriate to avoid imposition of additional costs in the health care area, to encourage providers to remain in the Medicaid program, and to avoid imposing significant costs on small, low-budget providers such as day-care centers or foster homes.

A recent change in the tax law may assist some recipients in meeting their obligations under this section. Under section 2122 of the Tax Reform Act of 1976, recipients that pay federal income tax are eligible to claim a tax deduction of up to \$25,000 for architectural and transportation modifications made to improve accessibility for handicapped persons. Many physicians and dentists, among others, may be eligible for this tax deduction. See 42 FR 17870 (April 4, 1977), adopting 26 CFR 7.190.

Several commenters expressed concern about the feasibility of compliance with the program accessibility standard. The Secretary believes that the standard is flexible enough to permit recipients to devise ways to make their programs accessible short of extremely expensive or impractical physical

changes in facilities. Accordingly, the section does not allow for waivers. The Department is ready at all times to provide technical assistance to recipients in meeting their program accessibility responsibilities. For this purpose, the Department is establishing a special technical assistance unit. Recipients are encouraged to call upon the unit staff for advice and guidance both on structural modifications and on other ways of meeting the program accessibility requirement.

Paragraph (d) has been amended to require recipients to make all nonstructural adjustments necessary for meeting the program accessibility standard within sixty days. Only where structural changes in facilities are necessary will a recipient be permitted up to three years to accomplish program accessibility. It should be emphasized that the three-year time period is not a waiting period and that all changes must be accomplished as expeditiously as possible. Further, it is the Department's belief, after consultation with experts in the field, that outside ramps to buildings can be constructed quickly and at relatively low cost. Therefore, it will be expected that such structural additions will be made promptly to comply with §84.22(d).

The regulation continues to provide, as did the proposed version, that a recipient planning to achieve program accessibility by making structural changes must develop a transition plan for such changes within six months of the effective date of the regulation. A number of commenters suggested extending that period to one year. The Secretary believes that such an extension is unnecessary and unwise. Planning for any necessary structural changes should be undertaken promptly to ensure that they can be completed within the three-year period. The elements of the transition plan as required by the regulation remain virtually unchanged from the proposal but §84.22(d) now includes a requirement that the recipient make the plan available for public inspection.

Several commenters expressed concern that the program accessibility standard would result in the segregation of handicapped persons in educational institutions. The regulation will not be applied to permit such a result. See §84.4(c)(2)(iv), prohibiting unnecessarily separate treatment; §84.35, requiring that students in elementary and secondary schools be educated in the most integrated setting appropriate to their needs; and new §84.43(d), applying the same standard to postsecondary education.

We have received some comments from organizations of handicapped persons on the subject of requiring, over an extended period of time, a barrier-free environment—that is, requiring the removal of all architectural

barriers in existing facilities. The Department has considered these comments but has decided to take no further action at this time concerning these suggestions, believing that such action should only be considered in light of experience in implementing the program accessibility standard.

21. *New construction.* Section 84.23 requires that all new facilities, as well as alterations that could affect access to and use of existing facilities, be designed and constructed in a manner so as to make the facility accessible to and usable by handicapped persons. Section 84.23(a) has been amended so that it applies to each newly constructed facility if the construction was commenced after the effective date of the regulation. The words "if construction has commenced" will be considered to mean "if groundbreaking has taken place." Thus, a recipient will not be required to alter the design of a facility that has progressed beyond groundbreaking prior to the effective date of the regulation.

Paragraph (b) requires certain alterations to conform to the requirement of physical accessibility in paragraph (a). If an alteration is undertaken to a portion of a building the accessibility of which could be improved by the manner in which the alteration is carried out, the alteration must be made in that manner. Thus, if a doorway or wall is being altered, the door or other wall opening must be made wide enough to accommodate wheelchairs. On the other hand, if the alteration consists of altering ceilings, the provisions of this section are not applicable because this alteration cannot be done in a way that affects the accessibility of that portion of the building. The phrase "to the maximum extent feasible" has been added to allow for the occasional case in which the nature of an existing facility is such as to make it impractical or prohibitively expensive to renovate the building in a manner that results in its being entirely barrier-free. In all such cases, however, the alteration should provide the maximum amount of physical accessibility feasible.

As proposed, §84.23(c) required compliance with the American National Standards Institute (ANSI) standard on building accessibility as the minimum necessary for compliance with the accessibility requirement of §84.23 (a) and (b). The reference to the ANSI standard created some ambiguity, since the standard itself provides for waivers where other methods are equally effective in providing accessibility to the facility. Moreover, the Secretary does not wish to discourage innovation in barrier-free construction by requiring absolute adherence to a rigid design standard. Accordingly, §84.23 (c) has been revised to permit departures from particular requirements of the ANSI standard where the recipient can demonstrate that equivalent access to the facility is provided.

Section 84.23(d) of the proposed regulation, providing for a limited deferral of action concerning facilities that are subject to section 502 as well as section 504 of the Act, has been deleted. The Secretary believes that the provision is unnecessary and inappropriate to this regulation. The Department will, however, seek to coordinate enforcement activities under this regulation with those of the Architectural and Transportation Barriers Compliance Board.

SUBPART D—PRESCHOOL, ELEMENTARY, AND SECONDARY EDUCATION

Subpart D sets forth requirements for non-discrimination in preschool, elementary, secondary, and adult education programs and activities, including secondary vocational education programs. In this context, the term "adult education" refers only to those educational programs and activities for adults that are operated by elementary and secondary schools.

The provisions of Subpart D apply to state and local educational agencies. Although the subpart applies, in general, to both public and private education programs and activities that are federally assisted, §§84.32 and 84.33 apply only to public programs and §84.39 applies only to private programs; §§84.35 and 84.36 apply both to public programs and to those private programs that include special services for handicapped students.

Subpart B generally conforms to the standards established for the education of handicapped persons in *Mills v. Board of Education* of the District of Columbia, 348 F. Supp. 866 (D.D.C. 1972), *Pennsylvania Association for Retarded Children v. Commonwealth of Pennsylvania*, 344 F. Supp. 1257 (E.D. 1971), 343 F. Supp. 279 (E.D. Pa. 1972), and *Lebanks v. Spears*, 60, F.R.D. 135 (E.D. La. 1973), as well as in the Education of the Handicapped Act, as amended by Pub. L. 94-142 (the EHA).

The basic requirements common to those cases, to the EHA, and to this regulation are (1) that handicapped persons, regardless of the nature or severity of their handicap, be provided a free appropriate public education, (2) that handicapped students be educated with nonhandicapped students to the maximum extent appropriate to their needs, (3) that educational agencies undertake to identify and locate all unserved handicapped children, (4) that evaluation procedures be improved in order to avoid the inappropriate education that results from the misclassification of students, and (5) that procedural safeguard be established to enable parents and guardians to influence decisions regarding the evaluation and placement of their children. These requirements are designed to ensure that no handicapped child is excluded from school on the basis of handicap and, if a recipient demonstrates

that placement in a regular educational setting cannot be achieved satisfactorily, that the student is provided with adequate alternative services suited to the student's needs without additional cost to the student's parents or guardian. Thus, a recipient that operates a public school system must either educate handicapped children in its regular program or provide such children with an appropriate alternative education at public expense.

It is not the intention of the Department, except in extraordinary circumstances, to review the result of individual placement and other educational decisions, so long as the school district complies with the "process" requirements of this subpart (concerning identification and location, evaluation, and due process procedures). However, the Department will place a high priority on investigating cases which may involve exclusion of a child from the education system or a pattern or practice of discriminatory placements or education.

22. *Location and notification.* Section 84.32 requires public schools to take steps annually to identify and locate handicapped children who are not receiving an education and to publicize to handicapped children and their parents the rights and duties established by section 504 and this regulation. This section has been shortened without substantive change.

23. *Free appropriate public education.* Former §§84.34 ("Free education") and 84.36(a) ("Suitable education") have been consolidated and revised in new §84.33. Under §84.34(a), a recipient is responsible for providing a free appropriate public education to each qualified handicapped person who is in the recipient's jurisdiction. The word "in" encompasses the concepts of both domicile and actual residence. If a recipient places a child in a program other than its own, it remains financially responsible for the child, whether or not the other program is operated by another recipient or educational agency. Moreover, a recipient may not place a child in a program that is inappropriate or that otherwise violates the requirements of Subpart D. And in no case may a recipient refuse to provide services to a handicapped child in its jurisdiction because of another person's or entity's failure to assume financial responsibility.

Section 84.33(b) concerns the provision of appropriate educational services to handicapped children. To be appropriate, such services must be designed to meet handicapped children's individual educational needs to the same extent that those of nonhandicapped children are met. An appropriate education could consist of education in regular classes, education in regular classes with the use of supplementary services, or special education and related services. Special education may include specially de-

signed instruction in classrooms, at home, or in private or public institutions and may be accompanied by such related services as developmental, corrective, and other supportive services (including psychological, counseling, and medical diagnostic services). The placement of the child must however, be consistent with the requirements of §84.34 and be suited to his or her educational needs.

The quality of the educational services provided to handicapped students must equal that of the services provided to nonhandicapped students; thus, handicapped student's teachers must be trained in the instruction of persons with the handicap in question and appropriate materials and equipment must be available. The Department is aware that the supply of adequately trained teachers may, at least at the outset of the imposition of this requirement, be insufficient to meet the demand of all recipients. This factor will be considered in determining the appropriateness of the remedy for noncompliance with this section. A new §84.33(b)(2) has been added, which allows this requirement to be met through the full implementation of an individualized education program developed in accordance with the standards of the EHA.

Paragraph (c) of §84.33 sets forth the specific financial obligations of a recipient. If a recipient does not itself provide handicapped persons with the requisite services, it must assume the cost of any alternate placement. If, however, a recipient offers adequate services and if alternate placement is chosen by a student's parent or guardian, the recipient need not assume the cost of the outside services. (If the parent or guardian believes that his or her child cannot be suitably educated in the recipient's program, he or she may make use of the procedures established in §84.36.) Under this paragraph, a recipient's obligation extends beyond the provision of tuition payments in the case of placement outside the regular program. Adequate transportation must also be provided. Recipients must also pay for psychological services and those medical services necessary for diagnostic and evaluative purposes.

If the recipient places a student, because of his or her handicap, in a program that necessitates his or her being away from home, the payments must also cover room and board and nonmedical care (including custodial and supervisory care). When residential care is necessitated not by the student's handicap but by factors such as the student's home conditions, the recipient is not required to pay the cost of room and board.

Two new sentences have been added to paragraph (c)(1) to make clear that a recipient's financial obligations need not be met solely through its own funds. Recipients may rely on funds from any public or private

source including insurers and similar third parties.

The EHA requires a free appropriate education to be provided to handicapped children "no later than September 1, 1978," but section 504 contains no authority for delaying enforcement. To resolve this problem, a new paragraph (d) has been added to §84.33. Section 84.33(d) requires recipients to achieve full compliance with the free appropriate public education requirements of §84.33 as expeditiously as possible, but in no event later than September 1, 1978. The provision also makes clear that, as of the effective date of this regulation, no recipient may exclude a qualified handicapped child from its educational program. This provision against exclusion is consistent with the order of providing services set forth in section 612(3) of the EHA, which places the highest priority on providing services to handicapped children who are not receiving an education.

24. *Educational setting.* Section 84.34 prescribes standards for educating handicapped persons with nonhandicapped persons to the maximum extent appropriate to the needs of the handicapped person in question. A handicapped student may be removed from the regular educational setting only where the recipient can show that the needs of the student would, on balance, be served by placement in another setting.

Although under §84.34, the needs of the handicapped person are determinative as to proper placement, it should be stressed that, where a handicapped student is so disruptive in a regular classroom that the education of other students is significantly impaired, the needs of the handicapped child cannot be met in that environment. Therefore, regular placement would not be appropriate to his or her needs and would not be required by §84.34.

Among the factors to be considered in placing a child is the need to place the child as close to home as possible. A new sentence has been added to paragraph (a) requiring recipients to take this factor into account. As pointed out in several comments, the parents' right under §84.36 to challenge the placement of their child extends not only to placement in special classes or separate schools but also to placement in a distant school and, in particular, to residential placement. An equally appropriate educational program may exist closer to home; this issue may be raised by the parent or guardian under §§84.34 and 84.36.

New paragraph (b) specified that handicapped children must also be provided non-academic services in as integrated a setting as possible. This requirement is especially important for children whose educational needs necessitate their being solely with other handicapped children during most of each day. To the maximum extent appro-

priate, children in residential settings are also to be provided opportunities for participation with other children.

Section 84.34(c) (formerly §84.38) requires that any facilities that are identifiable as being for handicapped students be comparable in quality to other facilities of the recipient. A number of comments objected to this section on the basis that it encourages the creation and maintenance of such facilities. This is not the intent of the provision. A separate facility violates section 504 unless it is indeed necessary to the provision of an appropriate education to certain handicapped students. In those instances in which such facilities are necessary (as might be the case, for example, for severely retarded persons), this provision requires that the educational services provided be comparable to those provided in the facilities of the recipient that are not identifiable as being for handicapped persons.

25. *Evaluation and placement.* Because the failure to provide handicapped persons with an appropriate education is so frequently the result of misclassification or misplacement, §84.33(b)(1) makes compliance with its provisions contingent upon adherence to certain procedures designed to ensure appropriate classification and placement. These procedures, delineated in §§84.35 and 84.36, are concerned with testing and other evaluation methods and with procedural due process rights.

Section 84.35(a) requires that an individual evaluation be conducted before any action is taken with respect either to the initial placement of a handicapped child in a regular or special education program or to any subsequent significant change in that placement. Thus, a full reevaluation is not required every time an adjustment in placement is made. "Any action" includes denials of placement.

Paragraphs (b) and (c) of §84.35 establishes procedures designed to ensure that children are not misclassified, unnecessarily labeled as being handicapped, or incorrectly placed because of inappropriate selection, administration, or interpretation of evaluation materials. This problem has been extensively documented in "Issues in the Classification of Children," a report by the Project on Classification of Exceptional Children, in which the HHS Interagency Task Force participated. The provisions of these paragraphs are aimed primarily at abuses in the placement process that result from misuse of, or undue or misplaced reliance on, standardized scholastic aptitude tests.

Paragraph (b) has been shortened but not substantively changed. The requirement in former subparagraph (1) that recipients provide and administer evaluation materials in the native language of the student has been deleted as unnecessary, since the same requirement already exists under title VI and

is more appropriately covered under that statute. Subparagraphs (1) and (2) are, in general, intended to prevent misinterpretation and similar misuse of test scores and, in particular, to avoid undue reliance on general intelligence tests. Subparagraph (3) requires a recipient to administer tests to a student with impaired sensory, manual, or speaking skills in whatever manner is necessary to avoid distortion of the test results by the impairment. Former subparagraph (4) has been deleted as unnecessarily repetitive of the other provisions of this paragraph.

Paragraph (c) requires a recipient to draw upon a variety of sources in the evaluation process so that the possibility of error in classification is minimized. In particular, it requires that all significant factors relating to the learning process, including adaptive behavior, be considered. (Adaptive behavior is the effectiveness with which the individual meets the standards of personal independence and social responsibility expected of his or her age and cultural group.) Information from all sources must be documented and considered by a group of persons, and the procedure must ensure that the child is placed in the most integrated setting appropriate.

The proposed regulation would have required a complete individual reevaluation of the student each year. The Department has concluded that it is inappropriate in the section 504 regulation to require full reevaluations on such a rigid schedule. Accordingly, §84.35(c) requires periodic reevaluations and specifies that reevaluations in accordance with the EHA will constitute compliance. The proposed regulation implementing the EHA allows reevaluation at three-year intervals except under certain specified circumstances.

Under §84.36, a recipient must establish a system of due process procedures to be afforded to parents or guardians before the recipient takes any action regarding the identification, evaluation, or educational placement of a person who, because of handicap, needs or is believed to need special education or related services. This section has been revised. Because the due process procedures of the EHA, incorporated by reference in the proposed section 504 regulation, are inappropriate for some recipients not subject to that Act, the section now specifies minimum necessary procedures: notice, a right to inspect records, an impartial hearing with a right to representation by counsel, and a review procedure. The EHA procedures remain one means of meeting the regulation's due process requirements, however, and are recommended to recipients as a model.

26. *Nonacademic services.* Section 84.37 requires a recipient to provide nonacademic and extracurricular services and activities in such manner as is necessary to afford handicapped students an equal opportunity for

participation. Because these services and activities are part of a recipient's education program, they must, in accordance with the provisions of §84.34, be provided in the most integrated setting appropriate.

Revised paragraph (c)(2) does permit separation or differentiation with respect to the provision of physical education and athletics activities, but only if qualified handicapped students are also allowed the opportunity to compete for regular teams or participate in regular activities. Most handicapped students are able to participate in one or more regular physical education and athletics activities. For example, a student in a wheelchair can participate in regular archery course, as can a deaf student in a wrestling course.

Finally, the one-year transition period provided in former §84.37(a)(3) was deleted in response to the almost unanimous objection of commenters to that provision.

27. *Preschool and adult education.* Section 84.38 prohibits discrimination on the basis of handicap in preschool and adult education programs. Former paragraph (b), which emphasized that compensatory programs for disadvantaged children are subject to section 504, has been deleted as unnecessary, since it is comprehended by paragraph (a).

28. *Private education.* Section 84.39 sets forth the requirements applicable to recipients that operate private education programs and activities. The obligations of these recipients have been changed in two significant respects: First, private schools are subject to the evaluation and due process provisions of the subpart only if they operate special education programs; second, under §84.39(b), they may charge more for providing services to handicapped students than to nonhandicapped students to the extent that additional charges can be justified by increased costs.

Paragraph (a) of §84.39 is intended to make clear that recipients that operate private education programs and activities are not required to provide an appropriate education to handicapped students with special educational needs if the recipient does not offer programs designed to meet those needs. Thus, a private school that has no program for mentally retarded persons is neither required to admit such a person into its program nor to arrange or pay for the provision of the person's education in another program. A private recipient without a special program for blind students, however, would not be permitted to exclude, on the basis of blindness, a blind applicant who is able to participate in the regular program with minor adjustments in the manner in which the program is normally offered.

SUBPART E—POSTSECONDARY EDUCATION

Subpart E prescribes requirements for nondiscrimination in recruitment, admission,

and treatment of students in postsecondary education programs and activities, including vocational education.

29. *Admission and recruitment.* In addition to a general prohibition of discrimination on the basis of handicap in §84.42(a), the regulation delineates, in §84.42(b), specific prohibitions concerning the establishment of limitations on admission of handicapped students, the use of tests or selection criteria, and preadmission inquiry. Several changes have been made in this provision.

Section 84.42(b) provides that postsecondary educational institutions may not use any test or criterion for admission that has a disproportionate, adverse effect on handicapped persons unless it has been validated as a predictor of academic success and alternate tests or criteria with a less disproportionate, adverse effect are shown by the Department to be available. There are two significant changes in this approach from the July 16 proposed regulation.

First, many commenters expressed concern that §84.42(b)(2)(ii) could be interpreted to require a “global search” for alternate tests that do not have a disproportionate, adverse impact on handicapped persons. This was not the intent of the provision and, therefore, it has been amended to place the burden on the Director of the Office for Civil Rights, rather than on the recipient, to identify alternate tests.

Second, a new paragraph (d), concerning validity studies, has been added. Under the proposed regulation, overall success in an education program, not just first-year grades, was the criterion against which admissions tests were to be validated. This approach has been changed to reflect the comment of professional testing services that use of first year grades would be less disruptive of present practice and that periodic validity studies against overall success in the education program would be sufficient check on the reliability of first-year grades.

Section 84.42(b)(3) also requires a recipient to assure itself that admissions tests are selected and administered to applicants with impaired sensory, manual, or speaking skills in such manner as is necessary to avoid unfair distortion of test results. Methods have been developed for testing the aptitude and achievement of persons who are not able to take written tests or even to make the marks required for mechanically scored objective tests; in addition, methods for testing persons with visual or hearing impairments are available. A recipient, under this paragraph, must assure itself that such methods are used with respect to the selection and administration of any admissions tests that it uses.

Section 84.42(b)(3)(iii) has been amended to require that admissions tests be administered in facilities that, on the whole, are accessible. In this context, *on the whole* means

that not all of the facilities need be accessible so long as a sufficient number of facilities are available to handicapped persons.

Revised §84.42(b)(4) generally prohibits preadmission inquiries as to whether an applicant has a handicap. The considerations that led to this revision are similar to those underlying the comparable revision of §84.14 on preemployment inquiries. The regulation does, however, allow inquiries to be made, after admission but before enrollment, as to handicaps that may require accommodation.

New paragraph (c) parallels the section on preemployment inquiries and allows postsecondary institutions to inquire about applicants' handicaps before admission, subject to certain safeguards, if the purpose of the inquiry is to take remedial action to correct past discrimination or to take voluntary action to overcome the limited participation of handicapped persons in postsecondary educational institutions.

Proposed §84.42(c), which would have allowed different admissions criteria in certain cases for handicapped persons, was widely misinterpreted in comments from both handicapped persons and recipients. We have concluded that the section is unnecessary, and it has been deleted.

30. *Treatment of students.* Section 84.43 contains general provisions prohibiting the discriminatory treatment of qualified handicapped applicants. Paragraph (b) requires recipients to ensure that equal opportunities are provided to its handicapped students in education programs and activities that are not operated by the recipient. The recipient must be satisfied that the outside education program or activity as a whole is non-discriminatory. For example, a college must ensure that discrimination on the basis of handicap does not occur in connection with teaching assignments of student teachers in elementary or secondary schools not operated by the college. Under the “as a whole” wording, the college could continue to use elementary or secondary school systems that discriminate if, and only if, the college's student teaching program, when viewed in its entirety, offered handicapped student teachers the same range and quality of choice in student teaching assignments afforded non-handicapped students.

Paragraph (c) of this section prohibits a recipient from excluding qualified handicapped students from any course, course of study, or other part of its education program or activity. This paragraph is designed to eliminate the practice of excluding handicapped persons from specific courses and from areas of concentration because of factors such as ambulatory difficulties of the student or assumptions by the recipient that no job would be available in the area in question for a person with that handicap.

New paragraph (d) requires postsecondary institutions to operate their programs and

activities so that handicapped students are provided services in the most integrated setting appropriate. Thus, if a college had several elementary physics classes and had moved one such class to the first floor of the science building to accommodate students in wheelchairs, it would be a violation of this paragraph for the college to concentrate handicapped students with no mobility impairments in the same class.

31. *Academic adjustments.* Paragraph (a) of §84.44 requires that a recipient make certain adjustments to academic requirements and practices that discriminate or have the effect of discriminating on the basis of handicap. This requirement, like its predecessor in the proposed regulation, does not obligate an institution to waive course or other academic requirements. But such institutions must accommodate those requirements to the needs of individual handicapped students. For example, an institution might permit an otherwise qualified handicapped student who is deaf to substitute an art appreciation or music history course for a required course in music appreciation or could modify the manner in which the music appreciation course is conducted for the deaf student. It should be stressed that academic requirements that can be demonstrated by the recipient to be essential to its program of instruction or to particular degrees need not be changed.

Paragraph (b) provides that postsecondary institutions may not impose rules that have the effect of limiting the participation of handicapped students in the education program. Such rules include prohibition of tape recorders or brailers in classrooms and dog guides in campus buildings. Several recipients expressed concern about allowing students to tape record lectures because the professor may later want to copyright the lectures. This problem may be solved by requiring students to sign agreements that they will not release the tape recording or transcription or otherwise hinder the professor's ability to obtain a copyright.

Paragraph (c) of this section, concerning the administration of course examinations to students with impaired sensory, manual, or speaking skills, parallels the regulation's provisions on admissions testing (§84.42(b)) and will be similarly interpreted.

Under §84.44(d), a recipient must ensure that no handicapped student is subject to discrimination in the recipient's program because of the absence of necessary auxiliary educational aids. Colleges and universities expressed concern about the costs of compliance with this provision.

The Department emphasizes that recipients can usually meet this obligation by assisting students in using existing resources for auxiliary aids such as state vocational rehabilitation agencies and private charitable organizations. Indeed, the Department

anticipates that the bulk of auxiliary aids will be paid for by state and private agencies, not by colleges or universities. In those circumstances where the recipient institution must provide the educational auxiliary aid, the institution has flexibility in choosing the methods by which the aids will be supplied. For example, some universities have used students to work with the institution's handicapped students. Other institutions have used existing private agencies that tape texts for handicapped students free of charge in order to reduce the number of readers needed for visually impaired students.

As long as no handicapped person is excluded from a program because of the lack of an appropriate aid, the recipient need not have all such aids on hand at all times. Thus, readers need not be available in the recipient's library at all times so long as the schedule of times when a reader is available is established, is adhered to, and is sufficient. Of course, recipients are not required to maintain a complete braille library.

32. *Housing.* Section 84.45(a) requires postsecondary institutions to provide housing to handicapped students at the same cost as they provide it to other students and in a convenient, accessible, and comparable manner. Commenters, particularly blind persons pointed out that some handicapped persons can live in any college housing and need not wait to the end of the transition period in Subpart C to be offered the same variety and scope of housing accommodations given to nonhandicapped persons. The Department concurs with this position and will interpret this section accordingly.

A number of colleges and universities reacted negatively to paragraph (b) of this section. It provides that, if a recipient assists in making off-campus housing available to its students, it should develop and implement procedures to assure itself that off-campus housing, as a whole, is available to handicapped students. Since postsecondary institutions are presently required to assure themselves that off-campus housing is provided in a manner that does not discriminate on the basis of sex (§86.32 of the title IX regulation), they may use the procedures developed under title IX in order to comply with §84.45(b). It should be emphasized that not every off-campus living accommodation need be made accessible to handicapped persons.

33. *Health and insurance.* Section 84.46 of the proposed regulation, providing that recipients may not discriminate on the basis of handicap in the provision of health related services, has been deleted as duplicative of the general provisions of §84.43. This deletion represents no change in the obligation of recipients to provide nondiscriminatory health and insurance plans. The Department will continue to require that nondiscriminatory health services be provided to handicapped

students. Recipients are not required, however, to provide specialized services and aids to handicapped persons in health programs. If, for example, a college infirmary treats only simple disorders such as cuts, bruises, and colds, its obligation to handicapped persons is to treat such disorders for them.

34. *Financial assistance.* Section 84.46(a) (formerly §84.47), prohibiting discrimination in providing financial assistance, remains substantively the same. It provides that recipients may not provide less assistance to or limit the eligibility of qualified handicapped persons for such assistance, whether the assistance is provided directly by the recipient or by another entity through the recipient's sponsorship. Awards that are made under wills, trusts, or similar legal instruments in a discriminatory manner are permissible, but only if the overall effect of the recipient's provision of financial assistance is not discriminatory on the basis of handicap.

It will not be considered discriminatory to deny, on the basis of handicap, an athletic scholarship to a handicapped person if the handicap renders the person unable to qualify for the award. For example, a student who has a neurological disorder might be denied a varsity football scholarship on the basis of his inability to play football, but a deaf person could not, on the basis of handicap, be denied a scholarship for the school's diving team. The deaf person could, however, be denied a scholarship on the basis of comparative diving ability.

Commenters on §84.46(b), which applies to assistance in obtaining outside employment for students, expressed similar concerns to those raised under §84.43(b), concerning cooperative programs. This paragraph has been changed in the same manner as §84.43(b) to include the "as a whole" concept and will be interpreted in the same manner as §84.43(b).

35. *Nonacademic services.* Section 84.47 (formerly §84.48) establishes nondiscrimination standards for physical education and athletics counseling and placement services, and social organizations. This section sets the same standards as does §84.38 of Subpart D, discussed above, and will be interpreted in a similar fashion.

SUBPART F—HEALTH, WELFARE, AND SOCIAL SERVICES

Subpart F applies to recipients that operate health, welfare, and social service programs. The Department received fewer comments on this subpart than on others.

Although many commented that Subpart F lacked specificity, these commenters provided neither concrete suggestions nor additions. Nevertheless, some changes have been made, pursuant to comment, to clarify the obligations of recipients in specific areas. In addition, in an effort to reduce duplication in the regulation, the section governing re-

cipients providing health services (proposed §84.52) has been consolidated with the section regulating providers of welfare and social services (proposed §84.53). Since the separate provisions that appeared in the proposed regulation were almost identical, no substantive change should be inferred from their consolidation.

Several commenters asked whether Subpart F applies to vocational rehabilitation agencies whose purpose is to assist in the rehabilitation of handicapped persons. To the extent that such agencies receive financial assistance from the Department, they are covered by Subpart F and all other relevant subparts of the regulation. Nothing in this regulation, however, precludes such agencies from servicing only handicapped persons. Indeed, §84.4(c) permits recipients to offer services or benefits that are limited by federal law to handicapped persons or classes of handicapped persons.

Many comments suggested requiring state health, welfare, and social service agencies to take an active role in the enforcement of section 504 with regard to local health and social service providers. The Department believes that the possibility for federal-state cooperation in the administration and enforcement of section 504 warrants further consideration. Moreover, the Department will rely largely on state Medicaid agencies, as it has under title VI, for monitoring compliance by individual Medicaid providers.

A number of comments also discussed whether section 504 should be read to require payment of compensation to institutionalized handicapped patients who perform services for the institution in which they reside. The Department of Labor has recently issued a proposed regulation under the Fair Labor Standards Act (FLSA) that covers the question of compensation for institutionalized persons, 42 FR 15224 (March 18, 1977). This Department will seek information and comment from the Department of Labor concerning that agency's experience administering the FLSA regulation.

36. *Health, welfare, and other social service providers.* As already noted, §84.53 has been combined with proposed §84.53 into a single section covering health, welfare, and other social services. Section 84.52(a) has been expanded in several respects. The addition of new paragraph (a)(2) is intended to make clear the basic requirement of equal opportunity to receive benefits or services in the health, welfare, and social service areas. The paragraph parallels §§84.4(b)(ii) and 84.43(b). New paragraph (a)(3) requires the provision of effective benefits or services, as defined in §84.4(b)(2) (i.e., benefits or services which "afford handicapped persons equal opportunity to obtain the same result (or) to gain the same benefit * * *").

Section 84.52(a) also includes provisions concerning the limitation of benefits or services to handicapped persons and the subjection of handicapped persons to different eligibility standards. (These provisions were previously included in the welfare recipient section (§84.53(a)).) One common misconception about the regulation is that it would require specialized hospitals and other health care providers to treat all handicapped persons. The regulation makes no such requirement. Thus, a burn treatment center need not provide other types of medical treatment to handicapped persons unless it provides such medical services to nonhandicapped persons. It could not, however, refuse to treat the burns of a deaf person because of his or her deafness.

Commenters had raised the question of whether the prohibition against different standards of eligibility might preclude recipients from providing special services to handicapped persons or classes of handicapped persons. The regulation will not be so interpreted, and the specific section in question has been eliminated. Section 84.4(c) makes clear that special programs for handicapped persons are permitted.

A new paragraph (a)(5) concerning the provision of different or separate services or benefits has been added. This provision prohibits such treatment unless necessary to provide qualified handicapped persons with benefits and services that are as effective as those provided to others.

Section 84.52(a)(2) of the proposed regulation has been omitted as duplicative of revised §84.22 (b) and (c) in Subpart C. As discussed above, these sections permit health care providers to arrange to meet patients in accessible facilities and to make referrals in carefully limited circumstances.

Section 84.52(a)(3) of the proposed regulation has been redesignated §84.52(b) and has been amended to cover written material concerning waivers of rights or consent to treatment as well as general notices concerning health benefits or services. The section requires the recipient to ensure that qualified handicapped persons are not denied effective notice because of their handicap. For example, recipients could use several different types of notice in order to reach persons with impaired vision or hearing, such as brailled messages, radio spots, and tactile devices on cards or envelopes to inform blind persons of the need to call the recipient for further information.

Sections 84.52(a)(4), 84.52(a)(5), and 84.52(b) have been omitted from the regulation as unnecessary. They are clearly comprehended by the more general sections banning discrimination.

Section 84.52(c) is a new section requiring recipient hospitals to establish a procedure for effective communication with persons with impaired hearing for the purpose of pro-

viding emergency health care. Although it would be appropriate for a hospital to fulfill its responsibilities under this section by having a full-time interpreter for the deaf on staff, there may be other means of accomplishing the desired result of assuring that some means of communication is immediately available for deaf persons needing emergency treatment.

Section 84.52(d), also a new provision, requires recipients with fifteen or more employees to provide appropriate auxiliary aids for persons with impaired sensory, manual, or speaking skills. Further, the Director may require a small provider to furnish auxiliary aids where the provision of aids would not adversely affect the ability of the recipient to provide its health benefits or service. Thus although a small nonprofit neighborhood clinic might not be obligated to have available an interpreter for deaf persons, the Director may require provision of such aids as may be reasonably available to ensure that qualified handicapped persons are not denied appropriate benefits or services because of their handicaps.

37. *Treatment of Drug Addicts and Alcoholics.* Section 84.53 is a new section that prohibits discrimination in the treatment and admission of drug and alcohol addicts to hospitals and outpatient facilities. This section is included pursuant to section 407, Pub. L. 92-255, the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1174), as amended, and section 321, Public Law 91-616, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4581), as amended, and section 321, Public Law 93-282. Section 504 itself also prohibits such discriminatory treatment and, in addition, prohibits similar discriminatory treatment by other types of health providers. Section 84.53 prohibits discrimination against drug abusers by operators of outpatient facilities, despite the fact that section 407 pertains only to hospitals, because of the broader application of section 504. This provision does not mean that all hospitals and outpatient facilities must treat drug addiction and alcoholism. It simply means, for example, that a cancer clinic may not refuse to treat cancer patients simply because they are also alcoholics.

38. *Education of institutionalized persons.* The regulation retains §84.54 of the proposed regulation that requires that an appropriate education be provided to qualified handicapped persons who are confined to residential institutions or day care centers.

SUBPART G—PROCEDURES

In §84.61, the Secretary has adopted the title VI complaint and enforcement procedures for use in implementing section 504 until such time as they are superseded by the issuance of a consolidated procedural regulation applicable to all of the civil

rights statutes and executive orders administered by the Department.

[42 FR 22677, May 4, 1977, as amended at 89 FR 37692, May 6, 2024]

APPENDIX B TO PART 84—GUIDELINES FOR ELIMINATING DISCRIMINATION AND DENIAL OF SERVICES ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AND HANDICAP IN VOCATIONAL EDUCATION PROGRAMS [NOTE]

NOTE: For the text of these guidelines, see 45 CFR part 80, appendix B.

[44 FR 17168, Mar. 21, 1979]

APPENDIX C TO PART 84—GUIDELINES RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

(a) *Interpretative guidelines relating to the applicability of this part to health care for handicapped infants.* The following are interpretative guidelines of the Department set forth here to assist recipients and the public in understanding the Department's interpretation of section 504 and the regulations contained in this part as applied to matters concerning health care for handicapped infants. These interpretative guidelines are illustrative; they do not independently establish rules of conduct.

(1) With respect to programs and activities receiving Federal financial assistance, health care providers may not, solely on the basis of present or anticipated physical or mental impairments of an infant, withhold treatment or nourishment from the infant who, in spite of such impairments, will medically benefit from the treatment or nourishment.

(2) Futile treatment or treatment that will do no more than temporarily prolong the act of dying of a terminally ill infant is not considered treatment that will medically benefit the infant.

(3) In determining whether certain possible treatments will be medically beneficial to an infant, reasonable medical judgments in selecting among alternative courses of treatment will be respected.

(4) Section 504 and the provisions of this part are not applicable to parents (who are not recipients of Federal financial assistance). However, each recipient health care provider must in all aspects of its health care programs receiving Federal financial assistance provide health care and related services in a manner consistent with the requirements of section 504 and this part. Such aspects includes decisions on whether to report, as required by State law or otherwise, to the appropriate child protective services agency a suspected instance of medical ne-

glect of a child, or to take other action to seek review or parental decisions to withhold consent for medically indicated treatment. Whenever parents make a decision to withhold consent for medically beneficial treatment or nourishment, such recipient providers may not, solely on the basis of the infant's present or anticipated future mental or physical impairments, fail to follow applicable procedures on reporting such incidents to the child protective services agency or to seek judicial review.

(5) The following are examples of applying these interpretative guidelines. These examples are stated in the context of decisions made by recipient health care providers. Were these decisions made by parents, the guideline stated in section (a)(4) would apply. These examples assume no facts or complications other than those stated. Because every case must be examined on its individual facts, these are merely illustrative examples to assist in understanding the framework for applying the nondiscrimination requirements of section 504 and this part.

(i) Withholding of medically beneficial surgery to correct an intestinal obstruction in an infant with Down's Syndrome when the withholding is based upon the anticipated future mental retardation of the infant and there are no medical contraindications to the surgery that would otherwise justify withholding the surgery would constitute a discriminatory act, violative of section 504.

(ii) Withholding of treatment for medically correctable physical anomalies in children born with spina bifida when such denial is based on anticipated mental impairment paralysis or incontinence of the infant, rather than on reasonable medical judgments that treatment would be futile, too unlikely of success given complications in the particular case, or otherwise not of medical benefit to the infant, would constitute a discriminatory act, violative of section 504.

(iii) Withholding of medical treatment for an infant born with anencephaly, who will inevitably die within a short period of time, would not constitute a discriminatory act because the treatment would be futile and do no more than temporarily prolong the act of dying.

(iv) Withholding of certain potential treatments from a severely premature and low birth weight infant on the grounds of reasonable medical judgments concerning the improbability of success or risks of potential harm to the infant would not violate section 504.

(b) *Guidelines for HHS investigations relating to health care for handicapped infants.* The following are guidelines of the Department in conducting investigations relating to health care for handicapped infants. They are set forth here to assist recipients and the public in understanding applicable investigative

procedures. These guidelines do not establish rules of conduct, create or affect legally enforceable rights of any person, or modify existing rights, authorities or responsibilities pursuant to this part. These guidelines reflect the Department's recognition of the special circumstances presented in connection with complaints of suspected life-threatening noncompliance with this part involving health care for handicapped infants. These guidelines do not apply to other investigations pursuant to this part, or other civil rights statutes and rules. Deviations from these guidelines may occur when, in the judgment of the responsible Department official, other action is necessary to protect the life or health of a handicapped infant.

(1) Unless impracticable, whenever the Department receives a complaint of suspected life-threatening noncompliance with this part in connection with health care for a handicapped infant in a program or activity receiving Federal financial assistance, HHS will immediately conduct a preliminary inquiry into the matter by initiating telephone contact with the recipient hospital to obtain information relating to the condition and treatment of the infant who is the subject of the complaint. The preliminary inquiry, which may include additional contact with the complainant and a requirement that pertinent records be provided to the Department, will generally be completed within 24 hours (or sooner if indicated) after receipt of the complaint.

(2) Unless impracticable, whenever a recipient hospital has an Infant Care Review Committee, established and operated substantially in accordance with the provisions of 45 CFR 84.55(f), the Department will, as part of its preliminary inquiry, solicit the information available to, and the analysis and recommendations of, the ICRC. Unless, in the judgment of the responsible Department official, other action is necessary to protect the life or health of a handicapped infant, prior to initiating an on-site investigation, the Department will await receipt of this information from the ICRC for 24 hours (or less if indicated) after receipt of the complaint. The Department may require a subsequent written report of the ICRC's findings, accompanied by pertinent records and documentation.

(3) On the basis of the information obtained during preliminary inquiry, including information provided by the hospital (including the hospital's ICRC, if any), information provided by the complainant, and all other information obtained, the Department will determine whether there is a need for an on-site investigation of the complaint. Whenever the Department determines that doubt remains that the recipient hospital or some other recipient is in compliance with this part or additional documentation is desired to substantiate a conclusion, the Department

will initiate an on-site investigation or take some other appropriate action. Unless impracticable, prior to initiating an on-site investigation, the Department's medical consultant (referred to in paragraph 6) will contact the hospital's ICRC or appropriate medical personnel of the recipient hospital.

(4) In conducting on-site investigations, when a recipient hospital has an ICRC established and operated substantially in accordance with the provisions of 45 CFR 84.55(f), the investigation will begin with, or include at the earliest practicable time, a meeting with the ICRC or its designees. In all on-site investigations, the Department will make every effort to minimize any potential inconvenience or disruption, accommodate the schedules of health care professionals and avoid making medical records unavailable. The Department will also seek to coordinate its investigation with any related investigations by the state child protective services agency so as to minimize potential disruption.

(5) It is the policy of the Department to make no comment to the public or media regarding the substance of a pending preliminary inquiry or investigation.

(6) The Department will obtain the assistance of a qualified medical consultant to evaluate the medical information (including medical records) obtained in the course of a preliminary inquiry or investigation. The name, title and telephone number of the Department's medical consultant will be made available to the recipient hospital. The Department's medical consultant will, if appropriate, contact medical personnel of the recipient hospital in connection with the preliminary inquiry, investigation or medical consultant's evaluation. To the extent practicable, the medical consultant will be a specialist with respect to the condition of the infant who is the subject of the preliminary inquiry or investigation. The medical consultant may be an employee of the Department or another person who has agreed to serve, with or without compensation, in that capacity.

(7) The Department will advise the recipient hospital of its conclusions as soon as possible following the completion of a preliminary inquiry or investigation. Whenever final administrative findings following an investigation of a complaint of suspected life-threatening noncompliance cannot be made promptly, the Department will seek to notify the recipient and the complainant of the Department's decision on whether the matter will be immediately referred to the Department of Justice pursuant to 45 CFR 80.8.

(8) Except as necessary to determine or effect compliance, the Department will (i) in conducting preliminary inquiries and investigations, permit information provided by the recipient hospital to the Department to

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be furnished without names or other identifying information relating to the infant and the infant's family; and (ii) to the extent permitted by law, safeguard the confidentiality of information obtained.

[49 FR 1653, Jan. 12, 1984]

PART 85—ENFORCEMENT OF NON-DISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES CONDUCTED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Sec.

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AUTHORITY: 29 U.S.C. 794.

SOURCE: 53 FR 25603, July 8, 1988, unless otherwise noted.

EDITORIAL NOTE: At the request of the Department of Health and Human Services, the "Section-by-Section Analysis" portion of the preamble of the document published at 53 FR 25595, July 8, 1988, as corrected at 53 FR 26559, July 13, 1988, appears at the end of part 85.

§ 85.1 Purpose.

The purpose of this part is to effectuate section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amended section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service.

§ 85.2 Application.

This part applies to all programs or activities conducted by the agency, except for programs or activities conducted outside the United States that do not involve individuals with handicaps in the United States.

§ 85.3 Definitions.

For purposes of this part, the term—
Agency means the Department of Health and Human Services or any component part of the Department of Health and Human Services that conducts a program or activity covered by this part. *Component agency* means such component part.

Assistant Attorney General means the Assistant Attorney General, Civil Rights Division, United States Department of Justice.

Auxiliary aids means services or devices that enable persons with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in, and enjoy the benefits of, programs or activities conducted by the agency. For example, auxiliary aids useful for persons with impaired vision include readers, Brailled materials, audio recordings, and other similar services and devices. Auxiliary aids useful for persons with impaired hearing include telephone handset amplifiers, telephones compatible with hearing aids, telecommunication devices for deaf persons (TDD's) interpreters, notetakers, written materials, and other similar services and devices.

Complete complaint means a written statement that contains the complainant's name and address and describes the agency's alleged discriminatory action in sufficient detail to inform the agency of the nature and date of the alleged violation of section 504. It shall be signed by the complainant or by someone authorized to do so on his or her behalf. Complaints filed on behalf of classes or third parties shall describe or identify (by name, if possible) the alleged victims of discrimination.

Facility means all or any portion of buildings, structures, equipment, roads, walks, parking lots, rolling stock or other conveyances, or other real or personal property.

Individual with Handicaps means any person who has a physical or mental

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impairment that substantially limits one or more major life activities, has a record of such an impairment, or is regarded as having such an impairment. As used in this definition, the phrase:

(1) *Physical or mental impairment* includes:

(i) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: neurological; musculoskeletal; special sense organs; respiratory, including speech organs; cardiovascular; reproductive; digestive; genito-urinary; hemic and lymphatic; skin; and endocrine; or

(ii) Any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities. The term *physical or mental impairment* includes, but is not limited to, such diseases and conditions as orthopedic, visual, speech and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, and drug addiction and alcoholism.

(2) *Major life activities* includes functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning and working.

(3) *Has a record of such impairment* means has a history of, or is misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(4) *Is regarded as having an impairment* means:

(i) Has a physical or mental impairment that does not substantially limit major life activities but is treated by the agency as constituting such a limitation.

(ii) Has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or

(iii) Has none of the impairments defined in paragraph (1) of this definition but is treated by the agency as having such an impairment.

OCR means the Office for Civil Rights of the Department of Health and Human Services.

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OCR Director/Special Assistant means the Director of the Office for Civil Rights, who serves concurrently as the Special Assistant to the Secretary for Civil Rights, or a designee of the Director/Special Assistant.

Qualified individual with handicaps means:

(1) With respect to preschool, elementary, or secondary education services provided by the agency, an individual with handicaps who is a member of a class of persons otherwise entitled by statute, regulation, or agency policy to receive educational services from the agency;

(2) With respect to any other agency program or activity under which a person is required to perform services or to achieve a particular level of accomplishment, an individual with handicaps who meets the essential eligibility requirements and who can achieve the purpose of the program or activity without modifications in the program or activity that the agency can demonstrate would result in a fundamental alteration in its nature; and

(3) With respect to any other program or activity, an individual with handicaps who meets the essential eligibility requirements for participation in, or receipt of benefits from, that program or activity; and

(4) *Qualified handicapped person* as that term is defined for purposes of employment in 29 CFR 1613.702(f), which is made applicable to this part by § 85.31.

Secretary means the Secretary of the Department of Health and Human Services or his/her designee.

Section 504 means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, 87 Stat. 394 (29 U.S.C. 794)), as amended by the Rehabilitation Act Amendments of 1974 (Pub. L. 93–516, 88 Stat. 1617); the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978 (Pub. L. 95–602, 92 Stat. 2955); the Rehabilitation Act Amendments of 1986 (Pub. L. 99–566, 100 Stat. 1810); and the Civil Rights Restoration Act of 1987 (Pub. L. 100–259, 102 Stat. 28). As used in this part, section 504 applies only to programs or activities conducted by the agency and not to federally assisted programs.

§§ 85.4–85.10 [Reserved]

§ 85.11 Self-evaluation.

(a) The agency shall, within one year of the effective date of this part, evaluate its current policies and practices, and the effects thereof, that do not or may not meet the requirements of this part, and, to the extent modification of any such policies and practices is required, the agency shall proceed to make the necessary modifications. Any new operating or staff divisions established within the agency shall have one year from the date of their establishment to carry out this evaluation.

(b) The agency shall provide an opportunity to interested persons, including individuals with handicaps or organizations representing individuals with handicaps, to participate in the self-evaluation by submitting comments (both oral and written).

(c) The agency shall, for at least three years following completion of the self-evaluation, maintain on file and make available for public inspection and copying—

(1) A description of areas examined and any problems identified; and

(2) A description of any modifications made.

§ 85.12 Notice.

The agency shall make available to employees, applicants, participants, beneficiaries, and other interested persons such information regarding the provisions of this part and its applicability to the programs or activities conducted by the agency, and make such information available to them in such a manner as the agency head finds necessary to apprise such persons of the protections against discrimination assured them by section 504 and this part.

§§ 85.13–85.20 [Reserved]

§ 85.21 General prohibitions against discrimination.

(a) No qualified individual with handicaps shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any program or activity conducted by the agency.

(b) (1) The agency, in providing any aid, benefit, or service, may not, directly or through contractual, licensing, or other arrangements, on the basis of handicap—

(i) Deny a qualified individual with handicaps the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified individual with handicaps an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

(iii) Provide a qualified individual with handicaps with an aid, benefit, or service that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others;

(iv) Provide different or separate aids, benefits, or services to individuals with handicaps or to any class or individuals with handicaps than is provided to others unless such action is necessary to provide qualified individuals with handicaps with aids, benefits or services that are as effective as those provided to others;

(v) Deny a qualified individual with handicaps the opportunity to participate as a member of a planning or advisory board; or

(vi) Otherwise limit a qualified individual with handicaps in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving the aid, benefit, or service.

(2) The agency may not deny a qualified individual with handicaps the opportunity to participate in programs or activities that are not separate or different, despite the existence of permissibly separate or different programs or activities.

(3) The agency may not, directly or through contractual or other arrangements, utilize criteria or methods of administration the purpose or effect of which would—

(i) Subject qualified individuals with handicaps to discrimination on the basis of handicap; or

(ii) Defeat or substantially impair accomplishment of the objectives of a program or activity with respect to individuals with handicaps.

§§ 85.22–85.30

(4) The agency may not, in determining the site or location of a facility, make selections the purpose or effect of which would—

(i) Exclude individuals with handicaps from, deny them the benefits of, or otherwise subject them to discrimination under any program or activity conducted by the agency; or

(ii) Defeat or substantially impair the accomplishment of the objectives of a program or activity with respect to individuals with handicaps.

(5) The agency, in the selection of procurement contractors, may not use criteria that subject qualified individuals with handicaps to discrimination on the basis of handicap.

(6) The agency may not administer a licensing or certification program in a manner that subjects qualified individuals with handicaps to discrimination on the basis of handicap, nor may the agency establish requirements for the programs or activities of licensees or certified entities that subject qualified individuals with handicaps to discrimination on the basis of handicap. However, the programs or activities of entities that are licensed or certified by the agency are not, themselves, covered by this part.

(c) The exclusion of individuals without handicaps from the benefits of a program limited by Federal statute or Executive order to individuals with handicaps or the exclusion of a specific class of individuals with handicaps from a program limited by Federal statute or Executive order to a different class of individuals with handicaps is not prohibited by this part.

(d) The agency shall administer programs and activities in the most integrated setting appropriate to the needs of qualified individuals with handicaps.

§§ 85.22–85.30 [Reserved]

§ 85.31 Employment.

No qualified individuals with handicaps shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity conducted by the agency. The definitions, requirements, and procedures of section 501 of the Rehabilitation Act of 1973 (9 U.S.C. 791), as established by the Equal Employment Opportunity Com-

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mission in 9 CFR part 1613, shall apply to employment in federally conducted programs and activities.

§§ 85.32–85.40 [Reserved]

§ 85.41 Program accessibility: Discrimination prohibited.

Except as otherwise provided in § 85.42, no qualified individual with handicaps shall, because the agency's facilities are inaccessible to or unusable by such persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity conducted by the agency.

§ 85.42 Program accessibility: Existing facilities.

(a) *General.* The agency shall operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by individuals with handicaps. This paragraph does not—

(1) Necessarily require the agency to make each of its existing facilities accessible to and usable by individuals with handicaps; or

(2) Require the agency to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where agency personnel believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the agency has the burden of proving that compliance with § 85.42(a) would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the agency head or his or her designee after considering all agency resources available for use in the funding and operation of the conducted program or activity in question, and must be accompanied by a written statement of reasons for reaching that conclusion. If an action would result in such an alteration or such burdens, the agency shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that individuals with handicaps receive

the benefits and services of the program or activity.

(b) *Methods.* (1) The agency may comply with the requirements of this section through such means as redesign of equipment, reassignment of services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of services at alternate accessible sites, alteration of existing facilities and construction of new facilities, use of accessible rolling stock, or any other methods that result in making its programs or activities readily accessible to and usable by individuals with handicaps. The agency is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with this section. The agency, in making alterations to existing buildings, shall meet accessibility requirements to the extent compelled by the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157), and any regulations implementing it.

(2) In choosing among available methods for meeting the requirements of this section, the agency shall give priority to those methods that offer programs and activities to qualified individuals with handicaps in the most integrated setting appropriate.

(c) *Time period for compliance.* The agency shall comply with the obligations established under this section within 60 days of the effective date of this part except where structural changes in facilities are undertaken; such changes shall be made within three years of the effective date of this part, but, in any event, as expeditiously as possible.

(d) *Transition plan.* In the event that structural changes to facilities must be undertaken to achieve program accessibility, and it is not expected that such changes can be completed within six months, the agency shall develop, within six months of the effective date of this part, a transition plan setting forth the steps necessary to complete such changes. The agency shall provide an opportunity to interested persons, including individuals with handicaps or organizations representing individuals with handicaps, to participate in the development of the transition plan by submitting comments (both oral and

written). A copy of the transition plan shall be made available for public inspection. The plan shall, at a minimum—

(1) Identify physical obstacles in the agency's facilities that limit the accessibility of its programs or activities to individuals with handicaps;

(2) Describe in detail the methods that will be used to make the facilities accessible;

(3) Specify the schedule for taking the steps necessary to achieve compliance with this section and, if the time period of the transition plan is longer than one year, identify steps that will be taken during each year of the transition period; and

(4) Indicate the official responsible for the implementation of the plan.

§ 85.43 Program accessibility: New construction and alterations.

Each building or part of a building that is constructed or altered by, or on behalf of, or for the use of the agency shall be designed, constructed, or altered so as to be readily accessible to and usable by individuals with handicaps. The definitions, requirements, and standards of the Architectural Barriers Act (42 U.S.C. 4151-4157) as established in 41 CFR 101-19.600 to 101-19.607 apply to buildings covered by this section.

§§ 85.44-85.50 [Reserved]

§ 85.51 Communications.

(a) The agency shall take appropriate steps to ensure effective communication with applicants, participants, personnel of other Federal entities, and members of the public.

(1) The agency shall furnish appropriate auxiliary aids where necessary to afford an individual with handicaps an equal opportunity to participate in, and enjoy the benefits of, program or activity conducted by the agency.

(i) In determining what type of auxiliary aid is necessary, the agency shall give primary consideration to the requests of the individual with handicaps.

(ii) The agency need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature.

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(2) Where the agency communicates with applicants and beneficiaries by telephone, telecommunications devices for deaf persons (TDD's) or equally effective telecommunication systems shall be used to communicate with persons with impaired hearing.

(b) The agency shall ensure that interested persons, including persons with impaired vision or hearing, can obtain information as to the existence and location of accessible services, activities, and facilities.

(c) The agency shall provide signage at a primary entrance to each of its inaccessible facilities, directing users to a location at which they can obtain information about accessible facilities. The international symbol for accessibility shall be used at each primary entrance of an accessible facility.

(d) This section does not require the agency to take any action that it can demonstrate would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens. In those circumstances where agency personnel believe that the proposed action would fundamentally alter the program or activity or would result in undue financial and administrative burdens, the agency has the burden of proving that compliance with §85.51 would result in such alteration or burdens. The decision that compliance would result in such alteration or burdens must be made by the agency head or his or her designee after considering all agency resources available for use in the funding and operation of the conducted program or activity in question and must be accompanied by a written statement of the reasons for reaching that conclusion. If an action required to comply with this section would result in such an alteration or such burdens, the agency shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with handicaps receive the benefits and services of the program or activity.

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§§ 85.52–85.60 [Reserved]

§ 85.61 Compliance procedures.

(a) Except as provided in paragraph (c) of this section, this section applies to all allegations of discrimination on the basis of handicap in programs or activities conducted by the agency.

(b) Responsibility for the implementation and operation of this section shall be vested in the CCR Director/Special Assistant.

(c) The agency shall process complaints alleging violations of section 504 with respect to employment according to the procedures established by the Equal Employment Opportunity Commission in 29 CFR part 1613 pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791) and HHS Instruction 1613–3. Part 1613 requires complainants to obtain pre-complaint counseling within 30 days of the alleged discriminatory act, and to file complaints within 15 days of the close of counseling. Responsibility for the acceptance, investigation, and the rendering of decisions with respect to employment complaints is vested in the Assistant Secretary for Personnel Administration.

(d) OCR shall accept and investigate all complete complaints for which it has jurisdiction. All complete complaints must be filed within 180 days of the alleged act of discrimination. OCR may extend this time for good cause.

(e) If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal government entity.

(f) OCR shall notify the Architectural and Transportation Barriers Compliance Board upon receipt of any complaint alleging that a building or facility that is subject to the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151–4157), is not readily accessible to and usable by individuals with handicaps.

(g) Within 180 days of the receipt of a complete complaint for which it has jurisdiction, OCR shall notify the complainant of the results of the investigations in a letter containing—

(1) Findings of fact and conclusions of law;

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(2) A description of a remedy for each violation found; and

(3) A notice of the right to appeal.

(h) Appeals of the findings of fact and conclusions of law or remedies must be filed by the complainant within 60 days of receipt from the agency of the letter required by §85.61(g). OCR may extend this time for good cause.

(i) Timely appeals shall be accepted and processed by the OCR Director/Special Assistant. Decisions on such appeals shall not be heard by the person who made the initial decision.

(j) OCR shall notify the complainant of the results of the appeal within 60 days of the receipt of the request. If OCR determines that it needs additional information from the complainant, it shall have 60 days from the date it receives the additional information to make its determination on the appeal.

(k) The time limits cited in (g) and (j) above may be extended with the permission of the Assistant Attorney General.

(l) The agency may delegate its authority for conducting complaint investigations to a component agency or other Federal agencies, except that the authority for making the final determination may not be delegated.

[53 FR 25603, July 8, 1988; 53 FR 26559, July 13, 1988]

§ 85.62 Coordination and compliance responsibilities.

(a) Each component agency shall be primarily responsible for compliance with this part in connection with the programs and activities it conducts.

(b) The OCR Director/Special Assistant shall have the overall responsibility to coordinate implementation of this part. The OCR Director/Special Assistant shall have authority to conduct investigations, to conduct compliance reviews, and to initiate such other actions as may be necessary to facilitate and ensure effective implementation of and compliance with, this part.

(c) If as a result of an investigation or in connection with any other compliance or implementation activity, the OCR Director/Special Assistant determines that a component agency appears to be in noncompliance with its responsibilities under this part, OCR

will undertake appropriate action with the component agency to assure compliance. In the event that OCR and the component agency are unable to agree on a resolution of any particular matter, the matter shall be submitted to the Secretary for resolution.

EDITORIAL NOTE: At the request of the Department of Health and Human Services, the "Section-by-Section Analysis" portion of the preamble of the document published at 53 FR 25595, July 8, 1988, as corrected at 53 FR 26559, July 13, 1988, follows:

SECTION-BY-SECTION ANALYSIS OF REGULATION AND RESPONSE TO COMMENTS

Where no discussion of comments follows the analysis of a section, no comments have been received thereon.

Section 85.1 Purpose.

Section 85.1 states the purpose of the rule, which is to effectuate section 119 of the Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, which amended section 504 of the Rehabilitation Act of 1973 to prohibit discrimination on the basis of handicap in programs or activities conducted by Executive agencies or the United States Postal Service.

Section 85.2 Application.

The proposed regulation covers all programs and activities conducted by the Department of Health and Human Services ("HHS" or the "agency").

This includes the following components:

The Office of the Secretary
Office of the Under Secretary
Office of the Deputy Under Secretary
Office of the Assistant Secretary for Public Affairs
Office of the Assistant Secretary for Legislation
Office of the Assistant Secretary for Planning and Evaluation
Office of the Assistant Secretary for Management and Budget
Office of the Assistant Secretary for Personnel Administration
Office of the General Counsel
Office of Inspector General
Office for Civil Rights
Office of Consumer Affairs
Office of Human Development Services
Office of the Assistant Secretary for Human Development Services
Administration on Aging
Administration for Children, Youth and Families
Administration for Native Americans
Administration on Developmental Disabilities
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Office of the Assistant Secretary for Health
Agency for Toxic Substances and Disease Registry
Alcohol, Drug Abuse and Mental Health Administration
Centers for Disease Control
Food and Drug Administration
Health Resources and Services Administration
Indian Health Service
National Institutes of Health
Health Care Financing Administration
Social Security Administration
Family Support Administration.

Under this section, a federally conducted program or activity is, in simple terms, anything a Federal agency does. Aside from employment, there are two major categories of federally conducted programs or activities covered by this regulation: those involving general public contact as part of ongoing agency operations, and those directly administered by the agency for program beneficiaries and participants. Activities in the first category include communication with the public (telephone contacts, office walk-ins, or interviews) and the public's use of the agency's facilities. Activities in the second category include programs that provide Federal services or benefits. This regulation does not, however, apply to programs or activities conducted outside the United States that do not involve individuals with handicaps in the United States.

The *major* programs subject to this regulation are listed below. Each of the components listed above occupies facilities which the public may have occasion to visit, engages in written and oral communication with the public, and hires Federal employees. In addition, some components operate programs which involve extensive public use, as summarized below:

Office of the Secretary—No major operating programs or activities conducted directly by the Federal government.
Office of Human Development Services—No major operating programs or activities conducted directly by the Federal government.¹
Public Health Service—Directly operated programs include the Indian Health Service, and intramural research conducted by the National Institutes of Health.¹
Health Care Financing Administration—Directly operates the Medicare program.¹
Social Security Administration—Directly operates the Old Age, Survivors, and Dis-

¹Financial assistance programs conducted through grants to States and other recipients are covered by the section 504 rule for federally assisted programs at 45 CFR part 84.

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ability Insurance, and Supplemental Security Income for the Aged, Blind, and Disabled programs.

Family Support Administration—No major operating programs or activities conducted directly by the Federal government.¹

One commenter urged the inclusion of a program operated by one component of the Office of the Secretary, and for a list of all programs and activities to be appended to the regulation. In light of the fact that all programs and activities are covered, that a comprehensive list of all programs would be very lengthy, and that such a list would have to be amended frequently as new programs are enacted and existing programs expire, the above list appears to be sufficient.

Section 85.3 Definitions.

Agency. For purposes of this part *agency* means the Department of Health and Human Services or any component part of the Department of Health and Human Services that conducts a program or activity covered by this part. *Component agency* means any such component part.

Assistant Attorney General. *Assistant Attorney General* refers to the Assistant Attorney General, Civil Rights Division, United States Department of Justice.

Auxiliary aids. *Auxiliary aids* means services or devices that enable persons with impaired sensory, manual, or speaking skills to have an equal opportunity to participate in, and enjoy the benefits of, the agency's programs or activities. The definition provides examples of commonly used auxiliary aids. Although auxiliary aids are required explicitly only by §85.51(a)(1), they may also be necessary to meet other requirements of this regulation.

Two commenters suggested expanding the definition of *auxiliary aids* and one of them further suggested re-naming *auxiliary aids* to read *aids for reasonable accommodation* and specifically include the services of attendants.

The items set out in §85.3 are clearly described as examples, and are not intended to constitute an exhaustive list. By giving examples rather than by including a list, other aids can be used, and, in appropriate cases, required, without amending the regulation. In certain instances, the services of attendants may indeed be appropriate; in those instances, they will fall under the definition in §85.3. Therefore, there is no need to change the text of the regulations.

Complete complaint. *Complete complaint* is defined to include all of the information necessary to enable the agency to investigate the complaint. The definition is necessary, because the 180 day period for the agency's investigation (*see* §85.61(g)) begins when the agency receives a complete complaint.

Two commenters stated their belief that the definition of *complete complaint* is too restrictive, and urged language which would give the complainant specific information as to what additional information is needed, and a further 30 days to submit such information, failing which the complaint would be dismissed without prejudice, and the complainant would be so informed.

Procedures similar to this suggestion are currently in place, and complainants will be given reasonable opportunities to complete the information submitted. There appears to be no need to spell these procedures out in the regulation.

Facility. The definition of *facility* is similar to that in the section 504 coordination regulation for federally assisted programs (28 CFR 41.3(f)), except that the term *rolling stock or other conveyances* has been added and the phrase *or interest in such property* has been deleted because the term *facility*, as used in this part, refers to structures and not to intangible property rights. It should, however, be noted that this part applies to all programs and activities conducted by the agency regardless of whether the facility in which they are conducted is owned, leased, or used on some other basis by the agency. The term *facility* is used in §§85.41, 85.42, and 85.61(f).

One commenter proposed not to delete the phrase *or interest in such property*. As previously stated, the phrase *or interest in such property* has been deleted because the term *facility*, as used in this part, refers to structures and not to intangible property rights.

Individual with Handicaps. The definition of *individual with handicaps* is identical to the definition of *handicapped person* appearing in the section 504 coordination regulation for federally assisted programs (28 CFR 41.31), and the HHS regulation for federally assisted programs (45 CFR 84.3(j)). Although section 103(d) of the Rehabilitation Act Amendments of 1986 changed the statutory term *handicapped individual* to *individual with handicaps*, the legislative history of the amendment indicates that no substantive change was intended. Thus, although the term has been changed in this regulation to be consistent with the statute as amended, the definition is unchanged. In particular, although the term as revised refers to *handicaps* in the plural, it does not exclude persons who have only one handicap.

One commenter suggested that we add *sensory* to the phrase *physical or mental impairment*. Since the definition set out in §85.3 specifically includes the sense organs among the body systems whose impairment constitutes a handicap, we have not found it necessary to amend the regulation.

OCR. *OCR* means the Office for Civil Rights of the Department of Health and Human Services.

OCR Director/Special Assistant means the Director of the Office for Civil Rights, who serves concurrently as the Special Assistant to the Secretary for Civil Rights, or a designee of the OCR Director/Special Assistant.

Qualified individual with handicaps. The definition of *qualified individual with handicaps* is a revised version of the definition of *qualified handicapped person* appearing in the section 504 coordination regulation for federally assisted programs (28 CFR 41.32) and the HHS section 504 regulation for federally assisted programs (45 CFR 84.3(k)).

Paragraph (1) is an adaptation of existing definitions of *qualified handicapped person* for purposes of federally assisted preschool, elementary, and secondary education programs (see, e.g., 45 CFR 84.3(k)(2)). It provides that an individual with handicaps is qualified for preschool, elementary, or secondary education programs conducted by the agency, if he or she is a member of a class of persons otherwise entitled by statute, regulation, or agency policy to receive these services from the agency. In other words, an individual with handicaps is qualified if, considering all factors other than the handicapping condition, he or she is entitled to receive educational services from the agency.

Paragraph (2) deviates from existing regulations for federally assisted programs because of intervening court decisions. It defines *qualified individual with handicaps* with regard to any program other than those covered by paragraph (1) under which a person is required to perform services or to achieve a level of accomplishment. In such programs, a qualified individual with handicaps is one who can achieve the purpose of the program without modifications in the program that the agency can demonstrate would result in a fundamental alteration in its nature. This definition reflects the decision of the Supreme Court in *Davis*.

In that case, the Court ruled that a hearing-impaired applicant to a nursing school was not a *qualified handicapped person* because her hearing impairment would prevent her from participating in the clinical training portion of the program. The Court found that, if the program were modified so as to enable the respondent to participate (by exempting her from the clinical training requirements), *she would not receive even a rough equivalent of the training a nursing program normally gives*. *Id.* at 410. It also found that *the purpose of [the] program was to train persons who could serve the nursing profession in all customary ways*. *Id.* at 413, and that the respondent would be unable, because of her hearing impairment, to perform some functions expected of a registered nurse. It, therefore, concluded that the school was not required by section 504 to make such modifications that would result in a *fundamental alteration in the nature of the program*. *Id.* at 410.

We have incorporated the Court's language in the definition of *qualified individual with handicaps* in order to make clear that such a person must be able to participate in the program offered by the agency. The agency is required to make modifications in order to enable an applicant with handicaps to participate, but is not required to offer a program of a fundamentally different nature. The test is whether, with appropriate modifications, the applicant can achieve the purpose of the program offered, not whether the applicant could benefit or obtain results from some other program that the agency does not offer. Although the revised definition allows exclusion of some individuals with handicaps from some programs, it requires that an individual with handicaps who is capable of achieving the purpose of the program must be accommodated, provided that the modifications do not fundamentally alter the purpose of the program.

One commenter proposed inserting the second sentence from the above paragraph into the regulatory text. We believe that the use of this language in the preamble is sufficient.

Another commenter commended HHS for the discussion of *Davis*, and the cases interpreting the *Davis* decision, in order to explain why the language of this part does not precisely track that of the regulations concerning federally assisted recipients (45 CFR part 84). Two other commenters stated their view that incorporating *Davis* and *Alexander* into the regulation was unduly restrictive, and that the differences between this part and part 84 would result in holding HHS to a lesser standard than HHS holds recipients of Federal financial assistance.

We believe that the Supreme Court's decision in *Davis* as well as the subsequent lower court decisions following *Davis* interpret section 504 and that it is necessary to reflect those decisions in the Department's regulation. The suggested changes are therefore not being adopted.

The agency has the burden of demonstrating that a proposed modification would constitute a fundamental alteration in the nature of its program or activity. Furthermore, in demonstrating that a modification would result in such an alteration, the agency must follow the procedures established in §§ 85.42(a) and 85.51(d), which are discussed below, for demonstrating that an action would result in undue financial and administrative burdens to the agency. That is, the decision must be made by the agency head or his or her designee in writing after consideration of all resources which are legally available to the agency for the purpose, and must be accompanied by an explanation of the reasons for the decision. If the agency head determines that an action would result in a fundamental alteration, the agency must consider options that would enable the

individual with handicaps to achieve the purpose of the program but would not result in such an alteration.

Two commenters suggested that the total resources of the agency be considered in determining *undue burden*. Because many Department funds are earmarked for specific purposes and are therefore unavailable for use elsewhere, the entire agency budget is not an appropriate consideration.

For programs or activities which do not fall under either of the first two paragraphs, paragraph (3) adopts the existing definition of *qualified handicapped person* with respect to services (28 CFR 41.32(b)) in the coordination regulation for programs receiving Federal financial assistance. Under this definition, a qualified individual with handicaps is an individual with handicaps who meets the essential eligibility requirements for participation in the program or activity.

Paragraph (4) explains that *qualified individual with handicaps* means *qualified handicapped person* as that term is defined for purposes of employment in the EEOC regulation at 29 CFR 1613.702(f), which is made applicable to this part by § 85.31. Nothing in this part changes existing regulations pertaining to employment.

One commenter proposed using the general section 504 definition of *qualified handicapped person* in employment cases rather than the definition of the EEOC regulation. The definition has been supplied by the Equal Employment Opportunity Commission which coordinates all employment discrimination matters throughout the government. It is also the Department's view that it is important to have a uniform definition of what constitutes employment discrimination throughout the Federal government.

Secretary means the Secretary of the Department of Health and Human Services or the Secretary's designee.

Section 504. This definition makes clear that, as used in this part, *section 504* applies only to programs or activities conducted by the agency itself and not to programs or activities to which it provides Federal financial assistance.

Section 85.11 Self-evaluation.

The agency shall conduct a self-evaluation of its compliance with section 504 within one year of the effective date of this regulation. The self-evaluation requirement is present in the existing section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.5(b)(2)) and the HHS regulations for federally assisted programs (45 CFR 84.6(k)). Experience has demonstrated the self-evaluation process to be a valuable means of establishing a working relationship with individuals with handicaps that promotes both effective and efficient implementation of section 504.

One commenter stated that a three-year retention period is insufficient, and proposed that self-evaluations be kept indefinitely. The regulation requires the self-evaluation to be kept for a minimum of three years, but does not include a maximum. It is expected that the self-evaluation will be retained for the period provided in current document retention policies.

Another commenter proposed that copies of the self-evaluation be made available for copying as well as for public inspection. This proposal has been adopted.

A further commenter proposed the inclusion of provisions for assurances, transition plans and specific modification requirements. We believe that while assurances are appropriate—and can be specifically enforced—in section 504 regulations for federally assisted programs or activities, all of the entities involved in this part are under the control of the Secretary, who can issue the necessary directives; assurances are therefore not required.

The final rule provides for participation in the self-evaluation process by individuals with handicaps or organizations representing individuals with handicaps by submitting comments, which may include the development of transition plans. It is expected that component agencies will consult with individuals with handicaps among their own staff in the course of preparing self-evaluations.

Because modification requirements are intended to address any potential problems in the agency's programs or activities, they are not specified in the regulation.

Section 85.12 Notice.

Section 85.12 requires the agency to disseminate sufficient information to employees, applicants, participants, beneficiaries, and other interested persons to apprise them of the rights and protections afforded by section 504 and this part. Methods of providing this information include, for example, the publication of information in handbooks, manuals, and pamphlets that are distributed to the public to describe the agency's programs and activities or in connection with recruitment; the display of informative posters in service centers and other public places; or the broadcasting of information by television or radio.

One commenter suggested the inclusion of a reference to recruitment materials in the above examples. Such a reference has been included.

Section 85.21 General prohibitions against discrimination.

Section 85.21 is an adaptation of the corresponding section of the section 504 coordination regulation for programs and activi-

ties receiving Federal financial assistance (28 CFR 41.51).

Paragraph (a) restates the nondiscrimination mandate of section 504. The remaining paragraphs in §85.21 establish the general principles for analyzing whether any particular action of the agency violates this mandate. These principles serve as the analytical foundation for the remaining sections of the part. If the agency violates a provision in any of the subsequent sections, it will also violate one of the general prohibitions found in §85.21. When there is no applicable subsequent provision, the general prohibitions stated in this section apply.

Paragraph (b) prohibits overt denials of equal treatment of individuals with handicaps. The agency may not refuse to provide an individual with handicaps with an equal opportunity to participate in or benefit from its program simply because the person is handicapped. Such blatantly exclusionary practices could result from the use of irrebuttable presumptions that absolutely exclude certain classes of disabled persons (*e.g.*, epileptics, hearing-impaired persons, persons with heart ailments) from participation in programs or activities without regard to an individual's actual ability to participate. Use of an irrebuttable presumption is permissible only when in all cases a physical condition by its very nature would prevent an individual from meeting the essential eligibility requirements for participation in the activity in question. It would be permissible, therefore, to exclude without an individual evaluation all persons who are blind in both eyes from eligibility for a license to operate a commercial vehicle in interstate commerce; but it may not be permissible to automatically disqualify all those who are blind in just one eye.

In addition, section 504 prohibits more than just the most obvious denials of equal treatment. It is not enough to admit persons in wheelchairs to a program if the facilities in which the program is conducted are inaccessible. Paragraph (b)(1)(iii), therefore, requires that the opportunity to participate or benefit afforded to an individual with handicaps be as effective as that afforded to others. The later sections on program accessibility (§§85.41–43) and communication (§85.51) are specific applications of this principle.

Despite the mandate of paragraph (d) that the agency administer its programs and activities in the most integrated setting appropriate to the needs of qualified individuals with handicaps, paragraph (b)(1)(iv), in conjunction with paragraph (d), permits the agency to develop separate or different aids, benefits, or services when necessary to provide individuals with handicaps with an equal opportunity to participate in or benefit from the agency's programs or activities. Paragraph (b)(1)(iv) requires that different or separate aids, benefits, or services

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be provided only when necessary to ensure that the aids, benefits, or services are as effective as those provided to others. Even when separate or different aids, benefits or services would be more effective, paragraph (b)(2) provides that a qualified individual with handicaps still has the right to choose to participate in the program that is not designed to accommodate individuals with handicaps.

Paragraph (b)(1)(v) prohibits the agency from denying a qualified individual with handicaps the opportunity to participate as a member of a planning or advisory board.

Paragraph (b)(1)(vi) prohibits the agency from limiting a qualified individual with handicaps in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving any aid, benefit, or service.

Paragraph (b)(3) prohibits the agency from utilizing criteria or methods of administration that deny individuals with handicaps access to the agency's programs or activities. The phrase *criteria or methods of administration* refers to official written agency policies, as well as the actual practices of the agency. This paragraph prohibits both blatantly exclusionary policies or practices and nonessential policies and practices that are neutral on their face, but deny individuals with handicaps an effective opportunity to participate.

Paragraph (b)(4) specifically applies the prohibition enunciated in §85.21(b)(3) to the process of selecting sites for construction of new facilities or existing facilities to be used by the agency. Paragraph (b)(4) does not apply to construction of additional buildings at an existing site.

Paragraph (b)(5) prohibits the agency, in the selection of procurement contractors, from using criteria that subject qualified individuals with handicaps to discrimination on the basis of handicap.

Paragraph (b)(6) prohibits the agency from discriminating against qualified individuals with handicaps on the basis of handicap in the granting of licenses or certifications. A person is a *qualified individual with handicaps* with respect to licensing or certification if he or she can meet the essential eligibility requirements for receiving the license or certification (see §85.3).

In addition, the agency may not establish requirements for the programs or activities of licensees or certified entities that subject qualified individuals with handicaps to discrimination on the basis of handicap. For example, the agency must comply with this requirement when establishing safety standards for the operations of licensees. In that case, the agency must ensure that the standards it promulgates do not discriminate against the employment of qualified individuals with handicaps in an impermissible manner.

Paragraph (b)(6) does not extend section 504 directly to the programs or activities of licensees or certified entities themselves. The programs or activities of Federal licensees or certified entities are not themselves federally conducted programs or activities; nor are they programs or activities receiving Federal financial assistance merely by virtue of the Federal license or certificate. However, as noted above, section 504 may affect the content of the rules established by the agency for the operation of the program or activity of the licensee or certified entity and thereby indirectly affect limited aspects of their operations.

One commenter suggested pointing out that Federal licensees or certified entities, having received services from Federal employees during the process of licensing or certification, thereby become Federally assisted recipients, and are covered by 45 CFR part 84. Such an argument is beyond the scope of this part, and is therefore not being included.

Another commenter suggested including language such as that found in 45 CFR 84.4(b)(1) to the effect that agencies may not perpetuate discrimination against qualified individuals with handicaps by providing significant assistance to an agency, organization or person that discriminates on the basis of handicap. Assistance from the agency that would provide significant support to an organization constitutes Federal financial assistance and the organization, as a recipient of such assistance, would be covered by the section 504 regulation for federally assisted programs.

Paragraph (c) provides that programs conducted pursuant to Federal statute or Executive order that are designed to benefit only individuals with handicaps or a given class of individuals with handicaps may be limited to individuals those with handicaps.

Paragraph (d) provides that the agency must administer programs and activities in the most integrated setting appropriate to the next of qualified individuals with handicaps, *i.e.* in a setting that enables individuals with handicaps to interact with nonhandicapped individuals to the fullest extent possible.

Section 85.31 Employment.

Section 85.31 prohibits discrimination on the basis of handicap in employment by the agency. Courts have held that section 504, as amended in 1978, covers the employment practices of Executive agencies. *Gardner v. Morris*, 752 F.2d 1271, 1277 (8th Cir. 1985); *Smith v. United States Postal Service*, 742 F.2d 257, 259–60 (6th Cir. 1984); *Prewitt v. United States Postal Service*, 662 F.2d 292, 302–04 (5th Cir. 1981). *Contra McGuiness v. United States Postal Service*, 744 F.2d 1318, 1320–21 (7th Cir. 1984); *Boyd v. United States Postal Service*, 752 F.2d 410, 413–14 (9th Cir. 1985).

Courts uniformly have held that, in order to give effect to section 501 of the Rehabilitation Act, which covers Federal employment, the administrative procedures of section 501 must be followed in processing complaints of employment discrimination under section 504. *Morgan v. United States Postal Service*, 798 F.2d 1162, 1164-65 (8th Cir. 1986); *Smith*, 742 F.2d at 262; *Prewitt*, 662 F.2d at 304. Accordingly, §85.31 (Employment) of this rule adopts the definitions, requirements, and procedures of section 501 as established in regulations of the EEOC at 29 CFR part 1613. Responsibility for coordinating enforcement of Federal laws prohibiting discrimination in employment is assigned to the EEOC by Executive Order 12067 (3 CFR, 1978 Comp., p. 206). Under this authority, the EEOC establishes government-wide standards on non-discrimination in employment on the basis of handicap.

One commenter proposed that the general definition of *qualified individual with handicaps* be used in this section, instead of that used under section 501. We believe that the above paragraphs sufficiently explain the need for using the section 501 definition.

In addition to this section, §85.61(c) specifies that the agency will use the existing EEOC procedures to resolve allegations of employment discrimination.

*Section 85.41 Program accessibility:
Discrimination prohibited.*

Section 85.41 states the general non-discrimination principle underlying the program accessibility requirements of §§85.42 and 85.43.

Section 85.42 Program accessibility: Existing facilities.

This part adopts the program accessibility concept found in the existing section 504 coordination regulation for programs or activities receiving Federal financial assistance (28 CFR 41.57) with certain modifications. Thus, §85.42 requires that each agency program or activity, when viewed in its entirety, be readily accessible to and usable by individuals with handicaps. The part also makes clear that the agency is not required to make each of its existing facilities accessible (§85.42(a)(1)). However, §85.42, unlike 28 CFR 41.57, places explicit limits on the agency's obligation to ensure program accessibility (§85.42(a)(2)).

One commenter stated that the provisions of §85.42(a)(1) were negatively worded and may reflect a misinterpretation of the decision of the Supreme Court in *Grove City College v. Bell*, 465 U.S. 555 (1984), and argued for deletion of this language.

The language is identical to that in the section 504 regulation for federally assisted programs or activities. We believe that the inclusion of this language is necessary in

order to make clear that, while every aspect of every Federal program or activity need not be accessible, each program or activity, when viewed as a whole, must be accessible.

Another commenter recommended adding the language "where other methods are equally effective in achieving compliance from §84.42(b) to §84.42(a)(1). We believe that, because §84.42 (a) and (b) treat different aspects of the subject, their language must necessarily differ.

Paragraph (a)(2) generally codifies recent case law that defines the scope of the agency's obligation to ensure program accessibility. This paragraph provides that in meeting the program accessibility requirement, the agency is not required to take any action that would result in a fundamental alteration in the nature of its program or activity, or in undue financial and administrative burdens. A similar limitation is provided in §85.51(d). This provision is based on the Supreme Court's holding in *Southeastern Community College v. Davis*, 442 U.S. 397 (1979), that section 504 does not require program modifications that result in a fundamental alteration in the nature of a program, and on the Court's statement that section 504 does not require modifications that would result in "undue financial and administrative burdens." 442 U.S. at 412. Since *Davis*, circuit courts have applied this limitation on a showing that only one of the two "undue burdens" would be created as a result of the modification sought to be imposed under section 504. See, e.g., *Dopico v. Goldschmidt*, 687 F.2d 644 (2d Cir. 1982); *American Public Transit Association v. Lewis*, 655 F.2d 1272 (D.C. Cir. 1981).

Paragraph (a)(2) and §85.51(d) are also supported by the Supreme Court's decision in *Alexander v. Choate*, 469 U.S. 287 (1985). *Alexander* involved a challenge to the State of Tennessee's reduction of inpatient hospital care coverage under Medicaid from 20 to 14 days per year. Plaintiffs argued that this reduction violated section 504 because it had an adverse impact on handicapped persons. The Court assumed without deciding that section 504 reaches at least some conduct that has an unjustifiable disparate impact on handicapped people, but held that the reduction was not "the sort of disparate impact" discrimination that might be prohibited by section 504 or its implementing regulation. *Id.* at 299.

Relying on *Davis*, the Court said that section 504 guarantees qualified handicapped persons "meaningful access to the benefits the grantee offers," *id.* at 301, and that "reasonable adjustments in the nature of the benefit offered must at times be made to assure meaningful access." *Id.* n.21 (emphasis added). However, section 504 does not require "changes," "adjustments," or "modifications"

to existing programs that would be 'substantial' * * * or that would constitute 'fundamental alteration[s] in the nature of a program.''' *Id.* at n.20 (citations omitted). *Alexander* supports the position, based on *Davis* and the earlier lower court decisions, that in some situations, certain accommodations for a handicapped person may so alter an agency's program or activity, or entail such extensive costs and administrative burdens that the refusal to undertake the accommodations is not discriminatory. Thus, failure to include such an "undue burdens" provision could lead to judicial invalidation of the regulation or reversal of a particular enforcement action taken pursuant to the regulation.

This paragraph, however, does not establish an absolute defense; it does not relieve the agency of all obligations to individuals with handicaps. Although the agency is not required to take actions that would result in a fundamental alteration in the nature of a program or activity or in undue financial and administrative burdens, it nevertheless must take any other steps necessary to ensure that individuals with handicaps receive the benefits and services of the federally conducted program or activity.

It is our view that compliance with §85.42(a) would in most cases not result in undue financial and administrative burdens on the agency. In determining whether financial and administrative burdens are undue, all agency resources available for use in the funding and operation of the conducted program or activity should be considered. The burden of proving that compliance with §85.42(a) would fundamentally alter the nature of a program or activity or would result in undue financial and administrative burdens rests with the agency. The decision that compliance would result in such alteration or burdens must be made by the agency head or his or her designee, and must be accompanied by a written statement of the reasons for reaching that conclusion. Any person who believes that he or she or any specific class of persons has been injured by the agency head's decision or failure to make a decision may file a complaint under the compliance procedures established in §85.61. The opportunity to file such a complaint responds to one commenter's suggestion that review by a high level Department official be assured.

Paragraph (b)(1) sets forth a number of means by which program accessibility may be achieved, including redesign of equipment, reassignment of services to accessible buildings, and provision of aides. In choosing among methods, the agency shall give priority consideration to those that will be consistent with provision of services in the most integrated setting appropriate to the needs of individuals with handicaps. Structural changes in existing facilities are required

only when there is no other feasible way to make the agency's program accessible. (It should be noted that "structural changes" include all physical changes to a facility; the term does not refer only to changes to structural features, such as removal of or alteration to a load-bearing structural member.) The agency may comply with the program accessibility requirement by delivering services at alternate accessible sites or making home visits as appropriate.

One commenter proposed that methods other than structural changes to ensure accessibility should be "equally effective". The regulations implementing section 504 for federally assisted programs do not contain such language. The addition of the proposed language would impose a regulatory standard on the Department not required of recipients. In view of the fact that the 1978 amendments were intended to apply the same requirements to federally conducted programs as apply to federally assisted programs, the proposed language is not being adopted.

Paragraphs (c) and (d) establish time periods for complying with the program accessibility requirement. As currently required for federally assisted programs by 28 CFR 41.57(b), the agency must make any necessary structural changes in facilities as soon as practicable, but in no event later than three (3) years after the effective date of this part. Where structural modifications are required and it is not expected that these can be completed within six months, a transition plan should be developed within six months of the effective date of this part. Aside from structural changes, all other necessary steps to achieve compliance shall be taken within sixty days.

One commenter proposes to limit the time allowed for making structural modifications to one year. We note that the basic requirement is that these changes be made "as soon as practicable," and that the three-year limit is the maximum period of time. Furthermore, the three-year maximum for transition plans is identical to that contained in the regulations for federally assisted recipients.

Section 85.43 Program accessibility: New construction and alterations.

Overlapping coverage exists with respect to new construction and alterations under section 504 and the Architectural Barriers Act of 1968, as amended (42 U.S.C. 4151-4157). Section 85.43 provides that those buildings that are constructed or altered by, on behalf of, or for the use of the agency shall be designed, constructed, or altered to be readily accessible to and usable by individuals with handicaps in accordance with 41 CFR part 101-19, 101-19.600 to 101-19.607 (GSA regulation which incorporates the Uniform Federal Accessibility Standards). This standard was promulgated pursuant to the Architectural

Barriers Act of 1968, as amended (42 U.S.C. 4151-4157). We believe that it is appropriate to adopt the existing Architectural Barriers Act standard for section 504 compliance because new and altered buildings subject to this regulation are also subject to the Architectural Barriers Act and because adoption of the standard will avoid duplicative and possibly inconsistent standards.

Existing buildings leased by the agency after the effective date of this regulation are not required by the regulation to meet accessibility standards simply by virtue of being leased. They are subject, however, to the program accessibility standards for existing facilities in § 85.42. To the extent the buildings are newly constructed or altered, they must also meet the new constructions and alteration requirements of § 85.43.

Federal practice under section 504 has always treated newly leased buildings as subject to the existing facility program accessibility standard. Unlike the construction of new buildings where architectural barriers can be avoided at little or no cost, the application of new construction standards to an existing building being leased raises the same prospect of retrofitting buildings as the use of an existing Federal facility, and the agency believes that same program accessibility standards should apply to both owned and leased existing buildings.

In *Rose v. United States Postal Service*, 774 F.2d 1355 (9th Cir. 1985), the Ninth Circuit held that the Architectural Barriers Act requires accessibility at the time of lease. The *Rose* court did not address the question of whether section 504 likewise requires accessibility as a condition of lease, and the case was remanded to the District Court for, among other things, consideration of this issue. Two commenters urged that leased buildings be required to be accessible at the time of lease. The agency may provide more specific guidance on section 504 requirements for leased buildings after the litigation is completed.

Section 85.51 Communications.

Section 85.51 requires the agency to take appropriate steps to ensure effective communication with personnel of other Federal entities, applicants, participants, and members of the public. These steps shall include procedures for determining when auxiliary aids are necessary under § 85.1(a)(1) to afford an individual with handicaps an equal opportunity to participate in, and enjoy the benefits of, the agency's program or activity. They shall also include an opportunity for individuals with handicaps to request the auxiliary aids of their choice. This expressed choice shall be given primary consideration by the agency (§ 85.51(a)(1)(i)). The agency shall honor the choice unless it can demonstrate that another effective means of communication exists or that use of the

means chosen would not be required under § 85.51(d). That paragraph limits the obligations of the agency to ensure effective communication in accordance with *Davis* and the circuit court opinions interpreting it (*see supra* preamble discussion of § 85.42(c)(2)). Unless not required by § 85.51(d), the agency shall provide auxiliary aids at no cost to the individual with handicaps.

One commenter proposed that the choice of auxiliary aid made by the individual with handicaps should govern unless it would constitute an undue hardship on the agency. We believe that the language set out above is adequate to ensure consideration of an individual's preference.

Another commenter proposed that the regulation require all films and videotapes produced by the agency to be captioned for the hearing-impaired. The Department intends to examine all appropriate methods of ensuring effective communication.

The same commenter applauded HHS for the inclusion of the language requiring HHS to inform individuals with handicaps of their section 504 rights.

The discussion of § 85.42(a), Program accessibility, Existing facilities, regarding the determination of what constitutes undue financial and administrative burdens, also applies to § 85.51(d) and should be referred to for a complete understanding of the agency's obligation to comply with § 85.51.

In some circumstances, a notepad and written materials may be sufficient to permit effective communication with a hearing-impaired person. In many circumstances, however, they may not be, particularly when the information being communicated is complex or exchanged for a lengthy period of time (*e.g.* a meeting) or where the hearing-impaired applicant or participant is not skilled in spoken or written language. In these cases, a sign language interpreter may be appropriate.

One commenter proposed changing the language to state that notepads rarely suffice for communication with the hearing-impaired. Considering that a significant number of the hearing-impaired may not be skilled in sign language, we believe that the language used is appropriate.

For vision-impaired persons, effective communication might be achieved by several means, including readers and audio recordings. In general, the agency intends to inform the public of (1) the communications services it offers to afford individuals with handicaps an equal opportunity to participate in or benefit from its programs and activities, (2) the opportunity to request a particular mode of communication, and (3) the agency's preferences regarding auxiliary aids if it can demonstrate that several different modes are effective.

The agency shall ensure effective communication with vision-impaired and hearing-

impaired persons involved in proceedings conducted by the agency. Auxiliary aids must be afforded where necessary to ensure effective communication at the proceedings. If sign language interpreters are necessary, the agency may require that it be given reasonable notice prior to the proceedings of the need for an interpreter. Moreover, the agency need not provide individually prescribed devices, readers for personal use or study, or other devices of a personal nature (§85.51(a)(1)(ii)). For example, the agency need not provide eye glasses or hearing aids to applicants or participants in its programs. Similarly, the regulation does not require the agency to provide wheelchairs to persons with mobility impairments.

One commenter proposed that the items which agencies are not required to provide and the circumstances involved be described in more detail. We believe that the description given is sufficient, because the interpretation of this provision will be made on a case-by-case basis.

Paragraph (b) requires the agency to ensure that individuals with handicaps can obtain information concerning accessible services, activities, and facilities.

Paragraph (c) requires the agency to provide signage at inaccessible facilities that direct users to locations with information about accessible facilities.

One commenter suggested specifically mentioning the international symbol for deafness, and placing such signs at the main entrance of buildings equipped to service the hearing-impaired. We believe that the language contained in §85.51 (b) and (c) requires the agency to ensure that individuals with handicaps, including those with impaired hearing, can obtain information regarding accessibility, and that this requirement is sufficient to afford flexibility on the part of the agency regarding use of appropriate signage.

One commenter proposed adding the words “in the most integrated setting appropriate” to the language in §85.51(d). This language already appears elsewhere in the regulation, *e.g.* in §85.42(b)(2), and it is the Department’s intention to act in accordance with that provision.

Section 85.61 Compliance procedures.

Paragraph (a) specifies that paragraphs (b) and (d) through (l) of this section establish the procedures for processing complaints other than employment complaints. Paragraph (c) provides that the agency will process employment complaints according to procedures established in existing regulations of the EEOC (29 CFR part 1613) pursuant to section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

Paragraph (b) designates the official responsible for coordinating implementation of §85.61. The NPRM stated that responsibility

for the implementation and operation of this “part” shall be vested in the OCR Director/Special Assistant. The final rule has been revised by replacing the word “part” with the word “section” to clarify the responsibility for coordinating implementation of §85.61.

The agency is required to accept and investigate all complete complaints (§85.61(d)). Two commenters suggested that a complainant have an opportunity to remedy an incomplete complaint. Current administrative procedures provide for this practice and it need not be included in the text of the regulation.

If the agency determines that it does not have jurisdiction over a complaint, it shall promptly notify the complainant and make reasonable efforts to refer the complaint to the appropriate entity of the Federal Government (§85.61(e)). One commenter pointed out that where a reference to another entity of the Federal government is required, the obligation to refer should be absolute, not limited to reasonable efforts. The language “shall make reasonable efforts to refer” is not intended to minimize the Department’s obligation.

Paragraph (f) requires the agency to notify the Architectural and Transportation Barriers Compliance Board (ATBCB) upon receipt of a complaint alleging that a building or facility subject to the Architectural Barriers Act was designed, constructed, or altered in a manner that does not provide ready access and use by individuals with handicaps.

Paragraph (g) requires the agency to provide to the complainant, in writing, findings of fact and conclusions of law, the relief granted if noncompliance is found, and notice of the right to appeal (§85.61(g)). One appeal within the agency shall be provided (§85.61(i)). The appeal will not be heard by the same person who made the initial determination of compliance or noncompliance.

Paragraph (l) permits the agency to delegate its authority for investigating complaints to other Federal agencies. However, the statutory obligation of the agency to make a final determination of compliance or noncompliance may not be delegated.

Commenters have suggested the following:

Notifying complainants whenever their complaints are referred to another agency. Current administrative procedures provide for this practice and it need not be included in the text of the regulation.

Describing the basic parameters for submitting or obtaining evidence used to decide appeals. Since the grounds for appeal may be extremely varied, it would not be practicable to set out parameters for every appeal.

Including a statement as to complainants’ rights to judicial review. These rights are statutory and beyond the scope of this regulation.

Obtaining the expertise of ATBCB in appropriate cases. A provision regarding notification of ATBCB is already included in the regulation.

Including a statement that all other regulations, forms and directives issued by HHS are superseded by the nondiscrimination requirements of this part. The Department views any other issuances falling short of the requirements of this regulation as insufficient to ensure compliance and therefore such a statement is unnecessary.

Provisions for attorneys fees and compensation to the prevailing party. Such provisions are statutory and beyond the scope of this regulation.

Section 85.62 Coordination and compliance responsibilities.

Section 85.62 sets out the respective responsibilities of the components of HHS and of the Director, OCR/Special Assistant in the implementation of section 504 to programs and activities conducted by HHS.

Paragraph (c) specifies the respective roles of OCR and of the HHS component in cases in which noncompliance is found.

In the event that OCR and the HHS component cannot agree on a resolution of any particular matter, such matter will be submitted to the Secretary for resolution.

PART 86—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

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AUTHORITY: 20 U.S.C. 1681 through 1688; Pub. L. 100-259, 102 Stat. 28 (Mar. 22, 1988).

§ 86.1

SOURCE: 40 FR 24137, June 4, 1975, unless otherwise noted.

Subpart A—Introduction

§ 86.1 Purpose and effective date.

The purpose of this part is to effectuate title IX of the Education Amendments of 1972, as amended by Pub. L. 93-568, 88 Stat. 1855 (except sections 904 and 906 of those Amendments) which is designed to eliminate (with certain exceptions) discrimination on the basis of sex in any education program or activity receiving Federal financial assistance, whether or not such program or activity is offered or sponsored by an educational institution as defined in this part. This part is also intended to effectuate section 844 of the Education Amendments of 1974, Pub. L. 93-380, 88 Stat. 484. The effective date of this part shall be July 21, 1975.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682, as amended by Pub. L. 93-568, 88 Stat. 1855, and sec. 844, Education Amendments of 1974, 88 Stat. 484, Pub. L. 93-380)

§ 86.2 Definitions.

As used in this part, the term—

(a) *Title IX* means title IX of the Education Amendments of 1972, Pub. L. 92-318, as amended by section 3 of Pub. L. 93-568, 88 Stat. 1855, except sections 904 and 906 thereof; 20 U.S.C. 1681, 1682, 1683, 1685, 1686, 1687, 1688.

(b) *Department* means the Department of Health and Human Services.

(c) *Secretary* means the Secretary of Health and Human Services.

(d) *Director* means the Director of the Office for Civil Rights of the Department.

(e) *Reviewing Authority* means that component of the Department delegated authority by the Secretary to appoint, and to review the decisions of, administrative law judges in cases arising under this part.

(f) *Administrative law judge* means a person appointed by the reviewing authority to preside over a hearing held under this part.

(g) *Federal financial assistance* means any of the following, when authorized or extended under a law administered by the Department:

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(1) A grant or loan of Federal financial assistance, including funds made available for:

(i) The acquisition, construction, renovation, restoration, or repair of a building or facility or any portion thereof; and

(ii) Scholarships, loans, grants, wages or other funds extended to any entity for payment to or on behalf of students admitted to that entity, or extended directly to such students for payment to that entity.

(2) A grant of Federal real or personal property or any interest therein, including surplus property, and the proceeds of the sale or transfer of such property, if the Federal share of the fair market value of the property is not, upon such sale or transfer, properly accounted for to the Federal Government.

(3) Provision of the services of Federal personnel.

(4) Sale or lease of Federal property or any interest therein at nominal consideration, or at consideration reduced for the purpose of assisting the recipient or in recognition of public interest to be served thereby, or permission to use Federal property or any interest therein without consideration.

(5) Any other contract, agreement, or arrangement which has as one of its purposes the provision of assistance to any education program or activity, except a contract of insurance or guaranty.

(h) *Program or activity* and *program* means all of the operations of—

(1)(i) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(ii) The entity of such a State or local government that distributes Federal financial assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(2)(i) A college, university, or other postsecondary institution, or a public system of higher education; or

(ii) A local educational agency (as defined in 20 U.S.C. 7801), system of vocational education, or other school system;

(3)(i) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(A) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(B) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(ii) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(4) Any other entity which is established by two or more of the entities described in paragraph (h)(1), (2), or (3) of this section; any part of which is extended Federal financial assistance.

(i) *Recipient* means any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient and which operates an education program or activity which receives such assistance, including any subunit, successor, assignee, or transferee thereof.

(j) *Applicant* means one who submits an application, request, or plan required to be approved by a Department official, or by a recipient, as a condition to becoming a recipient.

(k) *Educational institution* means a local educational agency (L.E.A.) as defined by section 801(f) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 881), a preschool, a private elementary or secondary school, or an applicant or recipient of the type defined by paragraph (l), (m), (n), or (o) of this section.

(l) *Institution of graduate higher education* means an institution which:

(1) Offers academic study beyond the bachelor of arts or bachelor of science degree, whether or not leading to a certificate of any higher degree in the liberal arts and sciences; or

(2) Awards any degree in a professional field beyond the first professional degree (regardless of whether

the first professional degree in such field is awarded by an institution of undergraduate higher education or professional education); or

(3) Awards no degree and offers no further academic study, but operates ordinarily for the purpose of facilitating research by persons who have received the highest graduate degree in any field of study.

(m) *Institution of undergraduate higher education* means:

(1) An institution offering at least two but less than four years of college level study beyond the high school level, leading to a diploma or an associate degree, or wholly or principally creditable toward a baccalaureate degree; or

(2) An institution offering academic study leading to a baccalaureate degree; or

(3) An agency or body which certifies credentials or offers degrees, but which may or may not offer academic study.

(n) *Institution of professional education* means an institution (except any institution of undergraduate higher education) which offers a program of academic study that leads to a first professional degree in a field for which there is a national specialized accrediting agency recognized by the Secretary of Education.

(o) *Institution of vocational education* means a school or institution (except an institution of professional or graduate or undergraduate higher education) which has as its primary purpose preparation of students to pursue a technical, skilled, or semiskilled occupation or trade, or to pursue study in a technical field, whether or not the school or institution offers certificates, diplomas, or degrees and whether or not it offers fulltime study.

(p) *Administratively separate unit* means a school, department or college of an educational institution (other than a local educational agency) admission to which is independent of admission to any other component of such institution.

(q) *Admission* means selection for part-time, full-time, special, associate, transfer, exchange, or any other enrollment, membership, or matriculation in or at an education program or activity operated by a recipient.

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(r) *Student* means a person who has gained admission.

(s) *Transition plan* means a plan subject to the approval of the United States Commissioner of Education pursuant to section 901(a)(2) of the Education Amendments of 1972, under which an educational institution operates in making the transition from being an educational institution which admits only students of one sex to being one which admits students of both sexes without discrimination.

(Secs. 901, 902, 908, Education Amendments of 1972, 20 U.S.C. 1681, 1682, 1687)

[40 FR 24137, June 4, 1975, as amended at 70 FR 24320, May 9, 2005; 85 FR 37243, June 19, 2020]

§ 86.3 Remedial and affirmative action and self-evaluation.

(a) *Remedial action*. If the Director finds that a recipient has discriminated against persons on the basis of sex in an education program or activity, such recipient shall take such remedial action as the Director deems necessary to overcome the effects of such discrimination.

(b) *Affirmative action*. In the absence of a finding of discrimination on the basis of sex in an education program or activity, a recipient may take affirmative action to overcome the effects of conditions which resulted in limited participation therein by persons of a particular sex. Nothing herein shall be interpreted to alter any affirmative action obligations which a recipient may have under Executive Order 11246.

(c) *Self-evaluation*. Each recipient education institution shall, within one year of the effective date of this part:

(1) Evaluate, in terms of the requirements of this part, its current policies and practices and the effects thereof concerning admission of students, treatment of students, and employment of both academic and non-academic personnel working in connection with the recipient's education program or activity;

(2) Modify any of these policies and practices which do not or may not meet the requirements of this part; and

(3) Take appropriate remedial steps to eliminate the effects of any discrimination which resulted or may

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have resulted from adherence to these policies and practices.

(d) *Availability of self-evaluation and related materials*. Recipients shall maintain on file for at least three years following completion of the evaluation required under paragraph (c) of this section, and shall provide to the Director upon request, a description of any modifications made pursuant to paragraph (c) (2) of this section and of any remedial steps taken pursuant to paragraph (c) (3) of this section.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.4 Assurance required.

(a) *General*. Every application for Federal financial assistance for any education program or activity shall as condition of its approval contain or be accompanied by an assurance from the applicant or recipient, satisfactory to the Director, that the education program or activity operated by the applicant or recipient and to which this part applies will be operated in compliance with this part. An assurance of compliance with this part shall not be satisfactory to the Director if the applicant or recipient to whom such assurance applies fails to commit itself to take whatever remedial action is necessary in accordance with § 86.3(a) to eliminate existing discrimination on the basis of sex or to eliminate the effects of past discrimination whether occurring prior or subsequent to the submission to the Director of such assurance.

(b) *Duration of obligation*. (1) In the case of Federal financial assistance extended to provide real property or structures thereon, such assurance shall obligate the recipient or, in the case of a subsequent transfer, the transferee, for the period during which the real property or structures are used to provide an education program or activity.

(2) In the case of Federal financial assistance extended to provide personal property, such assurance shall obligate the recipient for the period during which it retains ownership or possession of the property.

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(3) In all other cases such assurance shall obligate the recipient for the period during which Federal financial assistance is extended.

(c) *Form.* The Director will specify the form of the assurances required by paragraph (a) of this section and the extent to which such assurances will be required of the applicant's or recipient's subgrantees, contractors, sub-contractors, transferees, or successors in interest.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24137, June 4, 1975, as amended at 70 FR 24321, May 9, 2005]

§ 86.5 Transfers of property.

If a recipient sells or otherwise transfers property financed in whole or in part with Federal financial assistance to a transferee which operates any education program or activity, and the Federal share of the fair market value of the property is not upon such sale or transfer properly accounted for to the Federal Government both the transferor and the transferee shall be deemed to be recipients, subject to the provisions of subpart B of this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.6 Effect of other requirements.

(a) *Effect of other Federal provisions.* The obligations imposed by this part are independent of, and do not alter, obligations not to discriminate on the basis of sex imposed by Executive Order 11246, as amended; sections 799A and 845 of the Public Health Service Act (42 U.S.C. 295h-9 and 298b-2); Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*); the Equal Pay Act (29 U.S.C. 206 and 206(d)); and any other Act of Congress or Federal regulation.

(Secs. 901, 902, 905, Education Amendments of 1972, 86 Stat. 373, 374, 375; 20 U.S.C. 1681, 1682, 1685)

(b) *Effect of State or local law or other requirements.* The obligation to comply with this part is not obviated or alleviated by any State or local law or other requirement which would render any applicant or student ineligible, or limit the eligibility of any applicant or stu-

dent, on the basis of sex, to practice any occupation or profession.

(c) *Effect of rules or regulations of private organizations.* The obligation to comply with this part is not obviated or alleviated by any rule or regulation of any organization, club, athletic or other league, or association which would render any applicant or student ineligible to participate or limit the eligibility or participation of any applicant or student, on the basis of sex, in any education program or activity operated by a recipient and which receives Federal financial assistance.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24137, June 4, 1975, as amended at 70 FR 24321, May 9, 2005]

§ 86.7 Effect of employment opportunities.

The obligation to comply with this part is not obviated or alleviated because employment opportunities in any occupation or profession are or may be more limited for members of one sex than for members of the other sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.8 Designation of responsible employee and adoption of grievance procedures.

(a) *Designation of responsible employee.* Each recipient shall designate at least one employee to coordinate its efforts to comply with and carry out its responsibilities under this part, including any investigation of any complaint communicated to such recipient alleging its noncompliance with this part or alleging any actions which would be prohibited by this part. The recipient shall notify all its students and employees of the name, office address and telephone number of the employee or employees appointed pursuant to this paragraph.

(b) *Complaint procedure of recipient.* A recipient shall adopt and publish grievance procedures providing for prompt and equitable resolution of student and employee complaints alleging any action which would be prohibited by this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

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§ 86.9 Dissemination of policy.

(a) *Notification of policy.* (1) Each recipient shall implement specific and continuing steps to notify applicants for admission and employment, students and parents of elementary and secondary school students, employees, sources of referral of applicants for admission and employment, and all unions or professional organizations holding collective bargaining or professional agreements with the recipient, that it does not discriminate on the basis of sex in the educational programs or activities which it operates, and that is required by title IX and this part not to discriminate in such a manner. Such notification shall contain such information, and be made in such manner, as the Director finds necessary to apprise such persons of the protections against discrimination assured them by title IX and this part, but shall state at least that the requirement not to discriminate in education programs and activities extends to employment therein, and to admission thereto unless Subpart C does not apply to the recipient, and that inquiries concerning the application of title IX and this part to such recipient may be referred to the employee designated pursuant to § 86.8, or to the Director.

(2) Each recipient shall make the initial notification required by paragraph (a) (1) of this section within 90 days of the effective date of this part or of the date this part first applies to such recipient, whichever comes later, which notification shall include publication in:

- (i) Local newspapers;
- (ii) Newspapers and magazines operated by such recipient or by student, alumnae, or alumni groups for or in connection with such recipient; and
- (iii) Memoranda or other written communications distributed to every student and employee of such recipient.

(b) *Publications.* (1) Each recipient shall prominently include a statement of the policy described in paragraph (a) of this section in each announcement, bulletin, catalog, or application form which it makes available to any person of a type, described in paragraph (a) of this section, or which is otherwise used

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in connection with the recruitment of students or employees.

(2) A recipient shall not use or distribute a publication of the type described in this paragraph which suggests, by text or illustration, that such recipient treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by this part.

(c) *Distribution.* Each recipient shall distribute without discrimination on the basis of sex each publication described in paragraph (b) of this section, and shall apprise each of its admission and employment recruitment representatives of the policy of non-discrimination described in paragraph (a) of this section, and require such representatives to adhere to such policy.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

Subpart B—Coverage

§ 86.11 Application.

Except as provided in this subpart, this part 86 applies to every recipient and to the education program or activity operated by such recipient which receives Federal financial assistance.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24137, June 4, 1975, as amended at 70 FR 24321, May 9, 2005]

§ 86.12 Educational institutions controlled by religious organizations.

(a) *Application.* This part does not apply to an educational institution which is controlled by a religious organization to the extent application of this part would not be consistent with the religious tenets of such organization.

(b) *Exemption.* An educational institution which wishes to claim the exemption set forth in paragraph (a) of this section, shall do so by submitting in writing to the Director a statement by the highest ranking official of the institution, identifying the provisions of this part which conflict with a specific tenet of the religious organization.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

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§ 86.13 Military and merchant marine educational institutions.

This part does not apply to an educational institution whose primary purpose is the training of individuals for a military service of the United States or for the merchant marine.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.14 Membership practices of certain organizations.

(a) *Social fraternities and sororities.* This part does not apply to the membership practices of social fraternities and sororities which are exempt from taxation under section 501(a) of the Internal Revenue Code of 1954, the active membership of which consists primarily of students in attendance at institutions of higher education.

(b) *YMCA, YWCA, Girl Scouts, Boy Scouts and Camp Fire Girls.* This part does not apply to the membership practices of the Young Men's Christian Association, the Young Women's Christian Association, the Girl Scouts, the Boy Scouts and Camp Fire Girls.

(c) *Voluntary youth service organizations.* This part does not apply to the membership practices of voluntary youth service organizations which are exempt from taxation under section 501(a) of the Internal Revenue Code of 1954 and the membership of which has been traditionally limited to members of one sex and principally to persons of less than nineteen years of age.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682; sec. 3(a) of Pub. L. 93-568, 88 Stat. 1862 amending sec. 901)

§ 86.15 Admissions.

(a) Admissions to educational institutions prior to June 24, 1973, are not covered by this part.

(b) *Administratively separate units.* For the purposes only of this section, §§ 86.16 and 86.17, and subpart C, each administratively separate unit shall be deemed to be an educational institution.

(c) *Application of subpart C.* Except as provided in paragraphs (d) and (e) of this section, subpart C applies to each recipient. A recipient to which subpart C applies shall not discriminate on the

basis of sex in admission or recruitment in violation of that subpart.

(d) *Educational institutions.* Except as provided in paragraph (e) of this section as to recipients which are educational institutions, Subpart C applies only to institutions of vocational education, professional education, graduate higher education, and public institutions of undergraduate higher education.

(e) *Public institutions of undergraduate higher education.* Subpart C does not apply to any public institution of undergraduate higher education which traditionally and continually from its establishment has had a policy of admitting only students of one sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.16 Educational institutions eligible to submit transition plans.

(a) *Application.* This section applies to each educational institution to which subpart C applies which:

(1) Admitted only students of one sex as regular students as of June 23, 1972; or

(2) Admitted only students of one sex as regular students as of June 23, 1965, but thereafter admitted as regular students, students of the sex not admitted prior to June 23, 1965.

(b) *Provision for transition plans.* An educational institution to which this section applies shall not discriminate on the basis of sex in admission or recruitment in violation of subpart C unless it is carrying out a transition plan approved by the United States Commissioner of Education as described in § 86.17, which plan provides for the elimination of such discrimination by the earliest practicable date but in no event later than June 23, 1979.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.17 Transition plans.

(a) *Submission of plans.* An institution to which § 86.16 applies and which is composed of more than one administratively separate unit may submit either a single transition plan applicable to

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all such units, or a separate transition plan applicable to each such unit.

(b) *Content of plans.* In order to be approved by the United States Commissioner of Education, a transition plan shall:

(1) State the name, address, and Federal Interagency Committee on Education (FICE) Code of the educational institution submitting such plan, the administratively separate units to which the plan is applicable, and the name, address, and telephone number of the person to whom questions concerning the plan may be addressed. The person who submits the plan shall be the chief administrator or president of the institution, or another individual legally authorized to bind the institution to all actions set forth in the plan.

(2) State whether the educational institution or administratively separate unit admits students of both sexes, as regular students and, if so, when it began to do so.

(3) Identify and describe with respect to the educational institution or administratively separate unit any obstacles to admitting students without discrimination on the basis of sex.

(4) Describe in detail the steps necessary to eliminate as soon as practicable each obstacle so identified and indicate the schedule for taking these steps and the individual directly responsible for their implementation.

(5) Include estimates of the number of students, by sex, expected to apply for, be admitted to, and enter each class during the period covered by the plan.

(c) *Nondiscrimination.* No policy or practice of a recipient to which § 86.16 applies shall result in treatment of applicants to or students of such recipient in violation of Subpart C unless such treatment is necessitated by an obstacle identified in paragraph (b)(3) of this section and a schedule for eliminating that obstacle has been provided as required by paragraph (b)(4) of this section.

(d) *Effects of past exclusion.* To overcome the effects of past exclusion of students on the basis of sex, each educational institution to which § 86.16 applies shall include in its transition plan, and shall implement, specific steps designed to encourage individuals

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of the previously excluded sex to apply for admission to such institution. Such steps shall include instituting recruitment programs which emphasize the institution's commitment to enrolling students of the sex previously excluded.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.18 Amendments to conform to statutory exemptions.

(a) Nothing in this part shall be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion.

(b) Nothing in this part shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in the preceding sentence shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.

(c) This part shall be construed consistently with, as applicable, the First Amendment to the Constitution, Title IX's religious exemptions (20 U.S.C. 1681(a)(3) and 1687(4)), the Religious Freedom Restoration Act (42 U.S.C. 2000b *et seq.*), and provisions related to abortion in the Church Amendments (42 U.S.C. 300a–7), the Coats-Snowe Amendment (42 U.S.C. 238n), section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023), and appropriation rider provisions relating to abortion, to the extent they remain in effect or applicable, such as the Hyde Amendment (*e.g.*, Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, secs. 506–07), the Helms Amendment (*e.g.*, Continuing Appropriations Act, 2019, Pub. L. 116–6, Div. F, Title III), and the Weldon Amendment (*e.g.*, Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, sec. 507(d)).

[85 FR 37243, June 19, 2020]

§§ 86.19–86.20 [Reserved]

Subpart C—Discrimination on the Basis of Sex in Admission and Recruitment Prohibited**§ 86.21 Admission.**

(a) *General.* No person shall, on the basis of sex, be denied admission, or be subjected to discrimination in admission, by any recipient to which this subpart applies, except as provided in §§ 86.16 and 86.17.

(b) *Specific prohibitions.* (1) In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, a recipient to which this subpart applies shall not:

(i) Give preference to one person over another on the basis of sex, by ranking applicants separately on such basis, or otherwise;

(ii) Apply numerical limitations upon the number or proportion of persons of either sex who may be admitted; or

(iii) Otherwise treat one individual differently from another on the basis of sex.

(2) A recipient shall not administer or operate any test or other criterion for admission which has a disproportionately adverse effect on persons on the basis of sex unless the use of such test or criterion is shown to predict validly success in the education program or activity in question and alternative tests or criteria which do not have such a disproportionately adverse effect are shown to be unavailable.

(c) *Prohibitions relating to marital or parental status.* In determining whether a person satisfies any policy or criterion for admission, or in making any offer of admission, a recipient to which this subpart applies:

(1) Shall not apply any rule concerning the actual or potential parental, family, or marital status of a student or applicant which treats persons differently on the basis of sex;

(2) Shall not discriminate against or exclude any person on the basis of pregnancy, childbirth, termination of pregnancy, or recovery therefrom, or establish or follow any rule or practice which so discriminates or excludes;

(3) Shall treat disabilities related to pregnancy, childbirth, termination of

pregnancy, or recovery therefrom in the same manner and under the same policies as any other temporary disability or physical condition; and

(4) Shall not make pre-admission inquiry as to the marital status of an applicant for admission, including whether such applicant is “Miss” or “Mrs.” A recipient may make pre-admission inquiry as to the sex of an applicant for admission, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.22 Preference in admission.

A recipient to which this subpart applies shall not give preference to applicants for admission, on the basis of attendance at any educational institution or other school or entity which admits as students or predominantly members of one sex, if the giving of such preference has the effect of discriminating on the basis of sex in violation of this subpart.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.23 Recruitment.

(a) *Nondiscriminatory recruitment.* A recipient to which this subpart applies shall not discriminate on the basis of sex in the recruitment and admission of students. A recipient may be required to undertake additional recruitment efforts for one sex as remedial action pursuant to § 86.3(a), and may choose to undertake such efforts as affirmative action pursuant to § 86.3(b).

(b) *Recruitment at certain institutions.* A recipient to which this subpart applies shall not recruit primarily or exclusively at educational institutions, schools or entities which admit as students only or predominantly members of one sex, if such actions have the effect of discriminating on the basis of sex in violation of this subpart.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§§ 86.24–86.30 [Reserved]

Subpart D—Discrimination on the Basis of Sex in Education Programs or Activities Prohibited

§ 86.31 Education programs or activities.

(a) *General.* Except as provided elsewhere in this part, no person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any academic, extracurricular, research, occupational training, or other education program or activity operated by a recipient which receives Federal financial assistance. This subpart does not apply to actions of a recipient in connection with admission of its students to an education program or activity of (1) a recipient to which Subpart C does not apply, or (2) an entity, not a recipient, to which Subpart C would not apply if the entity were a recipient.

(b) *Specific prohibitions.* Except as provided in this subsection, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex:

(1) Treat one person differently from another in determining whether such person satisfies any requirement or condition for the provision of such aid, benefit, or service;

(2) Provide different aid, benefits, or services or provide aid, benefits, or services in a different manner;

(3) Deny any person any such aid, benefit, or service;

(4) Subject any person to separate or different rules of behavior, sanctions, or other treatment;

(5) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for in-State fees and tuition;

(6) Aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person which discriminates on the basis of sex in providing any aid, benefit or service to students or employees;

(7) Otherwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.

(c) *Assistance administered by a recipient educational institution to study at a foreign institution.* A recipient educational institution may administer or assist in the administration of scholarships, fellowships, or other awards established by foreign or domestic wills, trusts, or similar legal instruments, or by acts of foreign governments and restricted to members of one sex, which are designed to provide opportunities to study abroad, and which are awarded to students who are already matriculating at or who are graduates of the recipient institution; *Provided*, a recipient educational institution which administers or assists in the administration of such scholarships, fellowship, or other awards which are restricted to members of one sex provides, or otherwise makes available reasonable opportunities for similar studies for members of the other sex. Such opportunities may be derived from either domestic or foreign sources.

(d) *Aid, benefits, or services not provided by recipient.* (1) This paragraph applies to any recipient which requires participation by any applicant, student, or employee in any education program or activity not operated wholly by such recipient, or which facilitates, permits, or considers such participation as part of or equivalent to an education program or activity operated by such recipient, including participation in educational consortia and cooperative employment and student-teaching assignments.

(2) Such recipient;

(i) Shall develop and implement a procedure designed to assure itself that the operator or sponsor of such other education program or activity takes no action affecting any applicant, student, or employee of such recipient which this part would prohibit such recipient from taking; and

(ii) Shall not facilitate, require, permit, or consider such participation if such action occurs.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24137, June 4, 1975, as amended at 70 FR 24321, May 9, 2005; 85 FR 37244, June 19, 2020]

§ 86.32 Housing.

(a) *Generally.* A recipient shall not, on the basis of sex, apply different rules or regulations, impose different fees or requirements, or offer different services or benefits related to housing, except as provided in this section (including housing provided only to married students).

(b) *Housing provided by recipient.* (1) A recipient may provide separate housing on the basis of sex.

(2) Housing provided by a recipient to students of one sex, when compared to that provided to students of the other sex, shall be as a whole:

(i) Proportionate in quantity to the number of students of that sex applying for such housing; and

(ii) Comparable in quality and cost to the student.

(c) *Other housing.* (1) A recipient shall not, on the basis of sex, administer different policies or practices concerning occupancy by its students of housing other than provided by such recipient.

(2) A recipient which, through solicitation, listing, approval of housing, or otherwise, assists any agency, organization, or person in making housing available to any of its students, shall take such reasonable action as may be necessary to assure itself that such housing as is provided to students of one sex, when compared to that provided to students of the other sex, is as a whole: (i) Proportionate in quantity and (ii) comparable in quality and cost to the student. A recipient may render such assistance to any agency, organization, or person which provides all or part of such housing to students only of one sex.

(Secs. 901, 902, 907, Education Amendments of 1972, 86 Stat. 373, 374, 375; 20 U.S.C. 1681, 1682, 1686)

§ 86.33 Comparable facilities.

A recipient may provide separate toilet, locker room, and shower facilities on the basis of sex, but such facilities provided for students of one sex shall be comparable to such facilities provided for students of the other sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374)

§ 86.34 Access to course offerings.

A recipient shall not provide any course or otherwise carry out any of its education program or activity separately on the basis of sex, or require or refuse participation therein by any of its students on such basis, including health, physical education, industrial, business, vocational, technical, home economics, music, and adult education courses.

(a) With respect to classes and activities in physical education at the elementary school level, the recipient shall comply fully with this section as expeditiously as possible but in no event later than one year from the effective date of this regulation. With respect to physical education classes and activities at the secondary and post-secondary levels, the recipient shall comply fully with this section as expeditiously as possible but in no event later than three years from the effective date of this regulation.

(b) This section does not prohibit grouping of students in physical education classes and activities by ability as assessed by objective standards of individual performance developed and applied without regard to sex.

(c) This section does not prohibit separation of students by sex within physical education classes or activities during participation in wrestling, boxing, rugby, ice hockey, football, basketball and other sports the purpose or major activity of which involves bodily contact.

(d) Where use of a single standard of measuring skill or progress in a physical education class has an adverse effect on members of one sex, the recipient shall use appropriate standards which do not have such effect.

(e) Portions of classes in elementary and secondary schools which deal exclusively with human sexuality may be conducted in separate sessions for boys and girls.

(f) Recipients may make requirements based on vocal range or quality which may result in a chorus or choruses of one or predominantly one sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

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§ 86.35 Access to schools operated by L.E.A.s.

A recipient which is a local educational agency shall not, on the basis of sex, exclude any person from admission to:

(a) Any institution of vocational education operated by such recipient; or

(b) Any other school or educational unit operated by such recipient, unless such recipient otherwise makes available to such person, pursuant to the same policies and criteria of admission, courses, services, and facilities comparable to each course, service, and facility offered in or through such schools.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.36 Counseling and use of appraisal and counseling materials.

(a) *Counseling.* A recipient shall not discriminate against any person on the basis of sex in the counseling or guidance of students or applicants for admission.

(b) *Use of appraisal and counseling materials.* A recipient which uses testing or other materials for appraising or counseling students shall not use different materials for students on the basis of their sex or use materials which permit or require different treatment of students on such basis unless such different materials cover the same occupations and interest areas and the use of such different materials is shown to be essential to eliminate sex bias. Recipients shall develop and use internal procedures for ensuring that such materials do not discriminate on the basis of sex. Where the use of a counseling test or other instrument results in a substantially disproportionate number of members of one sex in any particular course of study or classification, the recipient shall take such action as is necessary to assure itself that such disproportion is not the result of discrimination in the instrument or its application.

(c) *Disproportion in classes.* Where a recipient finds that a particular class contains a substantially disproportionate number of individuals of one sex, the recipient shall take such action as is necessary to assure itself that such disproportion is not the re-

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sult of discrimination on the basis of sex in counseling or appraisal materials or by counselors.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.37 Financial assistance.

(a) *General.* Except as provided in paragraphs (b) and (c) of this section, in providing financial assistance to any of its students, a recipient shall not: (1) On the basis of sex, provide different amount or types of such assistance, limit eligibility for such assistance which is of any particular type or source, apply different criteria, or otherwise discriminate; (2) through solicitation, listing, approval, provision of facilities or other services, assist any foundation, trust, agency, organization, or person which provides assistance to any of such recipient's students in a manner which discriminates on the basis of sex; or (3) apply any rule or assist in application of any rule concerning eligibility for such assistance which treats persons of one sex differently from persons of the other sex with regard to marital or parental status.

(b) *Financial aid established by certain legal instruments.* (1) A recipient may administer or assist in the administration of scholarships, fellowships, or other forms of financial assistance established pursuant to domestic or foreign wills, trusts, bequests, or similar legal instruments or by acts of a foreign government which requires that awards be made to members of a particular sex specified therein; *Provided,* That the overall effect of the award of such sex-restricted scholarships, fellowships, and other forms of financial assistance does not discriminate on the basis of sex.

(2) To ensure nondiscriminatory awards of assistance as required in paragraph (b)(1) of this section, recipients shall develop and use procedures under which:

(i) Students are selected for award of financial assistance on the basis of nondiscriminatory criteria and not on the basis of availability of funds restricted to members of a particular sex;

(ii) An appropriate sex-restricted scholarship, fellowship, or other form of financial assistance is allocated to

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each student selected under paragraph (b)(2)(i) of this section; and

(iii) No student is denied the award for which he or she was selected under paragraph (b)(2)(i) of this section because of the absence of a scholarship, fellowship, or other form of financial assistance designated for a member of that student's sex.

(c) *Athletic scholarships.* (1) To the extent that a recipient awards athletic scholarships or grants-in-aid, it must provide reasonable opportunities for such awards for members of each sex in proportion to the number of students of each sex participating in interscholastic or intercollegiate athletics.

(2) Separate athletic scholarships or grants-in-aid for members of each sex may be provided as part of separate athletic teams for members of each sex to the extent consistent with this paragraph and § 86.41.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682; and sec. 844, Education Amendments of 1974, Pub. L. 93-380, 88 Stat. 484)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.38 Employment assistance to students.

(a) *Assistance by recipient in making available outside employment.* A recipient which assists any agency, organization or person in making employment available to any of its students:

(1) Shall assure itself that such employment is made available without discrimination on the basis of sex; and

(2) Shall not render such services to any agency, organization, or person which discriminates on the basis of sex in its employment practices.

(b) *Employment of students by recipients.* A recipient which employs any of its students shall not do so in a manner which violates subpart E of this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.39 Health and insurance benefits and services.

In providing a medical, hospital, accident, or life insurance benefit, service, policy, or plan to any of its students, a recipient shall not discriminate on the basis of sex, or provide such benefit, service, policy, or plan in

a manner which would violate Subpart E of this part if it were provided to employees of the recipient. This section shall not prohibit a recipient from providing any benefit or service which may be used by a different proportion of students of one sex than of the other, including family planning services. However, any recipient which provides full coverage health service shall provide gynecological care.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.40 Marital or parental status.

(a) *Status generally.* A recipient shall not apply any rule concerning a student's actual or potential parental, family, or marital status which treats students differently on the basis of sex.

(b) *Pregnancy and related conditions.*

(1) A recipient shall not discriminate against any student, or exclude any student from its education program or activity, including any class or extracurricular activity, on the basis of such student's pregnancy, childbirth, false pregnancy, termination of pregnancy or recovery therefrom, unless the student requests voluntarily to participate in a separate portion of the program or activity of the recipient.

(2) A recipient may require such a student to obtain the certification of a physician that the student is physically and emotionally able to continue participation so long as such a certification is required of all students for other physical or emotional conditions requiring the attention of a physician.

(3) A recipient which operates a portion of its education program or activity separately for pregnant students, admittance to which is completely voluntary on the part of the student as provided in paragraph (b)(1) of this section shall ensure that the separate portion is comparable to that offered to non-pregnant students.

(4) A recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom in the same manner and under the same policies as any other temporary disability with respect to any medical or hospital benefit, service, plan or policy which such recipient administers, operates, offers, or participates in with respect to students

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admitted to the recipient's educational program or activity.

(5) In the case of a recipient which does not maintain a leave policy for its students, or in the case of a student who does not otherwise qualify for leave under such a policy, a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom as a justification for a leave of absence for so long a period of time as is deemed medically necessary by the student's physician, at the conclusion of which the student shall be reinstated to the status which she held when the leave began.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24137, June 4, 1975, as amended at 70 FR 24321, May 9, 2005]

§ 86.41 Athletics.

(a) *General.* No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, be treated differently from another person or otherwise be discriminated against in any interscholastic, intercollegiate, club or intramural athletics offered by a recipient, and no recipient shall provide any such athletics separately on such basis.

(b) *Separate teams.* Notwithstanding the requirements of paragraph (a) of this section, a recipient may operate or sponsor separate teams for members of each sex where selection for such teams is based upon competitive skill or the activity involved is a contact sport. However, where a recipient operates or sponsors a team in a particular sport for members of one sex but operates or sponsors no such team for members of the other sex, and athletic opportunities for members of that sex have previously been limited, members of the excluded sex must be allowed to try-out for the team offered unless the sport involved is a contact sport. For the purposes of this part, contact sports include boxing, wrestling, rugby, ice hockey, football, basketball and other sports the purpose of major activity of which involves bodily contact.

(c) *Equal opportunity.* A recipient which operates or sponsors interscholastic, intercollegiate, club or intramural athletics shall provide equal athletic opportunity for members of

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both sexes. In determining whether equal opportunities are available the Director will consider, among other factors:

(1) Whether the selection of sports and levels of competition effectively accommodate the interests and abilities of members of both sexes;

(2) The provision of equipment and supplies;

(3) Scheduling of games and practice time;

(4) Travel and per diem allowance;

(5) Opportunity to receive coaching and academic tutoring;

(6) Assignment and compensation of coaches and tutors;

(7) Provision of locker rooms, practice and competitive facilities;

(8) Provision of medical and training facilities and services;

(9) Provision of housing and dining facilities and services;

(10) Publicity.

Unequal aggregate expenditures for members of each sex or unequal expenditures for male and female teams if a recipient operates or sponsors separate teams will not constitute non-compliance with this section, but the Director may consider the failure to provide necessary funds for teams for one sex in assessing equality of opportunity for members of each sex.

(d) *Adjustment period.* A recipient which operates or sponsors interscholastic, intercollegiate, club or intramural athletics at the elementary school level shall comply fully with this section as expeditiously as possible but in no event later than one year from the effective date of this regulation. A recipient which operates or sponsors interscholastic, intercollegiate, club or intramural athletics at the secondary or post-secondary school level shall comply fully with this section as expeditiously as possible but in no event later than three years from the effective date of this regulation.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682; and sec. 844, Education Amendments of 1974, Pub. L. 93-380, 88 Stat. 484)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

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§ 86.42 Textbooks and curricular material.

Nothing in this regulation shall be interpreted as requiring or prohibiting or abridging in any way the use of particular textbooks or curricular materials.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§§ 86.43–86.50 [Reserved]

Subpart E—Discrimination on the Basis of Sex in Employment in Education Programs or Activities Prohibited

§ 86.51 Employment.

(a) *General.* (1) No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination in employment, or recruitment, consideration, or selection therefor, whether full-time or part-time, under any education program or activity operated by a recipient which receives Federal financial assistance.

(2) A recipient shall make all employment decisions in any education program or activity operated by such recipient in a nondiscriminatory manner and shall not limit, segregate, or classify applicants or employees in any way which could adversely affect any applicant's or employee's employment opportunities or status because of sex.

(3) A recipient shall not enter into any contractual or other relationship which directly or indirectly has the effect of subjecting employees or students to discrimination prohibited by this subpart, including relationships with employment and referral agencies, with labor unions, and with organizations providing or administering fringe benefits to employees of the recipient.

(4) A recipient shall not grant preferences to applicants for employment on the basis of attendance at any educational institution or entity which admits as students only or predominantly members of one sex, if the giving of such preferences has the effect of discriminating on the basis of sex in violation of this part.

(b) *Application.* The provisions of this subpart apply to:

(1) Recruitment, advertising, and the process of application for employment;

(2) Hiring, upgrading, promotion, consideration for and award of tenure, demotion, transfer, layoff, termination, application of nepotism policies, right of return from layoff, and rehiring;

(3) Rates of pay or any other form of compensation, and changes in compensation;

(4) Job assignments, classifications and structure, including position descriptions, lines of progression, and seniority lists;

(5) The terms of any collective bargaining agreement;

(6) Granting and return from leaves of absence, leave for pregnancy, childbirth, false pregnancy, termination of pregnancy, leave for persons of either sex to care for children or dependents, or any other leave;

(7) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(8) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, selection for tuition assistance, selection for sabbaticals and leaves of absence to pursue training;

(9) Employer-sponsored activities, including those that are social or recreational; and

(10) Any other term, condition, or privilege of employment.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24137, June 4, 1975, as amended at 70 FR 24321, May 9, 2005]

§ 86.52 Employment criteria.

A recipient shall not administer or operate any test or other criterion for any employment opportunity which has a disproportionately adverse effect on persons on the basis of sex unless:

(a) Use of such test or other criterion is shown to predict validly successful performance in the position in question; and

(b) Alternative tests or criteria for such purpose, which do not have such

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disproportionately adverse effect, are shown to be unavailable.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.53 Recruitment.

(a) *Nondiscriminatory recruitment and hiring.* A recipient shall not discriminate on the basis of sex in the recruitment and hiring of employees. Where a recipient has been found to be presently discriminating on the basis of sex in the recruitment or hiring of employees, or has been found to have in the past so discriminated, the recipient shall recruit members of the sex so discriminated against so as to overcome the effects of such past or present discrimination.

(b) *Recruitment patterns.* A recipient shall not recruit primarily or exclusively at entities which furnish as applicants only or predominantly members of one sex if such actions have the effect of discriminating on the basis of sex in violation of this subpart.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.54 Compensation.

A recipient shall not make or enforce any policy or practice which, on the basis of sex:

(a) Makes distinctions in rates of pay or other compensation;

(b) Results in the payment of wages to employees of one sex at a rate less than that paid to employees of the opposite sex for equal work on jobs the performance of which requires equal skill, effort, and responsibility, and which are performed under similar working conditions.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.55 Job classification and structure.

A recipient shall not:

(a) Classify a job as being for males or for females;

(b) Maintain or establish separate lines of progression, seniority lists, career ladders, or tenure systems based on sex; or

(c) Maintain or establish separate lines of progression, seniority systems, career ladders, or tenure systems for

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similar jobs, position descriptions, or job requirements which classify persons on the basis of sex, unless sex is a bona-fide occupational qualification for the positions in question as set forth in § 86.61.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

[40 FR 24128, June 4, 1975; 40 FR 39506, Aug. 28, 1975]

§ 86.56 Fringe benefits.

(a) *Fringe benefits* defined. For purposes of this part, *fringe benefits* means: Any medical, hospital, accident, life insurance or retirement benefit, service, policy or plan, any profit-sharing or bonus plan, leave, and any other benefit or service of employment not subject to the provision of § 86.54.

(b) *Prohibitions.* A recipient shall not:

(1) Discriminate on the basis of sex with regard to making fringe benefits available to employees or make fringe benefits available to spouses, families, or dependents of employees differently upon the basis of the employee's sex;

(2) Administer, operate, offer, or participate in a fringe benefit plan which does not provide either for equal periodic benefits for members of each sex, or for equal contributions to the plan by such recipient for members of each sex; or

(3) Administer, operate, offer, or participate in a pension or retirement plan which establishes different optional or compulsory retirement ages based on sex or which otherwise discriminates in benefits on the basis of sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.57 Marital or parental status.

(a) *General.* A recipient shall not apply any policy or take any employment action:

(1) Concerning the potential marital, parental, or family status of an employee or applicant for employment which treats persons differently on the basis of sex; or

(2) Which is based upon whether an employee or applicant for employment is the head of household or principal wage earner in such employee's or applicant's family unit.

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(b) *Pregnancy.* A recipient shall not discriminate against or exclude from employment any employee or applicant for employment on the basis of pregnancy, childbirth, false pregnancy, termination of pregnancy, or recovery therefrom.

(c) *Pregnancy as a temporary disability.* A recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy, and recovery therefrom and any temporary disability resulting therefrom as any other temporary disability for all job related purposes, including commencement, duration and extensions of leave, payment of disability income, accrual of seniority and any other benefit or service, and reinstatement, and under any fringe benefit offered to employees by virtue of employment.

(d) *Pregnancy leave.* In the case of a recipient which does not maintain a leave policy for its employees, or in the case of an employee with insufficient leave or accrued employment time to qualify for leave under such a policy, a recipient shall treat pregnancy, childbirth, false pregnancy, termination of pregnancy and recovery therefrom as a justification for a leave of absence without pay for a reasonable period of time, at the conclusion of which the employee shall be reinstated to the status which she held when the leave began or to a comparable position, without decrease in rate of compensation or loss of promotional opportunities, or any other right or privilege of employment.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.58 Effect of State or local law or other requirements.

(a) *Prohibitory requirements.* The obligation to comply with this subpart is not obviated or alleviated by the existence of any State or local law or other requirement which imposes prohibitions or limits upon employment of members of one sex which are not imposed upon members of the other sex.

(b) *Benefits.* A recipient which provides any compensation, service, or benefit to members of one sex pursuant to a State or local law or other requirement shall provide the same compensa-

tion, service, or benefit to members of the other sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.59 Advertising.

A recipient shall not in any advertising related to employment indicate preference, limitation, specification, or discrimination based on sex unless sex is a *bona-fide* occupational qualification for the particular job in question.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.60 Pre-employment inquiries.

(a) *Marital status.* A recipient shall not make pre-employment inquiry as to the marital status of an applicant for employment, including whether such applicant is "Miss or Mrs."

(b) *Sex.* A recipient may make pre-employment inquiry as to the sex of an applicant for employment, but only if such inquiry is made equally of such applicants of both sexes and if the results of such inquiry are not used in connection with discrimination prohibited by this part.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§ 86.61 Sex as a bona-fide occupational qualification.

A recipient may take action otherwise prohibited by this subpart provided it is shown that sex is a bona-fide occupational qualification for that action, such that consideration of sex with regard to such action is essential to successful operation of the employment function concerned. A recipient shall not take action pursuant to this section which is based upon alleged comparative employment characteristics or stereotyped characterizations of one or the other sex, or upon preference based on sex of the recipient, employees, students, or other persons, but nothing contained in this section shall prevent a recipient from considering an employee's sex in relation to employment in a locker room or toilet facility used only by members of one sex.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

§§ 86.62–86.70

§§ 86.62–86.70 [Reserved]

Subpart F—Procedures [Interim]

§ 86.71 Enforcement procedures.

For the purposes of implementing this part, the procedural provisions applicable to Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) are hereby adopted and incorporated herein by reference. These procedures may be found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

[85 FR 37244, June 19, 2020]

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NOTE: For the text of these guidelines, see
45 CFR part 80, appendix B.

[44 FR 17168, Mar. 21, 1979]

**PART 87—EQUAL TREATMENT FOR
FAITH-BASED ORGANIZATIONS**

Sec.

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APPENDIX C TO PART 87—NOTICE OF AWARD OR
CONTRACT

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 2000bb *et*
seq.

SOURCE: 81 FR 19426, Apr. 4, 2016, unless
otherwise noted.

§ 87.1 Definitions.

The following definitions apply for
the purposes of this part.

(a) *Direct Federal financial assistance*,
Federal financial assistance provided di-
rectly, or *direct funding* means financial
assistance received by an entity se-
lected by the Government or a pass-
through entity (as defined in this part)
to carry out a service (e.g., by con-
tract, grant, or cooperative agree-
ment). References to Federal financial
assistance will be deemed to be re-
ferences to direct Federal financial as-
sistance, unless the referenced assist-
ance meets the definition of indirect
Federal financial assistance or Federal
financial assistance provided indi-
rectly.

(b) *Directly funded* means funded by
means of direct Federal financial as-
sistance.

(c) *Indirect Federal financial assistance*
or *Federal financial assistance provided*
indirectly means Federal financial as-

sistance received by a service provider
when the service provider is paid for
services rendered by means of a vouch-
er, certificate, or other means of Gov-
ernment-funded payment provided to a
beneficiary who is able to make a
choice of a service provider, and:

(1) The Government program through
which the beneficiary receives the
voucher, certificate, or other similar
means of Government-funded payment
is neutral toward religion; and

(2) The service provider receives the
assistance wholly as a result of a gen-
uine and independent private choice of
the beneficiary, not a choice of the
Government. The availability of ade-
quate secular alternatives is a signifi-
cant factor in determining whether a
program affords true private choice.

(d) *Federal financial assistance* means
assistance that non-Federal entities re-
ceive or administer in the form of
grants, contracts, loans, loan guaran-
tees, property, cooperative agreements,
food commodities, direct appropri-
ations, or other assistance, but does not
include a tax credit, deduction, or ex-
emption. Federal financial assistance
may be direct or indirect.

(e) *Pass-through entity* means an enti-
ty, including a nonprofit or nongovern-
mental organization, acting under a
contract, grant, or other agreement
with the Federal Government or with a
State or local government, such as a
State administering agency, that ac-
cepts direct Federal financial assist-
ance as a primary recipient or grantee
and distributes that assistance to other
organizations that, in turn, provide
government funded social services.

(f) *Recipient* means a non-Federal en-
tity that receives a Federal award di-
rectly from a Federal awarding agency
to carry out an activity under a Fed-
eral program. The term recipient does
not include subrecipients, but does in-
clude pass-through entities.

(g) *Religious exercise* has the meaning
given to the term in 42 U.S.C. 2000cc-
5(7)(A).

[85 FR 82145, Dec. 17, 2020, as amended at 89
FR 15721, Mar. 4, 2024]

§ 87.2 Applicability.

This part applies to grants awarded in HHS social service programs governed by either the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at 2 CFR parts 200 and 300 or Block Grant regulations at 45 CFR part 96, except as provided in paragraphs (a) and (b) of this section.

(a) *Discretionary grants.* This part is not applicable to the discretionary grant programs that are governed by the Substance Abuse and Mental Health Services Administration (SAMHSA) Charitable Choice regulations found at 42 CFR part 54a. This part is also not applicable to discretionary grant programs that are governed by the Community Services Block Grant (CSBG) Charitable Choice regulations at 45 CFR part 1050, with the exception of §§ 87.1 and 87.3(k) through (m) and (o), which do apply to such CSBG discretionary grants. Discretionary grants authorized by the Child Care and Development Block Grant Act are also not governed by this part.

(b) *Formula and block grants.* This part does not apply to non-discretionary and block grant programs governed by the SAMHSA Charitable Choice regulations found at 42 CFR part 54, or the Temporary Assistance for Needy Families (TANF) Charitable Choice regulations at 45 CFR part 260. Block grants governed by the CSBG Charitable Choice regulations at 45 CFR part 1050 are not subject to this part, with the exception of §§ 87.1 and 87.3(k) through (m) and (o), which do apply to such CSBG block grants. This part is not applicable to Child Care and Development Block Grants governed by 45 CFR part 98.

[81 FR 19426, Apr. 4, 2016, as amended at 89 FR 15721, Mar. 4, 2024; 89 FR 80070, Oct. 2, 2024]

§ 87.3 Faith-based organizations and Federal financial assistance.

(a) Faith-based organizations are eligible, on the same basis as any other organization, to participate in any HHS awarding agency program or service for which they are otherwise eligible. Neither the HHS awarding agency nor any State or local government or other pass-through entity receiving

funds under any HHS awarding agency program or service shall, in the selection of service providers, discriminate for or against an organization on the basis of the organization's religious character, motives, or affiliation, or lack thereof, or on the basis of conduct that would not be considered grounds to favor or disfavor a similarly situated secular organization.

(b) Nothing in this part shall be construed to preclude HHS from making an accommodation, including for religious exercise, with respect to one or more program requirements on a case-by-case basis in accordance with the Constitution and laws of the United States.

(c) HHS shall not disqualify an organization from participating in any HHS program for which it is eligible on the basis of the organization's indication that it may request an accommodation with respect to one or more program requirements, unless the organization has made clear that the accommodation is necessary to its participation and HHS has determined that it would deny the accommodation.

(d) Organizations that receive direct financial assistance from an HHS awarding agency may not engage in any explicitly religious activities (including activities that involve overt religious content such as worship, religious instruction, or proselytization) as part of the programs or services funded with direct financial assistance from the HHS awarding agency, or in any other manner prohibited by law. If an organization conducts such activities, the activities must be offered separately, in time or location, from the programs or services funded with direct financial assistance from the HHS awarding agency, and participation must be voluntary for beneficiaries of the programs or services funded with such assistance. The use of indirect Federal financial assistance is not subject to this restriction. Nothing in this part restricts HHS's authority under applicable Federal law to fund activities, such as the provision of chaplaincy services, that can be directly funded by the Government consistent with the Establishment Clause.

(e) A faith-based organization that participates in HHS awarding-agency

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funded programs or services will retain its autonomy; right of expression; religious character; and independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, development, practice, and expression of its religious beliefs. A faith-based organization may use space in its facilities to provide programs or services funded with financial assistance from the HHS awarding agency without concealing, removing, or altering religious art, icons, scriptures, or other religious symbols. Such a faith-based organization retains its authority over its internal governance, and it may retain religious terms in its name, select its board members on the basis of their acceptance of or adherence to the religious tenets of the organization, and include religious references in its mission statements and other governing documents. In addition, a faith-based organization that receives financial assistance from the HHS awarding agency does not lose the protections of law.

(f) An organization, whether faith-based or not, that receives Federal financial assistance from HHS shall not, in providing services supported in whole or in part with Federal financial assistance, or in their outreach activities related to such services, discriminate against a program beneficiary or prospective program beneficiary on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to attend or participate in a religious practice. However, a faith-based organization receiving indirect Federal financial assistance need not modify any religious components or integration with respect to its program activities to accommodate a beneficiary who chooses to expend the indirect aid on the organization's program.

(g) No grant document, agreement, covenant, memorandum of understanding, policy, or regulation used by an HHS awarding agency or a State or local government in administering Federal financial assistance from the HHS awarding agency shall require faith-based organizations to provide assurances or notices where they are not required of non-faith-based organizations. Any restrictions on the use of grant funds shall apply equally to

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faith-based and non-faith-based organizations. All organizations, whether faith-based or not, that participate in HHS awarding agency programs or services must carry out eligible activities in accordance with all program requirements, including those prohibiting the use of direct Federal financial assistance to engage in explicitly religious activities, subject to any accommodations that HHS grants to organizations on a case-by-case basis in accordance with the Constitution and laws of the United States. No grant document, agreement, covenant, memorandum of understanding, policy, or regulation used by an HHS awarding agency or a State or local government in administering Federal financial assistance from the HHS awarding agency shall disqualify faith-based organizations from participating in the HHS awarding agency's programs or services on the basis of the organization's religious character, motives, or affiliation, or lack thereof, or on the basis of conduct that would not be considered grounds to disqualify a similarly situated secular organization.

(h) A faith-based organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in the Civil Rights Act of 1964, 42 U.S.C. 2000e–1, is not forfeited when the faith-based organization receives direct or indirect Federal financial assistance from an HHS awarding agency. Some HHS awarding agency programs, however, contain independent statutory provisions requiring that all grantees agree not to discriminate in employment on the basis of religion. In this case, grantees should consult with the appropriate HHS awarding agency program office to determine the scope of any applicable requirements.

(i) In general, the HHS awarding agency does not require that a recipient, including a faith-based organization, obtain tax-exempt status under section 501(c)(3) of the Internal Revenue Code to be eligible for funding under HHS awarding agency programs. Many grant programs, however, do require an organization to be a nonprofit organization in order to be eligible for funding. Funding announcements and other grant application solicitations

that require organizations to have nonprofit status will specifically so indicate in the eligibility section of the solicitation. In addition, any solicitation that requires an organization to maintain tax-exempt status will expressly state the statutory authority for requiring such status. Recipients should consult with the appropriate HHS awarding agency program office to determine the scope of any applicable requirements. In HHS awarding agency programs in which an applicant must show that it is a nonprofit organization, the applicant may do so by any of the following means:

(1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code;

(2) A statement from a State or other governmental taxing body or the State secretary of State certifying that:

(i) The organization is a nonprofit organization operating within the State; and

(ii) No part of its net earnings may benefit any private shareholder or individual;

(3) A certified copy of the applicant's certificate of incorporation or similar document that clearly establishes the nonprofit status of the applicant; or

(4) Any item described in paragraphs (i)(1) through (3) of this section, if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

(j) If a recipient contributes its own funds in excess of those funds required by a matching or grant agreement to supplement HHS awarding agency-supported activities, the recipient has the option to segregate those additional funds or commingle them with the Federal award funds. If the funds are commingled, the provisions of this part shall apply to all of the commingled funds in the same manner, and to the same extent, as the provisions apply to the Federal funds. With respect to the matching funds, the provisions of this part apply irrespective of whether such funds are commingled with Federal funds or segregated.

(k) An organization providing social services under a discretionary grant program of HHS that is supported by Federal financial assistance must give written notice to beneficiaries and prospective beneficiaries of certain protections. A pass-through entity administering social service programs under a mandatory formula, block or entitlement grant of HHS that is supported by Federal financial assistance shall ensure that beneficiaries and prospective beneficiaries receive written notice of certain protections.

(1) The written notice to beneficiaries and prospective beneficiaries of directly funded social services shall include language substantially similar to that found in appendix A to this part. The notice must include the following information:

(i) The organization may not discriminate against a beneficiary or prospective beneficiary on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to attend or participate in a religious practice;

(ii) The organization may not require a beneficiary or prospective beneficiary to attend or participate in any explicitly religious activities that are offered by the organization, and any participation by a beneficiary in such activities must be purely voluntary;

(iii) The organization must separate in time or location any privately funded explicitly religious activities from activities supported by direct Federal financial assistance; and

(iv) A beneficiary or prospective beneficiary may report an organization's violation of these protections, including any denials of services or benefits by an organization, by contacting or filing a written complaint with either the HHS awarding entity or the pass-through entity that awarded funds to the organization, which must promptly report the complaint to the HHS awarding entity. The HHS awarding entity will address the complaint in consultation with the HHS Office for Civil Rights.

(2) The written notice to beneficiaries of indirectly funded social services must identify the protections in paragraphs (f) and (k)(1)(ii) and (iv) of this section; it must also provide the

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contact information of the HHS awarding entity or the pass-through entity that administers the program.

(l) The written notice described in paragraph (k) of this section must be given to a prospective beneficiary prior to the time the prospective beneficiary enrolls in the program or receives services from the program. When the nature of the service provided or exigent circumstances make it impracticable to provide such written notice in advance of the actual service, an organization must advise beneficiaries of their protections and provide the notice at the earliest available opportunity.

(m) The written notice described in paragraph (k) of this section must be given in a manner prescribed by the HHS awarding agency in consultation with the HHS Office for Civil Rights, such as by incorporating the notice into materials that are otherwise provided to beneficiaries. The HHS awarding agency, in consultation with the HHS Office for Civil Rights, may determine that the notice must inform each beneficiary or prospective beneficiary of the option to seek information from the HHS awarding agency, or another entity administering the applicable program, about other federally funded organizations in their area, if any, that provide the services available under the applicable program.

(n) Notices or announcements of award opportunities and notices of award or contracts shall include language substantially similar to that in appendices B and C to this part.

(o) Decisions about awards of direct Federal financial assistance must be made on the basis of merit, not on the basis of the religious affiliation, or lack thereof, of a recipient organization, and must be free from political interference or even the appearance of such interference.

(p) Neither the HHS awarding agency nor any State or local government or other pass-through entity receiving funds under any HHS awarding agency program or service shall construe these provisions in such a way as to advantage or disadvantage faith-based organizations affiliated with historic or well-established religions or sects in

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comparison with other religions or sects.

(q) If a pass-through entity, acting under a contract, grant, or other agreement with the Federal Government or with a State or local government that is administering a program supported by Federal financial assistance, is given the authority under the contract, grant, or agreement to select non-governmental organizations to provide services funded by the Federal Government, the pass-through entity must ensure compliance with the provisions of this part and any implementing regulations or guidance by the sub-recipient. If the pass-through entity is a non-governmental organization, it retains all other rights of a non-governmental organization under the program's statutory and regulatory provisions.

[85 FR 82146, Dec. 17, 2020, as amended at 89 FR 15721, Mar. 4, 2024]

§ 87.4 Severability.

To the extent that any provision of this part is declared invalid by a court of competent jurisdiction, the Department intends for all other provisions that are capable of operating in the absence of the specific provision that has been invalidated to remain in effect.

[89 FR 15723, Mar. 4, 2024]

APPENDIX A TO PART 87—DIRECT AID PROGRAMS: WRITTEN NOTICE OF BENEFICIARY PROTECTIONS

Name of Organization:

Name of Program:

Contact Information for Program Staff:
[provide name, phone number, and email address, if appropriate]

Because this program is supported in whole or in part by financial assistance from the Federal Government, we are required to let you know that—

(1) We may not discriminate against you on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to attend or participate in a religious practice;

(2) We may not require you to attend or participate in any explicitly religious activities (including activities that involve overt religious content such as worship, religious instruction or proselytization) that may be offered by our organization, and any participation by you in such activities must be purely voluntary;

(3) We must separate in time or location any privately funded explicitly religious activities (including activities that involve overt religious content such as worship, religious instruction or proselytization) from activities supported with direct Federal financial assistance;

(4) You may report violations of these protections, including any denials of services or benefits by an organization, by contacting or filing a written complaint with [identify the HHS awarding entity, or the pass-through entity that awarded funds to your organization, and the phone number and physical street and/or email address of the identified office]. The HHS awarding entity will address the complaint in consultation with the HHS Office for Civil Rights;

[When required by the HHS awarding agency, the notice must also state:] (5) If you would like to seek information about whether there are any other federally funded organizations that provide these kinds of services in your area, please use the contact information set forth above.

We must give you this notice before you enroll in or receive services from the program, unless the nature of the service provided or exigent circumstances make advanced notice impracticable. In that case, this notice must be given to you at the earliest available opportunity.

[89 FR 15723, Mar. 4, 2024]

APPENDIX B TO PART 87—NOTICE OR ANNOUNCEMENT OF AWARD OPPORTUNITIES

(a) Faith-based organizations may apply for this award on the same basis as any other organization, as set forth at, and subject to the protections and requirements of, this part and any applicable constitutional and statutory requirements, including 42 U.S.C. 2000bb *et seq.* HHS will not, in the selection of recipients, discriminate for or against an organization on the basis of the organization's religious character, motives, or affiliation, or lack thereof, or on the basis of conduct that would not be considered grounds to favor or disfavor a similarly situated secular organization.

(b) A faith-based organization that participates in this program will retain its independence from the Government and may continue to carry out its mission consistent with religious freedom, nondiscrimination, and conscience protections in Federal law.

(c) A faith-based organization may not use direct Federal financial assistance from HHS to support or engage in any explicitly religious activities (including activities that involve overt religious content such as worship, religious instruction, or proselytization) except when consistent with the Establishment Clause of the First Amendment and

any other applicable requirements. Such an organization also may not, in providing services funded by HHS, or in their outreach activities related to such services, discriminate against a program beneficiary or prospective program beneficiary on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.

[89 FR 15723, Mar. 4, 2024]

APPENDIX C TO PART 87—NOTICE OF AWARD OR CONTRACT

(a) A faith-based organization that participates in this program retains its independence from the Government and may continue to carry out its mission consistent with religious freedom, nondiscrimination, and conscience protections in Federal law.

(b) A faith-based organization may not use direct Federal financial assistance from HHS to support or engage in any explicitly religious activities (including activities that involve overt religious content such as worship, religious instruction, or proselytization) except when consistent with the Establishment Clause of the First Amendment and any other applicable requirements. Such an organization also may not, in providing services funded by the Department, or in their outreach activities related to such services, discriminate against a program beneficiary or prospective program beneficiary on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to attend or participate in a religious practice.

[89 FR 15723, Mar. 4, 2024]

PART 88—ENSURING THAT DEPARTMENT OF HEALTH AND HUMAN SERVICES FUNDS DO NOT SUPPORT COERCIVE OR DISCRIMINATORY POLICIES OR PRACTICES IN VIOLATION OF FEDERAL LAW

Sec.

88.1 Purpose.

88.2 Complaint handling and investigating.

88.3 Notice of Federal conscience and nondiscrimination laws.

88.4 Severability.

APPENDIX A TO PART 88—MODEL TEXT: NOTICE OF RIGHTS UNDER FEDERAL CONSCIENCE AND NONDISCRIMINATION LAWS

AUTHORITY: 5 U.S.C. 301.

SOURCE: 89 FR 2107, Jan. 11, 2024, unless otherwise noted.

§ 88.1 Purpose.

The purpose of this part is to provide for the enforcement of the Church Amendments, 42 U.S.C. 300a–7; the Coats-Snowe Amendment, section 245 of the Public Health Service Act, 42 U.S.C. 238n; the Weldon Amendment, e.g., Consolidated Appropriations Act, 2023, Public Law 117–328, div. H, title V General Provisions, section 507(d)(1) (Dec. 29, 2022); Sections 1303(b)(1)(A), (b)(4), and (c)(2)(A), and 1411(b)(5)(A), and 1553 of the ACA, 42 U.S.C. 18023(b)(1)(A), (b)(4), and (c)(2)(A), 18081(b)(5)(A), and 18113; certain Medicare and Medicaid provisions, 42 U.S.C. 1320a–1(h), 1320c–11, 1395i–5, 1395w–22(j)(3)(B), 1395x(e), 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u–2(b)(3)(B), 1397j–1(b), and 14406; the Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f), *accord*, e.g., Consolidated Appropriations Act, 2023, Public Law 117–328, div. K, title VII, section 7018 (Dec. 29, 2022); 22 U.S.C. 7631(d); 42 U.S.C. 280g–1(d), 290bb–36(f), 1396f, 1396s(c)(2)(B)(ii); 5106i(a)); and 29 U.S.C. 669(a)(5), referred to collectively as the “Federal health care conscience protection statutes.”

§ 88.2 Complaint handling and investigating.

(a) *Delegated authority.* The Office for Civil Rights (OCR) has been delegated the authority to facilitate and coordinate the Department’s enforcement of the Federal health care conscience protection statutes, which includes the authority to:

- (1) Receive and handle complaints;
- (2) Initiate compliance reviews;
- (3) Conduct investigations;
- (4) Consult on compliance within the Department;
- (5) Seek voluntary resolutions of complaints;
- (6) Consult and coordinate with the relevant Departmental funding component, and utilize existing enforcement regulations, such as those that apply to grants, contracts, or other programs and services;
- (7) In coordination with the relevant component or components of the Department, coordinate other appropriate remedial action as the Department deems necessary and as allowed by law and applicable regulation; and

(8) In coordination with the relevant component or components of the Department, make enforcement referrals to the Department of Justice.

(b) *Complaints.* Any entity or individual may file a complaint with OCR alleging a potential violation of Federal health care conscience protection statutes. OCR shall coordinate handling of complaints with the relevant Department component(s). The complaint filer is not required to be the entity whose rights under the Federal health care conscience protection statutes have been potentially violated.

(c) *Compliance reviews.* OCR may conduct compliance reviews of an entity subject to the Federal health care conscience protection statutes, where authorized for the funding at issue, to determine whether they are complying with Federal health care conscience protection statutes. OCR may initiate a compliance review of an entity subject to the Federal health care conscience protection statutes based on information from a complaint or other source that causes OCR to suspect non-compliance by such entity with the Federal health care conscience protection statutes.

(d) *Investigations.* OCR shall make a prompt investigation of a complaint alleging failure to comply with the Federal health care conscience protection statutes. This investigation may include a review of the pertinent practices, policies, communications, documents, compliance history, circumstances under which the possible noncompliance occurred, and other factors relevant to determining whether the Department, Department components, recipient, or sub-recipient has failed to comply. OCR may use fact-finding methods including site visits; interviews with the complainants, Department components, recipients, sub-recipients, or third parties; and written data requests. OCR may seek the assistance of any State agency.

(e) *Failure to respond.* OCR will adopt a negative inference if, absent good cause, an entity that is subject to the Federal health care conscience protection statutes fails to respond to a request for information or to a data or document request within a reasonable timeframe.

(f) *Supervision and coordination.* If, as a result of an investigation, OCR makes a determination of noncompliance with responsibilities under the Federal health care conscience protection statutes, OCR will coordinate and consult with the Departmental component responsible for the relevant funding to undertake appropriate action with the component to assure compliance.

(g) *Resolution of matters.* (1) If an investigation reveals that no action is warranted, OCR will in writing so inform any party who has been notified by OCR of the existence of the investigation.

(2) If an investigation indicates a failure to comply with the Federal health care conscience protection statutes, OCR will so inform the relevant parties and the matter will be resolved by informal means whenever possible.

(3) If a matter cannot be resolved by informal means, OCR will coordinate with the relevant Departmental component to:

(i) Utilize existing enforcement regulations, such as those that apply to grants, contracts, or other programs and services, or

(ii) Withhold relevant funding to the extent authorized under the statutes listed under § 88.1.

(4) If a matter cannot be resolved by informal means, OCR may, in coordination with the Office of the General Counsel, refer the matter to the Department of Justice to the extent permitted by law for proceedings to enforce the statutes listed under § 88.1.

§ 88.3 Notice of Federal conscience and nondiscrimination laws.

(a) *In general.* OCR considers the posting of a notice consistent with this part as a best practice towards achieving compliance with and educating the public about the Federal health care conscience protection statutes, and encourages all entities subject to the Federal health care conscience protection statutes to post the model notice provided in appendix A to this part. OCR will consider posting a notice as a factor in any investigation or compliance review under this rule.

(b) *Placement of the notice text.* The model notice in appendix A to this part

should be posted in the following places, where relevant:

(1) On the Department or recipient's website(s);

(2) In a prominent and conspicuous physical location in the Department's or covered entity's establishments where notices to the public and notices to its workforce are customarily posted to permit ready observation;

(3) In a personnel manual, handbook, orientation materials, trainings, or other substantially similar document likely to be reviewed by members of the covered entity's workforce;

(4) In employment applications to the Department or covered entity, or in applications for participation in a service, benefit, or other program, including for training or study; and

(5) In any student handbook, orientation materials, or other substantially similar document for students participating in a program of training or study, including for postgraduate interns, residents, and fellows.

(c) *Format of the notice.* The text of the notice should be large and conspicuous enough to be read easily and be presented in a format, location, and manner that impedes or prevents the notice being altered, defaced, removed, or covered by other material.

(d) *Content of the notice text.* A recipient or the Department should consider using the model text provided in appendix A to this part for the notice but may tailor its notice to address its particular circumstances and to more specifically address the Federal health care conscience protection statutes covered by this rule that apply to it. Where possible, and where the recipient does not have a conscience-based objection to doing so, the notice should include information about alternative providers that may offer patients services the recipient does not provide for reasons of conscience.

(e) *Combined nondiscrimination notices.* The Department and each recipient may post the notice text provided in appendix A of this part, or a notice it drafts itself, along with the content of other notices (such as other nondiscrimination notices).

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§ 88.4 Severability.

Any provision of this part held to be invalid or unenforceable either by its terms or as applied to any entity or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part, which shall remain in full force and effect to the maximum extent permitted by law. A severed provision shall not affect the remainder of this part or the application of the provision to other persons or entities not similarly situated or to other, dissimilar circumstances.

APPENDIX A TO PART 88—MODEL TEXT: NOTICE OF RIGHTS UNDER FEDERAL CONSCIENCE AND NONDISCRIMINATION LAWS

[Name of entity] complies with applicable Federal health care conscience protection statutes, including the Church Amendments, 42 U.S.C. 300a-7; the Coats-Snowe Amendment, section 245 of the Public Health Service Act, 42 U.S.C. 238n; the Weldon Amendment, e.g., Consolidated Appropriations Act, 2023, Public Law 117-328, div. H, title V General Provisions, section 507(d)(1) (Dec. 29, 2022); Sections 1303(b)(1)(A), (b)(4), and (c)(2)(A), and 1411(b)(5)(A), and 1553 of the ACA, 42 U.S.C. 18023(b)(1)(A), (b)(4), and (c)(2)(A), 18081(b)(5)(A), and 18113; certain Medicare and Medicaid provisions, 42 U.S.C. 1320a-1(h), 1320c-11, 1395i-5, 1395w-22(j)(3)(B), 1395x(e), 1395x(y)(1), 1395cc(f), 1396a(a), 1396a(w)(3), 1396u-2(b)(3)(B), 1397j-1(b), and 14406; the Helms, Biden, 1978, and 1985 Amendments, 22 U.S.C. 2151b(f), *accord*, e.g., Consolidated Appropriations Act, 2023, Public Law 117-328, div. K, title VII, section 7018 (Dec. 29, 2022); 22 U.S.C. 7631(d); 42 U.S.C. 280g-1(d), 290bb-36(f), 1396f, 1396s(c)(2)(B)(ii); 5106i(a)); and 29 U.S.C. 669(a)(5). More information to help entities determine which statutes are applicable to them is available at <https://www.hhs.gov/conscience/conscience-protections/index.html>. You may have rights as a provider, patient, or other individual under these Federal statutes, which prohibit coercion or other discrimination on the basis of conscience, whether based on religious beliefs or moral convictions, in certain circumstances. If you believe that [Name of entity] has violated any of these provisions, you may file a complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at [## 45 CFR Subtitle A \(10-1-25 Edition\)](https://www.hhs.gov/ocr/com-</p></div><div data-bbox=)

[plaints/index.html](https://www.hhs.gov/ocr/complaints/index.html) or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW, Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD) or by email at ocrmail@hhs.gov. Complaint forms and more information about Federal conscience protection laws are available at <https://www.hhs.gov/conscience>.

PART 89—ORGANIZATIONAL INTEGRITY OF ENTITIES IMPLEMENTING PROGRAMS AND ACTIVITIES UNDER THE LEADERSHIP ACT

Sec.

89.1 Applicability and requirements.

89.2 Definitions.

89.3 Organizational integrity of recipients.

AUTHORITY: Section 301(f) of the Leadership Act, Pub. L. 108-25, as amended (22 U.S.C. 7631(f)) and 5 U.S.C. 301.

SOURCE: 75 FR 18763, Apr. 13, 2010, unless otherwise noted.

§ 89.1 Applicability and requirements.

(a) This regulation applies to all recipients unless they are exempted from the policy requirement by the Leadership Act or other statute.

(b) The Department of Health and Human Services (HHS) components shall include in the public announcement of the availability of the grant, cooperative agreement, contract, or other funding instrument involving Leadership Act HIV/AIDS funds the requirement that recipients agree that they are opposed to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men, and children. This requirement shall also be included in the award documents for any grant, cooperative agreement or other funding instrument involving Leadership Act HIV/AIDS funds entered into with the recipient.

§ 89.2 Definitions.

For the purposes of this part:

Commercial sex act means any sex act on account of which anything of value is given to or received by any person.

Leadership Act means the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003,

Public Law 108–25, as amended (22 U.S.C. 7601–7682).

Prostitution means procuring or providing any commercial sex act.

Recipients are contractors, grantees, applicants or awardees who receive Leadership Act funds for HIV/AIDS programs directly or indirectly from HHS.

Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.

§ 89.3 Organizational integrity of recipients.

A recipient must have objective integrity and independence from any affiliated organization that engages in activities inconsistent with the recipient's opposition to the practices of prostitution and sex trafficking because of the psychological and physical risks they pose for women, men and children ("restricted activities"). A recipient will be found to have objective integrity and independence from such an organization if:

(a) The affiliated organization receives no transfer of Leadership Act HIV/AIDS funds, and Leadership Act HIV/AIDS funds do not subsidize restricted activities; and

(b) The recipient is, to the extent practicable in the circumstances, separate from the affiliated organization. Mere bookkeeping separation of Leadership Act HIV/AIDS funds from other funds is not sufficient. HHS will determine, on a case-by-case basis and based on the totality of the facts, whether sufficient separation exists. The presence or absence of any one or more factors relating to legal, physical, and financial separation will not be determinative. Factors relevant to this determination shall include, but not be limited to, the following:

(1) Whether the organization is a legally separate entity;

(2) The existence of separate personnel or other allocation of personnel that maintains adequate separation of the activities of the affiliated organization from the recipient;

(3) The existence of separate accounting and timekeeping records;

(4) The degree of separation of the recipient's facilities from facilities in which restricted activities occur; and

(5) The extent to which signs and other forms of identification that distinguish the recipient from the affiliated organization are present.

PART 90—NONDISCRIMINATION ON THE BASIS OF AGE IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

Subpart A—General

Sec.

90.1 What is the purpose of the Age Discrimination Act of 1975?

90.2 What is the purpose of these regulations?

90.3 What programs or activities does the Age Discrimination Act of 1975 cover?

90.4 How are the terms in the regulations defined?

Subpart B—What is Age Discrimination?

STANDARDS FOR DETERMINING DISCRIMINATORY PRACTICES

90.11 Purpose of this subpart.

90.12 Rules against age discrimination.

90.13 Definitions of normal operation and statutory objective.

90.14 Exceptions to the rules against age discrimination. Normal operation or statutory objective of any program or activity.

90.15 Exceptions to the rules against age discrimination. Reasonable factors other than age.

90.16 Burden of proof.

Subpart C—What are the Responsibilities of the Federal Agencies?

90.31 Issuance of regulations.

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90.34 Agency reports.

Subpart D—Investigation, Conciliation and Enforcement Procedures

90.41 What is the purpose of this subpart?

90.42 What responsibilities do recipients and agencies have generally to ensure compliance with the Act?

90.43 What specific responsibilities do agencies and recipients have to ensure compliance with the Act?

90.44 Compliance reviews.

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- 90.46 Prohibition against intimidation or retaliation.
- 90.47 What further provisions must an agency make in order to enforce its regulations after an investigation indicates that a violation of the Act has been committed?
- 90.48 Alternate funds disbursement procedure.
- 90.49 Remedial and affirmative action by recipients.
- 90.50 Exhaustion of administrative remedies.

Subpart E—Future Review of Age Discrimination Regulations

- 90.61 Review of general regulations.
- 90.62 Review of agency regulations.

AUTHORITY: Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 *et seq.*

SOURCE: 44 FR 33776, June 12, 1979, unless otherwise noted.

Subpart A—General

§ 90.1 What is the purpose of the Age Discrimination Act of 1975?

The Age Discrimination Act of 1975, as amended, is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Act also permits federally assisted programs or activities, and recipients of Federal funds, to continue to use certain age distinctions and factors other than age which meet the requirements of the Act and these regulations.

[44 FR 33776, June 12, 1979, as amended at 70 FR 24321, May 9, 2005]

§ 90.2 What is the purpose of these regulations?

(a) The purpose of these regulations is to state general, government-wide rules for the implementation of the Age Discrimination Act of 1975, as amended, and to guide each agency in the preparation of agency-specific age discrimination regulations.

(b) These regulations apply to each Federal agency which provides Federal financial assistance to any program or activity.

§ 90.3 What programs or activities does the Age Discrimination Act of 1975 cover?

(a) The Age Discrimination Act of 1975 applies to any program or activity receiving Federal financial assistance,

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including programs or activities receiving funds under the State and Local Fiscal Assistance Act of 1972 (31 U.S.C. 1221 *et seq.*).

(b) The Age Discrimination Act of 1975 does not apply to:

(1) An age distinction contained in that part of a Federal, State or local statute or ordinance adopted by an elected, general purpose legislative body which:

(i) Provides any benefits or assistance to persons based on age; or

(ii) Establishes criteria for participation in age-related terms; or

(iii) Describes intended beneficiaries or target groups in age-related terms.

(2) Any employment practice of any employer, employment agency, labor organization, or any labor-management joint apprenticeship training program, except for any program or activity receiving Federal financial assistance for public service employment under the Comprehensive Employment and Training Act of 1974 (CETA), (29 U.S.C. 801 *et seq.*).

§ 90.4 How are the terms in these regulations defined?

As used in these regulations, the term:

Act means the Age Discrimination Act of 1975, as amended, (Title III of Pub. L. 94–135).

Action means any act, activity, policy, rule, standard, or method of administration; or the use of any policy, rule, standard, or method of administration.

Age means how old a person is, or the number of elapsed years from the date of a person's birth.

Age distinction means any action using age or an age-related term.

Age-related term means a word or words which necessarily imply a particular age or range of ages (for example, *children*, *adult*, *older persons*, but not *student*).

Agency means a Federal department or agency that is empowered to extend financial assistance.

Federal financial assistance means any grant, entitlement, loan, cooperative

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agreement, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the agency provides or otherwise makes available assistance in the form of:

- (a) Funds;
- (b) Services of Federal personnel; or
- (c) Real and personal property or any interest in or use of property, including:

(1) Transfers or leases of property for less than fair market value or for reduced consideration; and

(2) Proceeds from a subsequent transfer or lease of property if the Federal share of its fair market value is not returned to the Federal Government.

Program or activity means all of the operations of—

(a)(1) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(2) The entity of such State or local government that distributes Federal financial assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(b)(1) A college, university, or other postsecondary institution, or a public system of higher education; or

(2) A local educational agency (as defined in 20 U.S.C. 7801), system of vocational education, or other school system;

(c)(1) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(i) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(ii) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(2) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(d) Any other entity which is established by two or more of the entities described in paragraph (a), (b), or (c) of

this definition; any part of which is extended Federal financial assistance.

Recipient means any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended, directly or through another recipient. Recipient includes any successor, assignee, or transferee, but excludes the ultimate beneficiary of the assistance.

Secretary means the Secretary of the Department of Health and Human Services.

United States means the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, the Trust Territory of the Pacific Islands, the Northern Marianas, and the territories and possessions of the United States.

(42 U.S.C. 6107)

[44 FR 33776, June 12, 1979, as amended at 70 FR 24321, May 9, 2005]

Subpart B—What is Age Discrimination?

STANDARDS FOR DETERMINING DISCRIMINATORY PRACTICES

§ 90.11 Purpose of this subpart.

The purpose of this subpart is to set forth the prohibitions against age discrimination and the exceptions to those prohibitions.

§ 90.12 Rules against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§ 90.14, and 90.15 of these regulations.

(a) *General rule:* No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.

(b) *Specific rules:* A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual, licensing, or

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other arrangements use age distinctions or take any other actions which have the effect, on the basis of age, of:

(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance, or

(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.

(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§ 90.13 Definitions of normal operation and statutory objective.

For purposes of §§ 90.14, and 90.15, the terms *normal operation* and *statutory objective* shall have the following meaning:

(a) *Normal operation* means the operation of a program or activity without significant changes that would impair its ability to meet its objectives.

(b) *Statutory objective* means any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

§ 90.14 Exceptions to the rules against age discrimination. Normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by § 90.12, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and

(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity; and

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(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and

(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§ 90.15 Exceptions to the rules against age discrimination. Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by § 90.12 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 90.16 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions outlined in §§ 90.14 and 90.15 is on the recipient of Federal financial assistance.

Subpart C—What are the Responsibilities of the Federal Agencies?

§ 90.31 Issuance of regulations.

(a) The head of each agency which extends Federal financial assistance to any program or activity shall publish proposed and final age discrimination regulations in the FEDERAL REGISTER to:

(1) Carry out the provisions of section 303 of the Age Discrimination Act of 1975; and

(2) Provide for appropriate investigative, conciliation, and enforcement procedures.

(b) Each agency shall publish its proposed agency age discrimination regulations no later than 90 days after the publication date of the final general, government-wide age discrimination regulations.

(c) Each agency shall submit its final agency regulations to HHS for review no later than 120 days after publication of proposed agency age discrimination regulations.

(d) Final agency age discrimination regulations shall be consistent with

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these general, government-wide age discrimination regulations and shall not be published until the Secretary approves them.

(e) Each agency shall include in its regulations a provision governing the operation of an alternate funds disbursement procedure as described in § 90.48 of these regulations.

(f) Each agency shall publish an appendix to its final age discrimination regulations containing a list of each age distinction provided in a Federal statute or in regulations affecting financial assistance administered by the agency.

§ 90.32 Review of agency policies and administrative practices.

(a) Each agency shall conduct a review of age distinctions it imposes on its recipients by regulations, policies, and administrative practices. The purpose of this review is to identify how age distinctions are used by each Federal agency and whether those age distinctions are permissible under the Act and implementing regulations.

(b) No later than 12 months from the date the agency published its final regulations, the agency shall publish, for public comment, a report in the FEDERAL REGISTER containing:

(1) The results of the review conducted under paragraph (a) of this section;

(2) A list of the age distinctions contained in regulations which are to be continued;

(3) The justification under the requirements of the Act and these regulations for each age distinction to be continued;

(4) A list of the age distinctions not contained in regulations but which will be adopted by regulation under the Administrative Procedure Act using the notice and comment procedures specified in 5 U.S.C. 553; and

(5) A list of the age distinctions to be eliminated.

(c) Beginning with the effective date of an agency's final regulations, the agency may not impose a new age distinction unless the age distinction is adopted by regulation under the Administrative Procedure Act using the notice and comment procedures specified in 5 U.S.C. 553.

(d) Beginning 12 months after the publication of its age discrimination regulations, an agency may not continue an existing age distinction, unless the age distinction has already been adopted by regulation or is adopted by regulation under the Administrative Procedure Act using the notice and comment procedures specified in 5 U.S.C. 553.

§ 90.33 Interagency cooperation.

Where two or more agencies provide Federal financial assistance to a recipient or class of recipients, the Secretary may designate one of the agencies as the sole agency for all compliance and enforcement purposes with respect to those recipients, except for the ordering of termination of funds and the notification of the appropriate committees of Congress.

§ 90.34 Agency reports.

Each agency shall submit to the Secretary not later than December 31 of each year, beginning in 1979, a report which:

(a) Describes in detail the steps taken during the preceding fiscal year to carry out the Act; and

(b) Contains data on the frequency, type, and resolution of complaints and on any compliance reviews, sufficient to permit analysis of the agency's progress in reducing age discrimination in programs or activities receiving Federal financial assistance from the agency; and

(c) Contains data directly relevant to the extent of any pattern or practice of age discrimination which the agency has identified in any programs or activities receiving Federal financial assistance from the agency and to progress toward eliminating it; and

(d) Contains evaluative or interpretative information which the agency determines is useful in analyzing agency progress in reducing age discrimination in programs or activities receiving Federal financial assistance from the agency; and

(e) Contains whatever other data the Secretary may require.

[44 FR 33776, June 12, 1979, as amended at 70 FR 24321, May 9, 2005]

Subpart D—Investigation, Conciliation and Enforcement Procedures

§ 90.41 What is the purpose of this subpart?

This subpart sets forth requirements for the establishment of compliance, investigation, conciliation, and enforcement procedures by agencies which extend Federal financial assistance.

§ 90.42 What responsibilities do recipients and agencies have generally to ensure compliance with the Act?

(a) A recipient has primary responsibility to ensure that its programs or activities are in compliance with the Age Discrimination Act and shall take steps to eliminate violations of the Act. A recipient also has responsibility to maintain records, provide information, and to afford access to its records to an agency to the extent required to determine whether it is in compliance with the Act.

(b) An agency has responsibility to attempt to secure recipient compliance with the Act by voluntary means. This may include the use of the services of appropriate Federal, State, local, or private organizations. An agency also has the responsibility to enforce the Age Discrimination Act when a recipient fails to eliminate violations of the Act.

[44 FR 33776, June 12, 1979, as amended at 70 FR 24322, May 9, 2005]

§ 90.43 What specific responsibilities do agencies and recipients have to ensure compliance with the Act?

(a) *Written notice, technical assistance, and educational materials.* Each agency shall: (1) Provide written notice to each recipient of its obligations under the Act. The notice shall include a requirement that where the recipient initially receiving funds makes the funds available to a sub-recipient, the recipient must notify the sub-recipient of its obligations under the Act.

(2) Provide technical assistance, where necessary, to recipients to aid them in complying with the Act.

(3) Make available educational materials setting forth the rights and obli-

gations of beneficiaries and recipients under the Act.

(b) *Self-evaluation.* (1) Each agency shall require each recipient employing the equivalent of 15 or more full time employees to complete a written self-evaluation of its compliance under the Act within 18 months of the effective date of the agency regulations.

(2) Each recipient's self-evaluation shall identify and justify each age distinction imposed by the recipient.

(3) Each recipient shall take corrective and remedial action whenever a self-evaluation indicates a violation of the Act.

(4) Each recipient shall make the self-evaluation available on request to the agency and to the public for a period of 3 years following its completion.

(c) *Complaints*—(1) *Receipt of complaints.* Each agency shall establish a complaint processing procedure which includes the following:

(i) A procedure for the filing of complaints with the agency;

(ii) A review of complaints to assure that they fall within the coverage of the Act and contain all information necessary for further processing;

(iii) Notice to the complainant and the recipient of their rights and obligations under the complaint procedure, including the right to have a representative at all stages of the complaint procedure; and

(iv) Notice to the complainant and the recipient (or their representatives) of their right to contact the agency for information and assistance regarding the complaint resolution process.

(2) *Prompt resolution of complaints.* Each agency shall establish procedures for the prompt resolution of complaints. These procedures shall require each recipient and complainant to participate actively in efforts toward speedy resolution of the complaint.

(3) *Mediation of complaints.* Each agency shall promptly refer all complaints which fall within the coverage of the Act to a mediation agency designated by the Secretary.

(i) The referring agency shall require the participation of the recipient and the complainant in the mediation process, although both parties need not

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meet with the mediator at the same time.

(ii) If the complainant and recipient reach a mutually satisfactory resolution of the complaint during the mediation period, they shall reduce the agreement to writing. The mediator shall send a copy of the settlement to the referring agency. No further action shall be taken based on that complaint unless it appears that the complainant or the recipient is failing to comply with the agreement.

(iii) Not more than 60 days after the agency receives the complaint, the mediator shall return a still unresolved complaint to the referring agency for initial investigation. The mediator may return a complaint at any time before the end of the 60 day period if it appears that the complaint cannot be resolved through mediation.

(iv) The mediator shall protect the confidentiality of all information obtained in the course of the mediation process. No mediator shall testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained in the course of the mediation process without prior approval of the head of the agency appointing the mediator.

(4) *Federal initial investigation.* Each agency shall investigate complaints unresolved after mediation or reopened because of a violation of the mediation agreement. As part of the initial investigation, the agency shall use informal fact finding methods including joint or individual discussions with the complainant and the recipient to establish the facts, and, if possible, resolve the complaint to the mutual satisfaction of the parties. The agency may seek the assistance of any involved State agency.

(5) *Formal investigation, conciliation, and hearing.* If the agency cannot resolve the complaint during the early stages of the investigation, it shall:

(i) Complete the investigation of the complaint.

(ii) Attempt to achieve voluntary compliance satisfactory to the agency, if the investigation indicates a violation.

(iii) Arrange for enforcement as described in § 90.47, if necessary.

[44 FR 33776, June 12, 1979, as amended at 70 FR 24322, May 9, 2005]

§ 90.44 Compliance reviews.

(a) Each agency shall provide in its regulations that it may conduct compliance reviews, pre-award reviews, and other similar procedures which permit the agency to investigate, and correct, violations of the Act without regard to its procedures for handling complaints.

(b) If a compliance review or pre-award review indicates a violation of the Act, the agency shall attempt to achieve voluntary compliance with the Act. If voluntary compliance cannot be achieved, the agency shall arrange for enforcement as described in § 90.47.

§ 90.45 Information requirements.

Each agency shall provide in its regulations a requirement that the recipient:

(a) Provide to the agency information necessary to determine whether the recipient is in compliance with the Act; and

(b) Permit reasonable access by the agency to the books, records, accounts, and other recipient facilities and sources of information to the extent necessary to determine whether a recipient is in compliance with the Act.

§ 90.46 Prohibition against intimidation or retaliation.

Each agency shall provide in its regulations that recipients may not engage in acts of intimidation or retaliation against any person who:

(a) Attempts to assert a right protected by the Act; or

(b) Cooperates in any mediation, investigation, hearing, or other part of the agency's investigation, conciliation, and enforcement process.

§ 90.47 What further provisions must an agency make in order to enforce its regulations after an investigation indicates that a violation of the Act has been committed?

(a) Each agency shall provide for enforcement of its regulations through:

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(1) Termination of a recipient's Federal financial assistance under the program or activity involved where the recipient has violated the Act or the agency's regulations. The determination of the recipient's violation may be made only after a recipient has had an opportunity for a hearing on the record before an administrative law judge.

(2) Any other means authorized by law including but not limited to:

(i) Referral to the Department of Justice for proceedings to enforce any rights of the United States or obligations of the recipient created by the Act or the agency's regulations.

(ii) Use of any requirement of or referral to any Federal, State, or local government agency which will have the effect of correcting a violation of the Act or implementing regulations.

(b) Any termination under paragraph (a)(1) shall be limited to the particular recipient and particular program or activity receiving Federal financial assistance or portion thereof found to be in violation of the Act or agency regulations. No termination shall be based in whole or in part on a finding with respect to any program or activity which does not receive Federal financial assistance.

(c) No action under paragraph (a) of this section may be taken until:

(1) The head of the agency involved has advised the recipient of its failure to comply with the Act or the agency's regulations and has determined that voluntary compliance cannot be obtained.

(2) Thirty days have elapsed after the head of the agency involved has sent a written report of the circumstances and grounds of the action to the committees of the Congress having legislative jurisdiction over the program or activity involved. A report shall be filed whenever any action is taken under paragraph (a) of this section.

(d) An agency may defer granting new Federal financial assistance to a recipient when termination proceedings under paragraph (a)(1) of this section are initiated.

(1) New Federal financial assistance includes all assistance administered by or through the agency for which an application or approval, including renewal or continuation of existing ac-

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tivities, or authorization of new activities, is required during the deferral period. New Federal financial assistance does not include assistance approved prior to the beginning of termination proceedings or to increases in funding as a result of changed computation of formula awards.

(2) A deferral may not begin until the recipient has received a notice of opportunity for a hearing under paragraph (a)(1). A deferral may not continue for more than 60 days unless a hearing has begun within that time or the time for beginning the hearing has been extended by mutual consent of the recipient and the agency. A deferral may not continue for more than 30 days after the close of the hearing, unless the hearing results in a finding against the recipient.

[44 FR 33776, June 12, 1979, as amended at 70 FR 24322, May 9, 2005]

§ 90.48 Alternate funds disbursal procedure.

When an agency withholds funds from a recipient under its regulations issued under § 90.31, the head of the agency may disburse the withheld funds so directly to any public or non-profit private organization or agency, or State or political subdivision of the State. These alternate recipients must demonstrate the ability to comply with the agency's regulations issued under this Act and to achieve the goals of the Federal statute authorizing the Federal financial assistance.

[44 FR 33776, June 12, 1979, as amended at 70 FR 24322, May 9, 2005]

§ 90.49 Remedial and affirmative action by recipients.

(a) Where a recipient is found to have discriminated on the basis of age, the recipient shall take any remedial action which the agency may require to overcome the effects of the discrimination. If another recipient exercises control over the recipient that has discriminated, both recipients may be required to take remedial action.

(b) Even in the absence of a finding of discrimination, a recipient may take affirmative action to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity on the basis of age.

(c) If a recipient operating a program or activity which serves the elderly or children in addition to persons of other ages, provides special benefits to the elderly or to children the provision of those benefits shall be presumed to be voluntary affirmative action provided that it does not have the effect of excluding otherwise eligible persons from participation in the program or activity.

[44 FR 33776, June 12, 1979, as amended at 70 FR 24322, May 9, 2005]

§ 90.50 Exhaustion of administrative remedies.

(a) The agency shall provide in its regulations that a complainant may file a civil action following the exhaustion of administrative remedies under the Act. Administrative remedies are exhausted if:

(1) 180 days have elapsed since the complainant filed the complaint and the agency has made no finding with regard to the complaint; or

(2) The agency issues any finding in favor of the recipient.

(b) If either of the conditions set forth in § 90.50(a) is satisfied the agency shall:

(1) Promptly advise the complainant of this fact; and

(2) Advise the complainant of his or her right, under section 305(e) of the Act, to bring a civil action for injunctive relief that will effect the purposes of the Act; and

(3) Inform the complainant:

(i) That a civil action can only be brought in a United States district court for the district in which the recipient is found or transacts business;

(ii) That a complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that these costs must be demanded in the complaint;

(iii) That before commencing the action the complainant shall give 30 days notice by registered mail to the Secretary, the Attorney General of the United States, the head of the granting agency, and the recipient;

(iv) That the notice shall state: the alleged violation of the Act; the relief requested; the court in which the action will be brought; and whether or

not attorney's fees are demanded in the event the complainant prevails; and

(v) That no action shall be brought if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

Subpart E—Future Review of Age Discrimination Regulations

§ 90.61 Review of general regulations.

The Secretary shall review the effectiveness of these regulations in securing compliance with the Act. As part of this review, 30 months after the effective date of these regulations, the Secretary shall publish a notice of opportunity for public comment on the effectiveness of the regulations. The Secretary will assess the comments and publish the results of the review and assessment in the FEDERAL REGISTER.

§ 90.62 Review of agency regulations.

Each agency shall review the effectiveness of its regulations in securing compliance with the Act. As part of this review, 30 months after the effective date of its regulations, each agency shall publish a notice of opportunity for public comment on the effectiveness of the agency regulations. Each agency shall assess the comments and publish the results of the review in the FEDERAL REGISTER.

PART 91—NONDISCRIMINATION ON THE BASIS OF AGE IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE FROM HHS

Subpart A—General

Sec.

91.1 What is the purpose of the Age Discrimination Act of 1975?

91.2 What is the purpose of HHS' age discrimination regulations?

91.3 To what programs or activities do these regulations apply?

91.4 Definition of terms used in these regulations.

Subpart B—Standards for Determining Age Discrimination

91.11 Rules against age discrimination.

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- 91.12 Definitions of normal operation and statutory objective.
- 91.13 Exceptions to the rules against age discrimination: Normal operation or statutory objective of any program or activity.
- 91.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.
- 91.15 Burden of proof.
- 91.16 Affirmative action by recipient.
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Subpart C—Duties of HHS Recipients

- 91.31 General responsibilities.
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- 91.34 Information requirements.

Subpart D—Investigation, Conciliation, and Enforcement Procedures

- 91.41 Compliance reviews.
- 91.42 Complaints.
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- 91.44 Investigation.
- 91.45 Prohibition against intimidation or retaliation.
- 91.46 Compliance procedure.
- 91.47 Hearings, decisions, post-termination proceedings.
- 91.48 Remedial action by recipient.
- 91.49 Alternate funds disbursement procedure.
- 91.50 Exhaustion of administrative remedies.

AUTHORITY: Age Discrimination Act of 1975, as amended, 42 U.S.C. 6101 *et seq.* (45 CFR part 90).

SOURCE: 47 FR 57858, Dec. 28, 1982, unless otherwise noted.

Subpart A—General

§91.1 What is the purpose of the Age Discrimination Act of 1975?

The Age Discrimination Act of 1975, as amended, is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Act also permits federally assisted programs or activities, and recipients of Federal funds, to continue to use certain age distinctions and factors other than age

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which meet the requirements of the Act and these regulations.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.2 What is the purpose of HHS' age discrimination regulations?

The purpose of these regulations is to set out HHS' policies and procedures under the Age Discrimination Act of 1975 and the general age discrimination regulations at 45 CFR part 90.¹ The Act and the general regulations prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Act and the general regulations permit federally assisted programs or activities, and recipients of Federal funds, to continue to use age distinctions and factors other than age which meet the requirements of the Act and its implementing regulations.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.3 To what programs or activities do these regulations apply?

(a) The Act and these regulations apply to each HHS recipient and to each program or activity operated by the recipient which receives Federal financial assistance provided by HHS.

(b) The Act and these regulations do not apply to:

(1) An age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which:

(i) Provides any benefits or assistance to persons based on age; or

(ii) Establishes criteria for participation in age-related terms; or

(iii) Describes intended beneficiaries or target groups in age-related terms.

(2) Any employment practice of any employer, employment agency, labor organization, or any labor-management joint apprenticeship training program, except for any program or activity receiving Federal financial assistance for public service employment under the Comprehensive Employment

¹Published at 44 FR 33768, June 12, 1979.

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and Training Act (CETA), (29 U.S.C. 801 *et seq.*)

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.4 Definition of terms used in these regulations.

As used in these regulations, the term:

Act means the Age Discrimination Act of 1975, as amended, (Title III of Pub. L. 94-135).

Action means any act, activity, policy, rule, standard, or method of administration; or the use of any policy, rule, standard, or method of administration.

Age means how old a person is, or the number of years from the date of a person's birth.

Age distinction means any action using age or an age-related term.

Age-related term means a word or words which necessarily imply a particular age or range of ages (for example, *children*, *adult*, *older persons*, but not *student*).

Agency means a Federal department or agency that is empowered to extend financial assistance.

Federal financial assistance means any grant, entitlement, loan, cooperative agreement, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the agency provides or otherwise makes available assistance in the form of:

- (a) Funds; or
- (b) Services of Federal personnel; or
- (c) Real and personal property or any interest in or use of property, including:

(1) Transfers or leases of property for less than fair market value or for reduced consideration; and

(2) Proceeds from a subsequent transfer or lease of property if the Federal share of its fair market value is not returned to the Federal Government.

HHS means the United States Department of Health and Human Services.

Program or activity means all of the operations of—

- (a)(1) A department, agency, special purpose district, or other instrumentality of a State or of a local government; or

(2) The entity of such State or local government that distributes Federal financial assistance and each such department or agency (and each other State or local government entity) to which the assistance is extended, in the case of assistance to a State or local government;

(b)(1) A college, university, or other postsecondary institution, or a public system of higher education; or

(2) A local educational agency (as defined in 20 U.S.C. 7801), system of vocational education, or other school system;

(c)(1) An entire corporation, partnership, or other private organization, or an entire sole proprietorship—

(i) If assistance is extended to such corporation, partnership, private organization, or sole proprietorship as a whole; or

(ii) Which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation; or

(2) The entire plant or other comparable, geographically separate facility to which Federal financial assistance is extended, in the case of any other corporation, partnership, private organization, or sole proprietorship; or

(d) Any other entity which is established by two or more of the entities described in paragraph (a), (b), or (c) of this definition; any part of which is extended Federal financial assistance.

Recipient means any State or its political subdivision, any instrumentality of a State or its political subdivision, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended, directly or through another recipient. Recipient includes any successor, assignee, or transferee, but excludes the ultimate beneficiary of the assistance.

Secretary means the Secretary of Health and Human Services, or his or her designee.

Subrecipient means any of the entities in the definition of *recipient* to which a recipient extends or passes on Federal financial assistance. A subrecipient is generally regarded as a recipient of Federal financial assistance and has all the duties of a recipient in these regulations.

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United States means the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, the Trust Territory of the Pacific Islands, the Northern Marianas, and the territories and possessions of the United States.

(Authority: 42 U.S.C. 6107)

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

Subpart B—Standards for Determining Age Discrimination

§91.11 Rules against age discrimination.

The rules stated in this section are limited by the exceptions contained in §§91.13 and 91.14 of these regulations.

(a) General rule: No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.

(b) Specific rules: A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual licensing, or other arrangements, use age distinctions or take any other actions which have the effect, on the basis of age, of:

(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance; or

(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.

(c) The specific forms of age discrimination listed in paragraph (b) of this section do not necessarily constitute a complete list.

§91.12 Definitions of normal operation and statutory objective.

For purposes of §§91.13 and 91.14, the terms *normal operation* and *statutory objective* shall have the following meaning:

(a) *Normal operation* means the operation of a program or activity without

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significant changes that would impair its ability to meet its objectives.

(b) *Statutory objective* means any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

§91.13 Exceptions to the rules against age discrimination: Normal operation or statutory objective of any program or activity.

A recipient is permitted to take an action, otherwise prohibited by §91.11, if the action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

(a) Age is used as a measure or approximation of one or more other characteristics; and

(b) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective of the program or activity; and

(c) The other characteristic(s) can be reasonably measured or approximated by the use of age; and

(d) The other characteristic(s) are impractical to measure directly on an individual basis.

§91.14 Exceptions to the rules against age discrimination: Reasonable factors other than age.

A recipient is permitted to take an action otherwise prohibited by §91.11 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§91.15 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions outlined in §§91.13 and

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91.14 is on the recipient of Federal financial assistance.

§91.16 Affirmative action by recipient.

Even in the absence of a finding of discrimination, a recipient may take affirmative action to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity on the basis of age.

§91.17 Special benefits for children and the elderly.

If a recipient operating a program or activity provides special benefits to the elderly or to children, such use of age distinctions shall be presumed to be necessary to the normal operation of the program or activity, notwithstanding the provisions of §91.13.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.18 Age distinctions contained in HHS regulations.

Any age distinctions contained in a rule or regulation issued by HHS shall be presumed to be necessary to the achievement of a statutory objective of the program or activity to which the rule or regulation applies, notwithstanding the provisions of §91.13.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

Subpart C—Duties of HHS Recipients

§91.31 General responsibilities.

Each HHS recipient has primary responsibility to ensure that its programs or activities are in compliance with the Act and these regulations, and shall take steps to eliminate violations of the Act. A recipient also has responsibility to maintain records, provide information, and to afford HHS access to its records to the extent HHS finds necessary to determine whether the recipient is in compliance with the Act and these regulations.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.32 Notice to subrecipients and beneficiaries.

(a) Where a recipient passes on Federal financial assistance from HHS to

subrecipients, the recipient shall provide the subrecipients written notice of their obligations under the Act and these regulations.

(b) Each recipient shall make necessary information about the Act and these regulations available to its beneficiaries in order to inform them about the protections against discrimination provided by the Act and these regulations.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.33 Assurance of compliance and recipient assessment of age distinctions.

(a) Each recipient of Federal financial assistance from HHS shall sign a written assurance as specified by HHS that it will comply with the Act and these regulations.

(b) *Recipient assessment of age distinctions.* (1) As part of a compliance review under §91.41 or complaint investigation under §91.44, HHS may require a recipient employing the equivalent of 15 or more employees to complete a written self-evaluation, in a manner specified by the responsible Department official, of any age distinction imposed in its program or activity receiving Federal financial assistance from HHS to assess the recipient's compliance with the Act.

(2) Whenever an assessment indicates a violation of the Act and the HHS regulations, the recipient shall take corrective action.

§91.34 Information requirements.

Each recipient shall:

(a) Keep records in a form and containing information which HHS determines may be necessary to ascertain whether the recipient is complying with the Act and these regulations.

(b) Provide to HHS, upon request, information and reports which HHS determines are necessary to ascertain whether the recipient is complying with the Act and these regulations.

(c) Permit reasonable access by HHS to the books, records, accounts, and other recipient facilities and sources of information to the extent HHS determines is necessary to ascertain whether the recipient is complying with the Act and these regulations.

Subpart D—Investigation, Conciliation, and Enforcement Procedures

§91.41 Compliance reviews.

(a) HHS may conduct compliance reviews and pre-award reviews or use other similar procedures that will permit it to investigate and correct violations of the Act and these regulations. HHS may conduct these reviews even in the absence of a complaint against a recipient. The reviews may be as comprehensive as necessary to determine whether a violation of the Act and these regulations has occurred.

(b) If a compliance review or pre-award review indicates a violation of the Act or these regulations, HHS will attempt to achieve voluntary compliance with the Act. If voluntary compliance cannot be achieved, HHS will arrange for enforcement as described in §91.46.

§91.42 Complaints.

(a) Any person, individually or as a member of a class or on behalf of others, may file a complaint with HHS, alleging discrimination prohibited by the Act or these regulations based on an action occurring on or after July 1, 1979. A complainant shall file a complaint within 180 days from the date the complainant first had knowledge of the alleged act of discrimination. However, for good cause shown, HHS may extend this time limit.

(b) HHS will consider the date a complaint is filed to be the date upon which the complaint is sufficient to be processed.

(c) HHS will attempt to facilitate the filing of complaints wherever possible, including taking the following measures:

(1) Accepting as a sufficient complaint, any written statement which identifies the parties involved and the date the complainant first had knowledge of the alleged violation, describes generally the action or practice complained of, and is signed by the complainant.

(2) Freely permitting a complainant to add information to the complaint to meet the requirements of a sufficient complaint.

(3) Notifying the complainant and the recipient of their rights and obligations under the complaint procedure, including the right to have a representative at all stages of the complaint procedure.

(4) Notifying the complainant and the recipient (or their representatives) of their right to contact HHS for information and assistance regarding the complaint resolution process.

(d) HHS will return to the complainant any complaint outside the jurisdiction of these regulations, and will state the reason(s) why it is outside the jurisdiction of these regulations.

§91.43 Mediation.

(a) HHS will promptly refer to a mediation agency designated by the Secretary all sufficient complaints that:

(1) Fall within the jurisdiction of the Act and these regulations, unless the age distinction complained of is clearly within an exception; and,

(2) Contain all information necessary for further processing.

(b) Both the complainant and the recipient shall participate in the mediation process to the extent necessary to reach an agreement or make an informed judgment that an agreement is not possible.

(c) If the complainant and the recipient reach an agreement, the mediator shall prepare a written statement of the agreement and have the complainant and the recipient sign it. The mediator shall send a copy of the agreement to HHS. HHS will take no further action on the complaint unless the complainant or the recipient fails to comply with the agreement.

(d) The mediator shall protect the confidentiality of all information obtained in the course of the mediation process. No mediator shall testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained in the course of the mediation process without prior approval of the head of the mediation agency.

(e) The mediation will proceed for a maximum of 60 days after a complaint is filed with HHS. Mediation ends if:

(1) 60 days elapse from the time the complaint is filed; *or*

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(2) Prior to the end of that 60-day period, an agreement is reached; *or*

(3) Prior to the end of that 60-day period, the mediator determines that an agreement cannot be reached.

This 60-day period may be extended by the mediator, with the concurrence of HHS, for not more than 30 days if the mediator determines that agreement will likely be reached during such extended period.

(f) The mediator shall return unresolved complaints to HHS.

§91.44 Investigation.

(a) *Informal investigation.* (1) HHS will investigate complaints that are unresolved after mediation or are reopened because of a violation of a mediation agreement.

(2) As part of the initial investigation HHS will use informal fact finding methods, including joint or separate discussions with the complainant and recipient, to establish the fact and, if possible, settle the complaint on terms that are mutually agreeable to the parties. HHS may seek the assistance of any involved State agency.

(3) HHS will put any agreement in writing and have it signed by the parties and an authorized official at HHS.

(4) The settlement shall not affect the operation of any other enforcement effort of HHS, including compliance reviews and investigation of other complaints which may involve the recipient.

(5) The settlement is not a finding of discrimination against a recipient.

(b) *Formal investigation.* If HHS cannot resolve the complaint through informal investigation, it will begin to develop formal findings through further investigation of the complaint. If the investigation indicates a violation of these regulations HHS will attempt to obtain voluntary compliance. If HHS cannot obtain voluntary compliance it will begin enforcement as described in §91.46.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.45 Prohibition against intimidation or retaliation.

A recipient may not engage in acts of intimidation or retaliation against any person who:

(a) Attempts to assert a right protected by the Act or these regulations; or

(b) Cooperates in any mediation, investigation, hearing, or other part of HHS' investigation, conciliation, and enforcement process.

§91.46 Compliance procedure.

(a) HHS may enforce the Act and these regulations through:

(1) Termination of a recipient's Federal financial assistance from HHS under the program or activity involved where the recipient has violated the Act or these regulations. The determination of the recipient's violation may be made only after a recipient has had an opportunity for a hearing on the record before an administrative law judge.

(2) Any other means authorized by law including but not limited to:

(i) Referral to the Department of Justice for proceedings to enforce any rights of the United States or obligations of the recipient created by the Act or these regulations.

(ii) Use of any requirement of or referral to any Federal, State, or local government agency that will have the effect of correcting a violation of the Act or these regulations.

(b) HHS will limit any termination under §91.46(a)(1) to the particular recipient and particular program or activity or part of such program or activity HHS finds in violation of these regulations. HHS will not base any part of a termination on a finding with respect to any program or activity of the recipient which does not receive Federal financial assistance from HHS.

(c) HHS will take no action under paragraph (a) until:

(1) The Secretary has advised the recipient of its failure to comply with the Act and these regulations and has determined that voluntary compliance cannot be obtained.

(2) Thirty days have elapsed after the Secretary has sent a written report of the circumstances and grounds of the action to the committees of the Congress having legislative jurisdiction over the program or activity involved. The Secretary will file a report whenever any action is taken under paragraph (a).

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(d) HHS also may defer granting new Federal financial assistance from HHS to a recipient when a hearing under §91.46(a)(1) is initiated.

(1) New Federal financial assistance from HHS includes all assistance for which HHS requires an application or approval, including renewal or continuation of existing activities, or authorization of new activities, during the deferral period. New Federal financial assistance from HHS does not include increases in funding as a result of changed computation of formula awards or assistance approved prior to the beginning of a hearing under §91.46(a)(1).

(2) HHS will not begin a deferral until the recipient has received a notice of an opportunity for a hearing under §91.46(a)(1). HHS will not continue a deferral for more than 60 days unless a hearing has begun within that time or the time for beginning the hearing has been extended by mutual consent of the recipient and the Secretary. HHS will not continue a deferral for more than 30 days after the close of the hearing, unless the hearing results in a finding against the recipient.

(3) HHS will limit any deferral to the particular recipient and particular program or activity or part of such program or activity HHS finds in violation of these regulations. HHS will not base any part of a deferral on a finding with respect to any program or activity of the recipient which does not, and would not in connection with the new funds, receive Federal financial assistance from HHS.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.47 Hearings, decisions, post-termination proceedings.

Certain HHS procedural provisions applicable to Title VI of the Civil Rights Act of 1964 apply to HHS enforcement of these regulations. They are found at 45 CFR 80.9 through 80.11 and 45 CFR part 81.

§91.48 Remedial action by recipient.

Where HHS finds a recipient has discriminated on the basis of age, the recipient shall take any remedial action that HHS may require to overcome the

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effects of the discrimination. If another recipient exercises control over the recipient that has discriminated, HHS may require both recipients to take remedial action.

§91.49 Alternate funds disbursement procedure.

(a) When HHS withholds funds from a recipient under these regulations, the Secretary may disburse the withheld funds directly to an alternate recipient: any public or non-profit private organization or agency, or State or political subdivision of the State.

(b) The Secretary will require any alternate recipient to demonstrate:

(1) The ability to comply with these regulations; and

(2) The ability to achieve the goals of the Federal statute authorizing the Federal financial assistance.

[47 FR 57858, Dec. 28, 1982, as amended at 70 FR 24322, May 9, 2005]

§91.50 Exhaustion of administrative remedies.

(a) A complainant may file a civil action following the exhaustion of administrative remedies under the Act. Administrative remedies are exhausted if:

(1) 180 days have elapsed since the complainant filed the complaint and HHS has made no finding with regard to the complaint; or

(2) HHS issues any finding in favor of the recipient.

(b) If HHS fails to make a finding within 180 days or issues a finding in favor of the recipient, HHS shall:

(1) Promptly advise the complainant of this fact; and

(2) Advise the complainant of his or her right to bring a civil action for injunctive relief; and

(3) Inform the complainant:

(i) That the complainant may bring a civil action only in a United States district court for the district in which the recipient is found or transacts business;

(ii) That a complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that the complainant must demand these costs in the complaint;

(iii) That before commencing the action the complainant shall give 30 days

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notice by registered mail to the Secretary, the Attorney General of the United States, and the recipient;

(iv) That the notice must state: the alleged violation of the Act; the relief requested; the court in which the complainant is bringing the action; and, whether or not attorney's fees are demanded in the event the complainant prevails; and

(v) That the complainant may not bring an action if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

PART 92—NONDISCRIMINATION IN HEALTH PROGRAMS OR ACTIVITIES

Subpart A—General Provisions

Sec.

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92.3 Relationship to other laws.

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92.303 Procedures for health programs and activities conducted by recipients and State Exchanges.

92.304 Procedures for health programs and activities administered by the Department.

AUTHORITY: 42 U.S.C. 18116.

SOURCE: 89 FR 37692, May 6, 2024, unless otherwise noted.

Subpart A—General Provisions

§ 92.1 Purpose and effective date.

(a) *Purpose.* The purpose of this part is to implement section 1557 of the Patient Protection and Affordable Care Act (ACA) (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in certain health programs and activities. Section 1557 provides that, except as otherwise provided in title I of the ACA, an individual shall not, on the grounds prohibited under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or section 504 of the Rehabilitation Act of 1973, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an executive agency or any entity established under title I of the ACA. This part applies to health programs or activities administered by recipients of Federal financial assistance from the Department, Department-administered health programs or activities, and title I entities that administer health programs or activities.

(b) *Effective date.* The regulations in this part are effective beginning July 5,

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2024, unless otherwise provided in the following schedule:

TABLE 1 TO PARAGRAPH (b)

Section 1557 requirement and provision	Date by which covered entities must comply
§ 92.7	Within 120 days of July 5, 2024.
§ 92.8	Within one year of July 5, 2024.
§ 92.9	Following a covered entity's implementation of the policies and procedures required by § 92.8, and no later than one year of July 5, 2024.
§ 92.10	Within 120 days of July 5, 2024.
§ 92.11	Within one year of July 5, 2024.
§ 92.207(b)(1) through (5) ...	For health insurance coverage or other health-related coverage that was not subject to this part as of July 5, 2024, by the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.207(b)(6)	By the first day of the first plan year (in the individual market, policy year) beginning on or after January 1, 2025.
§ 92.210(b) and (c)	Within 300 days of July 5, 2024.

§ 92.2 Application.

(a) Except as otherwise provided in this part, this part shall apply to:

(1) Every health program or activity, any part of which receives Federal financial assistance, directly or indirectly, from the Department;

(2) Every health program or activity administered by the Department; and

(3) Every health program or activity administered by a title I entity.

(b) The provisions of this part shall not apply to any employer or other plan sponsor of a group health plan, including but not limited to, a board of trustees (or similar body), association or other group, with regard to its employment practices, including the provision of employee health benefits.

(c) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.3 Relationship to other laws.

(a) Neither section 1557 nor this part shall be construed to apply a lesser standard for the protection of individuals from discrimination than the standards applied under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, or

the regulations issued pursuant to those laws.

(b) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available under title VI of the Civil Rights Act of 1964, title VII of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, or the Age Discrimination Act of 1975.

(c) Insofar as the application of any requirement under this part would violate applicable Federal protections for religious freedom and conscience, such application shall not be required. For example, 42 U.S.C. 18023 provides (among other things) that nothing in section 1557 shall be construed to have any effect on Federal laws regarding conscience protection; willingness or refusal to provide abortion; and discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

(d) Nothing in this part shall be construed to supersede State or local laws that provide additional protections against discrimination on any basis described in § 92.1.

§ 92.4 Definitions.

As used in this part, the term—

1991 Standards means the 1991 ADA Standards for Accessible Design, published at appendix A to 28 CFR part 36

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on July 26, 1991, and republished as appendix D to 28 CFR part 36 on September 15, 2010.

2010 Standards means 36 CFR part 1191, appendices B and D (2009), in conjunction with 28 CFR 35.151.

ACA means the Patient Protection and Affordable Care Act (Pub. L. 111-148, 124 Stat. 119 (2010) as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152, 124 Stat. 1029) (codified in scattered sections of U.S.C.)).

ADA means the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 *et seq.*), as amended.

Age means how old a person is, or the number of elapsed years from the date of a person's birth.

Age Act means the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), as amended.

Applicant means a person who applies to participate in a health program or activity.

Auxiliary aids and services include, for example:

(1) Qualified interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.104; note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunications products and systems, including text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible information and communication technology (ICT); or other effective methods of making aurally delivered information available to persons who are deaf or hard of hearing;

(2) Qualified readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs (SAP); large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials

available to persons who are blind or have low vision;

(3) Acquisition or modification of equipment and devices; and

(4) Other similar services and actions.

Companion means a family member, friend, or associate of an individual seeking access to a service, program, or activity of a covered entity, who along with such individual, is an appropriate person with whom a covered entity should communicate.

Covered entity means:

(1) A recipient of Federal financial assistance;

(2) The Department; and

(3) An entity established under title I of the ACA.

Department means the U.S. Department of Health and Human Services.

Director means the Director of the Office for Civil Rights (OCR) of the Department, or their designee(s).

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of "disability" in the ADA, 42 U.S.C. 12102, as amended and adopted at 28 CFR 35.108.

Exchange means the same as "Exchange" defined in 45 CFR 155.20.

Federal financial assistance, as used in this part:

(1) Federal financial assistance means any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal Government, directly or indirectly, provides assistance or otherwise makes assistance available in the form of:

(i) Funds;

(ii) Services of Federal personnel; or

(iii) Real or personal property or any interest in or use of such property, including:

(A) Transfers or leases of such property for less than fair market value or for reduced consideration; and

(B) Proceeds from a subsequent transfer or lease of such property if the

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Federal share of its fair market value is not returned to the Federal Government.

(2) Federal financial assistance the Department provides or otherwise makes available includes Federal financial assistance that the Department plays a role in providing or administering, including advance payments of the premium tax credit and cost-sharing reduction payments under title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to any entity providing health insurance coverage for payment to or on behalf of a person obtaining health insurance coverage from that entity or extended by the Department directly to such person for payment to any entity providing health insurance coverage.

Federally-facilitated Exchange means the same as “Federally-facilitated Exchange” defined in 45 CFR 155.20.

Health program or activity means:

(1) Any project, enterprise, venture, or undertaking to:

(i) Provide or administer health-related services, health insurance coverage, or other health-related coverage;

(ii) Provide assistance to persons in obtaining health-related services, health insurance coverage, or other health-related coverage;

(iii) Provide clinical, pharmaceutical, or medical care;

(iv) Engage in health or clinical research; or

(v) Provide health education for health care professionals or others.

(2) All of the operations of any entity principally engaged in the provision or administration of any health projects, enterprises, ventures, or undertakings described in paragraph (1) of this definition, including, but not limited to, a State or local health agency, hospital, health clinic, health insurance issuer, physician’s practice, pharmacy, community-based health care provider, nursing facility, residential or community-based treatment facility, or other similar entity or combination thereof. A health program or activity also includes all of the operations of a State Medicaid program, Children’s Health Insurance Program, and Basic Health Program.

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Individual with limited English proficiency means an individual whose primary language for communication is not English and who has a limited ability to read, write, speak, or understand English. An individual with limited English proficiency may be competent in English for certain types of communication (e.g., speaking or understanding), but still be limited English proficient for other purposes (e.g., reading or writing).

Information and communication technology (ICT) means information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include, but are not limited to: computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; telehealth interfaces or applications; customer premises equipment; multifunction office machines; software; mobile applications; websites; videos; and electronic documents.

Language assistance services may include, but are not limited to:

(1) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency;

(2) Written translation, performed by a qualified translator, of written content in paper or electronic form into or from languages other than English; and

(3) Written notice of availability of language assistance services.

Machine translation means automated translation, without the assistance of or review by a qualified human translator, that is text-based and provides instant translations between various languages, sometimes with an option for audio input or output.

National origin includes, but is not limited to, a person’s, or their ancestors’, place of origin (such as country or world region) or a person’s manifestation of the physical, cultural, or

linguistic characteristics of a national origin group.

OCR means the Office for Civil Rights of the Department.

Patient care decision support tool means any automated or non-automated tool, mechanism, method, technology, or combination thereof used by a covered entity to support clinical decision-making in its health programs or activities.

Qualified bilingual/multilingual staff means a member of a covered entity's workforce who is designated by the covered entity to provide in-language oral language assistance as part of the person's current, assigned job responsibilities and who has demonstrated to the covered entity that they are:

(1) Proficient in speaking and understanding both spoken English and at least one other spoken language, including any necessary specialized vocabulary, terminology and phraseology; and

(2) Able to effectively, accurately, and impartially communicate directly with individuals with limited English proficiency in their primary languages.

Qualified individual with a disability means an individual with a disability who, with or without reasonable modifications to rules, policies, or practices, the removal of architectural, communication, or transportation barriers, or the provision of auxiliary aids and services, meets the essential eligibility requirements for the receipt of services or the participation in programs or activities provided by the covered entity.

Qualified interpreter for an individual with a disability means an interpreter who, via a video remote interpreting service (VRI) or an on-site appearance:

(1) Has demonstrated proficiency in communicating in, and understanding:

(i) Both English and a non-English language (including American Sign Language, other sign languages); or

(ii) Another communication modality (such as cued-language transliterators or oral transliteration);

(2) Is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone,

sentiment, and emotional level of the original statement; and

(3) Adheres to generally accepted interpreter ethics principles including client confidentiality.

(4) Qualified interpreters include, for example, sign language interpreters, oral transliterators, and cued-language transliterators.

Qualified interpreter for an individual with limited English proficiency means an interpreter who via a remote interpreting service or an on-site appearance:

(1) Has demonstrated proficiency in speaking and understanding both spoken English and at least one other spoken language (qualified interpreters for relay interpretation must demonstrate proficiency in two non-English spoken languages);

(2) Is able to interpret effectively, accurately, and impartially to and from such language(s) and English (or between two non-English languages for relay interpretation), using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original oral statement; and

(3) Adheres to generally accepted interpreter ethics principles, including client confidentiality.

Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.

Qualified translator means a translator who:

(1) Has demonstrated proficiency in writing and understanding both written English and at least one other written non-English language;

(2) Is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary or terms without changes, omissions, or additions and while preserving the tone, sentiment, and emotional level of the original written statement; and

(3) Adheres to generally accepted translator ethics principles, including client confidentiality.

Recipient means any State or its political subdivision thereof; or any instrumentality of a State or political

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subdivision thereof; any public or private agency, institution, or organization; other entity; or any person, to whom Federal financial assistance is extended directly or indirectly, including any subunit, successor, assignee, or transferee of a recipient. Such term does not include any ultimate beneficiary.

Relay interpretation means interpreting from one language to another through an intermediate language. This mode of interpretation is often used for monolingual speakers of languages of limited diffusion, including select indigenous languages. In relay interpreting, the first interpreter listens to the speaker and renders the message into the intermediate language. The second interpreter receives the message in the intermediate language and interprets it into a third language for the speaker who speaks neither the first nor the second language.

Section 504 means section 504 of the Rehabilitation Act of 1973 (Pub. L. 93-112; 29 U.S.C. 794), as amended.

Section 1557 means section 1557 of the ACA (42 U.S.C. 18116).

State includes each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands.

State Exchange means an Exchange established by a State and approved by the Department pursuant to 45 CFR part 155, subpart B.

Telehealth means the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.

Title I entity means any entity established under title I of the ACA, as amended, including State Exchanges and Federally-facilitated Exchanges.

Title VI means title VI of the Civil Rights Act of 1964 (Pub. L. 88-352; 42 U.S.C. 2000d *et seq.*), as amended.

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Title VII means title VII of the Civil Rights Act of 1964 (Pub. L. 88-352; 42 U.S.C. 2000e *et seq.*), as amended.

Title IX means title IX of the Education Amendments of 1972 (Pub. L. 92-318; 20 U.S.C. 1681 *et seq.*), as amended.

UFAS means the Uniform Federal Accessibility Standards (Pub. L. 90-480; 42 U.S.C. 4151 *et seq.*), as amended.

§ 92.5 Assurances required.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies must, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director, that the entity's health programs and activities will be operated in compliance with section 1557 and this part. A health insurance issuer seeking certification to participate in an Exchange or a State seeking approval to operate a State Exchange to which section 1557 or this part applies must, as a condition of certification or approval, submit an assurance, on a form specified by the Director, that the health insurance issuer's or State's health program or activity will be operated in compliance with section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in an Exchange or approval to operate a State Exchange.

(b) *Duration of obligation.* The duration of the assurances required by this section is the same as the duration of the assurances required in the Department's regulations implementing section 504, 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing section 504, at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under section 1557 and this part.

§ 92.6 Remedial action and voluntary action.

(a) *Remedial action.* (1) If the Director finds that a recipient or State Exchange has discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of section 1557 or this part, such recipient or State Exchange must take such remedial action as the Director may require to overcome the effects of the discrimination.

(2) Where a recipient is found to have discriminated against an individual on the basis of race, color, national origin, sex, age, or disability, in violation of section 1557 or this part, and where another recipient exercises control over the recipient that has discriminated, the Director, where appropriate, may require either or both entities to take remedial action.

(3) The Director may, where necessary to overcome the effects of discrimination in violation of section 1557 or this part, require a recipient, in its health programs and activities, or State Exchange to take remedial action with respect to:

(i) Persons who are no longer participants in the recipient's or State Exchange's health program or activity but who were participants in the health program or activity when such discrimination occurred; or

(ii) Persons who would have been participants in the health program or activity had the discrimination not occurred.

(b) *Voluntary action.* A covered entity may take nondiscriminatory steps, in addition to any action that is required by section 1557 or this part, to overcome the effects of conditions that result or resulted in limited participation in the covered entity's health programs or activities by persons on the basis of race, color, national origin, sex, age, or disability.

§ 92.7 Designation and responsibilities of a Section 1557 Coordinator.

(a) *Section 1557 Coordinator and designees.* A covered entity that employs fifteen or more persons must designate and authorize at least one employee, a "Section 1557 Coordinator," to coordinate the covered entity's compliance with its responsibilities under section

1557 and this part in its health programs and activities, including the investigation of any grievance communicated to it alleging noncompliance with section 1557 or this part or alleging any action that would be prohibited by section 1557 or this part. As appropriate, a covered entity may assign one or more designees to carry out some of these responsibilities, but the Section 1557 Coordinator must retain ultimate oversight for ensuring coordination with the covered entity's compliance with this part.

(b) *Responsibilities of a Section 1557 Coordinator.* A covered entity must ensure that, at minimum, the Section 1557 Coordinator:

(1) Receives, reviews, and processes grievances, filed under the grievance procedure as set forth in § 92.8(c);

(2) Coordinates the covered entity's recordkeeping requirements as set forth in § 92.8(c);

(3) Coordinates effective implementation of the covered entity's language access procedures as set forth in § 92.8(d);

(4) Coordinates effective implementation of the covered entity's effective communication procedures as set forth in § 92.8(e);

(5) Coordinates effective implementation of the covered entity's reasonable modification procedures as set forth in § 92.8(f); and

(6) Coordinates training of relevant employees as set forth in § 92.9, including maintaining documentation required by such section.

§ 92.8 Policies and procedures.

(a) *General requirement.* A covered entity must implement written policies and procedures in its health programs and activities that are designed to comply with the requirements of this part. The policies and procedures must include an effective date and be reasonably designed, taking into account the size, complexity, and the type of health programs or activities undertaken by a covered entity, to ensure compliance with this part.

(b) *Nondiscrimination policy.* (1) A covered entity must implement a written policy in its health programs and activities that, at minimum, states the covered entity does not discriminate

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on the basis of race, color, national origin (including limited English proficiency and primary language), sex (consistent with the scope of sex discrimination described at § 92.101(a)(2)), age, or disability; that the covered entity provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with section 1557 or this part; that the covered entity will provide reasonable modifications for individuals with disabilities; and that provides the current contact information for the Section 1557 Coordinator required by § 92.7 (if applicable).

(2) OCR considers it a best practice toward achieving compliance for a covered entity to provide information that it has been granted a temporary exemption or granted an assurance of exemption under § 92.302(b) in the non-discrimination policy required by paragraph (b)(1) of this section.

(c) *Grievance procedures.* (1) A covered entity that employs fifteen or more persons must implement written grievance procedures in its health programs and activities that provide for the prompt and equitable resolution of grievances alleging any action that would be prohibited by section 1557 or this part.

(2) A covered entity to which this paragraph applies must retain records related to grievances filed pursuant to the covered entity's grievance procedures required under paragraph (c)(1) of this section that allege discrimination on the basis of race, color, national origin, sex, age, or disability for no less than three (3) calendar years from the date the covered entity resolves the grievance. The records must include the grievance; the name and contact information of the complainant (if provided by complainant); the alleged discriminatory action and alleged basis (or bases) of discrimination; the date the grievance was filed; the date the grievance was resolved; grievance resolution; and any other pertinent information.

(3) A covered entity to which this paragraph (c) applies must keep confidential the identity of an individual who has filed a grievance under this part except as required by law or to the extent necessary to carry out the pur-

poses of this part, including the conduct of any investigation.

(d) *Language access procedures.* A covered entity must implement written language access procedures in its health programs and activities describing the covered entity's process for providing language assistance services to individuals with limited English proficiency when required under § 92.201. At a minimum, the language access procedures must include current contact information for the section 1557 Coordinator (if applicable); how an employee identifies whether an individual has limited English proficiency; how an employee obtains the services of qualified interpreters and translators the covered entity uses to communicate with an individual with limited English proficiency; the names of any qualified bilingual staff members; and a list of any electronic and written translated materials the covered entity has, the languages they are translated into, date of issuance, and how to access electronic translations.

(e) *Effective communication procedures.* A covered entity must implement written effective communication procedures in its health programs and activities describing the covered entity's process for ensuring effective communication for individuals with disabilities when required under § 92.202. At a minimum, a covered entity's effective communication procedures must include current contact information for the Section 1557 Coordinator (if applicable); how an employee obtains the services of qualified interpreters the covered entity uses to communicate with individuals with disabilities, including the names of any qualified interpreter staff members; and how to access appropriate auxiliary aids and services.

(f) *Reasonable modification procedures.* A covered entity must implement written procedures in its health programs and activities describing the covered entity's process for making reasonable modifications to its policies, practices, or procedures when necessary to avoid discrimination on the basis of disability as required under § 92.205. At a minimum, the reasonable modification

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procedures must include current contact information for the covered entity's Section 1557 Coordinator (if applicable); a description of the covered entity's process for responding to requests from individuals with disabilities for changes, exceptions, or adjustments to a rule, policy, practice, or service of the covered entity; and a process for determining whether making the modification would fundamentally alter the nature of the health program or activity, including identifying an alternative modification that does not result in a fundamental alteration to ensure the individual with a disability receives the benefits or services in question.

(g) *Combined policies and procedures.* A covered entity may combine the content of the policies and procedures required by paragraphs (b) through (f) of this section with any policies and procedures pursuant to title VI, section 504, title IX, and the Age Act if section 1557 and the provisions in this part are clearly addressed therein.

(h) *Changes to policies and procedures.* (1) Covered entities must review and revise the policies and procedures required by paragraphs (b) through (g) of this section, as necessary, to ensure they are current and in compliance with section 1557 and this part; and

(2) A covered entity may change a policy or procedure required by paragraphs (b) through (g) of this section at any time, provided that such changes comply with section 1557 and this part.

§ 92.9 Training.

(a) A covered entity must train relevant employees of its health programs and activities on the civil rights policies and procedures required by § 92.8, as necessary and appropriate for the employees to carry out their functions within the covered entity consistent with the requirements of this part.

(b) A covered entity must provide training that meets the requirements of paragraph (a) of this section, as follows:

(1) To each relevant employee of the health program or activity as soon as possible, but no later than 30 days following a covered entity's implementation of the policies and procedures re-

quired by § 92.8, and no later than 300 days following July 5, 2024;

(2) Thereafter, to each new relevant employee of the health program or activity within a reasonable period of time after the employee joins the covered entity's workforce; and

(3) To each relevant employee of the health program or activity whose functions are affected by a material change in the policies or procedures required by § 92.8 and any other civil rights policies or procedures the covered entity has implemented within a reasonable period of time after the material change has been made.

(4) For purposes of this section, "relevant employees" includes permanent and temporary employees whose roles and responsibilities entail interacting with patients and members of the public; making decisions that directly or indirectly affect patients' health care, including the covered entity's executive leadership team and legal counsel; and performing tasks and making decisions that directly or indirectly affect patients' financial obligations, including billing and collections.

(c) A covered entity must contemporaneously document its employees' completion of the training required by paragraphs (a) and (b) of this section in written or electronic form and retain said documentation for no less than three (3) calendar years.

§ 92.10 Notice of nondiscrimination.

(a) A covered entity must provide a notice of nondiscrimination to participants, beneficiaries, enrollees, and applicants of its health programs and activities, and members of the public.

(1) The notice required under this paragraph (a) must include the following information relating to the covered entity's health programs and activities:

(i) The covered entity does not discriminate on the basis of race, color, national origin (including limited English proficiency and primary language), sex (consistent with the scope of sex discrimination described at § 92.101(a)(2)), age, or disability;

(ii) The covered entity provides reasonable modifications for individuals with disabilities, and appropriate auxiliary aids and services, including

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qualified interpreters for individuals with disabilities and information in alternate formats, such as braille or large print, free of charge and in a timely manner, when such modifications, aids, and services are necessary to ensure accessibility and an equal opportunity to participate to individuals with disabilities;

(iii) The covered entity provides language assistance services, including electronic and written translated documents and oral interpretation, free of charge and in a timely manner, when such services are a reasonable step to provide meaningful access to an individual with limited English proficiency;

(iv) How to obtain from the covered entity the reasonable modifications, appropriate auxiliary aids and services, and language assistance services in paragraphs (a)(1)(ii) and (iii) of this section;

(v) The contact information for the covered entity's Section 1557 Coordinator designated pursuant to § 92.7 (if applicable);

(vi) The availability of the covered entity's grievance procedure pursuant to § 92.8(c) and how to file a grievance (if applicable);

(vii) Details on how to file a discrimination complaint with OCR in the Department; and

(viii) How to access the covered entity's website, if it has one, that provides the information required under this paragraph (a)(1).

(2) The notice required under this paragraph (a) must be provided in a covered entity's health program or activity, as follows:

(i) On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity;

(ii) Upon request;

(iii) At a conspicuous location on the covered entity's health program or activity website, if it has one; and

(iv) In clear and prominent physical locations, in no smaller than 20-point sans serif font, where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice.

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(b) A covered entity may combine the content of the notice required by paragraph (a) of this section with the notices required by 45 CFR 80.6(d), 84.8, 86.9, and 91.32 if the combined notice clearly informs individuals of their civil rights under section 1557 and this part, so long as it includes each of the elements required by paragraph (a)(1) of this section.

§ 92.11 Notice of availability of language assistance services and auxiliary aids and services.

(a) A covered entity must provide a notice of availability of language assistance services and auxiliary aids and services that, at minimum, states that the covered entity, in its health programs or activities, provides language assistance services and appropriate auxiliary aids and services free of charge, when necessary for compliance with section 1557 or this part, to participants, beneficiaries, enrollees, and applicants of its health program or activities, and members of the public.

(b) The notice required under paragraph (a) of this section must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States in which a covered entity operates and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(c) The notice required under paragraph (a) of this section must be provided in a covered entity's health program or activity, as follows:

(1) On an annual basis to participants, beneficiaries, enrollees (including late and special enrollees), and applicants of its health program or activity;

(2) Upon request;

(3) At a conspicuous location on the covered entity's health program or activity website, if it has one;

(4) In clear and prominent physical locations, in no smaller than 20-point sans serif font, where it is reasonable to expect individuals seeking service from the health program or activity to be able to read or hear the notice; and

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(5) In the following electronic and written communications when these forms are provided by a covered entity:

(i) Notice of nondiscrimination required by § 92.10;

(ii) Notice of privacy practices required by 45 CFR 164.520;

(iii) Application and intake forms;

(iv) Notices of denial or termination of eligibility, benefits or services, including Explanations of Benefits, and notices of appeal and grievance rights;

(v) Communications related to an individual's rights, eligibility, benefits, or services that require or request a response from a participant, beneficiary, enrollee, or applicant;

(vi) Communications related to a public health emergency;

(vii) Consent forms and instructions related to medical procedures or operations, medical power of attorney, or living will (with an option of providing only one notice for all documents bundled together);

(viii) Discharge papers;

(ix) Communications related to the cost and payment of care with respect to an individual, including medical billing and collections materials, and good faith estimates required by section 2799B-6 of the Public Health Service Act;

(x) Complaint forms; and

(xi) Patient and member handbooks.

(d) A covered entity shall be deemed in compliance with this section with respect to an individual if it exercises the option to:

(1) On an annual basis, provide the individual with the option to opt out of receipt of the notice required by this section in their primary language and through any appropriate auxiliary aids and services, and:

(i) Does not condition the receipt of any aid or benefit on the individual's decision to opt out;

(ii) Informs the individual that they have a right to receive the notice upon request in their primary language and through the appropriate auxiliary aids and services;

(iii) Informs the individual that opting out of receiving the notice is not a waiver of their right to receive language assistance services and any appropriate auxiliary aids and services as required by this part;

(iv) Documents, on an annual basis, that the individual has opted out of receiving the notice required by this section for that year; and

(v) Does not treat a non-response from an individual as a decision to opt out; or

(2) Document the individual's primary language and any appropriate auxiliary aids and services and:

(i) Provides all materials and communications in that individual's primary language and through any appropriate auxiliary aids and services; or

(ii) Provides the notice required by paragraph (a) of this section in that individual's primary language and through any appropriate auxiliary aids and services in all communications that are identified in paragraph (c)(5) of this section.

Subpart B—Nondiscrimination Provisions

§ 92.101 Discrimination prohibited.

(a) *General.* (1) Except as provided in title I of the ACA, an individual must not, on the basis of race, color, national origin, sex, age, disability, or any combination thereof, be excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination under any health program or activity operated by a covered entity.

(2) Discrimination on the basis of sex includes, but is not limited to, discrimination on the basis of:

(i) Sex characteristics, including intersex traits;

(ii) Pregnancy or related conditions;

(iii) Sexual orientation;

(iv) Gender identity; and

(v) Sex stereotypes.

(b) *Specific prohibitions on discrimination.* (1) In any health program or activity to which this part applies:

(i) A recipient and State Exchange must comply with the specific prohibitions on discrimination in the Department's implementing regulations for title VI, section 504, title IX, and the Age Act, found at 45 CFR parts 80, 84, 86 (subparts C and D), and 91 (subpart B), respectively. Where this paragraph (b) cross-references regulatory provisions that use the term "recipient,"

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the term “recipient or State Exchange” shall apply in its place. Where this paragraph (b) cross-references regulatory provisions that use the term “student,” “employee,” or “applicant,” these terms shall be replaced with “individual.”

(ii) The Department, including Federally-facilitated Exchanges, must comply with specific prohibitions on discrimination in the Department’s implementing regulations for title VI, section 504, title IX, and the Age Act, found at 45 CFR parts 80, 85, 86 (subparts C and D), and 91 (subpart B), respectively. Where this paragraph (b) cross-references regulatory provisions that use the term “a recipient,” the term “the Department or a Federally-facilitated Exchange” shall apply in its place. Where this paragraph (b) cross-references regulatory provisions that use the term “student,” “employee,” or “applicant,” these terms shall be replaced with “individual.”

(2) The enumeration of specific prohibitions on discrimination in paragraph (b)(1) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

Subpart C—Specific Applications to Health Programs and Activities

§ 92.201 Meaningful access for individuals with limited English proficiency.

(a) *General requirement.* A covered entity must take reasonable steps to provide meaningful access to each individual with limited English proficiency (including companions with limited English proficiency) eligible to be served or likely to be directly affected by its health programs and activities.

(b) *Language assistance services requirements.* Language assistance services required under paragraph (a) of this section must be provided free of charge, be accurate and timely, and protect the privacy and the independent decision-making ability of the individual with limited English proficiency.

(c) *Specific requirements for interpreter and translation services.* (1) When interpretation services are required under this part, a covered entity must offer a

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qualified interpreter in its health programs and activities.

(2) When translation services are required under this part, a covered entity must utilize the services of a qualified translator in its health programs and activities.

(3) If a covered entity uses machine translation when the underlying text is critical to the rights, benefits, or meaningful access of an individual with limited English proficiency, when accuracy is essential, or when the source documents or materials contain complex, non-literal or technical language, the translation must be reviewed by a qualified human translator.

(d) *Evaluation of compliance.* In evaluating whether a covered entity has met its obligation under paragraph (a) of this section, the Director shall:

(1) Evaluate, and give substantial weight to, the nature and importance of the health program or activity and the particular communication at issue, to the individual with limited English proficiency; and

(2) Take into account other relevant factors, including the effectiveness of the covered entity’s written language access procedures for its health programs and activities, that the covered entity has implemented pursuant to § 92.8(d).

(e) *Restricted use of certain persons to interpret or facilitate communication.* A covered entity must not, in its health programs and activities:

(1) Require an individual with limited English proficiency to provide their own interpreter, or to pay the cost of their own interpreter;

(2) Rely on an adult, not qualified as an interpreter, to interpret or facilitate communication, except:

(i) As a temporary measure, while finding a qualified interpreter in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available and the qualified interpreter that arrives confirms or supplements the initial communications with an initial adult interpreter; or

(ii) Where the individual with limited English proficiency specifically requests, in private with a qualified interpreter present and without an accompanying adult present, that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, the request and agreement by the accompanying adult is documented, and reliance on that adult for such assistance is appropriate under the circumstances;

(3) Rely on a minor child to interpret or facilitate communication, except as a temporary measure while finding a qualified interpreter in an emergency involving an imminent threat to the safety or welfare of an individual or the public where there is no qualified interpreter for the individual with limited English proficiency immediately available and the qualified interpreter that arrives confirms or supplements the initial communications with the minor child; or

(4) Rely on staff other than qualified interpreters, qualified translators, or qualified bilingual/multilingual staff to communicate with individuals with limited English proficiency.

(f) *Video remote interpreting services.* A covered entity that provides a qualified interpreter for an individual with limited English proficiency through video remote interpreting services in the covered entity's health programs and activities must ensure the modality allows for meaningful access and must provide:

(1) Real-time, full-motion video and audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high quality video images that do not produce lags, choppy, blurry, or grainy images, or irregular pauses in communication;

(2) A sharply delineated image that is large enough to display the interpreter's face and the participating person's face regardless of the person's body position;

(3) A clear, audible transmission of voices; and

(4) Adequate training to users of the technology and other involved persons so that they may quickly and effi-

ciently set up and operate the video remote interpreting.

(g) *Audio remote interpreting services.* A covered entity that provides a qualified interpreter for an individual with limited English proficiency through audio remote interpreting services in the covered entity's health programs and activities must ensure the modality allows for meaningful access and must provide:

(1) Real-time audio over a dedicated high-speed, wide-bandwidth connection or wireless connection that delivers high-quality audio without lags or irregular pauses in communication;

(2) A clear, audible transmission of voices; and

(3) Adequate training to users of the technology and other involved persons so that they may quickly and efficiently set up and operate the remote interpreting services.

(h) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.202 Effective communication for individuals with disabilities.

(a) A covered entity must take appropriate steps to ensure that communications with individuals with disabilities (including companions with disabilities), are as effective as communications with non-disabled individuals in its health programs and activities, in accordance with the standards found at 28 CFR 35.130 and 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term "public entity," the term "covered entity" shall apply in its place.

(b) A covered entity must provide appropriate auxiliary aids and services where necessary to afford individuals with disabilities an equal opportunity to participate in, and enjoy the benefits of, the health program or activity in question. Such auxiliary aids and services must be provided free of charge, in accessible formats, in a timely manner, and in such a way to protect the privacy and the independence of the individual with a disability.

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§ 92.203 Accessibility for buildings and facilities.

(a) No qualified individual with a disability shall, because a covered entity's facilities are inaccessible to or unusable by individuals with disabilities, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any health program or activity to which this part applies.

(b) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange must comply with the 2010 Standards if the construction or alteration was commenced on or after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility must comply with the 2010 Standards if the construction or alteration was commenced after January 18, 2018. If construction or alteration was begun on or after July 18, 2016, and on or before January 18, 2018, in conformance with UFAS, and the facility or part of the facility was not covered by the 2010 Standards prior to July 18, 2016, then it shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b). Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section must comply with the requirements for a "public building or facility" as defined in section 106.5 of the 2010 Standards.

(c) Each facility or part of a facility in which health programs or activities under this part are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with the 1991 Standards at appendix D to 28 CFR part 36 or the 2010 Standards shall be deemed to comply with the requirements of this section and with 45 CFR

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84.23(a) and (b) with respect to those facilities, if the construction or alteration was commenced before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with UFAS shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), if the construction or alteration was commenced before July 18, 2016, and such facility would not have been required to conform with a different accessibility standard under 28 CFR 35.151.

§ 92.204 Accessibility of information and communication technology for individuals with disabilities.

(a) A covered entity must ensure that its health programs and activities provided through information and communication technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. If an action required to comply with this section would result in such an alteration or such burdens, a covered entity shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with disabilities receive the benefits or services of the health program or activity provided by the covered entity.

(b) A recipient or State Exchange shall ensure that its health programs and activities provided through websites and mobile applications comply with the requirements of section 504 of the Rehabilitation Act, as interpreted consistent with title II of the ADA (42 U.S.C. 12131 through 12165).

§ 92.205 Requirement to make reasonable modifications.

A covered entity must make reasonable modifications to policies, practices, or procedures in its health programs and activities when such modifications are necessary to avoid discrimination on the basis of disability,

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unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term “reasonable modifications” shall be interpreted in a manner consistent with the term as set forth in the ADA title II regulation at 28 CFR 35.130(b)(7).

§ 92.206 Equal program access on the basis of sex.

(a) A covered entity must provide individuals equal access to its health programs and activities without discriminating on the basis of sex.

(b) In providing access to health programs and activities, a covered entity must not:

(1) Deny or limit health services, including those that have been typically or exclusively provided to, or associated with, individuals of one sex, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;

(2) Deny or limit, on the basis of an individual's sex assigned at birth, gender identity, or gender otherwise recorded, a health care professional's ability to provide health services if such denial or limitation has the effect of excluding individuals from participation in, denying them the benefits of, or otherwise subjecting them to discrimination on the basis of sex under a covered health program or activity;

(3) Adopt or apply any policy or practice of treating individuals differently or separating them on the basis of sex in a manner that subjects any individual to more than de minimis harm, including by adopting a policy or engaging in a practice that prevents an individual from participating in a health program or activity consistent with the individual's gender identity; or

(4) Deny or limit health services sought for purpose of gender transition or other gender-affirming care that the covered entity would provide to an individual for other purposes if the denial or limitation is based on an individual's sex assigned at birth, gender identity, or gender otherwise recorded.

(c) Nothing in this section requires the provision of any health service

where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting that service, including where the covered entity typically declines to provide the health service to any individual or where the covered entity reasonably determines that such health service is not clinically appropriate for a particular individual. A covered entity's determination must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.

(d) The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

§ 92.207 Nondiscrimination in health insurance coverage and other health-related coverage.

(a) A covered entity must not, in providing or administering health insurance coverage or other health-related coverage, discriminate on the basis of race, color, national origin, sex, age, disability, or any combination thereof.

(b) A covered entity must not, in providing or administering health insurance coverage or other health-related coverage:

(1) Deny, cancel, limit, or refuse to issue or renew health insurance coverage or other health-related coverage, or deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, on the basis of race, color, national origin, sex, age, disability, or any combination thereof;

(2) Have or implement marketing practices or benefit designs that discriminate on the basis of race, color, national origin, sex, age, disability, or any combination thereof, in health insurance coverage or other health-related coverage;

(3) Deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, to an individual based upon the individual's sex assigned at birth, gender identity, or gender otherwise recorded;

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(4) Have or implement a categorical coverage exclusion or limitation for all health services related to gender transition or other gender-affirming care;

(5) Otherwise deny or limit coverage, deny or limit coverage of a claim, or impose additional cost sharing or other limitations or restrictions on coverage, for specific health services related to gender transition or other gender-affirming care if such denial, limitation, or restriction results in discrimination on the basis of sex; or

(6) Have or implement benefit designs that do not provide or administer health insurance coverage or other health-related coverage in the most integrated setting appropriate to the needs of qualified individuals with disabilities, including practices that result in the serious risk of institutionalization or segregation.

(c) Nothing in this section requires coverage of any health service where the covered entity has a legitimate, nondiscriminatory reason for denying or limiting coverage of the health service or determining that such health service fails to meet applicable coverage requirements, including reasonable medical management techniques such as medical necessity requirements. Such coverage denial or limitation must not be based on unlawful animus or bias, or constitute a pretext for discrimination. Nothing in this section is intended to preclude a covered entity from availing itself of protections described in §§ 92.3 and 92.302.

(d) The enumeration of specific forms of discrimination in paragraph (b) of this section does not limit the general applicability of the prohibition in paragraph (a) of this section.

§ 92.208 Prohibition on sex discrimination related to marital, parental, or family status.

In determining whether an individual satisfies any policy or criterion regarding access to its health programs or activities, a covered entity must not take an individual's sex, as defined in § 92.101(a)(2), into account in applying any rule concerning an individual's current, perceived, potential, or past marital, parental, or family status.

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§ 92.209 Nondiscrimination on the basis of association.

A covered entity must not exclude from participation in, deny the benefits of, or otherwise discriminate against an individual or entity in its health programs and activities on the basis of the respective race, color, national origin, sex, age, or disability of the individual and another person with whom the individual or entity has a relationship or association.

§ 92.210 Nondiscrimination in the use of patient care decision support tools.

(a) *General prohibition.* A covered entity must not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs or activities through the use of patient care decision support tools.

(b) *Identification of risk.* A covered entity has an ongoing duty to make reasonable efforts to identify uses of patient care decision support tools in its health programs or activities that employ input variables or factors that measure race, color, national origin, sex, age, or disability.

(c) *Mitigation of risk.* For each patient care decision support tool identified in paragraph (b) of this section, a covered entity must make reasonable efforts to mitigate the risk of discrimination resulting from the tool's use in its health programs or activities.

§ 92.211 Nondiscrimination in the delivery of health programs and activities through telehealth services.

A covered entity must not, in delivery of its health programs and activities through telehealth services, discriminate on the basis of race, color, national origin, sex, age, or disability.

Subpart D—Procedures

§ 92.301 Enforcement mechanisms.

The enforcement mechanisms available for and provided under title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975 shall apply for purposes of section 1557 as implemented by this part.

§ 92.302 Notification of views regarding application of Federal religious freedom and conscience laws.

(a) *General application.* A recipient may rely on applicable Federal protections for religious freedom and conscience, and consistent with § 92.3(c), application of a particular provision(s) of this part to specific contexts, procedures, or health care services shall not be required where such protections apply.

(b) *Assurance of religious freedom and conscience exemption.* A recipient that seeks assurance consistent with paragraph (a) of this section regarding the application of particular provision(s) of this part to specific contexts, procedures, or health care services may do so by submitting a notification in writing to the Director of OCR. Notification may be provided by the recipient at any time, including before an investigation is initiated or during the pendency of an investigation. The notification must include:

(1) The particular provision(s) of this part from which the recipient asserts they are exempt under Federal religious freedom or conscience protections;

(2) The legal basis supporting the recipient's exemption should include the standards governing the applicable Federal religious freedom and conscience protections, such as the provisions in the ACA itself; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of the Religious Freedom Restoration Act (RFRA); or any other applicable Federal laws; and

(3) The factual basis supporting the recipient's exemption, including identification of the conflict between the recipient's religious or conscience beliefs and the requirements of this part, which may include the specific contexts, procedures, or health care services that the recipient asserts will violate their religious or conscience beliefs overall or based on an individual patient matter.

(c) *Temporary exemption.* A temporary exemption from administrative investigation and enforcement will take effect upon the recipient's submission of the notification—regardless of whether the assurance is sought before or dur-

ing an investigation. The temporary exemption is limited to the application of the particular provision(s) in this part as applied to the specific contexts, procedures, or health care services identified in the notification to OCR.

(1) If the notification is received before an investigation is initiated, within 30 days of receiving the notification, OCR must provide the recipient with email confirmation acknowledging receipt of the notification. OCR will then work expeditiously to reach a determination of recipient's notification request.

(2) If the notification is received during the pendency of an investigation, the temporary exemption will exempt conduct as applied to the specific contexts, procedures, or health care services identified in the notification during the pendency of OCR's review and determination regarding the notification request. The notification shall further serve as a defense to the relevant investigation or enforcement activity regarding the recipient until the final determination of recipient's exemption assurance request or the conclusion of the investigation.

(d) *Effect of determination.* If OCR makes a determination to provide assurance of the recipient's exemption from the application of certain provision(s) of this part or that modified application of certain provision(s) is required, OCR will provide the recipient its determination in writing, and if granted, the recipient will be considered exempt from OCR's administrative investigation and enforcement with regard to the application of that provision(s) as applied to the specific contexts, procedures, or health care services provided. The determination does not otherwise limit the application of any other provision of this part to the recipient or to other contexts, procedures, or health care services.

(e) *Appeal.* A recipient subject to an adverse determination of its request for an exemption assurance may appeal OCR's determination under the administrative procedures set forth at 45 CFR part 81. The temporary exemption provided for in paragraph (c) of this section will expire upon a final decision under 45 CFR part 81.

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(f) *Final agency action.* A determination under this section is not final for purposes of judicial review until after a final decision under 45 CFR part 81.

§ 92.303 Procedures for health programs and activities conducted by recipients and State Exchanges.

(a) The procedural provisions applicable to title VI apply with respect to administrative enforcement actions against health programs and activities of recipients and State Exchanges concerning discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof, under section 1557 or this part. These procedures are found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

(b) If OCR receives a complaint over which it does not have jurisdiction, it shall promptly notify the complainant and shall make reasonable efforts to refer the complaint to the appropriate Federal Government entity.

(c) When a recipient or State Exchange fails to provide OCR with requested information in a timely, complete, and accurate manner, OCR may, after attempting to reach voluntary resolution, find noncompliance with section 1557 or this part and initiate appropriate enforcement procedures, found at 45 CFR 80.8, including beginning the process for fund suspension or termination and taking other action authorized by law.

§ 92.304 Procedures for health programs and activities administered by the Department.

(a) The procedural provisions applicable to section 504 shall apply with respect to administrative enforcement actions against the Department, including Federally-facilitated Exchanges, concerning discrimination on the basis of race, color, national origin, sex, age, disability, or any combination thereof, under section 1557 or this part. These procedures are found at 45 CFR 85.61 and 85.62. Where this section cross-references regulatory provisions that use the term “handicap,” the term “race, color, national origin, sex, age, or disability, or any combination thereof,” shall apply in its place.

(b) The Department must permit access by OCR to its books, records, ac-

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counts, other sources of information, and facilities as may be pertinent to ascertain compliance with section 1557 or this part. Where any information required of the Department is in the exclusive possession of any other agency, institution or person, and the other agency, institution or person fails or refuses to furnish this information, the Department shall so certify and shall set forth what efforts it has made to obtain the information. Asserted considerations of privacy or confidentiality may not operate to bar OCR from evaluating or seeking to enforce compliance with section 1557 or this part. Information of a confidential nature obtained in connection with compliance evaluation or enforcement shall not be disclosed except where necessary under the law.

(c) The Department must not intimidate, threaten, coerce, retaliate, or otherwise discriminate against any individual or entity for the purpose of interfering with any right or privilege secured by section 1557 or this part, or because such individual or entity has made a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under section 1557 or this part. The identity of complainants must be kept confidential by OCR in accordance with applicable Federal law.

PART 93—NEW RESTRICTIONS ON LOBBYING

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APPENDIX A TO PART 93—CERTIFICATION REGARDING LOBBYING

APPENDIX B TO PART 93—DISCLOSURE FORM TO REPORT LOBBYING

AUTHORITY: Section 319, Public Law 101-121 (31 U.S.C. 1352); (5 U.S.C. 301).

SOURCE: 55 FR 6754, Feb. 26, 1990, unless otherwise noted.

CROSS REFERENCE: See also Office of Management and Budget notice published at 54 FR 52306, December 20, 1989.

Subpart A—General

§ 93.100 Conditions on use of funds.

(a) No appropriated funds may be expended by the recipient of a Federal contract, grant, loan, or cooperative agreement to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions: the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(b) Each person who requests or receives from an agency a Federal contract, grant, loan, or cooperative agreement shall file with that agency a certification, set forth in appendix A to this part, that the person has not made, and will not make, any payment prohibited by paragraph (a) of this section.

(c) Each person who requests or receives from an agency a Federal contract, grant, loan, or a cooperative agreement shall file with that agency a disclosure form, set forth in appendix B to this part, if such person has made or has agreed to make any payment using nonappropriated funds (to include profits from any covered Federal action), which would be prohibited under para-

graph (a) of this section if paid for with appropriated funds.

(d) Each person who requests or receives from an agency a commitment providing for the United States to insure or guarantee a loan shall file with that agency a statement, set forth in appendix A to this part, whether that person has made or has agreed to make any payment to influence or attempt to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with that loan insurance or guarantee.

(e) Each person who requests or receives from an agency a commitment providing for the United States to insure or guarantee a loan shall file with that agency a disclosure form, set forth in appendix B to this part, if that person has made or has agreed to make any payment to influence or attempt to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with that loan insurance or guarantee.

§ 93.105 Definitions.

For purposes of this part:

(a) *Agency*, as defined in 5 U.S.C. 552(f), includes Federal executive departments and agencies as well as independent regulatory commissions and Government corporations, as defined in 31 U.S.C. 9101(1).

(b) *Covered Federal action* means any of the following Federal actions:

(1) The awarding of any Federal contract;

(2) The making of any Federal grant;

(3) The making of any Federal loan;

(4) The entering into of any cooperative agreement; and,

(5) The extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

Covered Federal action does not include receiving from an agency a commitment providing for the United States to insure or guarantee a loan. Loan guarantees and loan insurance are addressed independently within this part.

(c) *Federal contract* means an acquisition contract awarded by an agency, including those subject to the Federal Acquisition Regulation (FAR), and any other acquisition contract for real or personal property or services not subject to the FAR.

(d) *Federal cooperative agreement* means a cooperative agreement entered into by an agency.

(e) *Federal grant* means an award of financial assistance in the form of money, or property in lieu of money, by the Federal Government or a direct appropriation made by law to any person. The term does not include technical assistance which provides services instead of money, or other assistance in the form of revenue sharing, loans, loan guarantees, loan insurance, interest subsidies, insurance, or direct United States cash assistance to an individual.

(f) *Federal loan* means a loan made by an agency. The term does not include loan guarantee or loan insurance.

(g) *Indian tribe* and *tribal organization* have the meaning provided in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450B). Alaskan Natives are included under the definitions of Indian tribes in that Act.

(h) *Influencing or attempting to influence* means making, with the intent to influence, any communication to or appearance before an officer or employee or any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any covered Federal action.

(i) *Loan guarantee* and *loan insurance* means an agency's guarantee or insurance of a loan made by a person.

(j) *Local government* means a unit of government in a State and, if chartered, established, or otherwise recognized by a State for the performance of a governmental duty, including a local public authority, a special district, an intrastate district, a council of governments, a sponsor group representative organization, and any other instrumentality of a local government.

(k) *Officer or employee of an agency* includes the following individuals who are employed by an agency:

(1) An individual who is appointed to a position in the Government under title 5, U.S. Code, including a position under a temporary appointment;

(2) A member of the uniformed services as defined in section 101(3), title 37, U.S. Code;

(3) A special Government employee as defined in section 202, title 18, U.S. Code; and,

(4) An individual who is a member of a Federal advisory committee, as defined by the Federal Advisory Committee Act, title 5, U.S. Code appendix 2.

(l) *Person* means an individual, corporation, company, association, authority, firm, partnership, society, State, and local government, regardless of whether such entity is operated for profit or not for profit. This term excludes an Indian tribe, tribal organization, or any other Indian organization with respect to expenditures specifically permitted by other Federal law.

(m) *Reasonable compensation* means, with respect to a regularly employed officer or employee of any person, compensation that is consistent with the normal compensation for such officer or employee for work that is not furnished to, not funded by, or not furnished in cooperation with the Federal Government.

(n) *Reasonable payment* means, with respect to professional and other technical services, a payment in an amount that is consistent with the amount normally paid for such services in the private sector.

(o) *Recipient* includes all contractors, subcontractors at any tier, and subgrantees at any tier of the recipient of funds received in connection with a Federal contract, grant, loan, or cooperative agreement. The term excludes an Indian tribe, tribal organization, or any other Indian organization with respect to expenditures specifically permitted by other Federal law.

(p) *Regularly employed* means, with respect to an officer or employee of a person requesting or receiving a Federal contract, grant, loan, or cooperative agreement or a commitment providing for the United States to insure or guarantee a loan, an officer or employee who is employed by such person

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for at least 130 working days within one year immediately preceding the date of the submission that initiates agency consideration of such person for receipt of such contract, grant, loan, cooperative agreement, loan insurance commitment, or loan guarantee commitment. An officer or employee who is employed by such person for less than 130 working days within one year immediately preceding the date of the submission that initiates agency consideration of such person shall be considered to be regularly employed as soon as he or she is employed by such person for 130 working days.

(q) *State* means a State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, a territory or possession of the United States, an agency or instrumentality of a State, and a multi-State, regional, or interstate entity having governmental duties and powers.

§ 93.110 Certification and disclosure.

(a) Each person shall file a certification, and a disclosure form, if required, with each submission that initiates agency consideration of such person for:

(1) Award of a Federal contract, grant, or cooperative agreement exceeding \$100,000; or

(2) An award of a Federal loan or a commitment providing for the United States to insure or guarantee a loan exceeding \$150,000.

(b) Each person shall file a certification, and a disclosure form, if required, upon receipt by such person of:

(1) A Federal contract, grant, or cooperative agreement exceeding \$100,000; or

(2) A Federal loan or a commitment providing for the United States to insure or guarantee a loan exceeding \$150,000,

unless such person previously filed a certification, and a disclosure form, if required, under paragraph (a) of this section.

(c) Each person shall file a disclosure form at the end of each calendar quarter in which there occurs any event that requires disclosure or that materially affects the accuracy of the information contained in any disclosure form previously filed by such person

under paragraphs (a) or (b) of this section. An event that materially affects the accuracy of the information reported includes:

(1) A cumulative increase of \$25,000 or more in the amount paid or expected to be paid for influencing or attempting to influence a covered Federal action; or

(2) A change in the person(s) or individual(s) influencing or attempting to influence a covered Federal action; or,

(3) A change in the officer(s), employee(s), or Member(s) contacted to influence or attempt to influence a covered Federal action.

(d) Any person who requests or receives from a person referred to in paragraphs (a) or (b) of this section:

(1) A subcontract exceeding \$100,000 at any tier under a Federal contract;

(2) A subgrant, contract, or subcontract exceeding \$100,000 at any tier under a Federal grant;

(3) A contract or subcontract exceeding \$100,000 at any tier under a Federal loan exceeding \$150,000; or,

(4) A contract or subcontract exceeding \$100,000 at any tier under a Federal cooperative agreement,

shall file a certification, and a disclosure form, if required, to the next tier above.

(e) All disclosure forms, but not certifications, shall be forwarded from tier to tier until received by the person referred to in paragraphs (a) or (b) of this section. That person shall forward all disclosure forms to the agency.

(f) Any certification or disclosure form filed under paragraph (e) of this section shall be treated as a material representation of fact upon which all receiving tiers shall rely. All liability arising from an erroneous representation shall be borne solely by the tier filing that representation and shall not be shared by any tier to which the erroneous representation is forwarded. Submitting an erroneous certification or disclosure constitutes a failure to file the required certification or disclosure, respectively. If a person fails to file a required certification or disclosure, the United States may pursue all available remedies, including those authorized by section 1352, title 31, U.S. Code.

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(g) For awards and commitments in process prior to December 23, 1989, but not made before that date, certifications shall be required at award or commitment, covering activities occurring between December 23, 1989, and the date of award or commitment. However, for awards and commitments in process prior to the December 23, 1989 effective date of these provisions, but not made before December 23, 1989, disclosure forms shall not be required at time of award or commitment but shall be filed within 30 days.

(h) No reporting is required for an activity paid for with appropriated funds if that activity is allowable under either subpart B or C.

Subpart B—Activities by Own Employees

§ 93.200 Agency and legislative liaison.

(a) The prohibition on the use of appropriated funds, in § 93.100 (a), does not apply in the case of a payment of reasonable compensation made to an officer or employee of a person requesting or receiving a Federal contract, grant, loan, or cooperative agreement if the payment is for agency and legislative liaison activities not directly related to a covered Federal action.

(b) For purposes of paragraph (a) of this section, providing any information specifically requested by an agency or Congress is allowable at any time.

(c) For purposes of paragraph (a) of this section, the following agency and legislative liaison activities are allowable at any time only where they are not related to a specific solicitation for any covered Federal action:

(1) Discussing with an agency (including individual demonstrations) the qualities and characteristics of the person's products or services, conditions or terms of sale, and service capabilities; and,

(2) Technical discussions and other activities regarding the application or adaptation of the person's products or services for an agency's use.

(d) For purposes of paragraph (a) of this section, the following agencies and legislative liaison activities are allowable only where they are prior to formal solicitation of any covered Federal action:

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(1) Providing any information not specifically requested but necessary for an agency to make an informed decision about initiation of a covered Federal action;

(2) Technical discussions regarding the preparation of an unsolicited proposal prior to its official submission; and,

(3) Capability presentations by persons seeking awards from an agency pursuant to the provisions of the Small Business Act, as amended by Public Law 95–507 and other subsequent amendments.

(e) Only those activities expressly authorized by this section are allowable under this section.

§ 93.205 Professional and technical services.

(a) The prohibition on the use of appropriated funds, in § 93.100 (a), does not apply in the case of a payment of reasonable compensation made to an officer or employee of a person requesting or receiving a Federal contract, grant, loan, or cooperative agreement or an extension, continuation, renewal, amendment, or modification of a Federal contract, grant, loan, or cooperative agreement if payment is for professional or technical services rendered directly in the preparation, submission, or negotiation of any bid, proposal, or application for that Federal contract, grant, loan, or cooperative agreement or for meeting requirements imposed by or pursuant to law as a condition for receiving that Federal contract, grant, loan, or cooperative agreement.

(b) For purposes of paragraph (a) of this section, *professional and technical services* shall be limited to advice and analysis directly applying any professional or technical discipline. For example, drafting of a legal document accompanying a bid or proposal by a lawyer is allowable. Similarly, technical advice provided by an engineer on the performance or operational capability of a piece of equipment rendered directly in the negotiation of a contract is allowable. However, communications with the intent to influence made by a professional (such as a licensed lawyer) or a technical person (such as a licensed accountant) are not allowable

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under this section unless they provide advice and analysis directly applying their professional or technical expertise and unless the advice or analysis is rendered directly and solely in the preparation, submission or negotiation of a covered Federal action. Thus, for example, communications with the intent to influence made by a lawyer that do not provide legal advice or analysis directly and solely related to the legal aspects of his or her client's proposal, but generally advocate one proposal over another are not allowable under this section because the lawyer is not providing professional legal services. Similarly, communications with the intent to influence made by an engineer providing an engineering analysis prior to the preparation or submission of a bid or proposal are not allowable under this section since the engineer is providing technical services but not directly in the preparation, submission or negotiation of a covered Federal action.

(c) Requirements imposed by or pursuant to law as a condition for receiving a covered Federal award include those required by law or regulation, or reasonably expected to be required by law or regulation, and any other requirements in the actual award documents.

(d) Only those services expressly authorized by this section are allowable under this section.

§ 93.210 Reporting.

No reporting is required with respect to payments of reasonable compensation made to regularly employed officers or employees of a person.

Subpart C—Activities by Other than Own Employees

§ 93.300 Professional and technical services.

(a) The prohibition on the use of appropriated funds, in § 93.100 (a), does not apply in the case of any reasonable payment to a person, other than an officer or employee of a person requesting or receiving a covered Federal action, if the payment is for professional or technical services rendered directly in the preparation, submission, or negotiation of any bid, proposal, or appli-

cation for that Federal contract, grant, loan, or cooperative agreement or for meeting requirements imposed by or pursuant to law as a condition for receiving that Federal contract, grant, loan, or cooperative agreement.

(b) The reporting requirements in § 93.110 (a) and (b) regarding filing a disclosure form by each person, if required, shall not apply with respect to professional or technical services rendered directly in the preparation, submission, or negotiation of any commitment providing for the United States to insure or guarantee a loan.

(c) For purposes of paragraph (a) of this section, *professional and technical services* shall be limited to advice and analysis directly applying any professional or technical discipline. For example, drafting or a legal document accompanying a bid or proposal by a lawyer is allowable. Similarly, technical advice provided by an engineer on the performance or operational capability of a piece of equipment rendered directly in the negotiation of a contract is allowable. However, communications with the intent to influence made by a professional (such as a licensed lawyer) or a technical person (such as a licensed accountant) are not allowable under this section unless they provide advice and analysis directly applying their professional or technical expertise and unless the advice or analysis is rendered directly and solely in the preparation, submission or negotiation of a covered Federal action. Thus, for example, communications with the intent to influence made by a lawyer that do not provide legal advice or analysis directly and solely related to the legal aspects of his or her client's proposal, but generally advocate one proposal over another are not allowable under this section because the lawyer is not providing professional legal services. Similarly, communications with the intent to influence made by an engineer providing an engineering analysis prior to the preparation or submission of a bid or proposal are not allowable under this section since the engineer is providing technical services but not directly in the preparation, submission or negotiation of a covered Federal action.

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(d) Requirements imposed by or pursuant to law as a condition for receiving a covered Federal award include those required by law or regulation, or reasonably expected to be required by law or regulation, and any other requirements in the actual award documents.

(e) Persons other than officers or employees of a person requesting or receiving a covered Federal action include consultants and trade associations.

(f) Only those services expressly authorized by this section are allowable under this section.

Subpart D—Penalties and Enforcement

§ 93.400 Penalties.

(a) Any person who makes an expenditure prohibited herein shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000¹ for each such expenditure.

(b) Any person who fails to file or amend the disclosure form (see appendix B to this part) to be filed or amended if required herein, shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

(c) A filing or amended filing on or after the date on which an administrative action for the imposition of a civil penalty is commenced does not prevent the imposition of such civil penalty for a failure occurring before that date. An administrative action is commenced with respect to a failure when an investigating official determines in writing to commence an investigation of an allegation of such failure.

(d) In determining whether to impose a civil penalty, and the amount of any such penalty, by reason of a violation by any person, the agency shall consider the nature, circumstances, extent, and gravity of the violation, the

¹The amounts specified in this section are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74). Annually adjusted amounts are published at 45 CFR part 102.

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effect on the ability of such person to continue in business, any prior violations by such person, the degree of culpability of such person, the ability of the person to pay the penalty, and such other matters as may be appropriate.

(e) First offenders under paragraphs (a) or (b) of this section shall be subject to a civil penalty of \$10,000, absent aggravating circumstances. Second and subsequent offenses by persons shall be subject to an appropriate civil penalty between \$10,000 and \$100,000, as determined by the agency head or his or her designee.

(f) An imposition of a civil penalty under this section does not prevent the United States from seeking any other remedy that may apply to the same conduct that is the basis for the imposition of such civil penalty.

[55 FR 6754, Feb. 26, 1990, as amended at 81 FR 61565, Sept. 6, 2016]

§ 93.405 Penalty procedures.

Agencies shall impose and collect civil penalties pursuant to the provisions of the Program Fraud and Civil Remedies Act, 31 U.S.C. sections 3803 (except subsection (c)), 3804, 3805, 3806, 3807, 3808, and 3812, insofar as these provisions are not inconsistent with the requirements herein.

§ 93.410 Enforcement.

The head of each agency shall take such actions as are necessary to ensure that the provisions herein are vigorously implemented and enforced in that agency.

Subpart E—Exemptions

§ 93.500 Secretary of Defense.

(a) The Secretary of Defense may exempt, on a case-by-case basis, a covered Federal action from the prohibition whenever the Secretary determines, in writing, that such an exemption is in the national interest. The Secretary shall transmit a copy of each such written exemption to Congress immediately after making such a determination.

(b) The Department of Defense may issue supplemental regulations to implement paragraph (a) of this section.

Subpart F—Agency Reports**§ 93.600 Semi-annual compilation.**

(a) The head of each agency shall collect and compile the disclosure reports (see appendix B to this part) and, on May 31 and November 30 of each year, submit to the Secretary of the Senate and the Clerk of the House of Representatives a report containing a compilation of the information contained in the disclosure reports received during the six-month period ending on March 31 or September 30, respectively, of that year.

(b) The report, including the compilation, shall be available for public inspection 30 days after receipt of the report by the Secretary and the Clerk.

(c) Information that involves intelligence matters shall be reported only to the Select Committee on Intelligence of the Senate, the Permanent Select Committee on Intelligence of the House of Representatives, and the Committees on Appropriations of the Senate and the House of Representatives in accordance with procedures agreed to by such committees. Such information shall not be available for public inspection.

(d) Information that is classified under Executive Order 12356 or any successor order shall be reported only to the Committee on Foreign Relations of the Senate and the Committee on Foreign Affairs of the House of Representatives or the Committees on Armed Services of the Senate and the House of Representatives (whichever such committees have jurisdiction of matters involving such information) and to the Committees on Appropriations of the Senate and the House of Representatives in accordance with procedures agreed to by such committees. Such information shall not be available for public inspection.

(e) The first semi-annual compilation shall be submitted on May 31, 1990, and shall contain a compilation of the disclosure reports received from December 23, 1989 to March 31, 1990.

(f) Major agencies, designated by the Office of Management and Budget (OMB), are required to provide machine-readable compilations to the Secretary of the Senate and the Clerk of the House of Representatives no

later than with the compilations due on May 31, 1991. OMB shall provide detailed specifications in a memorandum to these agencies.

(g) Non-major agencies are requested to provide machine-readable compilations to the Secretary of the Senate and the Clerk of the House of Representatives.

(h) Agencies shall keep the originals of all disclosure reports in the official files of the agency.

§ 93.605 Inspector General report.

(a) The Inspector General, or other official as specified in paragraph (b) of this section, of each agency shall prepare and submit to Congress each year, commencing with submission of the President's Budget in 1991, an evaluation of the compliance of that agency with, and the effectiveness of, the requirements herein. The evaluation may include any recommended changes that may be necessary to strengthen or improve the requirements.

(b) In the case of an agency that does not have an Inspector General, the agency official comparable to an Inspector General shall prepare and submit the annual report, or, if there is no such comparable official, the head of the agency shall prepare and submit the annual report.

(c) The annual report shall be submitted at the same time the agency submits its annual budget justifications to Congress.

(d) The annual report shall include the following: All alleged violations relating to the agency's covered Federal actions during the year covered by the report, the actions taken by the head of the agency in the year covered by the report with respect to those alleged violations and alleged violations in previous years, and the amounts of civil penalties imposed by the agency in the year covered by the report.

APPENDIX A TO PART 93—CERTIFICATION REGARDING LOBBYING*Certification for Contracts, Grants, Loans, and Cooperative Agreements*

The undersigned certifies, to the best of his or her knowledge and belief, that:

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(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the

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required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000¹ for each such failure.

Statement for Loan Guarantees and Loan Insurance

The undersigned states, to the best of his or her knowledge and belief, that:

If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

[55 FR 6754, Feb. 26, 1990, as amended at 81 FR 61565, Sept. 6, 2016]

¹The amounts specified in Appendix A to Part 93 are updated annually, as adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101-140), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74). Annually adjusted amounts are published at 45 CFR part 102.

APPENDIX B TO PART 93—DISCLOSURE FORM TO REPORT LOBBYING

DISCLOSURE OF LOBBYING ACTIVITIES

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

Approved by OMB
0348-0046

1. Type of Federal Action: ☐ a. contract ☐ b. grant ☐ c. cooperative agreement ☐ d. loan ☐ e. loan guarantee ☐ f. loan insurance		2. Status of Federal Action: ☐ a. bid/offer/application ☐ b. initial award ☐ c. post-award		3. Report Type: ☐ a. initial filing ☐ b. material change For Material Change Only: year _____ quarter _____ date of last report _____	
4. Name and Address of Reporting Entity: ☐ Prime ☐ Subawardee Tier _____, if known: Congressional District, if known: _____			5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime: Congressional District, if known: _____		
6. Federal Department/Agency:			7. Federal Program Name/Description: CFDA Number, if applicable: _____		
8. Federal Action Number, if known:			9. Award Amount, if known: \$ _____		
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): (attach Continuation Sheet(s) SF-LLL-A, if necessary)			b. Individuals Performing Services (including address if different from No. 10a) (last name, first name, MI): (attach Continuation Sheet(s) SF-LLL-A, if necessary)		
11. Amount of Payment (check all that apply): \$ _____ ☐ actual ☐ planned			13. Type of Payment (check all that apply): ☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____		
12. Form of Payment (check all that apply): ☐ a. cash ☐ b. in-kind; specify: nature _____ value _____					
14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for Payment Indicated in Item 11: (attach Continuation Sheet(s) SF-LLL-A, if necessary)					
15. Continuation Sheet(s) SF-LLL-A attached: ☐ Yes ☐ No					
16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.			Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____		
Federal Use Only:			Authorized for Local Reproduction Standard Form - LLL		

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee or prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a followup report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee", then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number; Invitation for Bid (IFB) number; grant announcement number; the contract, grant, or loan award number; the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.
(b) Enter the full names of the individual(s) performing services, and include full address if different from 10 (a). Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material change report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

**DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET**

Approved by OMB
0348-0046

Reporting Entity: _____	Page _____ of _____

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Standard Form - LLL-A

**PART 94—RESPONSIBLE
PROSPECTIVE CONTRACTORS**

Sec.
94.1 Purpose.

94.2 Applicability.
94.3 Definitions.
94.4 Responsibilities of Institutions regard-
ing Investigator financial conflicts of in-
terest.

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94.5 Management and reporting of financial conflicts of interest.

94.6 Remedies.

AUTHORITY: 42 U.S.C. 216, 289b-1, 299c-4.

SOURCE: 76 FR 53288, Aug. 25, 2011, unless otherwise noted.

§ 94.1 Purpose.

This part promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research performed under PHS contracts will be free from bias resulting from Investigator financial conflicts of interest.

§ 94.2 Applicability.

This part is applicable to each Institution that submits a proposal, or that receives, Public Health Service (PHS) research funding by means of a contract and, through the implementation of this part by the Institution, to each Investigator who is planning to participate in, or is participating in such research; provided, however, that this part does not apply to SBIR Program Phase I applications.

§ 94.3 Definitions.

As used in this part:

Contractor means an entity that provides property or services under contract for the direct benefit or use of the Federal Government.

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agen-

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cy) that submits a proposal, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding, which may include, for example, collaborators or consultants.

Key personnel includes the PD/PI and any other personnel considered to be essential to work performance in accordance with HHSAR subpart 352.242-70 and identified as key personnel in the contract proposal and contract.

Manage means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.

PD/PI means a project director or principal Investigator of a PHS-funded research project; the PD/PI is included in the definitions of key personnel and Investigator under this part.

PHS means the Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

PHS Awarding Component means the organizational unit of the PHS that funds the research that is subject to this part.

Public Health Service Act or *PHS Act* means the statute codified at 42 U.S.C. 201 *et seq.*

Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and

social-sciences research. The term encompasses basic and applied research (e.g., a published article, book or book chapter) and product development (e.g., a diagnostic test or drug). As used in this part, the term includes any such activity for which research funding is available from a PHS Awarding Component through a contract, whether authorized under the PHS Act or other statutory authority.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

(i) With regard to any publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any non-publicly traded entity, a *significant financial interest* exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

(iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

(2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their

Institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the Institutional official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education; or income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

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Small Business Innovation Research (SBIR) Program means the extramural research program for small businesses that is established by the Awarding Components of the Public Health Service and certain other Federal agencies under Public Law 97-219, the Small Business Innovation Development Act, as amended. For purposes of this part, the term SBIR Program also includes the Small Business Technology Transfer (STTR) Program, which was established by Public Law 102-564.

§ 94.4 Responsibilities of Institutions regarding Investigator financial conflicts of interest.

Each Institution shall:

(a) Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this part, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the PHS award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this part (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the PHS Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this part.

(b) Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any PHS-funded contract and at least every four years, and immediately when any of the following circumstances apply:

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(1) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

(2) An Investigator is new to an Institution; or

(3) An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

(c) If the Institution carries out the PHS-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this part by

(1) Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

(i) If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this part. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

(ii) Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the PHS as required by this part;

(iii) Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit

all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this part.

(2) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this part, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

(d) Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

(e)(1) Require that each Investigator who is planning to participate in the PHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than date of submission of the Institution's proposal for PHS-funded research.

(2) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a PHS-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

(3) Require each Investigator who is participating in the PHS-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

(f) Provide guidelines consistent with this part for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to PHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to PHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the PHS-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the PHS-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

(g) Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to § 94.5(a).

(h) Provide initial and ongoing FCOI reports to the PHS as required pursuant to § 94.5(b).

(i) Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest), and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7.

(j) Establish adequate enforcement mechanisms and provide for employee

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sanctions or other administrative actions to ensure Investigator compliance as appropriate.

(k) Certify, in each contract proposal to which this part applies, that the Institution:

(1) Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the PHS;

(2) Shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;

(3) Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with this part;

(4) Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and

(5) Shall fully comply with the requirements of this part.

§ 94.5 Management and reporting of financial conflicts of interest.

(a) Management of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the designated official(s) of an Institution shall, consistent with § 94.4(f): review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

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(i) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

(ii) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

(iii) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial conflict of interest;

(iv) Modification of the research plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

(vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

(vii) Severance of relationships that create financial conflicts.

(2) Whenever, in the course of an ongoing PHS-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of the Institution's review.

(3) Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing PHS-funded research project (e.g., was not timely reviewed

or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine whether a financial conflict of interest exists; and, if so:

(i) Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

(ii) (A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of non-compliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-funded research, or portion thereof, conducted during the time period of the non-compliance, was biased in the design, conduct, or reporting of such research.

(B) The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- (1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

(iii) Based on the results of the retrospective review, if appropriate, the Institution shall update the previously

submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this part. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

(4) Whenever an Institution implements a management plan pursuant to this part, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

(5)(i) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

(A) The significant financial interest was disclosed and is still held by key personnel as defined in this part;

(B) The Institution determines that the significant financial interest is related to the PHS-funded research; and

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(C) The Institution determines that the significant financial interest is a financial conflict of interest.

(ii) The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: The Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

(iii) If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the PHS-funded research project, if the Institution determines that the significant financial interest is related to the PHS-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the In-

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stitution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

(iv) Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

(6) In addition to the types of financial conflicts of interest as defined in this part that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

(b) Reporting of financial conflicts of interest.

(1) Prior to the Institution's expenditure of any funds under a PHS-funded research project, the Institution shall provide to the PHS Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this part. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of PHS-awarded funds, the Institution shall not submit an FCOI report to the PHS Awarding Component.

(2) For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the PHS Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this part. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or,

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for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Institution is required to notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

(3) Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

- (i) Project/Contract number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) Value of the financial interest (dollar ranges are permissible: \$0–\$4,999; \$5,000–\$9,999; \$10,000–\$19,999; amounts between \$20,000–\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
- (vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of the Institution's management plan, including:

- (A) Role and principal duties of the conflicted Investigator in the research project;
- (B) Conditions of the management plan;
- (C) How the management plan is designed to safeguard objectivity in the research project;
- (D) Confirmation of the Investigator's agreement to the management plan;
- (E) How the management plan will be monitored to ensure Investigator compliance; and
- (F) Other information as needed.

(4) For any financial conflict of interest previously reported by the Institution with regard to an ongoing PHS-funded research project, the Institution shall provide to the PHS Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

(5) In addition to the types of financial conflicts of interest as defined in this part that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

§ 94.6 Remedies.

(a) If the failure of an Investigator to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Institution shall promptly notify the PHS Awarding Component of the corrective action

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taken or to be taken. The PHS Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS-funded research project.

(b) The PHS Awarding Component and/or HHS may inquire at any time (before, during, or after award) into any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, regardless of whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest. An Institution is required to submit, or permit on site review of, all records pertinent to compliance with this part. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS Awarding Component may decide that a particular financial conflict of interest will bias the objectivity of the PHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with this part. The PHS Awarding Component may determine that issuance of a Stop Work Order by the Contracting Officer or other enforcement action is necessary until the matter is resolved.

(c) In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by this part, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

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PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE, MEDICAL ASSISTANCE AND STATE CHILDREN'S HEALTH INSURANCE PROGRAMS)

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AUTHORITY: 5 U.S.C. 301, 42 U.S.C. 622(b), 629b(a), 652(a), 652(d), 654A, 671(a), 1302, and 1396a(a).

Subpart A—Time Limits for States To File Claims

SOURCE: 46 FR 3529, Jan. 15, 1981, unless otherwise noted.

§ 95.1 Scope.

(a) This subpart establishes a two year time limit (15 months in some cases) for a State to claim Federal financial participation in expenditures under State plans approved under the following titles of the Social Security Act:

Title I—Grants to States for Old-Age Assistance and Medical Assistance for the Aged.

Title IV-A—Grants to States for Aid and Services to Needy Families with Dependent Children (except for Section 402(a)(19)(G) of the Act).

Title IV-B—Child Welfare Services.

Title IV-D—Child Support and Establishment of Paternity.

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Title X—Grants to States for Aid to the Blind.

Title XIV—Grants to States for Aid to the Permanently and Totally Disabled.

Title XVI—Grants to States for Aid to the Aged, Blind, or Disabled (AABD), or for Such Aid and Medical Assistance for the Aged.

Title XIX—Grants to States for Medical Assistance Programs.

Title XX—Grants to States for Services.

Title XXI—Grants to States for State Children's Health Insurance Programs.

(b) This subpart also applies to claims for Federal financial participation by any State which are based on any provision of the Act that is enacted after issuance of these regulations and that provides, on an entitlement basis, for Federal financial participation in expenditures made under State plans or programs.

(c) This subpart explains under what conditions the Secretary may decide to extend the time limit for filing claims when a State believes it has good cause for not meeting the time limit.

[46 FR 3529, Jan. 15, 1981, as amended at 65 FR 33632, May 24, 2000]

§ 95.4 Definitions.

In this subpart—

Adjustment to prior year costs means an adjustment in the amount of a particular cost item that was previously claimed under an interim rate concept and for which it is later determined that the cost is greater or less than that originally claimed.

Audit exception means a proposed adjustment by the responsible Federal agency to any expenditure claimed by a State by virtue of an audit.

Claim means a request for Federal financial participation in the manner and format required by our program regulations, and instructions or directives issued thereunder.

Court-ordered retroactive payment means either a retroactive payment the State makes to an assistance recipient or an individual, under a Federal or State court order or a retroactive payment we make to a State under a Federal court order. Although

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we may accept these claims as timely, this provision does not mean that we necessarily agree to be bound by a State or Federal decision when we were not a party to the action.

Federal financial participation means the Federal government's share of an expenditure made by a State agency under any of the programs listed in § 95.1.

State means the 50 States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa and the Trust Territories of the Pacific.

State agency for the purposes of expenditures for financial assistance under title IV-A and for support enforcement services under title IV-D means any agency or organization of the State or local government which is authorized to incur matchable expenses; for purposes of expenditures under titles XIX and XXI, means any agency of the State, including the State Medicaid agency or State Child Health Agency, its fiscal agents, a State health agency, or any other State or local organization which incurs matchable expenses; for purposes of expenditures under all other titles, see the definitions in the appropriate program's regulations.

The Act means the Social Security Act, as amended.

We, our, and us refer to the HHS Centers for Medicare & Medicaid Services (CMS), and Administration for Children and Families (ACF), depending on the program involved.

[46 FR 3529, Jan. 15, 1981, as amended at 65 FR 33632, May 24, 2000; 75 FR 66336, Oct. 28, 2010]

§ 95.7 Time limit for claiming payment for expenditures made after September 30, 1979.

Under the programs listed in § 95.1, we will pay a State for a State agency expenditure made after September 30, 1979, only if the State files a claim with us for that expenditure within 2 years after the calendar quarter in which the State agency made the expenditure. Section 95.19 lists the exceptions to this rule.

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§ 95.10 Time limit for claiming payment for expenditures made before October 1, 1979.

Under the programs listed in § 95.1, we will pay a State for a State agency expenditure made before October 1, 1979, only if the State filed or files a claim with us for that expenditure before January 1, 1981. Section 95.19 lists the exceptions to this rule.

§ 95.11 Payment of claims subject to appropriations restrictions.

Notwithstanding any other provision of this Subpart, we will pay States' otherwise allowable claims for Federal financial participation under the programs covered by this subpart, subject to the availability of funds (as provided in Acts appropriating funds to the Department in effect at the time in which such claims are being considered for payment), and subject to conditions or restrictions applicable to payments out of such funds, including provisions of the first and second continuing resolutions for FY 1981 (Pub. L. 96-369 and Pub. L. 96-536) and the Supplemental Appropriations and Rescission Act, 1981 (Pub. L. 97-12) that make funds under those Acts available to pay for a State agency expenditure made before September 30, 1978, only if the State had filed a claim for that expenditure with us within one year of the expenditure.

(Pub. L. 96-369, 94 Stat. 1351; Pub. L. 96-536, 94 Stat. 3166; and Pub. L. 97-12, 95 Stat. 14)

[46 FR 46136, Sept. 17, 1981]

§ 95.13 In which quarter we consider an expenditure made.

In this subpart—

(a) We consider a State agency's expenditure for assistance payments under title I, IV-A, IV-E, X, XIV, or XVI (AABD) to have been made in the quarter in which a payment was made to the assistance recipient, his or her protective payee, or a vendor payee, even if the payment was for a month in a previous quarter.

(b) We consider a State agency's expenditure for services under title I, IV-A, IV-B, IV-D, IV-E, X, XIV, XVI (AABD), XIX, or XXI to have been made in the quarter in which any State agency made a payment to the service provider.

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(c) For purposes of title XX, the date of expenditure is governed by 45 CFR 1396.52(d).

(d) We consider a State agency's expenditure for administration or training under titles I, IV-A, IV-B, IV-D, IV-E, X, XIV, XVI (AABD), XIX, or XXI to have been made in the quarter payment was made by a State agency to a private agency or individual; or in the quarter to which the costs were allocated in accordance with the regulations for each program. We consider a State agency's expenditure under these titles for non-cash expenditures such as depreciation to have been made in the quarter the expenditure was recorded in the accounting records of any State agency in accordance with generally accepted accounting principles.

[46 FR 3529, Jan. 15, 1981, as amended at 65 FR 33632, May 24, 2000]

§ 95.19 Exceptions to time limits.

The time limits in §§ 95.7 and 95.10 do not apply to any of the following—

(a) Any claim for an adjustment to prior year costs.

(b) Any claim resulting from an audit exception.

(c) Any claim resulting from a court-ordered retroactive payment.

(d) Any claim for which the Secretary decides there was good cause for the State's not filing it within the time limit.

§ 95.22 Meaning of good cause.

(a) Good cause for the late filing of a claim is lateness due to circumstances beyond the State's control.

(b) Examples of circumstances beyond the State's control include:

(1) Acts of God;

(2) Documented action or inaction of the Federal government.

(c) Circumstances beyond the State's control do not include neglect or administrative inadequacy on the part of the State, State agencies, the State legislature or any of their offices, officers, or employees.

§ 95.25 When to request a waiver for good cause.

The State should request a waiver in writing as soon as the State recognizes that it will be unable to submit a claim within the appropriate time limit.

§ 95.28 What a waiver request for good cause must include.

The State's request for waiver must include a specific explanation, justification or documentation of why the claim is or will be late. This request must establish that the lateness in filing the claim is for good cause as defined in § 95.22 and not due to neglect or administrative inadequacy. If the claim has not been filed, the State must also tell us when the claim will be filed.

§ 95.31 Where to send a waiver request for good cause.

(a) A request which affects the program(s) of only one HHS agency, CMS or ACF and does not affect the programs of any other agency or Federal Department should be sent to the appropriate HHS agency.

(b) A request which affects programs of more than one HHS agency or Federal Department should be sent to the Director, Division of Cost Allocation in the appropriate HHS Regional Office.

[46 FR 3529, Jan. 15, 1981, as amended at 75 FR 66336, Oct. 28, 2010]

§ 95.34 The decision to waive the time limit for good cause.

The Secretary will make a decision after reviewing the State's request for waiver. If the Secretary decides that good cause exists, the State will be notified of the extended due date. If the Secretary decides that good cause does not exist or that the request for waiver does not provide enough information to make a decision, the State will be so advised.

Subparts B–D [Reserved]

Subpart E—Cost Allocation Plans

SOURCE: 47 FR 17509, Apr. 23, 1982, unless otherwise noted.

§ 95.501 Purpose.

This subpart establishes requirements for:

(a) Preparation, submission, and approval of State agency cost allocation plans for public assistance programs; and

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(b) Adherence to approved cost allocation plans in computing claims for Federal financial participation.

§ 95.503 Scope.

This subpart applies to all State agency costs applicable to awards made under titles I, IV-A, IV-B, IV-C, IV-D, IV-E, X, XIV, XVI (AABD), XIX, and XXI, of the Social Security Act, and under the Refugee Act of 1980, title IV, Chapter 2 of the Immigration and Nationality Act (8 U.S.C. 1521 *et seq.*), and under title V of Pub. L. 96-422, the Refugee Education Assistance Act of 1980.

[65 FR 33633, May 24, 2000]

§ 95.505 Definitions.

As used in this subpart:

State agency costs include all costs incurred by or allocable to the State agency except expenditures for financial assistance, medical vendor payments, and payments for services and goods provided directly to program recipients such as day care services, family planning services or household items as provided for under the approved State program plan.

Cost allocation plan means a narrative description of the procedures that the State agency will use in identifying, measuring, and allocating all State agency costs incurred in support of all programs administered or supervised by the State agency.

FFP or *Federal financial participation* means the Federal Government's share of expenditures made by a State agency under any of the programs cited in § 95.503.

Operating Divisions means the Department of Health and Human Services (HHS) organizational components responsible for administering public assistance programs. These components are the Administration for Children and Families (ACF) and the Centers for Medicare & Medicaid Services (CMS).

Public assistance programs means the programs cited in § 95.503.

State means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Northern Mariana Islands, and Guam.

State agency means the State agency administering or supervising the administration of the State plan for any program cited in § 95.503. A State agen-

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cy may be an organizational part of a larger State department that also contains other components and agencies. Where that occurs, the expression *State agency* refers to the specific component or agency within the State department that is directly responsible for the administration of, or supervising the administration of, one or more programs identified in § 95.503.

State Plan means a comprehensive written commitment by the State agency to administer or supervise the administration of any of the public assistance programs cited in § 95.503 in accordance with all Federal requirements.

[47 FR 17509, Apr. 23, 1982, as amended at 75 FR 66336, Oct. 28, 2010]

§ 95.507 Plan requirements.

(a) The State shall submit a cost allocation plan for the State agency as required below to the Director, Division of Cost Allocation (DCA), in the appropriate HHS Regional Office. The plan shall:

(1) Describe the procedures used to identify, measure, and allocate all costs to each of the programs operated by the State agency;

(2) Conform to the accounting principles and standards prescribed in Office of Management and Budget Circular A-87, and other pertinent Department regulations and instructions;

(3) Be compatible with the State plan for public assistance programs described in 45 CFR Chapter II, III and XIII, and 42 CFR Chapter IV Subchapters C and D; and

(4) Contain sufficient information in such detail to permit the Director, Division of Cost Allocation, after consulting with the Operating Divisions, to make an informed judgment on the correctness and fairness of the State's procedures for identifying, measuring, and allocating all costs to each of the programs operated by the State agency.

(b) The cost allocation plan shall contain the following information:

(1) An organizational chart showing the placement of each unit whose costs are charged to the programs operated by the State agency.

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(2) A listing of all Federal and all non-Federal programs performed, administered, or serviced by these organizational units.

(3) A description of the activities performed by each organizational unit and, where not self-explanatory an explanation of the benefits provided to Federal programs.

(4) The procedures used to identify, measure, and allocate all costs to each benefiting program and activity (including activities subject to different rates of FFP).

(5) The estimated cost impact resulting from the proposed changes to a previously approved plan. These estimated costs are required solely to permit an evaluation of the procedures used for identifying, measuring, and allocating costs. Therefore, approval of the cost allocation plan shall not constitute approval of these estimated costs for use in calculating claims for FFP. Where it is impractical to obtain this data, an alternative approach should then be negotiated with the Director, DCA, prior to submission of the cost allocation plan.

(6) A statement stipulating that wherever costs are claimed for services provided by a governmental agency outside the State agency, that they will be supported by a written agreement that includes, at a minimum (i) the specific service(s) being purchased, (ii) the basis upon which the billing will be made by the provider agency (e.g. time reports, number of homes inspected, etc.) and (iii) a stipulation that the billing will be based on the actual cost incurred. This statement would not be required if the costs involved are specifically addressed in a State-wide cost allocation plan, local-wide cost allocation plan, or an umbrella/departments cost allocation plan.

(7) If the public assistance programs are administered by local government agencies under a State supervised system, the overall State agency cost allocation plan shall also include a cost allocation plan for the local agencies. It shall be developed in accordance with the requirements set forth above. More than one local agency plan shall be submitted if the accounting systems or other conditions at the local agencies preclude an equitable allocation of

costs by the submission of a single plan for all local agencies. Prior to submitting multiple plans for local agencies, the State should consult with the Director, DCA. Where more than one local agency plan is submitted, the State shall identify the specific local agencies covered by each plan.

(8) A certification by a duly authorized official of the State stating:

(i) That the information contained in the proposed cost allocation plan was prepared in conformance with Office of Management and Budget Circular A-87.

(ii) That the costs are accorded consistent treatment through the application of generally accepted accounting principles appropriate to the circumstances.

(iii) That an adequate accounting and statistical system exists to support claims that will be made under the cost allocation plan; and

(iv) That the information provided in support of the proposed cost allocation plan is accurate.

(9) Other information as is necessary to establish the validity of the procedures used to identify, measure, and allocate costs to all programs being operated by the State agency.

[47 FR 17509, Apr. 23, 1982, as amended at 65 FR 33633, May 24, 2000]

§ 95.509 Cost allocation plan amendments and certifications.

(a) The State shall promptly amend the cost allocation plan and submit the amended plan to the Director, DCA if any of the following events occur:

(1) The procedures shown in the existing cost allocation plan become outdated because of organizational changes, changes in Federal law or regulations, or significant changes in program levels, affecting the validity of the approved cost allocation procedures.

(2) A material defect is discovered in the cost allocation plan by the Director, DCA or the State.

(3) The State plan for public assistance programs is amended so as to affect the allocation of costs.

(4) Other changes occur which make the allocation basis or procedures in the approval cost allocation plan invalid.

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(b) If a State has not submitted a plan or plan amendment during a given State fiscal year, an annual statement shall be submitted to the Director, DCA certifying that its approved cost allocation plan is not outdated. This statement shall be submitted within 60 days after the end of that fiscal year.

§ 95.511 Approval of the cost allocation plan or plan amendment.

(a) The Director, DCA, after consulting with the affected Operating Divisions, shall notify the State in writing of his/her findings. This notification will be made within 60 days after receipt of the proposed plan or amendment and shall either: (1) Advise the State that the plan or plan amendment is approved or disapproved, (2) advise the State of the changes required to make the plan or amendment acceptable, or (3) request the State to provide additional information needed to evaluate the proposed plan or amendment. If the DCA cannot make a determination within the 60-day period, it shall so advise the State.

(b) For purpose of this subpart, State agency cost allocation plans which have been approved by an authorized official of the Department of HHS prior to the effective date of this regulation are considered approved until such time as a new plan or plan amendment is required by § 95.509(a).

§ 95.515 Effective date of a cost allocation plan amendment.

As a general rule, the effective date of a cost allocation plan amendment shall be the first day of the calendar quarter following the date of the event that required the amendment (See § 95.509). However, the effective date of the amendment may be earlier or later under the following conditions:

(a) An earlier date is needed to avoid a significant inequity to either the State or the Federal Government.

(b) The information provided by the State which was used to approve a previous plan or plan amendment is later found to be materially incomplete or inaccurate, or the previously approved plan is later found to violate a Federal statute or regulation. In either situation, the effective date of any required modification to the plan will be the

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same as the effective date of the plan or plan amendment that contained the defect.

(c) It is impractical for the State to implement the amendment on the first day of the next calendar quarter. In these instances, a later date may be established by agreement between the State and the DCA.

§ 95.517 Claims for Federal financial participation.

(a) A State must claim FFP for costs associated with a program only in accordance with its approved cost allocation plan. However, if a State has submitted a plan or plan amendment for a State agency, it may, at its option claim FFP based on the proposed plan or plan amendment, unless otherwise advised by the DCA. However, where a State has claimed costs based on a proposed plan or plan amendment the State, if necessary, shall retroactively adjust its claims in accordance with the plan or amendment as subsequently approved by the Director, DCA. The State may also continue to claim FFP under its existing approved cost allocation plan for all costs not affected by the proposed amendment.

§ 95.519 Cost disallowance.

If costs under a Public Assistance program are not claimed in accordance with the approved cost allocation plan (except as otherwise provided in § 95.517), or if the State failed to submit an amended cost allocation plan as required by § 95.509, the costs improperly claimed will be disallowed.

(a)(1) If the issue affects the program(s) of only one Operating Division and does not affect the programs of other Operating Divisions or Federal departments, that Operating Division will determine the amount of the disallowance and will also inform the State of its opportunity for reconsideration of the determination in accordance with the Operating Division's procedures. Prior to issuing the notification, however, the Operating Division shall consult with the DCA to ensure that the issue does not affect the programs of other Operating Divisions or Federal departments.

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(2) If the State wishes to request a reconsideration of the Operating Division's determination, it must submit the request in accordance with the Operating Division's procedures.

(b) If the issue affects the programs of more than one Operating Division, or Federal department or the State, the Director, DCA, after consulting with the Operating Divisions, shall determine the amount inappropriately claimed under each program. The Director, DCA will notify the State of this determination, of the dollar affect of the determination on the claims made under each program, and will inform the State of its opportunity for appeal of the determination under 45 CFR part 16. The State will subsequently be notified by the appropriate Operating Division as to the disposition of the funds in question.

[47 FR 17509, Apr. 23, 1982, as amended at 62 FR 38218, July 17, 1997]

Subpart F—Automatic Data Processing Equipment and Services—Conditions for Federal Financial Participation (FFP)

SOURCE: 51 FR 45326, Dec. 18, 1986, unless otherwise noted.

GENERAL

§ 95.601 Scope and applicability.

This subpart prescribes part of the conditions under which the Department of Health and Human Services will approve the Federal Financial Participation (FFP) at the applicable rates for the costs of automated data processing incurred under an approved State plan for titles IV-B, IV-D, IV-E, XIX or XXI of the Social Security Act. The conditions of approval of this subpart add to the statutory and regulatory requirements for acquisition of Automated Data Processing (ADP) equipment and services under the specified titles of the Social Security Act.

[75 FR 66336, Oct. 28, 2010]

§ 95.605 Definitions.

As used in this part, the term:

Acceptance documents means a record of satisfactory completion of an approved phase of work or contract, and

acceptance thereof by the State agency.

Acquisition means acquiring ADP equipment or services from commercial sources or from State or local government resources.

Acquisition Checklist means the standard Department checklist that States can submit to meet prior written approval requirements instead of submitting the actual Request for Proposal (RFP), contracts or contract amendments. The Acquisition Checklist allows States to self-certify that their acquisition documents, which include RFPs, contracts, contract amendments or similar documents, meet State and Federal procurement requirements, contain appropriate language about software ownership and licensing rights in compliance with § 95.617, and provide access to documentation in compliance with § 95.615.

Advance Planning Document (APD), Initial advance automated data processing planning or Initial APD means a recorded plan of action to request funding approval for a project which will require the use of ADP service or equipment. The term APD refers to a Planning APD, or to a planning and/or development and implementation action document, i.e., Implementation APD, or to an Advance Planning Document Update. Requirements are detailed in § 95.610, paragraphs (a), (b), and (c).

Advance Planning Document Update (APDU) is a document or record submitted annually (Annual APDU) to report project status and/or post implementation cost-savings, or, on an as-needed (As-Needed APDU) basis, to request funding approval for project continuation when significant project changes are anticipated; for incremental funding authority and project continuation when approval is being granted by phase; or to provide detailed information on project and/or budget activities as specified in § 95.610(c).

Alternative approach to APD requirements means that the State has developed an APD that does not meet all conditions for APD approval in § 95.610, resulting in the need for a waiver under § 95.627(a).

Automated data processing or *ADP* means data processing performed by a system of electronic or electrical machines so interconnected and interacting as to minimize the need for human assistance or intervention.

Automated data processing equipment or *ADP equipment* or *Hardware* means automatic equipment that accepts and stores data, performs calculations and other processing steps, and produces information. This includes:

- (a) Electronic digital computers;
- (b) Peripheral or auxiliary equipment used in support of electronic computers;
- (c) Data transmission or communications equipment, and
- (d) Data input equipment.

Automatic Data Processing Services or *ADP Services* means:

- (a) Services to operate ADP equipment, either by agency, or by State or local organizations other than the State agency; and/or
- (b) Services provided by private sources or by employees of the State agency or by State and local organizations other than the State agency to perform such tasks as feasibility studies, system studies, system design efforts, development of system specifications, system analysis, programming, system conversion and system implementation and include, for example, the following:

- (1) Systems Training,
- (2) Systems Development,
- (3) Site Preparation,
- (4) Data Entry, and

- (5) Personal services related to automated systems development and operations that are specifically identified as part of a *Planning ADP* or *Implementation ADP*. As an example, a personal service would be the service of an *expert individual* to provide advice on the use of ADP software or hardware in developing a State automated management information system.

Base contract means the initial contractual activity, including all option years, allowed during a defined unit of time, for example, 2 years. The base contract includes option years but does not include amendments.

Commercial-off-the-shelf (COTS) software means proprietary software products that are ready-made and available

for sale to the general public at established catalog or market prices.

Data processing means the preparation of source media containing data or basic elements of information and the use of such source media according to precise rules or procedures to accomplish such operations as classifying, sorting, calculating, summarizing, recording and transmitting.

Department means the Department of Health and Human Service.

Design or *system design* means a combination of narrative and diagrams describing the structure of a new or more efficient automatic data processing system. This includes the use of hardware to the extent necessary for the design phase.

Development means the definition of system requirements, detailing of system and program specifications, programming and testing. This includes the use of hardware to the extent necessary for the development phase.

Emergency situation is defined as a situation where:

- (a) A State can demonstrate to the Department an immediate need to acquire ADP equipment or services in order to continue the operation of one or more of the Social Security Act programs covered by Subpart F, and

- (b) The State can clearly document that the need could not have been anticipated or planned for and the State was prevented from following the prior approval requirements of § 95.611.

Enhanced matching rate means the higher than regular rate of FFP authorized by Title IV-D, IV-E, and XIX of the Social Security Act for acquisition of services and equipment that conform to specific requirements designed to improve administration of the Child Support Enforcement, Foster Care and Adoption Assistance, and Medicaid programs.

Enhancement means modifications which change the functions of software and hardware beyond their original purposes, not just to correct errors or deficiencies which may have been present in the software or hardware, or to improve the operational performance of the software or hardware.

Feasibility study means a preliminary study to determine whether it is sufficiently probable that effective and efficient use of ADP equipment or systems can be made to warrant a substantial investment of staff, time, and money being requested and whether the plan is capable of being accomplished successfully.

Federal program office means the Federal program office within the Department that is authorized to approve requests for the acquisition of ADP equipment or ADP services. The Federal program offices within the Administration for Children and Families (ACF) are the Children's Bureau for titles IV-B (child welfare services) and IV-E (foster care and adoption assistance), the Office of Child Support Enforcement for title IV-D (child support enforcement), and the Centers for Medicare & Medicaid Services (CMS) for titles XIX (Medicaid) and XXI (the Children's Health Insurance Program) of the Social Security Act.

FFP means Federal financial participation.

Functional Requirements Specification is defined as an initial definition of the proposed system, which documents the goals, objectives, user or programmatic requirements, management requirements, the operating environment, and the proposed design methodology, e.g., centralized or distributed. This document details what the new system and/or hardware should do, not how it is to do it. The Specifications document shall be based upon a clear and accurate description of the functional requirements for the project, and shall not, in competitive procurements, lead to requirements which unduly restrict competition. The Specification document is the user's definition of the requirements the system must meet.

General Systems Design means a combination of narrative and graphic description of the generic architecture of a system as opposed to the detailed architecture of the system. A general systems design would include a systems diagram and narrative identifying overall logic flow and systems functions; a description of equipment needed (including processing data transmission and storage requirements); a description of other resource require-

ments which will be necessary to operate the system; a description of system performance requirements; and a description of the physical and organizational environment in which the system will operate including how the system will function within that environment (e.g. how workers will interface with the system).

Grantee means an organization receiving financial assistance directly from an HHS awarding agency to carry out a project or program.

Independent Verification and Validation—(IV&V) means a well-defined standard process for examining the organizational, management, and technical aspects of a project to determine the effort's adherence to industry standards and best practices, to identify risks, and make recommendations for remediation, where appropriate.

Implementation APD means a recorded plan of action to request Federal Financial Participation (FFP) in the costs of designing, developing, and implementing the system.

Independent Verification and Validation—(IV&V) means a well-defined standard process for examining the organizational, management, and technical aspects of a project to determine the effort's adherence to industry standards and best practices, to identify risks, and make recommendations for remediation, where appropriate.

Installation means the integrated testing of programs and subsystems, system conversion, and turnover to operation status. This includes the use of hardware to the extent necessary for the installation phase.

Medicaid Management Information System (MMIS) is a commonly accepted term for *Mechanized Claim Processing and Information Retrieval System* as provided by Section 1903(a)(3) and 1903(r) of the Social Security Act and at 42 CFR 433.110 *et seq.*

Noncompetitive means solicitation of a proposal from only one source, or after solicitation of a number of sources, negotiation with selected sources based on a finding that competition is inadequate.

Operational APD—An operational APD is a record of no more than two pages to be submitted annually by State programs whose system is not in

development. The Operational APD provides a short summary of the activities, method of acquisition, and annual budget for operations and software maintenance.

Operation means the automated processing of data used in the administration of State plans for titles I, IV-A, IV-B, IV-D, IV-E, X, XIV, XVI(AABD), XIX, and XXI of the Social Security Act. Operation includes the use of supplies, software, hardware, and personnel directly associated with the functioning of the mechanized system. See 45 CFR 205.38 and 307.10 for specific requirements for titles IV-A and IV-D, and 42 CFR 433.112 and 42 CFR 433.113 for specific requirements for title XIX.

Project means a defined set of information technology related tasks, undertaken by the State to improve the efficiency, economy and effectiveness of administration and/or operation of one or more of its human services programs. For example, a State may undertake a comprehensive, integrated initiative in support of its Child Support, Child Welfare and Medicaid program's intake, eligibility and case management functions. A project may also be a less comprehensive activity such as office automation, enhancements to an existing system or an upgrade of computer hardware.

Regular matching rate means the normal rate of FFP authorized by titles IV-A, IV-B, IV-D, IV-E, X, XIV, XVI(AABD), XIX, and XXI of the Social Security Act for State and local agency administration of programs authorized by those titles.

Requirements Analysis means determining and documenting the information needs and the functional and technical requirements the proposed computerized system must meet.

Service agreement means the document signed by the State or local agency and the State or local Central Data Processing facility whenever the latter provides data processing services to the former and:

(a) Identifies those ADP services the Central Data Processing facility will provide;

(b) Includes, preferably as an amendable attachment, a schedule of charges for each identified ADP service, and a

certification that these charges apply equally to all users;

(c) Includes a description of the method(s) of accounting for the services rendered under the agreement and computing services charges;

(d) Includes assurances that services provided will be timely and satisfactory; preferably through a service level agreement;

(e) Includes assurances that information in the computer system as well as access, use and disposal of ADP data will be safeguarded in accordance with provisions of all applicable federal statutes and regulations, including §§ 205.50 and 307.13;

(f) Requires the provider to obtain prior approval pursuant to § 95.611(a) from the Department for ADP equipment and ADP services that are acquired from commercial sources primarily to support the titles covered by this subpart and requires the provider to comply with § 95.613 for procurements related to the service agreement. ADP equipment and services are considered to be primarily acquired to support the titles covered by this subpart when the human service programs may reasonably be expected to either: be billed for more than 50 percent of the total charges made to all users of the ADP equipment and services during the time period covered by the service agreement, or directly charged for the total cost of the purchase or lease of ADP equipment or services;

(g) Includes the beginning and ending dates of the period of time covered by the service agreement; and

(h) Includes a schedule of expected total charges to the title covered by this subpart for the period of the service agreement.

Service Oriented Architecture (SOA), also referred to as *Service Component Based Architecture*, describes a means of organizing and developing Information Technology capabilities as collaborating services that interact with each other based on open standards. Agency SOA artifacts may include models, approach documents, inventories of services or other descriptive documents.

Software means a set of computer programs, procedures, and associated documentation used to operate the hardware.

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Software maintenance means routine support activities that normally include corrective, adaptive, and perfective changes, without introducing additional functional capabilities. Corrective changes are tasks to correct minor errors or deficiencies in software. Adaptive changes are minor revisions to existing software to meet changing requirements. Perfective changes are minor improvements to application software so it will perform in a more efficient, economical, and/or effective manner. Software maintenance can include activities such as revising/creating new reports, making limited data element/data base changes, and making minor alterations to data input and display screen designs.

State agency means the State agency administering or supervising the administration of the State plan under titles I, IV, X, XIV, XVI(AABD), XIX or XXI of the Social Security Act.

System specifications means information about the new ADP system—such as workload descriptions, input data, information to be maintained and processed, data processing techniques, and output data—which is required to determine the ADP equipment and software necessary to implement the system design.

System study means the examination of existing information flow and operational procedures within an organization. The study essentially consists of three basic phases: Data gathering investigation of the present system and new information requirements; analysis of the data gathered in the investigation; and synthesis, or refitting of the parts and relationships uncovered through the analysis into an efficient system.

Total Acquisition Cost means all anticipated expenditures (including State staff costs) for planning and implementation for the project. For purposes of this regulation total acquisition cost and project cost are synonymous.

[51 FR 45326, Dec. 18, 1986, as amended at 55 FR 4375, Feb. 7, 1990, 59 FR 30708, June 15, 1994; 65 FR 33633, May 24, 2000; 75 FR 66336, Oct. 28, 2010]

SPECIFIC CONDITIONS FOR FFP

§ 95.610 Submission of advance planning documents.

Advance Planning Document (APD) refers to an Initial advance automated data processing planning document or Initial APD, providing a recorded plan of action to request funding approval for a project which will require the use of ADP services or equipment, including the use of shared or purchased services in lieu of State acquired stand-alone resources. Requirements are detailed in paragraph (a), (b) and (c) of this section.

(a) *Planning APD.* (1) A separate planning effort and Planning APD is optional, but highly recommended, and generally applies to large statewide system developments and/or major hardware acquisitions. States with large, independent counties requesting funding at the regular match rate for county systems are strongly encouraged to engage in planning activities commensurate with the complexity of the projected ADP project and to submit a Planning APD to allow for time and to provide funding for its planning activities. Therefore, States must consider the scope and complexity of a project to determine whether to submit a Planning APD as a separate document to HHS or whether to combine the two phases of planning and implementation into one APD covering both the Planning APD and the Implementation APD requirements.

(2) The Planning APD is a relatively brief document, usually not more than 6–10 pages, which must contain:

(i) A statement of the problem/need that the existing capabilities can not resolve, new or changed program requirements or opportunities for improved economies and efficiencies and effectiveness of program and administration and operations;

(ii) A project management plan that addresses the planning project organization, planning activities/deliverables, State and contractor resource needs, planning project procurement activities and schedule;

(iii) A specific budget for the planning phase of the project;

(iv) An estimated total project cost and a prospective State and Federal

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cost allocation/distribution, including planning and implementation;

(v) A commitment to conduct/prepare the problem(s) needs assessment, feasibility study, alternatives analysis, cost benefit analysis, and to develop a Functional Requirements Specification and/or a General Systems Design (GSD);

(vi) A commitment to define the State's functional requirements, based on the State's business needs which may be used for the purpose of evaluating the transfer of an existing system, including the transfer of another State's General System Design that the State may adapt to meet State specific requirements;

(vii) Additional Planning APD content requirements, for enhanced funding projects as contained in § 307.15 and §§ 1355.50 through 1355.57; and

(viii) An acquisition summary for the upcoming year or development phase that provides the following information on proposed acquisitions:

(A) Type and scope of contract

(B) Procurement strategy

(C) Estimated cost or not to exceed amount

(D) Timeframe of contract

(E) A statement or certification that the proposed acquisition will comply with all State and Federal requirements including the retention of software ownership rights specified in § 95.617.

(b) *Implementation APD.* The Implementation APD shall include:

(1) The results of the activities conducted under a Planning APD, if any;

(2) A statement of problems/needs and outcomes/objectives;

(3) A requirements analysis, feasibility study and a statement of alternative considerations including, where appropriate, the use of service-orientated architecture and a transfer of an existing system and an explanation of why such a transfer is not feasible if another alternative is identified;

(4) A cost benefit analysis;

(5) A personnel resource statement indicating availability of qualified and adequate numbers of staff, including a project director to accomplish the project objectives;

(6) A detailed description of the nature and scope of the activities to be

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undertaken and the methods to be used to accomplish the project;

(7) The proposed activity schedule for the project;

(8) A proposed budget (including an accounting of all possible Implementation APD activity costs, e.g., system conversion, vendor and state personnel, computer capacity planning, supplies, training, hardware, software and miscellaneous ADP expenses) for the project;

(9) A statement indicating the duration the State expects to use the equipment and/or system;

(10) An estimate of the prospective cost allocation/distribution to the various State and Federal funding sources and the proposed procedures for distributing costs;

(11) A statement setting forth the security and interface requirements to be employed and the system failure and disaster recovery/business continuity procedures available or to be implemented; and

(12) Additional requirements, for acquisitions for which the State is requesting enhanced funding, as contained at § 307.15 and 42 CFR subchapter C, part 433 or funding for title IV–E agencies as contained at § 1355.52(i) of this title.

(c) *Advance Planning Document Update (APDU).* (1) The Annual APDU, which is due 60 days prior to the expiration of the FFP approval, includes:

(i) A reference to the approved APD and all approved changes;

(ii) A project activity report which includes the status of the past year's major project tasks and milestones, addressing the degree of completion and tasks/milestones remaining to be completed, and discusses past and anticipated problems or delays in meeting target dates in the approved APD and approved changes to it and provides a risk management plan that assesses project risk and identifies risk mitigation strategies;

(iii) A report of all project deliverables completed in the past year and degree of completion for unfinished products and tasks;

(iv) An updated project activity schedule for the remainder of the project;

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(v) A revised budget for the entirety of the project's life-cycle, including operational and development cost categories;

(vi) A project expenditures report that consists of a detailed accounting of all expenditures for project development over the past year and an explanation of the differences between projected expenses in the approved APD and actual expenditures for the past year;

(vii) A report of any approved or anticipated changes to the allocation basis in the APD's approved cost allocation methodology; and

(viii) An acquisition summary for the upcoming year or development phase that provides the following information on proposed acquisitions:

(A) Type and scope of contract

(B) Procurement strategy

(C) Estimated cost or not to exceed amount

(D) Timeframe of contract

(E) A statement or certification that the proposed acquisition will comply with all State and Federal requirements including the retention of software ownership rights specified in § 95.617.

(2) The As-Needed APDU is a document that requests approval for additional funding and/or authority for project continuation when significant changes are anticipated, when the project is being funded on a phased implementation basis, or to clarify project information requested as an approval condition of the Planning APD, Annual APDU, or Implementation APD. The As-Needed APDU may be submitted any time as a stand-alone funding or project continuation request, or may be submitted as part of the Annual APDU. The As-Needed APDU is submitted:

(i) When the State anticipates incremental project expenditures (exceeding specified thresholds);

(ii) When the State anticipates a schedule extension of more than 60 days for major milestones;

(iii) When the State anticipates major changes in the scope of its project, e.g., a change in its procurement plan, procurement activities, system concept or development approach;

(iv) When the State anticipates significant changes to its cost distribution methodology or distribution of costs among Federal programs; and/or,

(v) When the State anticipates significant changes to its cost benefit projections. The As-Needed APDU shall provide supporting documentation to justify the need for a change to the approved budget.

(vi) Changes to the acquisition summary in the following areas:

(A) Type and scope of contract

(B) Procurement strategy

(C) Estimated cost or not to exceed amount

(D) Timeframe of contract

(E) A statement or certification that the proposed acquisition will comply with all State and Federal requirements including the retention of software ownership rights specified in § 95.617.

(F) New acquisitions not summarized in the Annual APDU.

(3) The Operational Advance Planning Document Update (OAPDU) is an annual submission of no more than two pages, including:

(i) Summary of activities;

(ii) Acquisitions; and,

(iii) Annual budget by project/system receiving funding through the programs covered under this part.

[75 FR 66337, Oct. 28, 2010, as amended at 81 FR 35479, June 2, 2016]

§ 95.611 Prior approval conditions.

(a) *General acquisition requirements.* (1)

A State shall obtain prior approval from the Department which is reflected in a record, as specified in paragraph (b) of this section, when the State plans to acquire ADP equipment or services with proposed FFP at the regular matching rate that it anticipates will have total acquisition costs of \$5,000,000 or more in Federal and State funds. States will be required to submit an Operational APDU only if they exceed the threshold requiring Federal approval, and only upon the receipt of a submission request, which is reflected in a record, from the Department. See definition of software maintenance under § 95.605.

(2) A State must obtain prior approval from the Department which is reflected in a record, as specified in

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paragraph (b) of this section, when the State plans to acquire ADP equipment or services with proposed FFP at the enhanced matching rate subject to one of the following:

(i) If authorized by §205.35 of this title and part 307 of this title, regardless of the acquisition cost.

(ii) If authorized by 42 CFR part 433, subpart C, if the contract is anticipated to or will exceed \$500,000.

(3) A State shall obtain prior approval from the Department, which is reflected in a record, for a sole source/non-competitive acquisition, of ADP equipment or services with a total State and Federal acquisition cost of \$1,000,000 or more.

(4) Except as provided for in paragraph (a)(5) of this section, the State shall submit multi-program requests for Department approval, signed by the appropriate State official, to the Department's Secretary or his/her designee. For each HHS agency that has federal funding participation in the project, an additional copy must be provided to the applicable Federal program office and respective Regional Offices.

(5) States shall submit requests for approval which affect only one approving component of HHS (CMS, OCSE, or Children's Bureau), to the applicable Federal program office and Regional Administrator.

(6) The Department will not approve any Planning or Implementation APD that does not include all information required in §95.610.

(b) *Specific prior approval requirements.* The State agency shall obtain written approval of the Department prior to the initiation of project activity.

(1) For regular FFP requests.

(i) For the Planning APD subject to the dollar thresholds specified in paragraph (a) of this section.

(ii) For the Implementation APD subject to the dollar thresholds specified in paragraph (a) of this section.

(iii) For acquisition documents, an exemption from prior Federal prior approval shall be assumed in the approval of the Planning, Annual or As-Needed APDU provided that:

(A) The acquisition summary provides sufficient detail to base an exemption request;

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(B) The acquisition does not deviate from the terms of the exemption; and

(C) The acquisition is not the initial acquisition for a high risk activity, such as software application development. Acquisitions, whether exempted from prior Federal approval or not, must comply with the Federal provisions contained in §95.610(c)(1)(viii) or (c)(2)(vi) or submit an Acquisition Checklist.

(iv) For noncompetitive acquisitions, including contract amendments, when the resulting contract is anticipated to exceed \$1,000,000, States will be required to submit a sole source justification in addition to the acquisition document. The sole source justification can be provided as part of the Planning, Annual or As-Needed APDU.

(v) If the State does not opt for an exemption or submittal of an Acquisition Checklist for the contract, prior to the execution, the State will be required to submit the contract when it is anticipated to exceed the following thresholds, unless specifically exempted by the Department:

(A) Software application development—\$6,000,000 or more (competitive) and \$1,000,000 or more (noncompetitive);

(B) Hardware and Commercial Off-the-Shelf (COTS) software—\$20,000,000 or more (competitive) and \$1,000,000 or more (noncompetitive);

(C) Operations and Software Maintenance acquisitions combined with hardware, COTS or software application development—the thresholds stated in §95.611(b)(1)(v)(A) and (B) apply.

(vi) For contract amendments within the scope of the base contract, unless specifically exempted by the Department, prior to execution of the contract amendment involving contract cost increases which cumulatively exceed 20 percent of the base contract cost.

(2) For enhanced FFP requests.

(i) For the Planning APD.

(ii) For the Implementation APD.

(iii) For the acquisition solicitation documents and contract, unless specifically exempted by the Department, prior to release of the acquisition solicitation documents or prior to execution of the contract when the contract is anticipated to or will exceed \$500,000.

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(iv) For contract amendments, unless specifically exempted by the Department, prior to execution of the contract amendment, involving contract cost increases exceeding \$500,000 or contract time extensions of more than 60 days.

(3) Failure to submit any of the above to the satisfaction of the Department may result in disapproval or suspension of project funding.

(c) *Specific approval requirements.* The State agency shall obtain written approval from the Department:

(1) For regular FFP requests.

(i) For an annual APDU for projects with a total cost of more than \$5,000,000, and projects with a total estimated cost of less than \$5,000,000 only if requested by the Department.

(ii) For an "As Needed APDU" when changes cause any of the following:

(A) A projected cost increase of \$1,000,000 or more.

(B) A schedule extension of more than 60 days for major milestones;

(C) A significant change in procurement approach, and/or scope of procurement activities beyond that approved in the APD;

(D) A change in system concept, or a change to the scope of the project;

(E) A change to the approved cost allocation methodology.

The State shall submit the "As Needed APDU" to the Department, no later than 60 days after the occurrence of the project changes to be reported in the "As Needed APDU".

(2) For enhanced FFP requests.

(i) For an Annual APDU.

(ii) For an "As needed" APDU when changes cause any of the following:

(A) A projected cost increase of \$300,000 or 10 percent of the project cost, whichever is less;

(B) A schedule extension of more than 60 days for major milestones. For Aid to Families with Dependent Children (AFDC) Family Assistance Management Information System (FAMIS)-type projects, in accordance with section 402(e)(2)(C) of the Social Security Act, any schedule change which affects the State's implementation date as specified in the approved APD requires that the Department recover 40 percent of the amount expended. The Secretary may extend the implementation date,

if the implementation date is not met because of circumstances beyond the State's control. Examples of circumstances beyond the State's control are:

(1) Equipment failure due to physical damage or destruction; or,

(2) Change imposed by Federal judicial decisions, or by Federal legislation or regulations;

(C) A significant change in procurement approach, and/or a scope of procurement activities beyond that approved in the APD;

(D) A change in system concept or scope of the project;

(E) A change to the approved cost methodology;

(F) A change of more than 10% of estimated cost benefits.

The State shall submit the "As Needed APDU" to the Department, no later than 60 days after the occurrence of the project changes to be reported in the "As Needed APDU".

(3) Failure to submit any of the above to the satisfaction of the Department may result in disapproval or suspension of project funding.

(d) *Prompt action on requests for prior approval.* The Department will promptly send to the approving Federal program offices the items specified in paragraph (b) of this section. If the Department has not provided approval, disapproval, or a request for information which is reflected in a record, within 60 days of the date of the Departmental letter acknowledging receipt of a State's request, the Department will consider the request to have provisionally met the prior approval conditions of paragraph (b) of this section.

(e) *Acquisitions not subject to prior approval.* If the Department has not specifically requested in a record, the submittal of additional acquisition documentation for those acquisitions summarized in the APD, the approval of the Planning, Annual or As-Needed APDU will constitute an exemption of the acquisition documents from prior Federal approval. States will be required to submit acquisition documents, contracts and contract amendments under the threshold amounts on

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an exception basis if requested to do so in a record by the Department.

[51 FR 45326, Dec. 18, 1986, as amended at 55 FR 4377, Feb. 7, 1990; 56 FR 12356, Mar. 25, 1991; 59 FR 30708, June 15, 1994; 61 FR 39897, July 31, 1996; 75 FR 66338, Oct. 28, 2010; 80 FR 75843, Dec. 4, 2015]

§ 95.612 Disallowance of Federal Financial Participation (FFP).

If the Department finds that any ADP acquisition approved or modified under the provisions of § 95.611 fails to comply with the criteria, requirements, and other activities described in the approved APD to the detriment of the proper, efficient, economical and effective operation of the affected program, payment of FFP may be disallowed. In the case of a suspension of the approval of a Child Support APD for enhanced funding, *see* § 307.40(a). In the case of a suspension of the approval of an APD for a Comprehensive Child Welfare Information System (CCWIS) project and, if applicable the transitional project that preceded it, *see* § 1355.58 of this title.

[75 FR 66339, Oct. 28, 2010, as amended at 81 FR 35479, June 2, 2016]

§ 95.613 Procurement standards.

(a) *General.* Procurements of ADP equipment and services are subject to the procurement standards prescribed by 2 CFR parts 200 and 300 regardless of any conditions for prior approval. The Department retains the authority to provide greater oversight including requiring a State to comply with 2 CFR 200.319 if the Department determines that the State procurement process is an impediment to competition that could substantially impact project cost or risk of failure.

(b) Those standards, as well as the requirement for prior approval, apply to ADP services and equipment acquired by a State or local agency, and the ADP services and equipment acquired by a State or local Central Data Processing facility primarily to support the Social Security Act programs covered by this subpart. Service agreements are exempt from these procurement standards.

[51 FR 45326, Dec. 18, 1986, as amended at 75 FR 66339, Oct. 28, 2010; 81 FR 3020, Jan. 20, 2016; 89 FR 80071, Oct. 2, 2024]

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§ 95.615 Access to systems and records.

The State agency must allow the Department access to the system in all of its aspects, including pertinent state staff, design developments, operation, and cost records of contractors and subcontractors at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met and to determine the efficiency, economy and effectiveness of the system.

[75 FR 66340, Oct. 28, 2010]

§ 95.617 Software and ownership rights.

(a) *General.* The State or local government must include a clause in all procurement instruments that provides that the State or local government will have all ownership rights in software or modifications thereof and associated documentation designed, developed or installed with Federal financial participation under this subpart.

(b) *Federal license.* The Department reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish, or otherwise use and to authorize others to use for Federal Government purposes, such software, modifications, and documentation.

(c) *Proprietary software.* Proprietary operating/vendor software packages which are provided at established catalog or market prices and sold or leased to the general public shall not be subject to the ownership provisions in paragraphs (a) and (b) of this section. FFP is not available for proprietary applications software developed specifically for the public assistance programs covered under this subpart.

[51 FR 45326, Dec. 18, 1986, as amended at 75 FR 66340, Oct. 28, 2010]

§ 95.619 Use of ADP systems.

ADP systems designed, developed, or installed with FFP shall be used for a period of time specified in the advance planning document, unless the Department determines that a shorter period is justified.

§ 95.621 ADP reviews.

The Department will conduct periodic onsite surveys and reviews of State and local agency ADP methods

and practices to determine the adequacy of such methods and practices and to assure that ADP equipment and services are utilized for the purposes consistent with proper and efficient administration under the Act. Where practical, the Department will develop a mutually acceptable schedule between the Department and State or local agencies prior to conducting such surveys or reviews, which may include but are not limited to:

(a) *Pre-installation readiness.* A pre-installation survey including an onsite evaluation of the physical site and the agency's readiness to productively use the proposed ADP services, equipment or system when installed and operational.

(b) *Post-installation.* A review conducted after installation of ADP equipment or systems to assure that the objectives for which FFP was approved are being accomplished.

(c) *Utilization.* A continuing review of ADP facilities to determine whether or not the ADP equipment or services are being efficiently utilized in support of approved programs or projects.

(d) *Acquisitions not subject to prior approval.* Reviews will be conducted on an audit basis to assure that system and equipment acquisitions costing less than \$200,000 or acquisitions exempted from prior approval were made in accordance with 2 CFR parts 200 and 300 and the conditions of this subpart and to determine the efficiency, economy and effectiveness of the equipment or service.

(e) *State Agency Maintenance of Service Agreements.* The State agency will maintain a copy of each service agreement in its files for Federal review.

(f) *ADP System Security Requirements and Review Process—(1) ADP System Security Requirement.* State agencies are responsible for the security of all ADP projects under development, and operational systems involved in the administration of HHS programs. State agencies shall determine the appropriate ADP security requirements based on recognized industry standards or standards governing security of Federal ADP systems and information processing.

(2) *ADP Security Program.* State ADP Security requirements shall include the following components:

(i) Determination and implementation of appropriate security requirements as specified in paragraph (f)(1) of this section.

(ii) Establishment of a security plan and, as appropriate, policies and procedures to address the following area of ADP security:

(A) Physical security of ADP resources;

(B) Equipment security to protect equipment from theft and unauthorized use;

(C) Software and data security;

(D) Telecommunications security;

(E) Personnel security;

(F) Contingency plans to meet critical processing needs in the event of short or long-term interruption of service;

(G) Emergency preparedness; and,

(H) Designation of an Agency ADP Security Manager.

(iii) Periodic risk analyses. State agencies must establish and maintain a program for conducting periodic risk analyses to ensure that appropriate, cost effective safeguards are incorporated into new and existing systems. State agencies must perform risk analyses whenever significant system changes occur.

(3) *ADP System Security Reviews.* State agencies shall review the ADP system security of installations involved in the administration of HHS programs on a biennial basis. At a minimum, the reviews shall include an evaluation of physical and data security operating procedures, and personnel practices.

(4) Costs incurred in complying with provisions of paragraphs (f)(1)–(3) of this section are considered regular administrative costs which are funded at the regular match rate.

(5) The security requirements of this section apply to all ADP systems used by State and local governments to administer programs covered under 45 CFR part 95, subpart F.

(6) The State agency shall maintain reports of their biennial ADP system

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security reviews, together with pertinent supporting documentation, for HHS on-site review.

[43 FR 44853, Sept. 29, 1978, as amended at 51 FR 45329, Dec. 18, 1986; 53 FR 27, Jan. 4, 1988; 55 FR 4378, Feb. 7, 1990; 61 FR 39898, July 31, 1996; 75 FR 66340, Oct. 28, 2010; 81 FR 3020, Jan. 20, 2016; 89 FR 80071, Oct. 2, 2024]

§ 95.623 Reconsideration of denied FFP for failure to obtain prior approval.

For ADP equipment and services acquired by a State without prior approval, which is reflected in a record, the State may request reconsideration of the disallowance of FFP by written request to the head of the Federal program office within 30 days of the initial written disallowance determination. In such a reconsideration, the agency may take into account overall federal interests. The Department may grant a request for reconsideration if:

(a) The State submitted to the Department all information required under § 95.611, satisfactorily responded to all concerns raised by the Department and received a final letter of approval from the Department; or,

(b) The State requests reconsideration of a denial by submitting in a record information that addresses the following requirements:

(1) The acquisition must be reasonable, useful and necessary;

(2) The State's failure to obtain prior approval, which is reflected in a record, must have been inadvertent (i.e., the State did not knowingly avoid the prior approval requirements);

(3) The request was not previously denied by HHS;

(4) The acquisition must otherwise meet all other applicable Federal and State requirements, and would have been approved under part 95, subpart F had the State requested in a record, prior approval;

(5) The State must not have a record of recurrent failures, under any of the programs covered by the prior approval regulations, to comply with the requirement to obtain prior approval in a record, of its automatic data processing acquisitions (i.e., submissions under these procedures, from States that have failed in the past to acquire prior approval which is reflected in a

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record, in accordance with part 95, subpart F, may be denied);

[51 FR 3339, Jan. 27, 1986, as amended at 55 FR 4378, Feb. 7, 1990; 75 FR 66340, Oct. 28, 2010]

§ 95.624 Consideration for FFP in emergency situations.

For ADP equipment and services acquired by a State after December 1, 1985 to meet emergency situations, which preclude the State from following the requirements of § 95.611, the Department will consider providing FFP upon receipt of a request from the State which is reflected in a record. In order for the Department to consider providing FFP in emergency situations, the following conditions must be met:

(a) The State must submit a request to the Department, prior to the acquisition of any ADP equipment or services. The request must be reflected in a record, and include:

(1) A brief description of the ADP equipment and/or services to be acquired and an estimate of their costs;

(2) A brief description of the circumstances which result in the State's need to proceed prior to obtaining approval from the Department; and

(3) A description of the harm which will be caused if the State does not acquire immediately the ADP equipment and services.

(b) Upon receipt of the information, the Department will within 14 days take one of the following actions:

(1) Inform the State in writing that the request has been disapproved and the reason for disapproval; or

(2) Inform the State in a communication reflected in a record, that the Department recognizes that an emergency exists and that within 90 days from the date of the State's initial request, the State must submit a formal request for approval which includes the information specified at § 95.611 in order for the ADP equipment or services acquisition to be considered for the Department's approval.

(c) If the Department approves the request submitted under paragraph (b) of this section, FFP will be available

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from the date the State acquires the ADP equipment and services.

[51 FR 3339, Jan. 27, 1986, as amended at 55 FR 4378, Feb. 7, 1990; 75 FR 66340, Oct. 28, 2010]

§ 95.625 Increased FFP for certain ADP systems.

(a) *General.* FFP is available at enhanced matching rates for the development of individual or integrated systems and the associated computer equipment that support the administration of state plans for titles IV-D and/or XIX provided the systems meet the specifically applicable provisions referenced in paragraph (b) of the section.

(b) *Specific reference to other regulations.* The applicable regulations for the Title IV-D program are contained in 45 CFR part 307. The applicable regulations for the Title IV-E program are contained in 45 CFR 1355.55. The applicable regulations for the title IV-D program are contained in 45 CFR part 307. The applicable regulations for the title XIX program are contained in 42 CFR part 433, subpart C.

[59 FR 30708, June 15, 1994, as amended at 81 FR 35479, June 2, 2016]

§ 95.626 Independent Verification and Validation.

(a) An assessment for independent verification and validation (IV&V) analysis of a State's system development effort may be required in the case of APD projects that meet any of the following criteria:

- (1) Are at risk of missing statutory or regulatory deadlines for automation that is intended to meet program requirements;
- (2) Are at risk of failing to meet a critical milestone;
- (3) Indicate the need for a new project or total system redesign;
- (4) Are developing systems under waivers pursuant to sections 452(d)(3) or 627 of the Social Security Act;
- (5) Are at risk of failure, major delay, or cost overrun in their systems development efforts;
- (6) Fail to timely and completely submit APD updates or other required systems documentation.
- (7) State's procurement policies put the project at risk, including a pattern

of failing to pursue competition to the maximum extent feasible.

(8) State's failure to adequately involve the State program offices in the development and implementation of the project.

(b) Independent Verification and Validation efforts must be conducted by an entity that is independent from the State (unless the State receives an exception from the Department) and the entity selected must:

(1) Develop a project workplan. The plan must be provided directly to the Department at the same time it is given to the State.

(2) Review and make recommendations on both the management of the project, both State and vendor, and the technical aspects of the project. The IV&V provider must give the results of its analysis directly to the federal agencies that required the IV&V at the same time it reports to the State.

(3) Consult with all stakeholders and assess the user involvement and buy-in regarding system functionality and the system's ability to support program business needs.

(4) Conduct an analysis of past project performance sufficient to identify and make recommendations for improvement.

(5) Provide risk management assessment and capacity planning services.

(6) Develop performance metrics which allow tracking project completion against milestones set by the State.

(c) The acquisition document and contract for selecting the IV&V provider (or similar documents if IV&V services are provided by other State agencies) must include requirements regarding the experience and skills of the key personnel proposed for the IV&V analysis. The contract (or similar document if the IV&V services are provided by other State agencies) must specify by name the key personnel who actually will work on the project. The acquisition documents and contract for required IV&V services must be submitted to the Department for prior written approval.

[75 FR 66340, Oct. 28, 2010]

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§ 95.627 Waivers.

(a) *Application for a waiver.* A State may apply for a waiver of any requirement in subpart F by presenting an alternative approach. Waiver requests must be submitted and approved as part of the State's APD or APD Update.

(b) *Waiver approvals.* The Secretary, or his or her designee, may grant a State a waiver if the State demonstrates that it has an alternative approach to a requirement in this chapter that will safeguard the State and Federal Governments' interest and that enables the State to be in substantial compliance with the other requirements of this chapter.

(c) *Contents of waiver request.* The State's request for approval of an alternative approach or waiver of a requirement in this chapter must demonstrate why meeting the condition is unnecessary, diminishes the State's ability to meet program requirements, or that the alternative approach leads to a more efficient, economical, and effective administration of the programs for which federal financial participation is provided, benefiting both the State and Federal Governments.

(d) *Review of waiver requests.* The Secretary, or his or her designee, will review waiver requests to assure that all necessary information is provided, that all processes provide for effective economical and effective program operation, and that the conditions for waiver in this section are met.

(e) *Agency's response to a waiver request.* When a waiver is approved by an agency, it becomes part of the State's approved APD and is applicable to the approving agency. A waiver is subject to the APD suspension provisions in § 95.611(c)(3). When a waiver is disapproved, the entire APD will be disapproved. The APD disapproval is a final administrative decision and is not subject to administrative appeal.

[75 FR 66340, Oct. 28, 2010]

FEDERAL FINANCIAL PARTICIPATION IN COSTS OF ADP ACQUISITIONS

§ 95.631 Cost identification for purpose of FFP claims.

The conditions of this subpart apply notwithstanding the existence of an ap-

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proved cost allocation plan. State agencies shall assign and claim the costs incurred under an approved APD in accordance with the following criteria:

(a) *Development costs.* (1) Using its normal departmental accounting system, the State agency shall specifically identify what items of costs constitute development costs, assign these costs to specific project cost centers, and distribute these costs to funding sources based on the specific identification, assignment and distribution outlined in the approved APD; (2) the methods for distributing costs set forth in the APD should provide for assigning identifiable costs, to the extent practicable, directly to program/functions. The State agency shall amend the cost allocation plan required by subpart E of this part to include the approved APD methodology for the identification, assignment and distribution of the development costs.

(b) *Operational costs.* Costs incurred for the operation of an ADP system shall be identified and assigned by the State agency to funding sources in accordance with the approved cost allocation plan required by Subpart E of this part.

(c) *Service agreement costs.* States that operate a central data processing facility shall use their approved central service cost allocation plan required by OMB Circular A-87 to identify and assign costs incurred under service agreements with the State agency. The State agency will then distribute these costs to funding sources in accordance with paragraphs (a) and (b) of this section.

§ 95.633 Nondiscrimination requirements.

State agencies that acquire ADP equipment and services are subject to the nondiscrimination requirements in parts 80, 84, and 90.

[45 FR 10794, Feb. 19, 1980]

§ 95.635 Disallowance of Federal financial participation for automated systems that fail to comply substantially with requirements.

(a) Federal financial participation at the applicable matching rate is available for automated data processing system expenditures that meet the requirements specified under the approved APD including the approved cost allocation plan.

(b) All or part of any costs for system projects that have a major failure to comply with an APD approved under applicable regulation at § 95.611, or for the Title IV-D program contained in part 307, the applicable regulations for the Title IV-E and Title IV-B programs contained in Chapter 13, subchapter G, § 1355.55, or the applicable regulations for the Title XIX program contained in 42 CFR chapter 4 subchapter C, part 433, are subject to disallowance by the Department.

[75 FR 66340, Oct. 28, 2010]

EXEMPTIONS

§ 95.641 Applicability of rules for charging equipment in subpart G of this part.

ADP equipment, as well as other equipment acquired under public assistance programs, is subject to subpart G of this part. Among other things, subpart G provides that a State may charge only depreciation or use allowances for equipment with unit acquisition cost of over \$25,000. However, for ADP equipment HHS will consider requests for waivers of that restriction. If the acquisition of the equipment is part of an APD that is subject to the prior approval requirements of subpart F, the State may submit the request for a waiver as part of the APD.

Subpart G—Equipment Acquired Under Public Assistance Programs

SOURCE: 47 FR 41576, Sept. 21, 1982, unless otherwise noted.

§ 95.701 Purpose and scope of subpart.

(a) This subpart prescribes requirements concerning the computation of claims for Federal financial participation in the cost of equipment under

public assistance programs. This subpart also prescribes requirements for the management and disposition of equipment whose costs are claimed for Federal financial participation under these programs.

(b) This subpart applies to equipment purchased by State agencies (as defined in § 95.703) and to equipment purchased under service agreements with other State agencies and under cost-type contracts.

§ 95.703 Definitions.

As used in this subpart:

Acquisition cost of an item of purchased equipment means the net invoice price of the equipment, including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the equipment usable for the purpose for which it was acquired. Other charges such as the cost of installation, transportation, taxes, duty or protective intransit insurance shall be included in or excluded from the unit acquisition cost in accordance with the regular accounting practices of the organization purchasing the equipment. If the item is acquired by trading in another item and paying an additional amount, *acquisition cost* means the amount received for trade-in plus the additional outlay.

Equipment means an article of tangible personal property that has a useful life of more than two years and an acquisition cost of \$500 or more. Any recipient may use its own definition of equipment, if its definition would at least include all items of equipment as defined here.

Public Assistance Programs means programs authorized by titles I, IV-A, IV-B, IV-C, IV-D, IV-E, X, XIV, XVI (AABD), XIX and XXI of the Social Security Act, and programs authorized by the Immigration and Nationality Act as amended by the Refugee Act of 1980 (Pub. L. 96-212).

State means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Northern Mariana Islands and Guam.

State Agency means the State agency administering a public assistance program(s). This term includes local government public assistance agencies

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which administer public assistance programs under a State supervised system and the State agencies which supervise the local agencies.

[47 FR 41576, Sept. 21, 1982, as amended at 65 FR 33633, May 24, 2000]

§ 95.705 Equipment costs—Federal financial participation.

(a) *General rule.* In computing claims for Federal financial participation, equipment having a unit acquisition cost of \$25,000 or less may be claimed in the period acquired or depreciated, at the option of the State agency. Equipment having a unit acquisition cost of more than \$25,000 shall be depreciated. For purposes of this section, the term depreciate also includes use allowances computed in accordance with the cost principles prescribed in 2 CFR parts 200 and 300.

(b) *Exceptions.* (1) Equipment purchased under service agreements with other State agencies and under cost-type contracts shall be depreciated. However, equipment having a unit acquisition cost of \$25,000 or less may be claimed in the period acquired if (a) the State agency approved the specific purchase and the claiming of the cost of the item, and (b) the contract or service agreement requires that the equipment or its residual value be transferred to the State agency when the equipment is no longer needed to carry out the work under the contract or service agreement.

(2) Reimbursement for ADP equipment having an acquisition cost in excess of \$25,000 and subject to subpart F of this part must be depreciated over its useful life unless otherwise specifically provided for by the Department. ADP equipment not subject to subpart F is subject to the requirements of this subpart.

[47 FR 41576, Sept. 21, 1982, as amended at 75 FR 66341, Oct. 28, 2010; 81 FR 3020, Jan. 20, 2016; 89 FR 80071, Oct. 2, 2024]

§ 95.707 Equipment management and disposition.

(a) Once equipment, whose costs are claimed for Federal financial participation (i.e., equipment that is capitalized and depreciated or is claimed in the period acquired), has reached the end of its useful life (as defined in an ap-

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proved APD), the equipment shall be subject to the property disposal rules in 2 CFR 200.313.

(b) The State agency is responsible for adequately managing the equipment, maintaining records on the equipment, and taking periodic physical inventories. Physical inventories may be made on the basis of statistical sampling. The following requirements apply to the disposition of this equipment:

(1) If the cost of the equipment was claimed in the period acquired and the equipment is later sold, the proceeds of the sale shall be credited to current expenditures in approximate proportion to the distribution of the equipment's cost.

(2) If the cost of the equipment was claimed in the period acquired and the equipment is later transferred to an activity which is not involved in the performance of programs currently or previously funded by the Federal Government, an amount equal to the fair market value of the equipment on the date of the transfer shall be credited to current expenditures in approximate proportion to the distribution of the equipment's costs.

(3) If the cost of the equipment was claimed in the period acquired and the equipment is later traded in on other equipment claims for Federal financial participation in the costs of replacement equipment shall be limited to the additional outlay.

(4) If the equipment was depreciated, any gain or loss on the disposition of the equipment shall be treated as a decrease or an increase to the depreciation expense of the period in which the disposition takes place. This provision does not apply to equipment whose costs were claimed for Federal financial participation through use allowances.

[47 FR 41576, Sept. 21, 1982, as amended at 75 FR 66341, Oct. 28, 2010; 81 FR 3020, Jan. 20, 2016; 89 FR 80071, Oct. 2, 2024]

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APPENDIX A TO PART 96—UNIFORM DEFINITIONS OF SERVICES

APPENDIX B TO PART 96—SSBG REPORTING FORM AND INSTRUCTIONS

AUTHORITY: 31 U.S.C. 1243 note, 7501–7507; 42 U.S.C. 300w *et seq.*, § 300x *et seq.*, § 300y *et seq.*, § 701 *et seq.*, § 8621 *et seq.*, § 9901 *et seq.*, § 1397 *et seq.*, 5 U.S.C. § 301.

SOURCE: 47 FR 29486, July 6, 1982, unless otherwise noted.

Subpart A—Introduction

§ 96.1 Scope.

This part applies to the following block grant programs:

- (a) Community services (Pub. L. 97–35, sections 671–683) (42 U.S.C. 9901–9912).
- (b) Preventive health and health services (Pub. L. 97–35, section 901) (42 U.S.C. 300w–300w–8).
- (c) Community mental health services (Public Health Service Act, sections 1911–1920 and sections 1941–1954) (42 U.S.C. 300x–1–300x–9 and 300x–51–300x–64).
- (d) Substance abuse prevention and treatment (Public Health Service Act, sections 1921–1935 and sections 1941–1954) (42 U.S.C. 300x–21–300x–35 and 300x–51–300x–64).
- (e) Maternal and child health services (Social Security Act, Title V) (42 U.S.C. 701–709).
- (f) Social services, empowerment zones and enterprise communities (Pub. L. 97–35, sections 2351–55; Pub. L. 103–66, section 1371) (42 U.S.C. 1397–1397f).
- (g) Low-income home energy assistance (Pub. L. 97–35, sections 2601–11) (42 U.S.C. 8621–8629).

[47 FR 29486, July 6, 1982, as amended at 58 FR 60128, Nov. 15, 1993; 64 FR 55856, Oct. 15, 1999]

§ 96.2 Definitions.

- (a) *Secretary* means the Secretary of Health and Human Services or his designee.

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- (b) *Department* means the Department of Health and Human Services.

- (c) *Reconciliation Act* means the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97–35).

- (d) *State* includes the fifty States, the District of Columbia, and as appropriate with respect to each block grant, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and for purposes of the block grants administered by agencies of the Public Health Service, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37965, Oct. 13, 1987; 64 FR 55856, Oct. 15, 1999]

§ 96.3 Information collection approval numbers.

Information collection requirements pertaining to the block grant programs have been approved by the Office of Management and Budget under the provisions of the Paperwork Reduction Act, Pub. L. 96–511 (44 U.S.C. Chapter 35) and have been assigned OMB numbers:

- 0930–0080 Alcohol and Drug Abuse and Mental Health Services Block Grant Reporting Requirements
- 0920–0106 Preventive Health and Health Services Block Grant Reporting Requirements
- 0915–0023 Primary Care Block Grant Reporting Requirements
- 0915–0024 Maternal and Child Health Services Block Grant Reporting Requirements
- 0980–0125 Social Services Block Grant Reporting Requirements
- 0980–0126 Community Services Block Grant Reporting Requirements
- 0960–0261 Low-Income Home Energy Assistance Block Grant Reporting Requirements.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

Subpart B—General Procedures

§ 96.10 Prerequisites to obtain block grant funds.

- (a) Except where prescribed elsewhere in this rule or in authorizing legislation, no particular form is required for a State's application or the related submission required by the statute.

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For the maternal and child health block grant, the application shall be in the form specified by the Secretary, as provided by section 505(a) of the Social Security Act (42 U.S.C. 705(a)).

(b) The certifications required by the community services, primary care, preventive health and health services, alcohol and drug abuse and mental health services, and low-income home energy assistance block grant statutes to be made by the State's chief executive officer must be made by that individual personally, or by an individual authorized to make such certifications on behalf of the chief executive officer.

(c) Effective beginning in fiscal year 2001, submission dates for applications under the social service and low-income home energy assistance block grant programs are:

(1) for the social services block grant, States and territories which operate on a Federal fiscal year basis, and make requests for funding from the Department, must insure that their applications (pre-expenditure reports) for funding are submitted by September 1 of the preceding fiscal year unless the Department agrees to a later date. States and territories which operate their social services block grant on a July 1–June 30 basis, must insure that their applications are submitted by June 1 of the preceding funding period unless the Department agrees to a later date.

(2) for the low-income home energy assistance program, States and territories which make requests for funding from the Department must insure that their applications for a fiscal year are submitted by September 1 of the preceding fiscal year unless the Department agrees to a later date.

(d) Effective beginning in fiscal year 2001, for the low-income home energy assistance program, States and territories which make requests for funding from the Department must insure that all information necessary to complete their applications is received by December 15 of the fiscal year for which they are requesting funds unless the Department agrees to a later date.

[47 FR 29486, July 6, 1982, as amended at 64 FR 55856, Oct. 15, 1999]

§ 96.11 Basis of award to the States.

The Secretary will award the block grant funds allotted to the State in accordance with the apportionment of funds from the Office of Management and Budget. Such awards will reflect amounts reserved for Indian Tribes and Tribal Organizations and, in FY 1982, any amounts awarded by the Department under transition authorities. The grant award constitutes the authority to carry out the program and to draw and expend funds.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

§ 96.12 Grant payment.

The Secretary will make payments at such times and in such amounts to each State from its awards in advance or by way of reimbursement in accordance with section 203 of the Intergovernmental Cooperation Act (42 U.S.C. 4213) and Treasury Circular No. 1075 (31 CFR part 205). When matching funds are involved, the Secretary shall take into account the ratio that such payment bears to such State's total expenditures under its awards.

§ 96.13 Reallotments.

The Secretary will re-allot to eligible States those funds available as of September 1 of each fiscal year under the reallotment provisions pertaining to the alcohol and drug abuse and mental health services, maternal and child health services, and preventive health and health services block grants. The reallotment procedure for the low-income home energy assistance block grant is specified in section 2607 of the Reconciliation Act (42 U.S.C. 8626) and § 96.81 of this part.

§ 96.14 Time period for obligation and expenditure of grant funds.

(a) *Obligations.* Amounts unobligated by the State at the end of the fiscal year in which they were first allotted shall remain available for obligation during the succeeding fiscal year for all block grants except:

(1) *Primary care.* Amounts are available only if the Secretary determines that the State acted in accordance with section 1926(a)(1) of the Public Health Service Act (42 U.S.C. 300y–

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5(a)(1)) and there is good cause for funds remaining unobligated.

(2) *Low-income home energy assistance.* Regular LIHEAP block grant funds authorized under section 2602(b) of Public Law 97-35 (42 U.S.C. 8621(b)) are available only in accordance with section 2607(b)(2)(B) of Public Law 97-35 (42 U.S.C. 8626(b)(2)(B)), as follows. From allotments for fiscal year 1982 through fiscal year 1984, a maximum of 25 percent may be held available for the next fiscal year. From allotments for fiscal year 1985 through fiscal year 1990, a maximum of 15 percent of the amount payable to a grantee and not transferred to another block grant according to section 2604(f) of Public Law 97-35 (42 U.S.C. 8623(f)) may be held available for the next fiscal year. From allotments for fiscal year 1991 through fiscal year 1993, a maximum of 10 percent of the amount payable to a grantee and not transferred to another block grant according to section 2604(f) of Public Law 97-35 (42 U.S.C. 8623(f)) may be held available for the next fiscal year. Beginning with allotments for fiscal year 1994, a maximum of 10 percent of the amount payable to a grantee may be held available for the next fiscal year. No funds may be obligated after the end of the fiscal year following the fiscal year for which they were allotted.

(b) *Expenditure.* No limitations exist on the time for expenditure of block grant funds, except those imposed by statute with respect to the community services, maternal and child health services, and social services block grants.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982, as amended at 52 FR 37965, Oct. 13, 1987; 60 FR 21357, May 1, 1995]

§ 96.15 Waivers.

Applications for waivers that are permitted by statute for the block grants should be submitted to the Director, Centers for Disease Control and Prevention in the case of the preventive health and health services block grant; to the Administrator, Substance Abuse and Mental Health Services Administration in the case of the community mental health services block grant and the substance abuse prevention and treatment block grant; to the Director, Maternal and Child Health Bureau in

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the case of the maternal and child health services block grant; and to the Director, Office of Community Services in the case of the community services block grant, the low-income home energy assistance program and the social services block grant. Beginning with fiscal year 1986, the Secretary's authority to waive the provisions of section 2605(b) of Public Law 97-35 (42 U.S.C. 8624(b)) under the low-income home energy assistance program is repealed.

[64 FR 55856, Oct. 15, 1999]

§ 96.16 Applicability of title XVII of the Reconciliation Act (31 U.S.C. 7301-7305).

This section interprets the applicability of the general provisions governing block grants set forth in title XVII of the Reconciliation Act (31 U.S.C. 7301-7305):

(a) Except as otherwise provided in this section or unless inconsistent with provisions in the individual block grant statutes, 31 U.S.C. 7301-7305 apply to the community services, preventive health and health services, and alcohol and drug abuse and mental health services block grants.

(b) The requirement in 31 U.S.C. 7303(b) relating to public hearings does not apply to any of the block grants governed by this part. Instead, the provisions in the individual block grant statutes apply.

(c) The maternal and child health services block grant is not subject to any requirements of 31 U.S.C. 7301-7305.

(d) The social services and low-income home energy assistance programs are subject only to 31 U.S.C. 7304.

(e) The audit provisions of 31 U.S.C. 7305 have, in most cases, been overridden by the Single Audit Act. Pub. L. 98-502, 31 U.S.C. 75, *et seq.*, and do not apply to the block grants. Pursuant to § 96.31(b)(2), certain entities may, however, elect to conduct audits under the block grant audit provisions. For entities making this election, the provisions of 31 U.S.C. 7305 apply to the community services block grant.

(f) The applicability of 31 U.S.C. 7303(a) relating to the contents of a report on proposed uses of funds is specified in § 96.10.

[52 FR 37966, Oct. 13, 1987]

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§ 96.17 Annual reporting requirements.

(a) Except for the low-income home energy assistance program activity reports, a state must make public and submit to the Department each annual report required by statute:

(1) Within six months of the end of the period covered by the report; or

(2) At the time the state submits its application for funding for the federal or state fiscal year, as appropriate, which begins subsequent to the expiration of that six-month period.

(b) These reports are required annually for preventive health and health services (42 U.S.C. 300w-5(a)(1)), community mental health services (42 U.S.C. 300x *et. seq.*), the prevention and treatment of substance abuse block grant (42 U.S.C. 300x-21 *et. seq.*), maternal and child health services (42 U.S.C. 706(a)(1)), and the social services block grant (42 U.S.C. 1397e(a)). See § 96.82 for requirements governing the submission of activity reports for the low-income home energy assistance program.

[58 FR 60128, Nov. 15, 1993]

§ 96.18 Participation by faith-based organizations.

The funds provided under this part shall be administered in compliance with the standards set forth in part 87 (Equal Treatment for Faith-based Organizations) of this chapter.

[69 FR 42592, July 16, 2004]

Subpart C—Financial Management

§ 96.30 Fiscal and administrative requirements.

(a) *Fiscal control and accounting procedures.* Except where otherwise required by Federal law or regulation, a State shall obligate and expend block grant funds in accordance with the laws and procedures applicable to the obligation and expenditure of its own funds. Fiscal control and accounting procedures must be sufficient to (a) permit preparation of reports required by the statute authorizing the block grant and (b) permit the tracing of funds to a level of expenditure adequate to establish that such funds have not been used in violation of the restrictions and prohibi-

tions of the statute authorizing the block grant.

(b) *Financial summary of obligation and expenditure of block grant funds—*(1) *Block grants containing time limits on both the obligation and the expenditure of funds.* After the close of each statutory period for the obligation of block grant funds and after the close of each statutory period for the expenditure of block grant funds, each grantee shall report to the Department:

(i) Total funds obligated and total funds expended by the grantee during the applicable statutory periods; and

(ii) The date of the last obligation and the date of the last expenditure.

(2) *Block grants containing time limits only on obligation of funds.* After the close of each statutory period for the obligation of block grant funds, each grantee shall report to the Department:

(i) Total funds obligated by the grantee during the applicable statutory period; and

(ii) The date of the last obligation.

(3) *Block grants containing time limits only on expenditure of funds.* After the close of each statutory period for the expenditure of block grant funds, each grantee shall report to the Department:

(i) Total funds expended by the grantee during the statutory period; and

(ii) The date of the last expenditure.

(4) *Submission of information.* Grantees shall submit the information required by paragraph (b)(1), (2), and (3) of this section on OMB Standard Form 269A, Financial Status Report (short form). Grantees are to provide the requested information within 90 days of the close of the applicable statutory grant periods.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37966, Oct. 13, 1987; 53 FR 11656, Apr. 8, 1988; 64 FR 55857, Oct. 15, 1999]

§ 96.31 Audits.

(a) *Basic rule.* Grantees and subgrantees are responsible for obtaining audits in accordance with the Single Audit Act Amendments of 1996 (31 U.S.C. 7501-7507) and revised OMB Circular A-133, "Audits of State, Local Governments, and Non-Profit Organizations." The audits shall be made by

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an independent auditor in accordance with generally accepted Government auditing standards covering financial audits.

(b) *Subgrantees.* State or local governments, as those terms are defined for purposes of the Single Audit Act Amendments of 1996, that provide Federal awards to a subgrantee, expending \$300,000 or more (or other amount as specified by OMB) in Federal awards in a fiscal year, shall:

(1) Determine whether subgrantees have met the audit requirements of the Act. Commercial contractors (private for-profit and private and governmental organizations) providing goods and services to State and local governments are not required to have a single audit performed. State and local governments should use their own procedures to ensure that the contractor has complied with laws and regulations affecting the expenditure of Federal funds;

(2) Determine whether the subgrantee spent Federal assistance funds provided in accordance with applicable laws and regulations. This may be accomplished by reviewing an audit of the subgrantee made in accordance with the Act or through other means (e.g., program reviews) if the subgrantee has not had such an audit;

(3) Ensure that appropriate corrective action is taken within six months after receipt of the audit report in instances of noncompliance with Federal laws and regulations;

(4) Consider whether subgrantee audits necessitate adjustment of the grantee's own records; and

(5) Require each subgrantee to permit independent auditors to have access to the records and financial statements.

[62 FR 45963, Aug. 29, 1997]

§ 96.32 Financial settlement.

The State must repay to the Department amounts found after audit resolution to have been expended improperly. In the event that repayment is not made voluntarily, the Department will undertake recovery.

[52 FR 37966, Oct. 13, 1987]

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§ 96.33 Referral of cases to the Inspector General.

State or tribal officials who have information indicating the commission or potential commission of fraud or other offenses against the United States involving block grant funds should promptly provide the information to the appropriate Regional Office of Investigations of the Department's Office of the Inspector General.

[52 FR 37966, Oct. 13, 1987]

Subpart D—Direct Funding of Indian Tribes and Tribal Organizations

§ 96.40 Scope.

This subpart applies to the community services, alcohol and drug abuse and mental health services, preventive health and health services, primary care, and low-income home energy assistance block grants.

§ 96.41 General determination.

(a) The Department has determined that, with the exception of the circumstances addressed in paragraph (c) of this section, Indian tribes and tribal organizations would be better served by means of grants provided directly by the Department to such tribes and organizations out of their State's allotment of block grant funds than if the State were awarded its entire allotment. Accordingly, with the exception of situations described in paragraph (c) of this section, the Department will, upon request of an eligible Indian tribe or tribal organization and where provided for by statute, reserve a portion of the allotment of the State(s) in which the tribe is located, and, upon receipt of a complete application and related submission meeting statutory and regulatory requirements, grant it directly to the tribe or organization.

(b) An Indian tribe or tribal organization may request direct funding under a block grant program included in this subpart regardless of whether the State in which it is located is receiving funds under the block grant program.

(c) The Department has determined that Indian tribal members eligible for the funds or services provided through the block grants would be better served

by the State(s) in which the tribe is located rather than by the tribe, where:

(1) The tribe has not used its block grant allotment substantially in accordance with the provisions of the relevant statute(s); and

(2) Following the procedures of 45 CFR 96.51, the Department has withheld tribal funds because of those deficiencies; and

(3) The tribe has not provided sufficient evidence that it has removed or corrected the reason(s) for withholding. In these cases, block grant funds reserved or set aside for a direct grant to the Indian tribe will be awarded to the State(s), and the State(s) will provide block grant services to the service population of the tribe. Before awarding these funds to the State(s), the Department will allow as much time as it determines to be reasonable for the tribe to correct the conditions that led to withholding, consistent with provision of timely and meaningful services to the tribe's service population during the fiscal year. If a State(s) is awarded funds under this paragraph, the State(s) will receive all remaining funds set aside for the tribe for the Federal fiscal year for which the award is made. Where the Department has withheld funds from a tribe and the tribe has not taken satisfactory corrective action by the first day of the following fiscal year, all of the funds to serve the tribe's service population for the following fiscal year will be awarded to the State(s). The State(s) is responsible for providing services to the service population of the tribe in these cases. This paragraph also applies when funds are withheld from a tribal organization.

[47 FR 29486, July 6, 1982, as amended at 64 FR 55857, Oct. 15, 1999]

§ 96.42 General procedures and requirements.

(a) An Indian tribe or tribal organization applying for or receiving direct funding from the Secretary under a block grant program shall be subject to all statutory and regulatory requirements applicable to a State applying for or receiving block grant funds to the extent that such requirements are relevant to an Indian tribe or tribal or-

ganization except where otherwise provided by statute or in this part.

(b) A tribal organization representing more than one Indian tribe will be eligible to receive block grant funds on behalf of a particular tribe only if the tribe has by resolution authorized the organization's action.

(c) If an Indian tribe or tribal organization whose service population resides in more than one State applies for block grant funds that, by statute, are apportioned on the basis of population, the allotment awarded to the tribe or organization shall be taken from the allotments of the various States in which the service population resides in proportion to the number of eligible members or households to be served in each State. If block grant funds are required to be apportioned on the basis of grants during a base year, the allotment to the Indian tribe or tribal organization shall be taken from the allotment of the State whose base year grants included the relevant grants to the tribe or organization.

(d) The audit required under the block grant programs shall be conducted by an entity that is independent of the Indian tribe or tribal organization receiving grant funds from the Secretary.

(e) Beginning with fiscal year 1983, any request by an Indian tribe or tribal organization for direct funding by the Secretary must be submitted to the Secretary, together with the required application and related materials, by September 1 preceding the Federal fiscal year for which funds are sought. A separate application is required for each block grant. After the September 1 deadline, tribal applications will be accepted only with the concurrence of the State (or States) in which the tribe or tribal organization is located.

(f) A State receiving block grant funds is not required to use those funds to provide tangible benefits (e.g., cash or goods) to Indians who are within the service population of an Indian tribe or tribal organization that received direct funding from the Department under the same block grant program for the same fiscal year. A State, however, may not deny Indians access to intangible services funded by block grant

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programs (e.g., treatment at a community health center) even if the Indians are members of a tribe receiving direct funding for a similar service. A tribe receiving direct block grant funding is not required to use those funds to provide tangible benefits to non-Indians living within the tribe's service area unless the tribe and the State(s) in which the tribe is located agree in writing that the tribe will do so.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37966, Oct. 13, 1987; 64 FR 55857, Oct. 15, 1999]

§ 96.43 Procedures during FY 1982.

(a) This section applies to the fiscal year beginning October 1, 1981.

(b) A request for direct funding must be received by the Secretary before the Secretary has awarded all of the allotment to the State involved. The application and related submission may be submitted later but must be submitted within 75 days after the beginning of the quarter in which the State qualified for block grant funds, (or by August 20, 1982 in the case of an Indian tribe located in a State that has not qualified for block grant funds in FY 1982) except that the application and related submission for the low-income home energy assistance program must be submitted by December 15, 1981. A separate request and application are required for each block grant.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

§ 96.44 Community services.

(a) This section applies to direct funding of Indian tribes and tribal organizations under the community services block grant.

(b) The terms *Indian tribe* and *tribal organization* as used in the Reconciliation Act have the same meaning given such terms in section 4(b) and 4(c) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b). The terms also include organized groups of Indians that the State in which they reside has determined are Indian tribes. An organized group of Indians is eligible for direct funding based on State recognition if the State has expressly determined that the group is an Indian tribe. In addition,

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the statement of the State's chief executive officer verifying that a tribe is recognized by that State will also be sufficient to verify State recognition for the purpose of direct funding.

(c) For purposes of section 674(c)(2) of the Act (42 U.S.C. 9903(c)(2)) an *eligible Indian* means a member of an Indian tribe whose income is at or below the poverty line defined in section 673(2) of the Act (42 U.S.C. 9902(2)). An *eligible individual* under section 674(c)(2) of the Reconciliation Act (42 U.S.C. 9903(c)(2)) means a resident of the State whose income is at or below the poverty line.

(d) An Indian tribe or tribal organization will meet the requirements of section 675(c)(1) (42 U.S.C. 9904(c)(1)) if it certifies that it agrees to use the funds to provide at least one of the services or activities listed in that section.

(e) An Indian tribe or tribal organization is not required to comply with section 675(b) (42 U.S.C. 9904(b)) or to provide the certifications required by the following other provisions of the Reconciliation Act.

(1) Section 675(c)(2)(A) (42 U.S.C. 9904(c)(2)(A));

(2) Section 675(c)(3) (42 U.S.C. 9904(c)(3)); and

(3) Section 675(c)(4) (42 U.S.C. 9904(c)(4)).

(4) Section 675(c)(11) (42 U.S.C. 9904(c)(11)).

(f) In each fiscal year, Indian tribes and tribal organizations may expend for administrative expenses—comparable to the administrative expenses incurred by State at the State level—an amount not to exceed the greater of the amounts determined by:

(1) Multiplying their allotment under section 674 of the Reconciliation Act (42 U.S.C. 9903) by five percent; or

(2) Multiplying the allotment by the percentage represented by the ratio of \$55,000 to the smallest State allotment (excluding territorial allotments) for that fiscal year.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37967, Oct. 13, 1987]

§ 96.45 Preventive health and health services.

(a) This section applies to direct funding of Indian tribes and tribal organizations under the preventive health and health services block grant.

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(b) For the purposes of determining eligible applicants under section 1902(d) of the Public Health Service Act, a grantee that received a grant directly from the Secretary in FY 1981 under any of the programs replaced by the preventive health and health services block grant that was specifically targeted toward serving a particular Indian tribe or tribal organization will be considered eligible if the grantee is an Indian tribe or tribal organization at the time it requests funds under this part. Grantees that received funds under formula or Statewide grants, and subgrantees that received funds from any program replaced by the preventive health and health services block grant, are not eligible.

§ 96.46 Substance abuse prevention and treatment services.

(a) This section applies to direct funding of Indian tribes and tribal organizations under the substance abuse prevention and treatment Block Grant.

(b) For the purpose of determining eligible applicants under section 1933(d) of the Public Health Service Act (42 U.S.C. 300x-33(d)) an Indian tribe or tribal organization (as defined in subsections (b) and (c) of section 4 of the Indian Self-Determination and Education Assistance Act) that received a direct grant under subpart I of part B of title XIX of the PHS Act (as such existed prior to October 1, 1992) in fiscal year 1991 will be considered eligible for a grant under subpart 2 of part B of title XIX of the PHS Act.

(c) For purposes of the substance abuse prevention and treatment Block Grant, an Indian tribe or tribal organization is not required to comply with the following statutory provisions of the Public Health Service Act: 1923 (42 U.S.C. 300x-23), 1925 (42 U.S.C. 300x-25), 1926 (42 U.S.C. 300x-26), 1928 (42 U.S.C. 300x-28), 1929 (42 U.S.C. 300x-29), and 1943(a)(1) (42 U.S.C. 300x-53(a)(1)). An Indian tribe or tribal organization is to comply with all other statutes and regulations applicable to the Substance Abuse Prevention and Treatment Block Grant. In each case in which an Indian Tribe receives a direct grant, the State is also responsible for providing services to Native Americans

under the State's Block Grant program.

[58 FR 17070, Mar. 31, 1993]

§ 96.47 Primary care.

Applications for direct funding of Indian tribes and tribal organizations under the primary care block grant must comply with 42 CFR part 51c (Grants for Community Health Services).

§ 96.48 Low-income home energy assistance.

(a) This section applies to direct funding of Indian tribes under the low-income home energy assistance program.

(b) The terms *Indian tribe* and *tribal organization* as used in the Reconciliation Act have the same meaning given such terms in section 4(b) and 4(c) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b) except that the terms shall also include organized groups of Indians that the State in which they reside has expressly determined are Indian tribes or tribal organizations in accordance with State procedures for making such determinations.

(c) For purposes of section 2604(d) of the Act (42 U.S.C. 8623(d)), an organized group of Indians is eligible for direct funding based on State recognition if the State has expressly determined that the group is an Indian tribe. A statement by the State's chief executive officer verifying that a tribe is recognized by that State will also be sufficient to verify State recognition for the purpose of direct funding.

(d) The plan required by section 2604(d)(4) of the Reconciliation Act (42 U.S.C. 8623(d)(4)) shall contain the certification and information required for States under section 2605 (b) and (c) of that Act (42 U.S.C. 8624 (b) and (c)). An Indian tribe or tribal organization is not required to comply with section 2605(a)(2) of the Act (42 U.S.C. 8624(a)(2)).

(e) Where a tribe requests that the Secretary fund another entity to provide energy assistance for tribal members, as provided by section 2604(d)(3) of

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the Act (42 U.S.C. 8623(d)(3)), the Secretary shall consider the following factors in selecting the grantee: the ability of the other entity to provide low-income home energy assistance, existing tribal-State agreements as to the size and location of the service population, and the history of State services to the Indian people to be served by the other entity.

§ 96.49 Due date for receipt of all information required for completion of tribal applications for the low-income home energy assistance block grants.

Effective beginning in FY 2001, for the low-income home energy assistance program, Indian tribes and tribal organizations that make requests for direct funding from the Department must insure that all information necessary to complete their application is received by December 15 of the fiscal year for which funds are requested, unless the State(s) in which the tribe is located agrees to a later date. After December 15, funds will revert to the State(s) in which the tribe is located, unless the State(s) agrees to a later date. If funds revert to a State, the State is responsible for providing low-income home energy assistance program services to the service population of the tribe.

[64 FR 55857, Oct. 15, 1999]

Subpart E—Enforcement

§ 96.50 Complaints.

(a) This section applies to any complaint (other than a complaint alleging violation of the nondiscrimination provisions) that a State has failed to use its allotment under a block grant in accordance with the terms of the act establishing the block grant or the certifications and assurances made by the State pursuant to that act. The Secretary is not required to consider a complaint unless it is submitted as required by this section.

(b) Complaints with respect to the health block grants must be submitted in writing to either the Assistant Secretary for Health or: For the preventive health and health services block grant, the Director, Centers for Disease Control; for the alcohol and drug abuse and mental health services block

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grant, the Administrator, Alcohol, Drug Abuse, and Mental Health Administration; for the maternal and child health services block grant, the Administrator, Health Resources and Services Administration. Complaints with respect to the social services block grant must be submitted in writing to the Assistant Secretary for Human Development Services. Complaints with respect to the low-income home energy assistance program and the community services block grant must be submitted in writing to the Director, Office of Community Services. (The address for the Director, Center for Disease Control is 1600 Clifton Road, NE., Atlanta, Georgia 30333. For each of the other officials cited above the address is 200 Independence Avenue SW., Washington, DC 20201.) The complaint must identify the provision of the act, assurance, or certification that was allegedly violated; must specify the basis for the violations it charges; and must include all relevant information known to the person submitting it.

(c) The Department shall promptly furnish a copy of any complaint to the affected State. Any comments received from the State within 60 days (or such longer period as may be agreed upon between the State and the Department) shall be considered by the Department in responding to the complaint. The Department will conduct an investigation of complaints where appropriate.

(d) The Department will provide a written response to complaints within 180 days after receipt. If a final resolution cannot be provided at that time, the response will state the reasons why additional time is necessary. Under the low-income home energy assistance program, within 60 days after receipt of complaints, the Department will provide a written response to the complainant, stating the actions that it has taken to date and, if the complaint has not yet been fully resolved, the timetable for final resolution of the complaint.

(e) The Department recognizes that under the block grant programs the States are primarily responsible for interpreting the governing statutory provisions. As a result, various States may reach different interpretations of

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the same statutory provisions. This circumstance is consistent with the intent of and statutory authority for the block grant programs. In resolving any issue raised by a complaint or a Federal audit the Department will defer to a State's interpretation of its assurances and of the provisions of the block grant statutes unless the interpretation is clearly erroneous. In any event, the Department will provide copies of complaints to the independent entity responsible for auditing the State's activities under the block grant program involved. Any determination by the Department that a State's interpretation is not clearly erroneous shall not preclude or otherwise prejudice the State auditors' consideration of the question.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982, as amended at 52 FR 37967, Oct. 13, 1987; 57 FR 1977, Jan. 16, 1992; 60 FR 21358, May 1, 1995]

§ 96.51 Hearings.

(a) The Department will order a State to repay amounts found not to have been expended in accordance with law of the certifications provided by the State only after the Department has provided the State notice of the order and an opportunity for a hearing. Opportunity for a hearing will not be provided, however, when the State, in resolving audit findings or at another time, has agreed that the amounts were not expended in accordance with law or the certifications. The hearing will be governed by subpart F of this part and will be held in the State if required by statute.

(b) If a State refuses to repay amounts after a final decision that is not subject to further review in the Department, the amounts may be offset against payments to the State. If a statute requires an opportunity for a hearing before such an offset may be made, the hearing will be governed by subpart F of this part and will be held in the State if required by statute.

(c) The Department will withhold funds from a State only if the Department has provided the State an opportunity for a hearing. The hearing will be governed by subpart F of this part

and will be held in the State if required by statute.

[47 FR 29486, July 6, 1982, as amended at 52 FR 37967, Oct. 13, 1987]

§ 96.52 Appeals.

(a) Decisions resulting from repayment hearings held pursuant to § 96.51(a) of this part may be appealed by either the State or the Department to the Grant Appeals Board.

(b) Decisions resulting from offset hearings held pursuant to § 96.51(b) of this part may not be appealed.

(c) Decisions resulting from withholding hearings held pursuant to § 96.51(c) of this part may be appealed to the Secretary by the State or the Department as follows:

(1) An application for appeal must be received by the Secretary no later than 60 days after the appealing party receives a copy of the presiding officer's decision. The application shall clearly identify the questions for which review is sought and shall explain fully the party's position with respect to those questions. A copy shall be furnished to the other party.

(2) The Secretary may permit the filing of opposing briefs, hold informal conferences, or take whatever other steps the Secretary finds appropriate to decide the appeal.

(3) The Secretary may refer an application for appeal to the Grant Appeals Board. Notwithstanding part 16 of this title, in the event of such a referral, the Board shall issue a recommended decision that will not become final until affirmed, reversed, or modified by the Secretary.

(d) Any appeal to the Grant Appeals Board under this section shall be governed by part 16 of this title except that the Board shall not hold a hearing. The Board shall accept any findings with respect to credibility of witnesses made by the presiding officer. The Board may otherwise review and supplement the record as provided for in part 16 of this title and decide the issues raised.

§ 96.53 Length of withholding.

Under the low-income home energy assistance program and community services block grant, the Department

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may withhold funds until the Department finds that the reason for the withholding has been removed.

[64 FR 55857, Oct. 15, 1999]

Subpart F—Hearing Procedure

§ 96.60 Scope.

The procedures in this subpart apply when opportunity for a hearing is provided for by § 96.51 of this part.

§ 96.61 Initiation of hearing.

(a) A hearing is initiated by a notice of opportunity for hearing from the Department. The notice will:

(1) Be sent by mail, telegram, telex, personal delivery, or any other mode of written communication;

(2) Specify the facts and the action that are the subject of the opportunity for a hearing;

(3) State that the notice of opportunity for hearing and the hearing are governed by these rules; and

(4) State the time within which a hearing may be requested, and state the name, address, and telephone number of the Department employee to whom any request for hearing is to be addressed.

(b) A State offered an opportunity for a hearing has the amount of time specified in the notice, which may not be less than 10 days after receipt of the notice, within which to request a hearing. The request may be filed by mail, telegram, telex, personal delivery, or any other mode of written communication, addressed to the designated Department employee. If no response is filed within that time, the offer is deemed to have been refused and no hearing will be held.

(c) If a hearing is requested, the Department will designate a presiding officer, and (subject to § 96.51 of this part) the hearing will take place at a time and location agreed upon by the State requesting the hearing, the Department, and the presiding officer or, if agreement cannot be reached, at a reasonable time and location designated by the presiding officer.

§ 96.62 Presiding officer.

(a) A Department employee to whom the Secretary delegates such author-

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ity, or any other agency employee designated by an employee to whom such authority is delegated, may serve as the presiding officer and conduct a hearing under this subpart.

(b) The presiding officer is to be free from bias or prejudice and may not have participated in the investigation or action that is the subject of the hearing or be subordinate to a person, other than the Secretary, who has participated in such investigation or action.

(c) The Secretary is not precluded by this section from prior participation in the investigation or action that is the subject of the hearing.

(d) A different presiding officer may be substituted for the one originally designated under § 96.61 of this part without notice to the parties.

§ 96.63 Communications to presiding officer.

(a) Those persons who are directly involved in the investigation or presentation of the position of the Department or any party at a hearing that is subject to this subpart should avoid any off-the-record communication on the matter to the presiding officer or his advisers if the communication is inconsistent with the requirement of § 96.68 of this part that the administrative record be the exclusive record for decision. If any communication of this type occurs, it is to be reduced to writing and made part of the record, and the other party provided an opportunity to respond.

(b) A copy of any communications between a participant in the hearing and the presiding officer, e.g., a response by the presiding officer to a request for a change in the time of the hearing is to be sent to all parties by the person initiating the communication.

§ 96.64 Intervention.

Participation as parties in the hearing by persons other than the State and the Department is not permitted.

§ 96.65 Discovery.

The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

§ 96.66 Hearing procedure.

(a) A hearing is public, except when the Secretary or the presiding officer determines that all or part of a hearing should be closed to prevent a clearly unwarranted invasion of personal privacy (such as disclosure of information in medical records that would identify patients), to prevent the disclosure of a trade secret or confidential commercial or financial information, or to protect investigatory records compiled for law enforcement purposes that are not available for public disclosure.

(b) A hearing will be conducted by the presiding officer. Employees of the Department will first give a full and complete statement of the action which is the subject of the hearing, together with the information and reasons supporting it, and may present any oral or written information relevant to the hearing. The State may then present any oral or written information relevant to the hearing. Both parties may confront and conduct reasonable cross-examination of any person (except for the presiding officer and counsel for the parties) who makes any statement on the matter at the hearing.

(c) The hearing is informal in nature, and the rules of evidence do not apply. No motions or objections relating to the admissibility of information and views will be made or considered, but either party may comment upon or rebut all such data, information, and views.

(d) The presiding officer may order the hearing to be transcribed. The State may have the hearing transcribed, at the State's expense, in which case a copy of the transcript is to be furnished to the Department at the Department's expense.

(e) The presiding officer may, if appropriate, allow for the submission of post-hearing briefs. The presiding officer shall prepare a written decision, which shall be based on a preponderance of the evidence, shall include a statement of reasons for the decision, and shall be final unless appealed pursuant to § 96.52 of this part. If post-hearing briefs were not permitted, the parties to the hearing will be given the opportunity to review and comment on

the presiding officer's decision prior to its being issued.

(f) The presiding officer shall include as part of the decision a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue.

(g) The presiding officer shall furnish a copy of the decision to the parties.

(h) The presiding officer has the power to take such actions and make such rulings as are necessary or appropriate to maintain order and to conduct a fair, expeditious, and impartial hearing, and to enforce the requirements of this subpart concerning the conduct of hearings. The presiding officer may direct that the hearing be conducted in any suitable manner permitted by law and these regulations.

(i) The Secretary or the presiding officer has the power to suspend, modify, or waive any provision of this subpart.

§ 96.67 Right to counsel.

Any party to a hearing under this part has the right at all times to be advised and accompanied by counsel.

§ 96.68 Administrative record of a hearing.

(a) The exclusive administrative record of the hearing consists of the following:

(1) The notice of opportunity for hearing and the response.

(2) All written information and views submitted to the presiding officer at the hearing or after if specifically permitted by the presiding officer.

(3) Any transcript of the hearing.

(4) The presiding officer's decision and any briefs or comments on the decision under § 96.66(e) of this part.

(5) All letters or communications between participants and the presiding officer or the Secretary referred to in § 96.63 of this part.

(b) The record of the hearing is closed to the submission of information and views at the close of the hearing, unless the presiding officer specifically permits additional time for a further submission.

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Subpart G—Social Services Block Grants

§ 96.70 Scope.

This subpart applies to the social services block grant.

§ 96.71 Definitions.

(a) Section 2005 (a)(2) and (a)(5) (42 U.S.C. 1397d (a)(2) and (a)(5)) of the Social Security Act establishes prohibitions against the provision of room and board and medical care unless, among other reasons, they are an “integral but subordinate” part of a State-authorized social service. “Integral but subordinate” means that the room and board provided for a short term or medical care is a minor but essential adjunct to the service of which it is a part and is necessary to achieve the objective of that service. Room and board provided for a short term shall not be considered an integral but subordinate part of a social service when it is provided to an individual in a foster family home or other facility the primary purpose of which is to provide food, shelter, and care or supervision, except for temporary emergency shelter provided as a protective service.

(b) As used in section 2005(a)(5) of the Social Security Act (42 U.S.C. 1397d (a)(5)) with respect to the limitations governing the provision of services by employees of certain institutions, *employees* includes staff, contractors, or other individuals whose activities are under the professional direction or direct supervision of the institution.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

§ 96.72 Transferability of funds.

Under section 2002(d) of the Social Security Act (42 U.S.C. 1397a(d)), funds may be transferred in accordance with the provisions of that section to the preventive health and health services, alcohol and drug abuse and mental health services, primary care, maternal and child health services, and low-income home energy assistance block grants. In addition, funds may be transferred to other Federal block grants for support of health services, health promotion and disease prevention activities, or low-income home en-

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ergy assistance (or any combination of those activities).

§ 96.73 Sterilization.

If a State authorizes sterilization as a family planning service, it must comply with the provisions of 42 CFR part 441, subpart F, except that the State plan requirement under 42 CFR 441.252 does not apply.

[47 FR 33702, Aug. 4, 1982]

§ 96.74 Annual reporting requirements.

(a) *Annual report.* In accordance with 42 U.S.C. 1397e, each state must submit an annual report to the Secretary by the due dates specified in § 96.17 of this part. The annual report must cover the most recently completed fiscal year and, except for the data in paragraphs (a) (1) through (4) of this section, may be submitted in the format of the state’s choice. The annual report must address the requirements in section 2006(a) of the Act, include the specific data required by section 2006(c), and include other information as follows:

(1) The number of individuals who receive services paid for in whole or in part with federal funds under the Social Services Block Grant, showing separately the number of children and the number of adults who received such services (section 2006(c)(1));

(2) The amount of Social Services Block Grant funds spent in providing each service, showing separately for each service the average amount spent per child recipient and per adult recipient (section 2006(c)(2));

(3) The total amount of federal, state and local funds spent in providing each service, including Social Services Block Grant funds;

(4) The method(s) by which each service is provided, showing separately the services provided by public agencies, private agencies, or both (section 2006(c)(4)); and

(5) The criteria applied in determining eligibility for each service such as income eligibility guidelines, sliding fee scales, the effect of public assistance benefits, and any requirements for enrollment in school or training programs (section 2006(c)(3)).

(b) *Reporting requirement.* (1) Each state must use the uniform definitions of services in appendix A of this part,

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categories 1–28, in submitting the data required in paragraph (a) of this section. Where a state cannot use the uniform definitions, it should report the data under category 29, “Other Services.” The state’s definitions of each of the services listed in category 29 must be included in the annual report.

(2) Each state must use the reporting form issued by the Department to report the data required in paragraphs (a) (1) through (4) of this section.

(3) In reporting recipient and expenditure data, each state must report actual numbers of recipients and actual expenditures when this information is available. For purposes of this report, each state should, if possible, count only a single recipient for each service. States should also consider a service provided to a recipient for the length of the reporting period (one year) or any fraction thereof as a single service. Data based on sampling and/or estimates will be accepted when actual figures are unavailable. Each state must indicate for each service whether the data are based on actual figures, sampling, or estimates and must describe the sampling and/or estimation process(es) it used to obtain these data in the annual report. Each state must also indicate, in reporting recipient data, whether the data reflects an unduplicated count of recipients.

(4) Each state must use category 30, “Other Expenditures,” to report non-service expenditures. Only total dollar amounts in this category are required, i.e., they need not be reported by recipient count or cost per adult/child. This will include carry over balances, carry forward balances, funds transferred to or from the SSBG program, and administrative costs as defined by the state.

(5) Each state must use its own definition of the terms “child” and “adult” in reporting the data required in paragraphs (a) (1) through (5) of this section.

(6) Each state’s definition of “child” and “adult” must be reported as a part of the eligibility criteria for each service required in paragraph (a)(5) of this section. The data on eligibility criteria may be submitted in whatever format the state chooses as a part of its annual report.

(c) *Transfer of computer data.* In addition to making the annual report available to the public and to the Department, a state may submit the information specified in paragraphs (a) (1) through (4) of this section using electronic equipment. A full description of procedures for electronic transmission of data, and of the availability of computer diskettes, is included in appendix B to this part.

[58 FR 60129, Nov. 15, 1993]

Subpart H—Low-income Home Energy Assistance Program

§ 96.80 Scope.

This subpart applies to the low-income home energy assistance program.

§ 96.81 Carryover and reallocation.

(a) *Scope.* Pursuant to section 2607(b) of Public Law 97–35 (42 U.S.C. 8626(b)), this section concerns procedures relating to carryover and reallocation of regular LIHEAP block grant funds authorized under section 2602(b) of Public Law 97–35 (42 U.S.C. 8621(b)).

(b) *Required carryover and reallocation report.* Each grantee must submit a report to the Department by August 1 of each year, containing the information in paragraphs (b)(1) through (b)(4) of this section. The Department shall make no payment to a grantee for a fiscal year unless the grantee has complied with this paragraph with respect to the prior fiscal year.

(1) The amount of funds that the grantee requests to hold available for obligation in the next (following) fiscal year, not to exceed 10 percent of the funds payable to the grantee;

(2) A statement of the reasons that this amount to remain available will not be used in the fiscal year for which it was allotted;

(3) A description of the types of assistance to be provided with the amount held available; and

(4) The amount of funds, if any, to be subject to reallocation.

(c) *Conditions for reallocation.* If the total amount available for reallocation for a fiscal year is less than \$25,000, the Department will not reallocate such amount. If the total amount available for reallocation for a fiscal year is

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\$25,000 or more, the Department will reallocate such amount, except that the Department will not award less than \$25 in reallocated funds to a grantee.

[64 FR 55858, Oct. 15, 1999]

§ 96.82 Required report on households assisted.

(a) Each grantee which is a State or an insular area which receives an annual allotment of at least \$200,000 shall submit to the Department, as part of its LIHEAP grant application, the data required by section 2605(c)(1)(G) of Public Law 97-35 (42 U.S.C. 8624(c)(1)(G)) for the 12-month period corresponding to the Federal fiscal year (October 1–September 30) preceding the fiscal year for which funds are requested. The data shall be reported separately for LIHEAP heating, cooling, crisis, and weatherization assistance.

(b) Each grantee which is an insular area which receives an annual allotment of less than \$200,000 or which is an Indian tribe or tribal organization which receives direct funding from the Department shall submit to the Department, as part of its LIHEAP grant application, data on the number of households receiving LIHEAP assistance during the 12-month period corresponding to the Federal fiscal year (October 1–September 30) preceding the fiscal year for which funds are requested. The data shall be reported separately for LIHEAP heating, cooling, crisis, and weatherization assistance.

(c) Grantees will not receive their LIHEAP grant allotment for the fiscal year until the Department has received the report required under paragraph (a) or (b) of this section.

[64 FR 55858, Oct. 15, 1999]

§ 96.83 Increase in maximum amount that may be used for weatherization and other energy-related home repair.

(a) *Scope.* This section concerns requests for waivers increasing from 15 percent to up to 25 percent of LIHEAP funds allotted or available to a grantee for a fiscal year, the maximum amount that grantees may use for low-cost residential weatherization and other energy-related home repair for low-income households (hereafter referred to as “weatherization”), pursuant to sec-

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tion 2605(k) of Public Law 97-35 (42 U.S.C. 8624(k)).

(b) *Public inspection and comment.* Before submitting waiver requests to the Department, grantees must make proposed waiver requests available for public inspection within their jurisdictions in a manner that will facilitate timely and meaningful review of, and comment upon, these requests. Written public comments on proposed waiver requests must be made available for public inspection upon their receipt by grantees, as must any summaries prepared of written comments, and transcripts and/or summaries of verbal comments made on proposed requests at public meetings or hearings. Proposed waiver requests, and any preliminary waiver requests, must be made available for public inspection and comment until at least March 15 of the fiscal year for which the waiver is to be requested. Copies of actual waiver requests must be made available for public inspection upon submission of the requests to the Department.

(c) *Waiver request.* After March 31 of each fiscal year, the chief executive officer (or his or her designee) may request a waiver of the weatherization obligation limit for this fiscal year, if the grantee meets criteria in paragraphs (c)(2)(i), (c)(2)(ii), and (c)(2)(iii) of this section, or can show “good cause” for obtaining a waiver despite a failure to meet one or more of these criteria. (If the request is made by the chief executive officer’s designee and the Department does not have on file written evidence of the designation, the request also must include evidence of the appropriate delegation of authority.) Waiver requests must be in writing and must include the information specified in paragraphs (c)(1) through (c)(6) of this section. The grantee may submit a preliminary waiver request for a fiscal year, between February 1 and March 31 of the fiscal year for which the waiver is requested. If a grantee chooses to submit a preliminary waiver request, the preliminary request must include the information specified in paragraphs (c)(1) through (c)(6) of this section; in addition, after March 31 the chief executive officer (or his or her designee) must submit the information specified in

paragraphs (c)(7) through (c)(10) of this section, to complete the preliminary waiver request.

(1) A statement of the total percent of its LIHEAP funds allotted or available in the fiscal year for which the waiver is requested, that the grantee desires to use for weatherization.

(2) A statement of whether the grantee has met each of the following three criteria:

(i) In the fiscal year for which the waiver is requested, the combined total (aggregate) number of households in the grantee's service population that will receive LIHEAP heating, cooling, and crisis assistance benefits that are provided from Federal LIHEAP allotments from regular and supplemental appropriations will not be fewer than the combined total (aggregate) number that received such benefits in the preceding fiscal year;

(ii) In the fiscal year for which the waiver is requested, the combined total (aggregate) amount, in dollars, of LIHEAP heating, cooling, and crisis assistance benefits received by the grantee's service population that are provided from Federal LIHEAP allotments from regular and supplemental appropriations will not be less than the combined total (aggregate) amount received in the preceding fiscal year; and

(iii) All LIHEAP weatherization activities to be carried out by the grantee in the fiscal year for which the waiver is requested have been shown to produce measurable savings in energy expenditures.

(3) With regard to criterion in paragraph (c)(2)(i) of this section, a statement of the grantee's best estimate of the appropriate household totals for the fiscal year for which the waiver is requested and for the preceding fiscal year.

(4) With regard to criterion in paragraph (c)(2)(ii) of this section, a statement of the grantee's best estimate of the appropriate benefit totals, in dollars, for the fiscal year for which the waiver is requested and for the preceding fiscal year.

(5) With regard to criterion in paragraph (c)(2)(iii) of this section, a description of the weatherization activities to be carried out by the grantee in the fiscal year for which the waiver is

requested (with all LIHEAP funds proposed to be used for weatherization, not just with the amount over 15 percent), and an explanation of the specific criteria under which the grantee has determined whether these activities have been shown to produce measurable savings in energy expenditures.

(6) A description of how and when the proposed waiver request was made available for timely and meaningful public review and comment, copies and/or summaries of public comments received on the request (including transcripts and/or summaries of any comments made on the request at public meetings or hearings), a statement of the method for reviewing public comments, and a statement of the changes, if any, that were made in response to these comments.

(7) To complete a preliminary waiver request: Official confirmation that the grantee wishes approval of the waiver request.

(8) To complete a preliminary waiver request: A statement of whether any public comments were received after preparation of the preliminary waiver request and, if so, copies and/or summaries of these comments (including transcripts and/or summaries of any comments made on the request at public meetings or hearings), and a statement of the changes, if any, that were made in response to these comments.

(9) To complete a preliminary waiver request: A statement of whether any material/substantive changes of fact have occurred in information included in the preliminary waiver request since its submission, and, if so, a description of the change(s).

(10) To complete a preliminary waiver request: A description of any other changes to the preliminary request.

(d) "*Standard*" waiver. If the Department determines that a grantee has met the three criteria in paragraph (c)(2) of this section, has provided all information required by paragraph (c) of this section, has shown adequate concern for timely and meaningful public review and comment, and has proposed weatherization that meets all relevant requirements of title XXVI of Public Law 97-35 (42 U.S.C. 8621 *et seq.*) and 45 CFR part 96, the Department will approve a "standard" waiver.

(e) “*Good cause*” waiver. (1) If a grantee does not meet one or more of the three criteria in paragraph (c)(2) of this section, then the grantee may submit documentation that demonstrates good cause why a waiver should be granted despite the grantee’s failure to meet this criterion or these criteria. “Good cause” waiver requests must include the following information, in addition to the information specified in paragraph (c) of this section:

(i) For each criterion under paragraph (c)(2) of this section that the grantee does not meet, an explanation of the specific reasons demonstrating good cause why the grantee does not meet the criterion and yet proposes to use additional funds for weatherization, citing measurable, quantified data, and stating the source(s) of the data used;

(ii) A statement of the grantee’s LIHEAP heating, cooling, and crisis assistance eligibility standards (eligibility criteria) and benefits levels for the fiscal year for which the waiver is requested and for the preceding fiscal year; and, if eligibility standards were less restrictive and/or benefit levels were higher in the preceding fiscal year for one or more of these program components, an explanation of the reasons demonstrating good cause why a waiver should be granted in spite of this fact;

(iii) A statement of the grantee’s opening and closing dates for applications for LIHEAP heating, cooling, and crisis assistance in the fiscal year for which the waiver is requested and in the preceding fiscal year, and a description of the grantee’s outreach efforts for heating, cooling, and crisis assistance in the fiscal year for which the waiver is requested and in the preceding fiscal year, and, if the grantee’s application period was longer and/or outreach efforts were greater in the preceding fiscal year for one or more of these program components, an explanation of the reasons demonstrating good cause why a waiver should be granted in spite of this fact; and

(iv) If the grantee took, or will take, other actions that led, or will lead, to a reduction in the number of applications for LIHEAP heating, cooling, and/or crisis assistance, from the pre-

ceding fiscal year to the fiscal year for which the waiver is requested, a description of these actions and an explanation demonstrating good cause why a waiver should be granted in spite of these actions.

(2) If the Department determines that a grantee requesting a “good cause” waiver has demonstrated good cause why a waiver should be granted, has provided all information required by paragraphs (c) and (e)(1) of this section, has shown adequate concern for timely and meaningful public review and comment, and has proposed weatherization that meets all relevant requirements of title XXVI of Public Law 97–35 (42 U.S.C. 8621 *et seq.*) and 45 CFR part 96, the Department will approve a “good cause” waiver.

(f) *Approvals and disapprovals.* After receiving the grantee’s complete waiver request, the Department will respond in writing within 45 days, informing the grantee whether the request is approved on either a “standard” or “good cause” basis. The Department may request additional information and/or clarification from the grantee. If additional information and/or clarification is requested, the 45-day period for the Department’s response will start when the additional information and/or clarification is received. No waiver will be granted for a previous fiscal year.

(g) *Effective period.* Waivers will be effective from the date of the Department’s written approval until the funds for which the waiver is granted are obligated in accordance with title XXVI of Public Law 97–35 (42 U.S.C. 8621 *et seq.*) and 45 CFR part 96. Funds for which a weatherization waiver was granted that are carried over to the following fiscal year and used for weatherization shall not be considered “funds allotted” or “funds available” for the purposes of calculating the maximum amount that may be used for weatherization in the succeeding fiscal year.

[60 FR 21358, May 1, 1995; 60 FR 33260, June 27, 1995]

§ 96.84 Miscellaneous.

(a) *Rights and responsibilities of territories.* Except as otherwise provided, a territory eligible for funds shall have

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the same rights and responsibilities as a State.

(b) *Applicability of assurances.* The assurances in section 2605(b) of Public Law 97-35 (42 U.S.C. 8624(b)), as amended, pertain to all forms of assistance provided by the grantee, with the exception of assurance 15, which applies to heating, cooling, and energy crisis intervention assistance.

(c) *Prevention of waste, fraud, and abuse.* Grantees must establish appropriate systems and procedures to prevent, detect, and correct waste, fraud, and abuse in activities funded under the low-income home energy assistance program. The systems and procedures are to address possible waste, fraud, and abuse by clients, vendors, and administering agencies.

(d) *End of transfer authority.* Beginning with funds appropriated for FY 1994, grantees may not transfer any funds pursuant to section 2604(f) of Public Law 97-35 (42 U.S.C. 8623(f)) that are payable to them under the LIHEAP program to the block grant programs specified in section 2604(f).

[57 FR 1978, Jan. 16, 1992, as amended at 64 FR 55858, Oct. 15, 1999]

§ 96.85 Income eligibility.

(a) *Application of poverty income guidelines and State median income estimates.* In implementing the income eligibility standards in section 2605(b)(2) of Public Law 97-35 (42 U.S.C. 8624(b)(2)), grantees using the Federal government's official poverty income guidelines and State median income estimates for households as a basis for determining eligibility for assistance shall, by October 1 of each year, or by the beginning of the State fiscal year, whichever is later, adjust their income eligibility criteria so that they are in accord with the most recently published update of the guidelines or estimates. Grantees may adjust their income eligibility criteria to accord with the most recently published revision to the poverty income guidelines or State median income estimates for households at any time between the publication of the revision and the following October 1, or the beginning of the State fiscal year, whichever is later.

(b) *Adjustment of annual median income for household size.* In order to de-

termine the State median income for households that have other than four individuals, grantees shall adjust the State median income figures (published annually by the Secretary), by the following percentages:

- (1) One-person household, 52 percent;
 - (2) Two-person household, 68 percent;
 - (3) Three-person household, 84 percent;
 - (4) Four-person household, 100 percent;
 - (5) Five-person household, 116 percent;
 - (6) Six-person household, 132 percent;
- and
- (7) For each additional household member above six persons, add three percentage points to the percentage adjustment for a six-person household.

[53 FR 6827, Mar. 3, 1988, as amended at 64 FR 55858, Oct. 15, 1999]

§ 96.86 Exemption from requirement for additional outreach and intake services.

The requirement in section 2605(b)(15) of Public Law 97-35 (42 U.S.C. 8624(b)(15)), as amended by section 704(a)(4) of the Augustus F. Hawkins Human Services Reauthorization Act of 1990 (Pub. L. 101-501)—concerning additional outreach and intake services—does not apply to:

- (a) Indian tribes and tribal organizations; and
- (b) Territories whose annual LIHEAP allotments under section 2602(b) of Public Law 97-35 (42 U.S.C. 8621(b)) are \$200,000 or less.

[57 FR 1978, Jan. 16, 1992]

§ 96.87 Leveraging incentive program.

(a) *Scope and eligible grantees.* (1) This section concerns the leveraging incentive program authorized by section 2607A of Public Law 97-35 (42 U.S.C. 8626a).

(2)(i) The only entities eligible to receive leveraging incentive funds from the Department are States (including the District of Columbia), Indian tribes, tribal organizations, and territories that received direct Federal LIHEAP funding under section 2602(b) of Public Law 97-35 (42 U.S.C. 8621(b)) in both the base period for which leveraged resources are reported, and the

award period for which leveraging incentive funds are sought; and tribes and tribal organizations described in paragraphs (a)(2)(ii) and (a)(2)(iii) of this section.

(ii) Indian tribes that received LIHEAP services under section 2602(b) of Public Law 97–35 (42 U.S.C. 8621(b)) through a directly-funded tribal organization in the base period for which leveraged resources are reported, and receive direct Federal LIHEAP funding under section 2602(b) in the award period, will receive leveraging incentive funds allocable to them if they submit leveraging reports meeting all applicable requirements. If the tribal organization continues to receive direct funding under section 2602(b) in the award period, the tribal organization also will receive incentive funds allocable to it if it submits a leveraging report meeting all applicable requirements. In such cases, incentive funds will be allocated among the involved entities that submit leveraging reports, as agreed by these entities. If they cannot agree, HHS will allocate incentive funds based on the comparative role of each entity in obtaining and/or administering the leveraged resources, and/or their relative number of LIHEAP-eligible households.

(iii) If a tribe received direct Federal LIHEAP funding under section 2602(b) of Public Law 97–35 (42 U.S.C. 8621(b)) in the base period for which resources leveraged by the tribe are reported, and the tribe receives LIHEAP services under section 2602(b) through a directly-funded tribal organization in the award period, the tribal organization will receive leveraging incentive funds on behalf of the tribe for the resources if the tribal organization submits a leveraging report meeting all applicable requirements.

(b) *Definitions*—(1) *Award period* means the fiscal year during which leveraging incentive funds are distributed to grantees by the Department, based on the countable leveraging activities they reported to the Department for the preceding fiscal year (the base period).

(2) *Base period* means the fiscal year for which a grantee's leveraging activities are reported to the Department; grantees' countable leveraging activi-

ties during the base period or base year are the basis for the distribution of leveraging incentive funds during the succeeding fiscal year (the award period or award year). Leveraged resources are counted in the base period during which their benefits are provided to low-income households.

(3) *Countable loan fund* means revolving loan funds and similar loan instruments in which:

(i) The sources of both the loaned and the repaid funds meet the requirements of this section, including the prohibitions of paragraphs (f)(1), (f)(2), and (f)(3) of this section;

(ii) Neither the loaned nor the repaid funds are Federal funds or payments from low-income households, and the loans are not made to low-income households; and

(iii) The benefits provided by the loaned funds meet the requirements of this section for countable leveraged resources and benefits.

(4) *Countable petroleum violation escrow funds* means petroleum violation escrow (oil overcharge) funds that were distributed to a State or territory by the Department of Energy (DOE) after October 1, 1990, and interest earned in accordance with DOE policies on petroleum violation escrow funds that were distributed to a State or territory by DOE after October 1, 1990, that:

(i) Were used to assist low-income households to meet the costs of home energy through (that is, within and as a part of) a State or territory's LIHEAP program, another Federal program, or a non-Federal program, in accordance with a submission for use of these petroleum violation escrow funds that was approved by DOE;

(ii) Were not previously required to be allocated to low-income households; and

(iii) Meet the requirements of paragraph (d)(1) of this section, and of paragraph (d)(2)(ii) or (d)(2)(iii) or this section.

(5) *Home energy* means a source of heating or cooling in residential dwellings.

(6) *Low-income households* means federally eligible (federally qualified) households meeting the standards for LIHEAP income eligibility and/or LIHEAP categorical eligibility as set

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by section 2605(b)(2) of Public Law 97-35 (42 U.S.C. 8624(b)(2)).

(7) *Weatherization* means low-cost residential weatherization and other energy-related home repair for low-income households. Weatherization must be directly related to home energy.

(c) *LIHEAP funds used to identify, develop, and demonstrate leveraging programs.* (1) Each fiscal year, States (excluding Indian tribes, tribal organizations, and territories) may spend up to the greater of \$35,000 or 0.08 percent of their net Federal LIHEAP allotments (funds payable) allocated under section 2602(b) of Public Law 97-35 (42 U.S.C. 8621(b)) specifically to identify, develop, and demonstrate leveraging programs under section 2607A(c)(2) of Public Law 97-35 (42 U.S.C. 8626a(c)(2)). Each fiscal year, Indian tribes, tribal organizations, and territories may spend up to the greater of two (2.0) percent or \$100 of their Federal LIHEAP allotments allocated under section 2602(b) of Public Law 97-35 (42 U.S.C. 8621(b)) specifically to identify, develop, and demonstrate leveraging programs under section 2607A(c)(2) of Public Law 97-35 (42 U.S.C. 8626a(c)(2)). For the purpose of this paragraph, Federal LIHEAP allotments include funds from regular and supplemental appropriations, with the exception of leveraging incentive funds provided under section 2602(d) of Public Law 97-35 (42 U.S.C. 8621(d)).

(2) LIHEAP funds used under section 2607A(c)(2) of Public Law 97-35 (42 U.S.C. 8626a(c)(2)) specifically to identify, develop, and demonstrate leveraging programs are not subject to the limitation in section 2605(b)(9) of Public Law 97-35 (42 U.S.C. 8624(b)(9)) on the maximum percent of Federal funds that may be used for costs of planning and administration.

(d) *Basic requirements for leveraged resources and benefits.* (1) In order to be counted under the leveraging incentive program, leveraged resources and benefits must meet all of the following five criteria:

(i) They are from non-Federal sources.

(ii) They are provided to the grantee's low-income home energy assistance program, or to federally qualified low-income households as described in

section 2605(b)(2) of Public Law 97-35 (42 U.S.C. 8624(b)(2)).

(iii) They are measurable and quantifiable in dollars.

(iv) They represent a net addition to the total home energy resources available to low-income households in excess of the amount of such resources that could be acquired by these households through the purchase of home energy, or the purchase of items that help these households meet the cost of home energy, at commonly available household rates or costs, or that could be obtained with regular LIHEAP allotments provided under section 2602(b) of Public Law 97-35 (42 U.S.C. 8621(b)).

(v) They meet the requirements for countable leveraged resources and benefits throughout this section and section 2607A of Public Law 97-35 (42 U.S.C. 8626a).

(2) Also, in order to be counted under the leveraging incentive program, leveraged resources and benefits must meet at least one of the following three criteria:

(i) The grantee's LIHEAP program had an active, substantive role in developing and/or acquiring the resource/benefits from home energy vendor(s) through negotiation, regulation, and/or competitive bid. The actions or efforts of one or more staff of the grantee's LIHEAP program—at the central and/or local level—and/or one or more staff of LIHEAP program subrecipient(s) acting in that capacity, were substantial and significant in obtaining the resource/benefits from the vendor(s).

(ii) The grantee appropriated or mandated the resource/benefits for distribution to low-income households through (that is, within and as a part of) its LIHEAP program. The resource/benefits are provided through the grantee's LIHEAP program to low-income households eligible under the grantee's LIHEAP standards, in accordance with the LIHEAP statute and regulations and consistent with the grantee's LIHEAP plan and program policies that were in effect during the base period, as if they were provided from the grantee's Federal LIHEAP allotment.

(iii) The grantee appropriated or mandated the resource/benefits for distribution to low-income households as described in its LIHEAP plan (referred

to in section 2605(c)(1)(A) of Public Law 97–35 (42 U.S.C. 8624(c)(1)(A)). The resource/benefits are provided to low-income households as a supplement and/or alternative to the grantee's LIHEAP program, outside (that is, not through, within, or as a part of) the LIHEAP program. The resource/benefits are integrated and coordinated with the grantee's LIHEAP program. Before the end of the base period, the plan identifies and describes the resource/benefits, their source(s), and their integration/coordination with the LIHEAP program. The Department will determine resources/benefits to be integrated and coordinated with the LIHEAP program if they meet at least one of the following eight conditions. If a resource meets at least one of conditions A through F when the grantee's LIHEAP program is operating (and meets all other applicable requirements), the resource also is countable when the LIHEAP program is not operating.

(A) For all households served by the resource, the assistance provided by the resource depends on and is determined by the assistance provided to these households by the grantee's LIHEAP program in the base period. The resource supplements LIHEAP assistance that was not sufficient to meet households' home energy needs, and the type and amount of assistance provided by the resource is directly affected by the LIHEAP assistance received by the households.

(B) Receipt of LIHEAP assistance in the base period is necessary to receive assistance from the resource. The resource serves only households that received LIHEAP assistance in the base period.

(C) Ineligibility for the grantee's LIHEAP program, or denial of LIHEAP assistance in the base period because of unavailability of LIHEAP funds, is necessary to receive assistance from the resource.

(D) For discounts and waivers: eligibility for and/or receipt of assistance under the grantee's LIHEAP program in the base period, and/or eligibility under the Federal standards set by section 2605(b)(2) of Public Law 97–35 (42 U.S.C. 8624(b)(2)), is necessary to receive the discount or waiver.

(E) During the period when the grantee's LIHEAP program is operating, staff of the grantee's LIHEAP program and/or staff assigned to the LIHEAP program by a local LIHEAP administering agency or agencies, and staff assigned to the resource communicate orally and/or in writing about how to meet the home energy needs of specific, individual households. For the duration of the LIHEAP program, this communication takes place before assistance is provided to each household to be served by the resource, unless the applicant for assistance from the resource presents documentation of LIHEAP eligibility and/or the amount of LIHEAP assistance received or to be received.

(F) A written agreement between the grantee's LIHEAP program or local LIHEAP administering agency, and the agency administering the resource, specifies the following about the resource: eligibility criteria; benefit levels; period of operation; how the LIHEAP program and the resource are integrated/coordinated; and relationship between LIHEAP eligibility and/or benefit levels, and eligibility and/or benefit levels for the resource. The agreement provides for annual or more frequent reports to be provided to the LIHEAP program by the agency administering the resource.

(G) The resource accepts referrals from the grantee's LIHEAP program, and as long as the resource has benefits available, it provides assistance to all households that are referred by the LIHEAP program and that meet the resource's eligibility requirements. Under this condition, only the benefits provided to households referred by the LIHEAP program are countable.

(H) Before the grantee's LIHEAP heating, cooling, crisis, and/or weatherization assistance component(s) open and/or after the grantee's LIHEAP heating, cooling, crisis, and/or weatherization assistance component(s) close for the season or for the fiscal year, or before the entire LIHEAP program opens and/or after the entire LIHEAP program closes for the season or for the fiscal year, the resource is made available specifically to fill the gap caused by the absence of the LIHEAP component(s) or program. The resource is not

available while the LIHEAP component(s) or program is operating.

(e) *Countable leveraged resources and benefits.* Resources and benefits that are countable under the leveraging incentive program include but are not limited to the following, provided that they also meet all other applicable requirements:

(1) Cash resources: State, tribal, territorial, and other public and private non-Federal funds, including countable loan funds and countable petroleum violation escrow funds as defined in paragraphs (b)(3) and (b)(4) of this section, that are used for:

(i) Heating, cooling, and energy crisis assistance payments and cash benefits made in the base period to or on behalf of low-income households toward their home energy costs (including home energy bills, taxes on home energy sales/purchases and services, connection and reconnection fees, application fees, late payment charges, bulk fuel tank rental or purchase costs, and security deposits that are retained for six months or longer);

(ii) Purchase of fuels that are provided to low-income households in the base period for home energy (such as fuel oil, liquefied petroleum gas, and wood);

(iii) Purchase of weatherization materials that are installed in recipients' homes in the base period;

(iv) Purchase of the following tangible items that are provided to low-income households and/or installed in recipients' homes in the base period: blankets, space heating devices, equipment, and systems; space cooling devices, equipment, and systems; and other tangible items that help low-income households meet the costs of home energy and are specifically approved by the Department as countable leveraged resources;

(v) Installation, replacement, and repair of the following in the base period: weatherization materials; space heating devices, equipment, and systems; space cooling devices, equipment, and systems; and other tangible items that help low-income households meet the costs of home energy and are specifically approved by the Department;

(vi) The following services, when they are an integral part of weatheriza-

tion to help low-income households meet the costs of home energy in the base period: installation, replacement, and repair of windows, exterior doors, roofs, exterior walls, and exterior floors; pre-weatherization home energy audits of homes that were weatherized as a result of these audits; and post-weatherization inspection of homes; and

(vii) The following services, when they are provided (carried out) in the base period: installation, replacement, and repair of smoke/fire alarms that are an integral part, and necessary for safe operation, of a home heating or cooling system installed or repaired as a weatherization activity; and asbestos removal and that is an integral part of, and necessary to carry out, weatherization to help low-income households meet the costs of home energy.

(2) Home energy discounts and waivers that are provided in the base period to low-income households and pertain to generally applicable prices, rates, fees, charges, costs, and/or requirements, in the amount of the discount, reduction, waiver, or forgiveness, or that apply to certain tangible fuel and non-fuel items and to certain services, that are provided in the base period to low-income households and help these households meet the costs of home energy, in the amount of the discount or reduction:

(i) Discounts or reductions in utility and bulk fuel prices, rates, or bills;

(ii) Partial or full forgiveness of home energy bill arrearages;

(iii) Partial or full waivers of utility and other home energy connection and reconnection fees, application fees, late payment charges, bulk fuel tank rental or purchase costs, and home energy security deposits that are retained for six months or longer;

(iv) Reductions in and partial or full waivers of non-Federal taxes on home energy sales/purchases and services, and reductions in and partial or full waivers of other non-Federal taxes provided as tax "credits" to low-income households to offset their home energy costs, except when Federal funds or Federal tax "credits" provide payment or reimbursement for these reductions/waivers;

(v) Discounts or reductions in the cost of the following tangible items that are provided to low-income households and/or installed in recipients' homes: weatherization materials; blankets; space heating devices, equipment, and systems; space cooling devices, equipment, and systems; and other tangible items that are specifically approved by the Department;

(vi) Discounts or reductions in the cost of installation, replacement, and repair of the following: weatherization materials; space heating devices, equipment, and systems; space cooling devices, equipment, and systems; and other tangible items that help low-income households meet the costs of home energy and are specifically approved by the Department;

(vii) Discounts or reductions in the cost of the following services, when the services are an integral part of weatherization to help low-income households meet the costs of home energy: installation, replacement, and repair of windows, exterior doors, roofs, exterior walls, and exterior floors; pre-weatherization home energy audits of homes that were weatherized as a result of these audits; and post-weatherization inspection of homes; and

(viii) Discounts or reductions in the cost of installation, replacement, and repair of smoke/fire alarms that are an integral part, and necessary for safe operation, of a home heating or cooling system installed or repaired as a weatherization activity; and discounts or reductions in the cost of asbestos removal that is an integral part of, and necessary to carry out, weatherization to help low-income households meet the costs of home energy.

(3) Certain third-party in-kind contributions that are provided in the base period to low-income households:

(i) Donated fuels used by recipient households for home energy (such as fuel oil, liquefied petroleum gas, and wood);

(ii) Donated weatherization materials that are installed in recipients' homes;

(iii) Donated blankets; donated space heating devices, equipment, and systems; donated space cooling devices, equipment, and systems; and other donated tangible items that help low-income households meet the costs of home energy and are specifically approved by the Department as countable leveraged resources;

(iv) Unpaid volunteers' services specifically to install, replace, and repair the following: weatherization materials; space heating devices, equipment, and systems; space cooling devices, equipment, and systems; and other items that help low-income households meet the costs of home energy and are specifically approved by the Department;

(v) Unpaid volunteers' services specifically to provide (carry out) the following, when these services are an integral part of weatherization to help low-income households meet the costs of home energy: installation, replacement, and repair of windows, exterior doors, roofs, exterior walls, and exterior floors; pre-weatherization home energy audits of homes that were weatherized as a result of these audits; and post-weatherization inspection of homes;

(vi) Unpaid volunteers' services specifically to: install, replace, and repair smoke/fire alarms as an integral part, and necessary for safe operation, of a home heating or cooling system installed or repaired as a weatherization activity; and remove asbestos as an integral part of, and necessary to carry out, weatherization to help low-income households meet the costs of home energy;

(vii) Paid staff's services that are donated by the employer specifically to install, replace, and repair the following: weatherization materials; space heating devices, equipment, and systems; space cooling devices, equipment, and systems; and other items that help low-income households meet the costs of home energy and are specifically approved by the Department;

(viii) Paid staff's services that are donated by the employer specifically to provide (carry out) the following, when these services are an integral part of weatherization to help low-income households meet the costs of home energy: installation, replacement, and repair of windows, exterior doors, roofs, exterior walls, and exterior floors; pre-weatherization home energy audits of

homes that were weatherized as a result of these audits; and post-weatherization inspection of homes; and

(ix) Paid staff's services that are donated by the employer specifically to: install, replace, and repair smoke/fire alarms as an integral part, and necessary for safe operation, of a home heating or cooling system installed or repaired as a weatherization activity; and remove asbestos as an integral part of, and necessary to carry out, weatherization to help low-income households meet the costs of home energy.

(f) *Resources and benefits that cannot be counted.* The following resources and benefits are not countable under the leveraging incentive program:

(1) Resources (or portions of resources) obtained, arranged, provided, contributed, and/or paid for, by a low-income household for its own benefit, or which a low-income household is responsible for obtaining or required to provide for its own benefit or for the benefit of others, in order to receive a benefit of some type;

(2) Resources (or portions of resources) provided, contributed, and/or paid for by building owners, building managers, and/or home energy vendors, if the cost of rent, home energy, or other charge(s) to the recipient were or will be increased, or if other charge(s) to the recipient were or will be imposed, as a result;

(3) Resources (or portions of resources) directly provided, contributed, and/or paid for by member(s) of the recipient household's family (parents, grandparents, great-grandparents, sons, daughters, grandchildren, great-grandchildren, brothers, sisters, aunts, uncles, first cousins, nieces, and nephews, and their spouses), regardless of whether the family member(s) lived with the household, unless the family member(s) also provided the same resource to other low-income households during the base period and did not limit the resource to members of their own family;

(4) Deferred home energy obligations;

(5) Projected future savings from weatherization;

(6) Delivery, and discounts in the cost of delivery, of fuel, weatherization materials, and all other items;

(7) Purchase, rental, donation, and loan, and discounts in the cost of purchase and rental, of: supplies and equipment used to deliver fuel, weatherization materials, and all other items; and supplies and equipment used to install and repair weatherization materials and all other items;

(8) Petroleum violation escrow (oil overcharge) funds that do not meet the definition in paragraph (b)(4) of this section;

(9) Interest earned/paid on petroleum violation escrow funds that were distributed to a State or territory by the Department of Energy on or before October 1, 1990;

(10) Interest earned/paid on Federal funds;

(11) Interest earned/paid on customers' security deposits, utility deposits, etc., except when forfeited by the customer and used to provide countable benefits;

(12) Borrowed funds that do not meet the requirements in paragraph (b)(3) above (including loans made by and/or to low-income households), interest paid on borrowed funds, and reductions in interest paid on borrowed funds;

(13) Resources (or portions of resources) for which Federal payment or reimbursement has been or will be provided/received;

(14) Tax deductions and tax credits received from any unit(s) of government by donors/contributors of resources for these donations, and by vendors for providing rate reductions, discounts, waivers, credits, and/or arrearage forgiveness to or for low-income households, etc.;

(15) Funds and other resources that have been or will be used as matching or cost sharing for any Federal program;

(16) Leveraged resources counted under any other Federal leveraging incentive program;

(17) Costs of planning and administration, space costs, and intake costs;

(18) Outreach activities, budget counseling, case management, and energy conservation education;

(19) Training;

(20) Installation, replacement, and repair of lighting fixtures and light bulbs;

(21) Installation, replacement, and repair of smoke/fire alarms that are not an integral part, and necessary for safe operation, of a home heating or cooling system installed or repaired as a weatherization activity;

(22) Asbestos removal that is not an integral part of, and necessary to carry out, weatherization to help low-income households meet the costs of home energy;

(23) Paid services where payment is not made from countable leveraged resources, unless these services are donated as a countable in-kind contribution by the employer;

(24) All in-kind contributions except those described in paragraph (e)(3) of this section; and

(25) All other resources that do not meet the requirements of this section and of section 2607A of Public Law 97–35 (42 U.S.C. 8626a).

(g) *Valuation and documentation of leveraged resources and offsetting costs.* (1) Leveraged cash resources will be valued at the fair market value of the benefits they provided to low-income households, as follows. Payments to or on behalf of low-income households for heating, cooling, and energy crisis assistance will be valued at their actual amount or value at the time they were provided. Purchased fuel, weatherization materials, and other countable tangible items will be valued at their fair market value (the commonly available household rate or cost in the local market area) at the time they were purchased. Installation, replacement, and repair of weatherization materials, and other countable services, will be valued at rates consistent with those ordinarily paid for similar work, by persons of similar skill in this work, in the grantee's or subrecipient's organization in the local area, at the time these services were provided. If the grantee or subrecipient does not have employees performing similar work, the rates will be consistent with those ordinarily paid by other employers for similar work, by persons of similar skill in this work, in the same labor market, at the time these services were provided. Fringe benefits and overhead costs will not be counted.

(2) Home energy discounts, waivers, and credits will be valued at their actual amount or value.

(3) Donated fuel, donated weatherization materials, and other countable donated tangible items will be valued at their fair market value (the commonly available household cost in the local market area) at the time of donation.

(4) Donated unpaid services, and donated third-party paid services that are not in the employee's normal line of work, will be valued at rates consistent with those ordinarily paid for similar work, by persons of similar skill in this work, in the grantee's or subrecipient's organization in the local area, at the time these services were provided. If the grantee or subrecipient does not have employees performing similar work, the rates will be consistent with those ordinarily paid by other employers for similar work, by persons of similar skill in this work, in the same labor market, at the time these services were provided. Fringe benefits and overhead costs will not be counted. Donated third-party paid services of employees in their normal line of work will be valued at the employee's regular rate of pay, excluding fringe benefits and overhead costs.

(5) Offsetting costs and charges will be valued at their actual amount or value.

(i) Funds from grantees' regular LIHEAP allotments that are used specifically to identify, develop, and demonstrate leveraging programs under section 2607A(c)(2) of Public Law 97–35 (42 U.S.C. 8626a(c)(2)) will be deducted as offsetting costs in the base period in which these funds are obligated, whether or not there are any resulting leveraged benefits. Costs incurred from grantees' own funds to identify, develop, and demonstrate leveraging programs will be deducted in the first base period in which resulting leveraged benefits are provided to low-income households. If there is no resulting leveraged benefit from the expenditure of the grantee's own funds, the grantee's expenditure will not be counted or deducted.

(ii) Any costs assessed or charged to low-income households on a continuing or on-going basis, year after year, specifically to participate in a counted

leveraging program or to receive counted leveraged resources/benefits will be deducted in the base period these costs are paid. Any one-time costs or charges to low-income households specifically to participate in a counted leveraging program or to receive counted leveraged resources/benefits will be deducted in the first base period the leveraging program or resource is counted. Such costs or charges will be subtracted from the gross value of a counted resource or benefit for low-income households whose benefits are counted, but not for any households whose benefits are not counted.

(6) Only the amount of the net addition to recipient low-income households' home energy resources may be counted in the valuation of a leveraged resource.

(7) Leveraged resources and benefits, and offsetting costs and charges, will be valued according to the best data available to the grantee.

(8) Grantees must maintain, or have readily available, records sufficient to document leveraged resources and benefits, and offsetting costs and charges, and their valuation. These records must be retained for three years after the end of the base period whose leveraged resources and benefits they document.

(h) *Leveraging report.* (1) In order to qualify for leveraging incentive funds, each grantee desiring such funds must submit to the Department a report on the leveraged resources provided to low-income households during the preceding base period. These reports must contain the following information in a format established by the Department.

(i) For each separate leveraged resource, the report must:

(A) Briefly describe the specific leveraged resource and the specific benefit(s) provided to low-income households by this resource, and state the source of the resource;

(B) State whether the resource was acquired in cash, as a discount/waiver, or as an in-kind contribution;

(C) Indicate the geographical area in which the benefit(s) were provided to recipients;

(D) State the month(s) and year(s) when the benefit(s) were provided to recipients;

(E) State the gross dollar value of the countable benefits provided by the resource as determined in accordance with paragraph (g) of this section, indicate the source(s) of the data used, and describe how the grantee quantified the value and calculated the total amount;

(F) State the number of low-income households to whom the benefit(s) were provided, and state the eligibility standard(s) for the low-income households to whom the benefit(s) were provided;

(G) Indicate the agency or agencies that administered the resource/benefit(s); and

(H) Indicate the criterion or criteria for leveraged resources in paragraph (d)(2) of this section that the resource/benefits meet, and for criteria in paragraphs (d)(2)(i) and (d)(2)(iii) of this section, explain how resources/benefits valued at \$5,000 or more meet the criterion or criteria.

(ii) State the total gross dollar value of the countable leveraged resources and benefits provided to low-income households during the base period (the sum of the amounts listed pursuant to paragraph (h)(1)(i)(E) of this section).

(iii) State in dollars any costs incurred by the grantee to leverage resources, and any costs and charges imposed on low-income households to participate in a counted leveraging program or to receive counted leveraged benefits, as determined in accordance with paragraph (g)(5) of this section. Also state the amount of the grantee's regular LIHEAP allotment that the grantee used during the base period specifically to identify, develop, and demonstrate leveraging programs under section 2607A(c)(2) of Public Law 97-35 (42 U.S.C. 8626a(c)(2)).

(iv) State the net dollar value of the countable leveraged resources and benefits for the base period. (Subtract the amounts in paragraph (h)(1)(iii) of this section from the amount in paragraph (h)(1)(ii) of this section.)

(2) Leveraging reports must be postmarked or hand-delivered not later than November 30 of the fiscal year for which leveraging incentive funds are requested.

(3) The Department may require submission of additional documentation and/or clarification as it determines necessary to verify information in a grantee's leveraging report, to determine whether a leveraged resource is countable, and/or to determine the net valuation of a resource. In such cases, the Department will set a date by which it must receive information sufficient to document countability and/or valuation. In such cases, if the Department does not receive information that it considers sufficient to document countability and/or valuation by the date it has set, then the Department will not count the resource (or portion of resource) in question.

(i) *Determination of grantee shares of leveraging incentive funds.* Allocation of leveraging incentive funds to grantees will be computed according to a formula using the following factors and weights:

(1) Fifty (50) percent based on the final net value of countable leveraged resources provided to low-income households during the base period by a grantee relative to its net Federal allotment of funds allocated under section 2602(b) of Public Law 97–35 (42 U.S.C. 8621(b)) during the base period, as a proportion of the final net value of the countable leveraged resources provided by all grantees during the base period relative to their net Federal allotment of funds allocated under that section during the base period; and

(2) Fifty (50) percent based on the final net value of countable leveraged resources provided to low-income households during the base period by a grantee as a proportion of the total final net value of the countable leveraged resources provided by all grantees during the base period; except that: No grantee may receive more than twelve (12.0) percent of the total amount of leveraging incentive funds available for distribution to grantees in any award period; and no grantee may receive more than the smaller of its net Federal allotment of funds allocated under section 2602(b) of Public Law 97–35 (42 U.S.C. 8621(b)) during the base period, or two times (double) the final net value of its countable leveraged resources for the base period. The calculations will be based on data con-

tained in the leveraging reports submitted by grantees under paragraph (h) of this section as approved by the Department, and allocation data developed by the Department.

(j) *Uses of leveraging incentive funds.*

(1) Funds awarded to grantees under the leveraging incentive program must be used to increase or maintain heating, cooling, energy crisis, and/or weatherization benefits through (that is, within and as a part of) the grantee's LIHEAP program. These funds can be used for weatherization without regard to the weatherization maximum in section 2605(k) of Public Law 97–35 (42 U.S.C. 8624(k)). However, they cannot be counted in the base for calculation of the weatherization maximum for regular LIHEAP funds authorized under section 2602(b) of Public Law 97–35 (42 U.S.C. 8621(b)). Leveraging incentive funds cannot be used for costs of planning and administration. However, in either the award period or the fiscal year following the award period, they can be counted in the base for calculation of maximum grantee planning and administrative costs under section 2605(b)(9) of Public Law 97–35 (42 U.S.C. 8624(b)(9)). They cannot be counted in the base for calculation of maximum carryover of regular LIHEAP funds authorized under section 2602(b) of Public Law 97–35 (42 U.S.C. 8621(b)).

(2) Grantees must include the uses of leveraging incentive funds in their LIHEAP plans (referred to in section 2605(c)(1)(A) of Public Law 97–35) (42 U.S.C. 8624(c)(1)(A)) for the fiscal year in which the grantee obligates these funds. Grantees must document uses of leveraging incentive funds in the same way they document uses of regular LIHEAP funds authorized under section 2602(b) of Public Law 97–35 (42 U.S.C. 8621(b)). Leveraging incentive funds are subject to the same audit requirements as regular LIHEAP funds.

(k) *Period of obligation for leveraging incentive funds.* Leveraging incentive funds are available for obligation during both the award period and the fiscal year following the award period, without regard to limitations on carryover of funds in section 2607(b)(2)(B) of Public Law 97–35 (42 U.S.C. 8626(b)(2)(B)). Any leveraging incentive

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funds not obligated for allowable purposes by the end of this period must be returned to the Department.

[60 FR 21359, May 1, 1995; 60 FR 36334, July 14, 1995]

§ 96.88 Administrative costs.

(a) *Costs of planning and administration.* Any expenditure for governmental functions normally associated with administration of a public assistance program must be included in determining administrative costs subject to the statutory limitation on administrative costs, regardless of whether the expenditure is incurred by the State, a subrecipient, a grantee, or a contractor of the State.

(b) *Administrative costs for territories and Indian tribes.* For Indian tribes, tribal organizations and territories with allotments of \$20,000 or less, the limitation on the cost of planning and administering the low-income home energy assistance program shall be 20 percent of funds payable and not transferred for use under another block grant. For tribes, tribal organizations and territories with allotments over \$20,000, the limitation on the cost of planning and administration shall be \$4,000 plus 10% of the amount of funds payable (and not transferred for use under another block grant) that exceeds \$20,000.

[52 FR 37967, Oct. 13, 1987]

§ 96.89 Exemption from standards for providing energy crisis intervention assistance.

The performance standards in section 2604(c) of Pub. L. 97-35 (42 U.S.C. 8623), as amended by section 502(a) of the Human Services Reauthorization Act of 1986 (Pub. L. 99-425)—concerning provision of energy crisis assistance within specified time limits, acceptance of applications for energy crisis benefits at geographically accessible sites, and provision to physically infirm low-income persons of the means to apply for energy crisis benefits at their residences or to travel to application sites—shall not apply under the conditions described in this section.

(a) These standards shall not apply to a program in a geographical area affected by (1) a major disaster or emer-

gency designated by the President under the Disaster Relief Act of 1974, or (2) a natural disaster identified by the chief executive officer of a State, territory, or direct-grant Indian tribe or tribal organization, if the Secretary (or his or her designee) determines that the disaster or emergency makes compliance with the standards impracticable.

(b) The Secretary's determination will be made after communication by the chief executive officer (or his or her designee) to the Secretary (or his or her designee) of the following:

(1) Information substantiating the existence of a disaster or emergency;

(2) Information substantiating the impracticability of compliance with the standards, including a description of the specific conditions caused by the disaster or emergency which make compliance impracticable; and

(3) Information on the expected duration of the conditions that make compliance impracticable.

If the communication is made by the chief executive officer's designee and the Department does not have on file written evidence of the designation, the communication must also include:

(4) Evidence of the appropriate delegation of authority.

(c) The initial communication by the chief executive officer may be oral or written. If oral, it must be followed as soon as possible by written communication confirming the information provided orally. The Secretary's exemption initially may be oral. If so, the Secretary will provide written confirmation of the exemption as soon as possible after receipt of appropriate written communication from the chief executive officer.

(d) Exemption from the standards shall apply from the moment of the Secretary's determination, only in the geographical area affected by the disaster or emergency, and only for so long as the Secretary determines that the disaster or emergency makes compliance with the standards impracticable.

[53 FR 6827, Mar. 3, 1988]

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Subpart I—Community Services Block Grants

§ 96.90 Scope.

This subpart applies to the community services block grant.

§ 96.91 Audit requirement.

Pursuant to section 1745(b) of the Reconciliation Act (31 U.S.C. 1243 note) an audit is required with respect to the 2-year period beginning on October 1, 1981, and with respect to each 2-year period thereafter. In its application for funds, a State may modify the assurance required by section 675(c)(9) of the Reconciliation Act (42 U.S.C. 9904(c)(9)) to conform to the requirements of section 1745(b).

§ 96.92 Termination of funding.

Where a State determines pursuant to section 675(c)(11) of the Community Services Block Grant Act that it will terminate present or future funding of any community action agency or migrant and seasonal farmworker organization which received funding in the previous fiscal year, the State must provide the organization with notice and an opportunity for hearing on the record prior to terminating funding. If a review by the Secretary of the State's final decision to terminate funding is requested pursuant to section 676A, the request must be made in writing, within 30 days of notification by the State of its final decision to terminate funding. The Department will confirm or reject the State's finding of cause, normally within 90 days. If a request for a review has been made, the State may not discontinue present or future funding until the Department confirms the State's finding of cause. If no request for a review is made within the 30-day limit, the State's decision will be effective at the expiration of that time.

[52 FR 37968, Oct. 13, 1987]

Subpart J—Primary Care Block Grants

§ 96.100 Scope.

This subpart applies to the primary care block grant.

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§ 96.101 Review of a State decision to discontinue funding of a community health center.

Where a State determines for FY 1983, pursuant to section 1926(a)(2) of the Public Health Service Act (42 U.S.C. 300y–5(a)(2)), that a community health center does not meet the criteria for continued funding set forth in section 330 of the Public Health Service Act (42 U.S.C. 254c), the State must advise the Department of the decision and the basis upon which it was made. The Department will permit the center 30 days to respond to the State's determination. After evaluating the reasons advanced by the State and the center, the Department will determine within 30 days after the center's response is due whether the center meets the requirements for receiving a grant under the Public Health Service Act. The State may not discontinue funding the center until the Department has completed its review.

[47 FR 29486, July 6, 1982; 47 FR 43062, Sept. 30, 1982]

§ 96.102 Carryover of unobligated funds.

In implementing section 1925(a)(2) of the Public Health Service Act (42 U.S.C. 300y–4(a)(2)), the Secretary will determine that there is good cause for funds remaining unobligated if planned obligations could not be carried out because of a bona fide reason or if the State has determined that program objectives would be better served by deferring obligation of the funds to the following year.

Subpart K—Transition Provisions

§ 96.110 Scope.

Except as otherwise stated, this subpart applies to the community services, preventive health and health services, alcohol and drug abuse and mental health services, and maternal and child health services block grants for the fiscal year beginning October 1, 1981. The social services block grant and the low-income home energy assistance program are not subject to the provisions of this subpart.

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§ 96.111 Continuation of pre-existing regulations.

The regulations previously issued by the Department and the Community Services Administration to govern administration of the programs replaced by the block grants specified in § 96.1 of this part shall continue in effect until revised to govern administration of those programs by the Department in those circumstances in which States have not qualified for block grants.

§ 96.112 Community services block grant.

(a) For the fiscal year beginning October 1, 1981, only, a State may choose to operate programs under the community services block grant or, instead, have the Secretary operate the programs replaced by the block grant. If a State does not notify the Secretary in accordance with the statutory deadlines each quarter, it will be deemed to have requested the Secretary to operate the programs for the following quarter.

(b) A State or territory that does not have any eligible entity'' as that term is defined in section 673(1) of the Reconciliation Act (42 U.S.C. 9902), as amended by section 17 of Pub. L. 97-115 (December 19, 1981), or any other entity for which funding is allowed under section 138 of Pub. L. 97-276, may distribute its allotment for the Fiscal Year beginning October 1, 1982 according to section 675(c)(2)(A)(ii) of the Reconciliation Act.

(c) For any quarter in which the Secretary administers the programs, the Department's administration costs will be deducted from the State's allotment. The Department's total administration costs for making grants during fiscal year 1982 and for any monitoring of these grants in fiscal year 1983 will be deducted from each State's allotment in proportion to the total amount of grants awarded from the allotment during the period of administration by the Department (but not to exceed 5 percent of the State's fiscal year 1982 allotment).

[47 FR 29486, July 6, 1982, as amended at 48 FR 9271, Mar. 4, 1983]

Subpart L—Substance Abuse Prevention and Treatment Block Grant

AUTHORITY: 42 U.S.C. 300x-21 to 300x-35 and 300x-51 to 300x-64.

SOURCE: 58 FR 17070, Mar. 31, 1993, unless otherwise noted.

§ 96.120 Scope.

This subpart applies to the Substance Abuse Prevention and Treatment Block Grant administered by the Substance Abuse and Mental Health Services Administration. 45 CFR part 96, subparts A through F, are applicable to this subpart to the extent that those subparts are consistent with subpart L. To the extent subparts A through F are inconsistent with subpart L, the provisions of subpart L are applicable.

§ 96.121 Definitions.

Block Grant means the Substance Abuse Prevention and Treatment Block Grant, 42 U.S.C. 300x-21, *et seq.*

Early Intervention Services Relating to HIV means:

(1) appropriate pretest counseling for HIV and AIDS;

(2) testing individuals with respect to such disease, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease;

(3) appropriate post-test counseling; and

(4) providing the therapeutic measures described in Paragraph (2) of this definition.

Fiscal Year, unless provided otherwise, means the Federal fiscal year.

Interim Services or Interim Substance Abuse Services means services that are provided until an individual is admitted to a substance abuse treatment program. The purposes of the services are to reduce the adverse health effects of such abuse, promote the health of the individual, and reduce the risk of

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transmission of disease. At a minimum, interim services include counseling and education about HIV and tuberculosis (TB), about the risks of needle-sharing, the risks of transmission to sexual partners and infants, and about steps that can be taken to ensure that HIV and TB transmission does not occur, as well as referral for HIV or TB treatment services if necessary. For pregnant women, interim services also include counseling on the effects of alcohol and drug use on the fetus, as well as referral for prenatal care.

Primary Prevention Programs are those directed at individuals who have not been determined to require treatment for substance abuse. Such programs are aimed at educating and counseling individuals on such abuse and providing for activities to reduce the risk of such abuse.

Principal Agency is the single State agency responsible for planning, carrying out and evaluating activities to prevent and treat substance abuse and related activities.

Rural Area The definition of a rural area within a State shall be the latest definition of the Bureau of the Census, Department of Commerce.

Secretary is the Secretary of the United States Department of Health and Human Services or the Secretary's designee.

State, unless provided otherwise, includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, America Samoa, the Commonwealth of the Northern Mariana Islands, Palau, Micronesia, and the Marshall Islands.

State Medical Director for Substance Abuse Services is a licensed physician with the knowledge, skill and ability to address the multiple physical and psychological problems associated with substance abuse, and who provides the principle agency with clinical consultation and direction regarding effective substance abuse treatment, effective primary medical care, effective infection control and public health and quality assurance.

Substance Abuse is defined to include the abuse or illicit use of alcohol or other drugs.

Tuberculosis Services means:

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(1) Counseling the individual with respect to tuberculosis;

(2) Testing to determine whether the individual has been infected with mycobacteria tuberculosis to determine the appropriate form of treatment for the individual; and

(3) Providing for or referring the individuals infected by mycobacteria tuberculosis for appropriate medical evaluation and treatment.

§ 96.122 Application content and procedures.

(a) For each fiscal year, beginning with fiscal year 1993, the State shall submit an application to such address as the Secretary determines is appropriate.

(b) For fiscal year 1993, applicants must submit an application containing information which conforms to the assurances listed under § 96.123, the report as provided in § 96.122(f), and the State plan as provided in § 96.122(g).

(c) Beginning fiscal year 1994, applicants shall only use standard application forms prescribed by the granting agency with the approval of the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. Applicants must follow all applicable instructions that bear OMB clearance numbers. The application will require the State to submit the assurances listed under § 96.123, the report as provided in § 96.122(f), and the State Plan as provided in § 96.122(g).

(d) The State shall submit the application for a block grant by the date prescribed by law. The annual report required under § 96.130(e) is not required to be submitted as part of the application, but must be submitted no later than December 31 of the fiscal year for which the State is seeking a grant. Grant awards will not be made without the report required under § 96.130(e).

(e) The funding agreements and assurances in the application shall be made through certification by the State's chief executive officer personally, or by an individual authorized to make such certification on behalf of the chief executive officer. When a delegation has occurred, a copy of the current delegation of authority must be submitted with the application.

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(f) A report shall be submitted annually with the application and State Plan. Among other things, the report must contain information as determined by the Secretary to be necessary to determine the purposes and the activities of the State, for which the Block Grant was expended. The report shall include (but is not limited to) the following:

(1) For the fiscal year three years prior to the fiscal year for which the State is applying for funds:

(i) A statement of whether the State exercised its discretion under applicable law to transfer Block Grant funds from substance abuse services to mental health services or vice versa, and a description of the transfers which were made;

(ii) A description of the progress made by the State in meeting the prevention and treatment goals, objectives and activities submitted in the application for the relevant year;

(iii) A description of the amounts expended under the Block Grant by the State agency, by activity;

(iv) A description of the amounts expended on primary prevention and early intervention activities (if reporting on fiscal years 1990, 1991, and 1992 only) and for primary prevention activities (if reporting on fiscal years 1993 and subsequent years);

(v) A description of the amounts expended for activities relating to substance abuse such as planning, coordination, needs assessment, quality assurance, training of counselors, program development, research and development and the development of information systems;

(vi) A description of the entities, their location, and the total amount the entity received from Block Grant funds with a description of the activities undertaken by the entity;

(vii) A description of the use of the State's revolving funds for establishment of group homes for recovering substance abusers, as provided by § 96.129, including the amount available in the fund throughout the fiscal year and the number and amount of loans made that fiscal year;

(viii) A detailed description of the State's programs for women and, in particular for pregnant women and

women with dependent children, if reporting on fiscal years 1990, 1991, or 1992; and pregnant women or women with dependent children for fiscal year 1993 and subsequent fiscal years;

(ix) A detailed description of the State's programs for intravenous drug users; and

(x) For applications for fiscal year 1996 and subsequent fiscal years, a description of the State's expenditures for tuberculosis services and, if a designated State, early intervention services for HIV.

(2) For the most recent 12 month State expenditure period for which expenditure information is complete:

(i) A description of the amounts expended by the principal agency for substance abuse prevention and treatment activities, by activity and source of funds;

(ii) A description of substance abuse funding by other State agencies and offices, by activity and source of funds when available; and

(iii) A description of the types and amounts of substance abuse services purchased by the principal agency.

(3) For the fiscal year two years prior to the fiscal year for which the State is applying for funds:

(i) A description of the amounts obligated under the Block Grant by the principal agency, by activity;

(ii) A description of the amounts obligated for primary prevention and early intervention (if reporting on fiscal years 1990, 1991, and 1992 activities only) and primary prevention activities (if reporting on fiscal years 1993 and subsequent year activities);

(iii) A description of the entities to which Block Grant funds were obligated;

(iv) A description of the State's policies, procedures and laws regarding substance abuse prevention, especially the use of alcohol and tobacco products by minors;

(v) For applications for fiscal year 1995 and all subsequent fiscal years, a description of the State's procedures and activities undertaken to comply with the requirement to conduct independent peer review as provided by § 96.136;

(vi) For applications for fiscal year 1995 and all subsequent fiscal years, a

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description of the State's procedures and activities undertaken to comply with the requirement to develop capacity management and waiting list systems, as provided by §§96.126 and 96.131, as well as an evaluation summary of these activities; and

(vii) For applications for fiscal year 1995 and subsequent fiscal years, a description of the strategies used for monitoring program compliance with §§96.126(f), 96.127(b), and 96.131(f), as well as a description of the problems identified and the corrective actions taken.

(4) The aggregate State expenditures by the principle agency for authorized activities for the two State fiscal years preceding the fiscal year for which the State is applying for a grant, pursuant to §96.134(d).

(5) For the previous fiscal year:

(i) A description of the State's progress in meeting the goals, objectives and activities included in the previous year's application, and a brief description of the recipients of the Block Grant funds;

(ii) A description of the methods used to calculate the following:

(A) The base for services to pregnant women and women with dependent children as required by §96.124;

(B) The base for tuberculosis services as required for §96.127; and

(C) For designated States, the base for HIV early intervention services as required by §96.128;

(iii) For applications for fiscal years 1994 and 1995 only, a description of the State's progress in the development of protocols for and the implementation of tuberculosis services, and, if a designated State, early intervention services for HIV; and

(iv) For applications for fiscal year 1994 only, a description of the States progress in the development, implementation, and utilization of capacity management and waiting list systems.

(v) A description of the activities the State has undertaken to comply with 42 CFR part 54.

(6) For the first applicable fiscal year for which the State is applying for a grant, a copy of the statute enacting the law as described in §96.130(b) and, for subsequent fiscal years for which the State is applying for a grant, any

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amendment to the law described in §96.130(b).

(7) In addition to the information above, any information that the Secretary may, from time to time, require, consistent with the Paperwork Reduction Act.

(g) For each fiscal year, beginning fiscal year 1993, the State Plan shall be submitted to the Secretary and shall include the following:

(1) For fiscal years 1993 and 1994, a statement on whether the Governor intends to exercise discretion under applicable law to transfer Block Grant funds from the Substance Abuse Prevention and Treatment Block Grant allotment under section 1921 of the PHS Act to the Community Mental Health Services Block Grant allotment under section 1911 of the PHS Act or vice versa and a description of the planned transfer;

(2) A budget of expenditures which provides an estimate of the use and distribution of Block Grant and other funds to be spent by the agency administering the Block Grant during the period covered by the application, by activity and source of funds;

(3) A description of how the State carries out planning, including how the State identifies substate areas with the greatest need, what process the State uses to facilitate public comment on the plan, and what criteria the State uses in deciding how to allocate Block Grant funds;

(4) A detailed description of the State procedures to monitor programs that reach 90% capacity pursuant to §96.126(a);

(5) A detailed description of the State procedures to implement the 14/120 day requirement provided by §96.126(b) as well as the interim services to be provided and a description of the strategies to be used in monitoring program compliance in accordance with §96.126(f);

(6) A full description of the outreach efforts States will require entities which receive funds to provide pursuant to §96.126(e);

(7) A detailed description of the State procedures implementing TB services pursuant to §96.127, and a description

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of the strategies to be used in monitoring program compliance in accordance with § 96.127(b);

(8) A detailed description of the State's procedures implementing HIV services pursuant to § 96.128, if considered a designated State;

(9) A description of estimates of non-Federal dollars to be spent for early intervention services relating to HIV, if a designated State, and tuberculosis services for the fiscal year covered by the application, as well as the amounts actually spent for such services for the two previous fiscal years;

(10) For fiscal year 1993, a detailed description of the State's revolving fund for establishment of group homes for recovering substance abusers pursuant to § 96.129 and, for subsequent years, any revisions to the program;

(11) A detailed description of State procedures implementing § 96.131 relating to treatment services for pregnant women;

(12) Unless waived, a description on how the State will improve the process for referrals for treatment, will ensure that continuing education is provided, and will coordinate various activities and services as provided by § 96.132;

(13) Statewide assessment of needs as provided in § 96.133;

(14) The aggregate State dollar projected expenditures by the principal agency of a State for authorized activities for the fiscal year for which the Block Grant is to be expended, as well as the aggregate obligations or expenditures, when available, for authorized activities for the two years prior to such fiscal year as required by § 96.134;

(15) Unless waived, a description of the services and activities to be provided by the State with Block Grant funds consistent with § 96.124 for allocations to be spent on services to pregnant women and women with dependent children, alcohol and other drug treatment and prevention, including primary prevention, and any other requirement;

(16) A description of the State procedures to implement § 96.132(e) regarding inappropriate disclosure of patient records;

(17) A description of the amounts to be spent for primary prevention in accordance with § 96.125;

(18) A description of the amounts to be spent on activities relating to substance abuse such as planning coordination, needs assessment, quality assurance, training of counselors, program development, research and development and the development of information systems;

(19) A description of the State plans regarding purchasing substance abuse services;

(20) A description of how the State intends to monitor and evaluate the performance of substance abuse service providers in accordance with § 96.136;

(21) A description of the State's overall goals for Block Grant expenditures, specific objectives under each goal, and the activities the State will carry out to achieve these objectives; and

(22) Such other information as the Secretary may, from time to time, require, consistent with the Paperwork Reduction Act.

(h) The Secretary will approve an application which includes the assurances, the State plan and the report that satisfies the requirements of this part and the relevant sections of the PHS Act. As indicated above, the State is required to provide descriptions of the State's procedures to implement the provisions of the Act and the regulations. Unless provided otherwise by these regulations, the Secretary will approve procedures which are provided as examples in the regulations, or the State may submit other procedures which the Secretary determines to reasonably implement the requirements of the Act.

[58 FR 17070, Mar. 31, 1993, as amended at 61 FR 1508, Jan. 19, 1996; 65 FR 45305, July 21, 2000; 66 FR 46226, Sept. 4, 2001; 68 FR 56448, Sept. 4, 2003]

§ 96.123 Assurances.

(a) The application must include assurances that:

(1) the State will expend the Block Grant in accordance with the percentage to be allocated to treatment, prevention, and other activities as prescribed by law and, also, for the purposes prescribed by law;

(2) The activities relating to intravenous drug use pursuant to § 96.126 will be carried out;

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(3) The TB services and referral will be carried out pursuant to § 96.127, as well as the early intervention services for HIV provided for in § 96.128, if a designated State;

(4) The revolving funds to establish group homes for recovering substance abusers is in place consistent with the provisions of § 96.129 and the loans will be made and used as provided for by law;

(5) The State has a law in effect making it illegal to sell or distribute tobacco products to minors as provided in § 96.130(b), will conduct annual, unannounced inspections as prescribed in § 96.130, will enforce such law in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18, and will submit an annual report as required under §§ 96.122(d) and 96.130(e);

(6) Pregnant women are provided preference in admission to treatment centers as provided by § 96.131, and are provided interim services as necessary and as required by law;

(7) The State will improve the process in the State for referrals of individuals to the treatment modality that is most appropriate for the individuals, will ensure that continuing education is provided to employees of any funded entity providing prevention activities or treatment services, and will coordinate prevention activities and treatment services with the provision of other appropriate services as provided by § 96.132;

(8) The State will submit an assessment of need as required by section 96.133;

(9) The State will for such year maintain aggregate State expenditures by the principal agency of a State for authorized activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying for the grant as provided by § 96.134;

(10) The Block Grant will not be used to supplant State funding of alcohol and other drug prevention and treatment programs;

(11) For purposes of maintenance of effort pursuant to §§ 96.127(f), 96.128(f), and 96.134, the State will calculate the

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base using Generally Accepted Accounting Principles and the composition of the base will be applied consistently from year to year;

(12) The State will for the fiscal year for which the grant is provided comply with the restrictions on the expenditure of Block Grant funds as provided by § 96.135;

(13) The State will make the State Plan public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during the development of the State Plan and after the submission of the State Plan (including any revisions) to the Secretary as provided by § 1941 of the PHS Act;

(14) The State will for the fiscal year for which the grant is provided, provide for independent peer review to assess the quality, appropriateness, and efficacy of treatment services provided in the State to individuals under the program involved as required by § 96.136;

(15) The State has in effect a system to protect from inappropriate disclosure patient records maintained by the State in connection with an entity which is receiving amounts from the grant;

(16) The State will comply with chapter 75 of title 31, United States Code, pertaining to audits; and

(17) The State will abide by all applicable Federal laws and regulations, including those relating to lobbying (45 CFR part 93), drug-free workplace (45 CFR 76.600), discrimination (PHS Act Sec. 1947), false statements or failure to disclose certain events (PHS Act Sec. 1946), and, as to the State of Hawaii, services for Native Hawaiians (PHS Act Sec. 1953).

(18) The State will comply with the requirements of 42 CFR part 54.

[58 FR 17070, Mar. 31, 1993, as amended at 61 FR 1508, Jan. 19, 1996; 66 FR 46227, Sept. 4, 2001; 68 FR 56448, Sept. 30, 2003]

§ 96.124 Certain allocations.

(a) States are required to expend the Block Grant on various activities in certain proportions. Specifically, as to treatment and prevention, the State shall expend the grant as follows:

(1) not less than 35 percent for prevention and treatment activities regarding alcohol; and

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(2) not less than 35 percent for prevention and treatment activities regarding other drugs.

(b) The States are also to expend the Block Grant on primary prevention programs as follows:

(1) Consistent with § 96.125, the State shall expend not less than 20 percent for programs for individuals who do not require treatment for substance abuse, which programs—

(i) educate and counsel the individuals on such abuse; and

(ii) provide for activities to reduce the risk of such abuse by the individuals;

(2) The State shall, in carrying out paragraph (b)(1) of this section—

(i) give priority to programs for populations that are at risk of developing a pattern of such abuse; and

(ii) ensure that programs receiving priority under paragraph (b)(2)(i) of this section develop community-based strategies for prevention of such abuse, including strategies to discourage the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(c) Subject to paragraph (d) of this section, a State is required to expend the Block Grant on women services as follows:

(1) The State for fiscal year 1993 shall expend not less than five percent of the grant to increase (relative to fiscal year 1992) the availability of treatment services designed for pregnant women and women with dependent children (either by establishing new programs or expanding the capacity of existing programs). The base for fiscal year 1993 shall be an amount equal to the fiscal year 1992 alcohol and drug services Block Grant expenditures and State expenditures for pregnant women and women with dependent children as described in paragraph (e) of this section, and to this base shall be added at least 5 percent of the 1993 Block Grant allotment. The base shall be calculated using Generally Accepted Accounting Principles and the composition of the base shall be applied consistently from year to year. States shall report the methods used to calculate their base for fiscal year 1992 expenditures on

treatment for pregnant women and women with dependent children.

(2) For fiscal year 1994, the State shall, consistent with paragraph (c)(1) of this section, expend not less than five percent of the grant to increase (relative to fiscal year 1993) the availability of such services to pregnant women and women with dependent children.

(3) For grants beyond fiscal year 1994, the States shall expend no less than an amount equal to the amount expended by the State for fiscal year 1994.

(d) Upon the request of a State, the Secretary may waive all or part of the requirement in paragraph (c) of this section if the Secretary determines that the State is providing an adequate level of services for this population. In determining whether an adequate level of services is being provided the Secretary will review the extent to which such individuals are receiving services. This determination may be supported by a combination of criminal justice data, the National Drug and Treatment Units Survey, statewide needs assessment data, waiting list data, welfare department data, including medicaid expenditures, or other State statistical data that are systematically collected. The Secretary will also consider the extent to which the State offers the minimum services required under § 96.124(e). The Secretary shall approve or deny a request for a waiver not later than 120 days after the date on which the request is made. Any waiver provided by the Secretary shall be applicable only to the fiscal year involved.

(e) With respect to paragraph (c) of this section, the amount set aside for such services shall be expended on individuals who have no other financial means of obtaining such services as provided in § 96.137. All programs providing such services will treat the family as a unit and therefore will admit both women and their children into treatment services, if appropriate. The State shall ensure that, at a minimum, treatment programs receiving funding for such services also provide or arrange for the provision of the following services to pregnant women and women with dependent children, including women who are attempting to regain custody of their children:

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(1) primary medical care for women, including referral for prenatal care and, while the women are receiving such services, child care;

(2) primary pediatric care, including immunization, for their children;

(3) gender specific substance abuse treatment and other therapeutic interventions for women which may address issues of relationships, sexual and physical abuse and parenting, and child care while the women are receiving these services;

(4) therapeutic interventions for children in custody of women in treatment which may, among other things, address their developmental needs, their issues of sexual and physical abuse, and neglect; and

(5) sufficient case management and transportation to ensure that women and their children have access to services provided by paragraphs (e) (1) through (4) of this section.

(f) Procedures for the implementation of paragraphs (c) and (e) of this section will be developed in consultation with the State Medical Director for Substance Abuse Services.

§ 96.125 Primary prevention.

(a) For purposes of § 96.124, each State/Territory shall develop and implement a comprehensive prevention program which includes a broad array of prevention strategies directed *at individuals not identified to be in need of treatment*. The comprehensive program shall be provided either directly or through one or more public or non-profit private entities. The comprehensive primary prevention program shall include activities and services provided in a variety of settings for both the general population, as well as targeting sub-groups who are at high risk for substance abuse.

(b) In implementing the prevention program the State shall use a variety of strategies, as appropriate for each target group, including but not limited to the following:

(1) *Information Dissemination*: This strategy provides awareness and knowledge of the nature and extent of alcohol, tobacco and drug use, abuse and addiction and their effects on individuals, families and communities. It also provides knowledge and awareness

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of available prevention programs and services. Information dissemination is characterized by one-way communication from the source to the audience, with limited contact between the two. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Clearinghouse/information resource center(s);
- (ii) Resource directories;
- (iii) Media campaigns;
- (iv) Brochures;
- (v) Radio/TV public service announcements;
- (vi) Speaking engagements;
- (vii) Health fairs/health promotion; and
- (viii) Information lines.

(2) *Education*: This strategy involves two-way communication and is distinguished from the Information Dissemination strategy by the fact that interaction between the educator/facilitator and the participants is the basis of its activities. Activities under this strategy aim to affect critical life and social skills, including decision-making, refusal skills, critical analysis (e.g. of media messages) and systematic judgment abilities. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Classroom and/or small group sessions (all ages);
- (ii) Parenting and family management classes;
- (iii) Peer leader/helper programs;
- (iv) Education programs for youth groups; and
- (v) Children of substance abusers groups.

(3) *Alternatives*: This strategy provides for the participation of target populations in activities that exclude alcohol, tobacco and other drug use. The assumption is that constructive and healthy activities offset the attraction to, or otherwise meet the needs usually filled by alcohol, tobacco and other drugs and would, therefore, minimize or obviate resort to the latter. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Drug free dances and parties;
- (ii) Youth/adult leadership activities;

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- (iii) Community drop-in centers; and
- (iv) Community service activities.

(4) *Problem Identification and Referral:*

This strategy aims at identification of those who have indulged in illegal/age-inappropriate use of tobacco or alcohol and those individuals who have indulged in the first use of illicit drugs in order to assess if their behavior can be reversed through education. It should be noted, however, that this strategy does not include any activity designed to determine if a person is in need of treatment. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Employee assistance programs;
- (ii) Student assistance programs; and
- (iii) Driving while under the influence/driving while intoxicated education programs.

(5) *Community-Based Process:* This strategy aims to enhance the ability of the community to more effectively provide prevention and treatment services for alcohol, tobacco and drug abuse disorders. Activities in this strategy include organizing, planning, enhancing efficiency and effectiveness of services implementation, inter-agency collaboration, coalition building and networking. Examples of activities conducted and methods used for this strategy include (but are not limited to) the following:

- (i) Community and volunteer training, e.g., neighborhood action training, training of key people in the system, staff/officials training;
- (ii) Systematic planning;
- (iii) Multi-agency coordination and collaboration;
- (iv) Accessing services and funding; and
- (v) Community team-building.

(6) *Environmental:* This strategy establishes or changes written and unwritten community standards, codes and attitudes, thereby influencing incidence and prevalence of the abuse of alcohol, tobacco and other drugs used in the general population. This strategy is divided into two subcategories to permit distinction between activities which center on legal and regulatory initiatives and those which relate to the service and action-oriented initiatives. Examples of activities conducted

and methods used for this strategy shall include (but not be limited to) the following:

- (i) Promoting the establishment and review of alcohol, tobacco and drug use policies in schools;
- (ii) Technical assistance to communities to maximize local enforcement procedures governing availability and distribution of alcohol, tobacco and other drug use;
- (iii) Modifying alcohol and tobacco advertising practices; and
- (iv) Product pricing strategies.

§ 96.126 Capacity of treatment for intravenous substance abusers.

(a) In order to obtain Block Grant funds, the State must require programs that receive funding under the grant and that treat individuals for intravenous substance abuse to provide to the State, upon reaching 90 percent of its capacity to admit individuals to the program, a notification of that fact within seven days. In carrying out this section, the State shall establish a capacity management program which reasonably implements this section—that is, which enables any such program to readily report to the State when it reaches 90 percent of its capacity—and which ensures the maintenance of a continually updated record of all such reports and which makes excess capacity information available to such programs.

(b) In order to obtain Block Grant funds, the State shall ensure that each individual who requests and is in need of treatment for intravenous drug abuse is admitted to a program of such treatment not later than—

(1) 14 days after making the request for admission to such a program; or

(2) 120 days after the date of such request, if no such program has the capacity to admit the individual on the date of such request and if interim services, including referral for prenatal care, are made available to the individual not later than 48 hours after such request.

(c) In carrying out subsection (b), the State shall establish a waiting list management program which provides systematic reporting of treatment demand. The State shall require that any program receiving funding from the

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grant, for the purposes of treating injecting drug abusers, establish a waiting list that includes a unique patient identifier for each injecting drug abuser seeking treatment including those receiving interim services, while awaiting admission to such treatment. For individuals who cannot be placed in comprehensive treatment within 14 days, the State shall ensure that the program provide such individuals interim services as defined in § 96.121 and ensure that the programs develop a mechanism for maintaining contact with the individuals awaiting admission. The States shall also ensure that the programs consult the capacity management system as provided in paragraph (a) of this section so that patients on waiting lists are admitted at the earliest possible time to a program providing such treatment within reasonable geographic area.

(d) In carrying out paragraph (b)(2) of this section the State shall ensure that all individuals who request treatment and who can not be placed in comprehensive treatment within 14 days, are enrolled in interim services and those who remain active on a waiting list in accordance with paragraph (c) of this section, are admitted to a treatment program within 120 days. If a person cannot be located for admission into treatment or, if a person refuses treatment, such persons may be taken off the waiting list and need not be provided treatment within 120 days. For example, if such persons request treatment later, and space is not available, they are to be provided interim services, placed on a waiting list and admitted to a treatment program within 120 days from the latter request.

(e) The State shall require that any entity that receives funding for treatment services for intravenous drug abuse carry out activities to encourage individuals in need of such treatment to undergo such treatment. The States shall require such entities to use outreach models that are scientifically sound, or if no such models are available which are applicable to the local situation, to use an approach which reasonably can be expected to be an effective outreach method. The model shall require that outreach efforts include the following:

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(1) Selecting, training and supervising outreach workers;

(2) Contacting, communicating and following-up with high risk substance abusers, their associates, and neighborhood residents, within the constraints of Federal and State confidentiality requirements, including 42 CFR part 2;

(3) Promoting awareness among injecting drug abusers about the relationship between injecting drug abuse and communicable diseases such as HIV;

(4) Recommend steps that can be taken to ensure that HIV transmission does not occur; and

(5) Encouraging entry into treatment.

(f) The State shall develop effective strategies for monitoring programs compliance with this section. States shall report under the requirements of § 96.122(g) on the specific strategies to be used to identify compliance problems and corrective actions to be taken to address those problems.

§ 96.127 Requirements regarding tuberculosis.

(a) States shall require any entity receiving amounts from the grant for operating a program of treatment for substance abuse to follow procedures developed by the principal agency of a State for substance abuse, in consultation with the State Medical Director for Substance Abuse Services, and in cooperation with the State Department of Health/Tuberculosis Control Officer, which address how the program—

(1) Will, directly or through arrangements with other public or nonprofit private entities, routinely make available tuberculosis services as defined in § 96.121 to each individual receiving treatment for such abuse;

(2) In the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to admit the individual, will refer the individual to another provider of tuberculosis services; and

(3) Will implement infection control procedures established by the principal agency of a State for substance abuse, in cooperation with the State Department of Health/Tuberculosis Control Officer, which are designed to prevent

the transmission of tuberculosis, including the following:

- (i) Screening of patients;
 - (ii) Identification of those individuals who are at high risk of becoming infected; and
 - (iii) Meeting all State reporting requirements while adhering to Federal and State confidentiality requirements, including 42 CFR part 2; and
- (4) will conduct case management activities to ensure that individuals receive such services.

(b) The State shall develop effective strategies for monitoring programs compliance with this section. States shall report under the requirements of § 96.122(g) on the specific strategies to be used to identify compliance problems and corrective actions to be taken to address those problems. The principal agency, in cooperation with the State Department of Health/Tuberculosis Control Officer, shall also establish linkages with other health care providers to ensure that tuberculosis services are routinely made available. All individuals identified with active tuberculosis shall be reported to the appropriate State official as required by law and consistent with paragraph (a)(3)(iii) of this section.

(c) With respect to services provided for by a State for purposes of compliance with this section, the State shall maintain Statewide expenditures of non-Federal amounts for such services at a level that is not less than an average level of such expenditures maintained by the State for the 2-year period preceding the first fiscal year for which the State receives such a grant. In making this determination, States shall establish a reasonable funding base for fiscal year 1993. The base shall be calculated using Generally Accepted Accounting Principles and the composition of the base shall be applied consistently from year to year.

§ 96.128 Requirements regarding human immunodeficiency virus.

(a) In the case of a designated State as described in paragraph (b) of this section, the State shall do the following—

(1) with respect to individuals undergoing treatment for substance abuse, the State shall, subject to paragraph

(c) of this section, carry out one or more projects to make available to the individuals early intervention services for HIV disease as defined in § 96.121 at the sites at which the individuals are undergoing such treatment;

(2) for the purpose of providing such early intervention services through such projects, the State shall make available from the grant the amounts prescribed by section 1924 of the PHS Act;

(3) the State shall, subject to paragraph (d) of this section, carry out such projects only in geographic areas of the State that have the greatest need for the projects;

(4) the State shall require programs participating in the project to establish linkages with a comprehensive community resource network of related health and social services organizations to ensure a wide-based knowledge of the availability of these services; and

(5) the State shall require any entity receiving amounts from the Block Grant for operating a substance abuse treatment program to follow procedures developed by the principal agency of a State for substance abuse, in consultation with the State Medical Director for Substance Abuse Services, and in cooperation with the State Department of Health/Communicable Disease Officer.

(b) For purposes of this section, a “designated State” is any State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control for the most recent calendar year for which the data are available).

(c) With respect to programs that provide treatment services for substance abuse, the State shall ensure that each such program participating in a project under paragraph (a) of this section will be a program that began operation prior to the fiscal year for which the State is applying to receive the grant. A program that so began operation may participate in a project under paragraph (a) of this section without regard to whether the program

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has been providing early intervention services for HIV disease.

(d) If the State plans to carry out 2 or more projects under paragraph (a) of this section, the State shall carry out one such project in a rural area of the State, unless the requirement is waived. The Secretary shall waive the requirement if the State certifies to the Secretary that:

(1) The rate of cases of acquired immune deficiency syndrome is less than or equal to two such cases per 100,000 individuals in any rural area of the State, or there are so few infected persons that establishing a project in the area is not reasonable; or

(2) There are no rural areas in the State as defined in § 96.121.

(e) With respect to the provision of early intervention services for HIV disease to an individual, the State shall ensure that the entities comply with § 96.137 regarding payment and § 96.135 regarding restrictions on expenditure of grant. The State shall also ensure that such services will be undertaken voluntarily by, and with the informed consent of, the individual, and undergoing such services will not be required as a condition of receiving treatment services for substance abuse or any other services.

(f) With respect to services provided for a State for purposes of compliance with this section, the State shall maintain Statewide expenditures of non-Federal amounts for such services at a level that is not less than the average level of such expenditures maintained by the State for 2-year period preceding the first fiscal year for which the State receives such a grant. In making this determination, States shall establish a reasonable base for fiscal year 1993. The base shall be calculated using Generally Accepted Accounting Principles and the composition of the base shall be applied consistently from year to year.

§ 96.129 Revolving funds for establishment of homes in which recovering substance abusers may reside.

(a) The State shall establish and provide for the ongoing operation of a revolving fund as follows:

(1) The purpose of the fund is to make loans for the costs of estab-

lishing programs for the provision of housing in which individuals recovering from alcohol and drug abuse may reside in groups of not less than six individuals;

(2) Not less than \$100,000 will be available for the revolving fund;

(3) Loans made from the revolving fund do not exceed \$4,000 and that each such loan is repaid to the revolving fund not later than 2 years after the date on which the loan is made;

(4) Each such loan is repaid by such residents through monthly installments by the date specified in the loan agreement involved;

(5) Such loans are made only to non-profit private entities agreeing that, in the operation of the program established pursuant to the loan—

(i) The use of alcohol or any illegal drug in the housing provided by the program will be prohibited;

(ii) Any resident of the housing who violates such prohibition will be expelled from the housing;

(iii) The costs of the housing, including fees for rent and utilities, will be paid by the residents of the housing; and

(iv) The residents of the housing will, through a majority vote of the residents, otherwise establish policies governing residence in the housing, including the manner in which applications for residence in the housing are approved;

(6) States shall identify and clearly define legitimate purposes for which the funds will be spent, such as first month's rent, necessary furniture (e.g., beds), facility modifications (e.g., conversion of basement into a game room or extra bedrooms), and purchase of amenities which foster healthy group living (e.g., dishwasher);

(7) In managing the revolving fund, the State and the financial entity managing the fund for the State shall abide by all Federal, State and local laws and regulations;

(8) If the State decides to indirectly manage the fund using a private non-profit entity as the fund management group, the State shall establish reasonable criteria for selecting the group, such as qualifications, expertise, experience, and capabilities of the group, and the State shall require that these

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entities abide by all Federal, State and local laws and regulations;

(9) The State may seek assistance to approve or deny applications from entities that meet State-established criteria;

(10) The State shall set reasonable criteria in determining the eligibility of prospective borrowers such as qualifications, expertise, capabilities, the acceptability of a proposed plan to use the funds and operate the house, and an assessment of the potential borrower's ability to pay back the funds;

(11) The State shall establish a procedure and process for applying for a loan under the program which may include completion of the application, personal interviews and submission of evidence to support eligibility requirements, as well as establish a written procedure for repayment which will set forth reasonable penalties for late or missed payments and liability and recourse for default;

(12) The State shall provide clearly defined written instructions to applicants which lays out timeliness, milestones, required documentation, notification of reasonable penalties for late or missed payments and recourse for default, notification on legitimate purposes for which the loan may be spent, and other procedures required by the State; and

(13) The State shall keep a written record of the number of loans and amount of loans provided, the identities of borrowers and the repayment history of each borrower and retain it for three years.

(b) The requirements established in paragraph (a) of this section shall not apply to any territory of the United States other than the Commonwealth of Puerto Rico.

§ 96.130 State law regarding sale of tobacco products to individuals under age of 18.

(a) For purposes of this section, the term "first applicable fiscal year" means fiscal year 1994, except in the case of any State described in section 1926(a)(2) of the PHS Act, in which case "first applicable fiscal year" means fiscal year 1995. The term "outlet" is any location which sells at retail or otherwise distributes tobacco products to

consumers including (but not limited to) locations that sell such products over-the-counter or through vending machines.

(b) The Secretary may make a grant to a State only if the State, for the first applicable fiscal year and subsequent fiscal years, has in effect a law providing that it is unlawful for any manufacturer, retailer, or distributor of tobacco products to sell or distribute any such product to any individual under age 18 through any sales or distribution outlet, including over-the-counter and vending machine sales.

(c) For the first and second applicable fiscal years, the State shall, at a minimum, conduct annually a reasonable number of random, unannounced inspections of outlets to ensure compliance with the law and plan and begin to implement any other actions which the State believes are necessary to enforce the law.

(d) For the third and subsequent fiscal years, the States shall do the following:

(1) The State shall conduct annual, random, unannounced inspections of both over-the-counter and vending machine outlets. The random inspections shall cover a range of outlets (not preselected on the basis of prior violations) to measure overall levels of compliance as well as to identify violations.

(2) Random, unannounced inspections shall be conducted annually to ensure compliance with the law and shall be conducted in such a way as to provide a probability sample of outlets. The sample must reflect the distribution of the population under age 18 throughout the State and the distribution of the outlets throughout the State accessible to youth.

(e) As provided by § 96.122(d), the State shall annually submit to the Secretary a report which shall include the following:

(1) a detailed description of the State's activities to enforce the law required in paragraph (b) of this section during the fiscal year preceding the fiscal year for which that State is seeking the grant;

(2) a detailed description regarding the overall success the State has achieved during the previous fiscal

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year in reducing the availability of tobacco products to individuals under the age of 18, including the results of the unannounced inspections as provided by paragraph (d) of this section for which the results of over-the-counter and vending machine outlet inspections shall be reported separately;

(3) a detailed description of how the unannounced inspections were conducted and the methods used to identify outlets;

(4) the strategies to be utilized by the State for enforcing such law during the fiscal year for which the grant is sought; and

(5) the identity of the agency or agencies designated by the Governor to be responsible for the implementation of the requirements of section 1926 of the PHS Act.

(f) Beginning in the second applicable fiscal year, the annual report required under paragraph (e) of this section shall be made public within the State, along with the State plan as provided in section 1941 of the PHS Act.

(g) Beginning with applications for the fourth applicable fiscal year and all subsequent fiscal years, the Secretary will negotiate with the State, as part of the State's plan, the interim performance target the State will meet for that fiscal year and in subsequent years will seek evidence of progress toward achieving or surpassing a performance objective in which the inspection failure rate would be no more than 20% within several years.

(h) Beginning with the second applicable fiscal year and all subsequent fiscal years, the Secretary shall make a determination, before making a Block Grant to a State for that fiscal year, whether the State reasonably enforced its law in the previous fiscal year pursuant to this section. In making this determination, the Secretary will consider the following factors:

(1) During the first and second applicable fiscal years, the State must conduct the activities prescribed in paragraph (c) of this section.

(2) During the third applicable fiscal year, the State must conduct random, unannounced inspections in accordance with paragraph (d) of this section.

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(3) During the fourth and all subsequent applicable fiscal years, the State must do the following:

(i) conduct random, unannounced inspections in accordance with paragraph (d); and

(ii) except as provided by paragraph (h)(4) of this section, the State must be in substantial compliance with the target negotiated with the Secretary under paragraph (g) of this section for that fiscal year.

(4) If a State has not substantially complied with the target as prescribed under paragraph (h)(3)(ii) of this section for any fiscal year, the Secretary, in extraordinary circumstances, may consider a number of factors, including survey data showing that the State is making significant progress toward reducing use of tobacco products by children and youth, data showing that the State has progressively decreased the availability of tobacco products to minors, the composition of the outlets inspected as to whether they were over-the-counter or vending machine outlets, and the State's plan for improving the enforcement of the law in the next fiscal year.

(i) If, after notice to the State and an opportunity for a hearing, the Secretary determines under paragraph (h) of this section that the State has not maintained compliance, the Secretary will reduce the amount of the allotment in such amounts as is required by section 1926(c) of the PHS Act.

(j) States may not use the Block Grant to fund the enforcement of their statute, except that they may expend funds from the primary prevention set-aside of their Block Grant allotment under 45 CFR 96.124(b)(1) for carrying out the administrative aspects of the requirements such as the development of the sample design and the conducting of the inspections.

[61 FR 1508, Jan. 19, 1996, as amended at 66 FR 46227, Sept. 4, 2001]

§ 96.131 Treatment services for pregnant women.

(a) The State is required to, in accordance with this section, ensure that each pregnant woman in the State who

seeks or is referred for and would benefit from such services is given preference in admissions to treatment facilities receiving funds pursuant to the grant. In carrying out this section, the State shall require all entities that serve women and who receive such funds to provide preference to pregnant women. Programs which serve an injecting drug abuse population and who receive Block Grant funds shall give preference to treatment as follows:

- (1) Pregnant injecting drug users;
- (2) Pregnant substance abusers;
- (3) Injecting drug users; and
- (4) All others.

(b) The State will, in carrying out this provision publicize the availability to such women of services from the facilities and the fact that pregnant women receive such preference. This may be done by means of street outreach programs, ongoing public service announcements (radio/television), regular advertisements in local/regional print media, posters placed in targeted areas, and frequent notification of availability of such treatment distributed to the network of community based organizations, health care providers, and social service agencies.

(c) The State shall in carrying out paragraph (a) of this section require that, in the event that a treatment facility has insufficient capacity to provide treatment services to any such pregnant woman who seeks the services from the facility, the facility refer the woman to the State. This may be accomplished by establishing a capacity management program, utilizing a toll-free number, an automated reporting system and/or other mechanisms to ensure that pregnant women in need of such services are referred as appropriate. The State shall maintain a continually updated system to identify treatment capacity for any such pregnant women and will establish a mechanism for matching the women in need of such services with a treatment facility that has the capacity to treat the woman.

(d) The State, in the case of each pregnant woman for whom a referral under paragraph (a) of this section is made to the State—

- (1) will refer the woman to a treatment facility that has the capacity to

provide treatment services to the woman; or

(2) will, if no treatment facility has the capacity to admit the woman, make available interim services, including a referral for prenatal care, available to the woman not later than 48 hours after the woman seeks the treatment services.

(e) Procedures for the implementation of this section shall be developed in consultation with the State Medical Director for Substance Abuse Services.

(f) The State shall develop effective strategies for monitoring programs compliance with this section. States shall report under the requirements of § 96.122(g) on the specific strategies to be used to identify compliance problems and corrective actions to be taken to address those problems.

§ 96.132 Additional agreements.

(a) With respect to individuals seeking treatment services, the State is required to improve (relative to fiscal year 1992) the process in the State for referring the individuals to treatment facilities that can provide to the individuals the treatment modality that is most appropriate for the individuals. Examples of how this may be accomplished include the development and implementation of a capacity management/waiting list management system; the utilization of a toll-free number for programs to report available capacity and waiting list data; and the utilization of standardized assessment procedures that facilitate the referral process.

(b) With respect to any facility for treatment services or prevention activities that is receiving amounts from a Block Grant, continuing education in such services or activities (or both, as the case may be) shall be made available to employees of the facility who provide the services or activities. The States will ensure that such programs include a provision for continuing education for employees of the facility in its funding agreement.

(c) The State shall coordinate prevention and treatment activities with the provision of other appropriate services (including health, social, correctional and criminal justice, educational, vocational rehabilitation, and

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employment services). In evaluating compliance with this section, the Secretary will consider such factors as the existence of memoranda of understanding between various service providers/agencies and evidence that the State has included prevention and treatment services coordination in its grants and contracts.

(d) Upon the request of a State, the Secretary may provide to a State a waiver of any or all of the requirements established in paragraphs (a), (b) and (c) of this section, if the Secretary determines that, with respect to services for the prevention and treatment of substance abuse, the requirement involved is unnecessary for maintaining quality in the provision of such services in the State. In evaluating whether to grant or deny a waiver, the Secretary will rely on information drawn from the independent peer review/quality assurance activities conducted by the State. For example, a State may be eligible for a waiver of the requirement of paragraph (a) of this section if a State already has a well developed process for referring individuals to treatment facilities that can provide to the individuals the treatment modality that is most appropriate for the individuals. The Secretary will approve or deny a request for a waiver not later than 120 days after the date on which the request is made. Any waiver provided by the Secretary for paragraphs (a), (b) and (c) of this section, will be applicable only to the fiscal year involved.

(e) The State is also required to have in effect a system to protect from inappropriate disclosure patient records maintained by the State in connection with an activity funded under the program involved or by any entity which is receiving amounts from the grant and such system shall be in compliance with all applicable State and Federal laws and regulations, including 42 CFR part 2. This system shall include provisions for employee education on the confidentiality requirements and the fact that disciplinary action may occur upon inappropriate disclosures. This requirement cannot be waived.

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§ 96.133 Submission to Secretary of Statewide assessment of needs.

(a) The State is required to submit to the Secretary an assessment of the need in the State for authorized activities, both by locality and by the State in general. The State is to provide a broad range of information which includes the following:

(1) The State is to submit data which shows the incidence and prevalence in the State of drug abuse and the incidence and prevalence in the State of alcohol abuse and alcoholism. For fiscal years 1993 through 1996, the State shall submit its best available data on the incidence and prevalence of drug and alcohol abuse and alcoholism. The State shall also provide a summary describing the weakness and bias in the data and a description on how the State plans to strengthen the data in the future.

(2) The State shall provide a description on current substance abuse prevention and treatment activities:

(i) For fiscal year 1993, the State shall provide its best available data on current prevention and treatment activities in the State in such detail as it finds reasonably practicable given its own data collection activities and records.

(ii) For fiscal year 1994 and subsequent years, the State shall provide a detailed description on current prevention and treatment activities in the State. This report shall include a detailed description of the intended use of the funds relating to prevention and treatment, as well as a description of treatment capacity. As to primary prevention activities, the activities must be broken down by strategies used, such as those provided in section 96.125, including the specific activities conducted. The State shall provide the following data if available: the specific risk factors being addressed by activity; the age, race/ethnicity and gender of the population being targeted by the prevention activity; and the community size and type where the activity is carried out. As to all treatment and prevention activities, including primary prevention, the State shall provide the identities of the entities that provide the services and describe the

services provided. The State shall submit information on treatment utilization to describe the type of care and the utilization according to primary diagnosis of alcohol or drug abuse, or a dual diagnosis of drug and alcohol abuse.

(3) The State may describe the need for technical assistance to carry out Block Grant activities, including activities relating to the collection of incidence and prevalence data identified in paragraph (a)(1) of this section.

(4) The State shall establish goals and objectives for improving substance abuse treatment and prevention activities and shall report activities taken in support of these goals and objectives in its application.

(5) The State shall submit a detailed description on the extent to which the availability of prevention and treatment activities is insufficient to meet the need for the activities, the interim services to be made available under sections 96.126 and 96.131, and the manner in which such services are to be so available. Special attention should be provided to the following groups:

- (i) Pregnant addicts;
- (ii) Women who are addicted and who have dependent children;
- (iii) Injecting drug addicts; and
- (iv) Substance abusers infected with HIV or who have tuberculosis.

(6) Documentation describing the results of the State's management information system pertaining to capacity and waiting lists shall also be submitted, as well as a summary of such information for admissions and, when available, discharges. As to prevention activities, the report shall include a description of the populations at risk of becoming substance abusers.

§ 96.134 Maintenance of effort regarding State expenditures.

(a) With respect to the principal agency of a State for carrying out authorized activities, the agency shall for each fiscal year maintain aggregate State expenditures by the principal agency for authorized activities at a level that is not less than the average level of such expenditures maintained by the State for the two year period preceding the fiscal year for which the State is applying for the grant. The

Block Grant shall not be used to supplant State funding of alcohol and other drug prevention and treatment programs.

(b) Upon the request of a State, the Secretary may waive all or part of the requirement established in paragraph (a) of this section if the Secretary determines that extraordinary economic conditions in the State justify the waiver. The State involved must submit information sufficient for the Secretary to make the determination, including the nature of the extraordinary economic circumstances, documented evidence and appropriate data to support the claim, and documentation on the year for which the State seeks the waiver. The Secretary will approve or deny a request for a waiver not later than 120 days after the date on which the request is made. Any waiver provided by the Secretary shall be applicable only to the fiscal year involved. "Extraordinary economic conditions" mean a financial crisis in which the total tax revenue declines at least one and one-half percent, and either unemployment increases by at least one percentage point, or employment declines by at least one and one-half percent.

(c) In making a Block Grant to a State for a fiscal year, the Secretary shall make a determination of whether, for the previous fiscal year or years, the State maintained material compliance with any agreement made under paragraph (a) of this section. If the Secretary determines that a State has failed to maintain such compliance, the Secretary shall reduce the amount of the allotment for the State for the fiscal year for which the grant is being made by an amount equal to the amount constituting such failure for the previous fiscal year.

(d) The Secretary may make a Block Grant for a fiscal year only if the State involved submits to the Secretary information sufficient for the Secretary to make the determination required in paragraph (a) of this section, which includes the dollar amount reflecting the aggregate State expenditures by the principal agency for authorized activities for the two State fiscal years preceding the fiscal year for which the State is applying for the grant. The

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base shall be calculated using Generally Accepted Accounting Principles and the composition of the base shall be applied consistently from year to year.

§ 96.135 Restrictions on expenditure of grant.

(a) The State shall not expend the Block Grant on the following activities:

(1) To provide inpatient hospital services, except as provided in paragraph (c) of this section;

(2) To make cash payments to intended recipients of health services;

(3) To purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) To satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds;

(5) To provide financial assistance to any entity other than a public or non-profit private entity; or

(6) To provide individuals with hypodermic needles or syringes so that such individuals may use illegal drugs, unless the Surgeon General of the Public Health Service determines that a demonstration needle exchange program would be effective in reducing drug abuse and the risk that the public will become infected with the etiologic agent for AIDS.

(b) The State shall limit expenditures on the following:

(1) The State involved will not expend more than 5 percent of the grant to pay the costs of administering the grant; and

(2) The State will not, in expending the grant for the purpose of providing treatment services in penal or correctional institutions of the State, expend more than an amount prescribed by section 1931(a)(3) of the PHS Act.

(c) Exception regarding inpatient hospital services.

(1) With respect to compliance with the agreement made under paragraph (a) of this section, a State (acting through the Director of the principal agency) may expend a grant for inpatient hospital-based substance abuse programs subject to the limitations of

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paragraph (c)(2) of this section only when it has been determined by a physician that:

(i) The primary diagnosis of the individual is substance abuse, and the physician certifies this fact;

(ii) The individual cannot be safely treated in a community-based, nonhospital, residential treatment program;

(iii) The Service can reasonably be expected to improve an individual's condition or level of functioning;

(iv) The hospital-based substance abuse program follows national standards of substance abuse professional practice; and

(2) In the case of an individual for whom a grant is expended to provide inpatient hospital services described above, the allowable expenditure shall conform to the following:

(i) The daily rate of payment provided to the hospital for providing the services to the individual will not exceed the comparable daily rate provided for community-based, nonhospital, residential programs of treatment for substance abuse; and

(ii) The grant may be expended for such services only to the extent that it is medically necessary, i.e., only for those days that the patient cannot be safely treated in a residential, community-based program.

(d) The Secretary may approve a waiver for construction under paragraph (a)(3) of this section within 120 days after the date of a request only if:

(1) The State demonstrates to the Secretary that adequate treatment cannot be provided through the use of existing facilities and that alternative facilities in existing suitable buildings are not available;

(2) The State has carefully designed a plan that minimizes the costs of renovation or construction;

(3) The State agrees, with respect to the costs to be incurred by the State in carrying out the purpose of the waiver, to make available non-Federal contributions in cash toward such costs in an amount equal to not less than \$1 for each \$1 of Federal funds provided under the Block Grant; and

(4) The State submits the following to support paragraphs (b)(1), (2) and (3), of this section:

(i) Documentation to support paragraph (d)(1) of this section, such as local needs assessments, waiting lists, survey data and other related information;

(ii) A brief description of the project to be funded, including the type(s) of services to be provided and the projected number of residential and/or outpatient clients to be served;

(iii) The specific amount of Block Grant funds to be used for this project;

(iv) The number of outpatient treatment slots planned or the number of residential beds planned, if applicable;

(v) The estimate of the total cost of the construction or rehabilitation (and a description of how these estimates were determined), based on an independent estimate of said cost, using standardized measures as determined by an appropriate State construction certifying authority;

(vi) An assurance by the State that all applicable National (e.g., National Fire Protection Association, Building Officials and Codes Administrators International), Federal (National Environmental Policy Act), State, and local standards for construction or rehabilitation of health care facilities will be complied with;

(vii) Documentation of the State's commitment to obligate these funds by the end of the first year in which the funds are available, and that such funds must be expended by the end of the second year (section 1914(a)(2) of the PHS Act);

(viii) A certification that there is public support for a waiver, as well as a description of the procedure used (and the results therein) to ensure adequate comment from the general public and the appropriate State and local health planning organizations, local governmental entities and public and private-sector service providers that may be impacted by the waiver request;

(ix) Evidence that a State is committed to using the proposed new or rehabilitated substance abuse facility for the purposes stated in the request for at least 20 years for new construction and at least 10 years for rehabilitated facilities;

(x) An assurance that, if the facility ceases to be used for such services, or if

the facility is sold or transferred for a purpose inconsistent with the State's waiver request, monies will be returned to the Federal Government in an amount proportionate to the Federal assistance provided, as it relates to the value of the facility at the time services cease or the facility sold or transferred;

(xi) A description of the methods used to minimize the costs of the construction or rehabilitation, including documentation of the costs of the residential facilities in the local area or other appropriate equivalent sites in the State;

(xii) An assurance that the State shall comply with the matching requirements of paragraph (d)(3) of this section; and

(xiii) Any other information the Secretary may determine to be appropriate.

§ 96.136 Independent peer review.

(a) The State shall for the fiscal year for which the grant is provided, provide for independent peer review to assess the quality, appropriateness, and efficacy of treatment services provided in the State to individuals under the program involved, and ensure that at least 5 percent of the entities providing services in the State under such program are reviewed. The programs reviewed shall be representative of the total population of such entities.

(b) The purpose of independent peer review is to review the quality and appropriateness of treatment services. The review will focus on treatment programs and the substance abuse service system rather than on the individual practitioners. The intent of the independent peer review process is to continuously improve the treatment services to alcohol and drug abusers within the State system. "Quality," for purposes of this section, is the provision of treatment services which, within the constraints of technology, resources, and patient/client circumstances, will meet accepted standards and practices which will improve patient/client health and safety status in the context of recovery. "Appropriateness," for purposes of this section, means the provision of treatment

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services consistent with the individual's identified clinical needs and level of functioning.

(c) The independent peer reviewers shall be individuals with expertise in the field of alcohol and drug abuse treatment. Because treatment services may be provided by multiple disciplines, States will make every effort to ensure that individual peer reviewers are representative of the various disciplines utilized by the program under review. Individual peer reviewers must also be knowledgeable about the modality being reviewed and its underlying theoretical approach to addictions treatment, and must be sensitive to the cultural and environmental issues that may influence the quality of the services provided.

(d) As part of the independent peer review, the reviewers shall review a representative sample of patient/client records to determine quality and appropriateness of treatment services, while adhering to all Federal and State confidentiality requirements, including 42 CFR part 2. The reviewers shall examine the following:

- (1) Admission criteria/intake process;
- (2) Assessments;
- (3) Treatment planning, including appropriate referral, e.g., prenatal care and tuberculosis and HIV services;
- (4) Documentation of implementation of treatment services;
- (5) Discharge and continuing care planning; and
- (6) Indications of treatment outcomes.

(e) The State shall ensure that the independent peer review will not involve practitioners/providers reviewing their own programs, or programs in which they have administrative oversight, and that there be a separation of peer review personnel from funding decisionmakers. In addition, the State shall ensure that independent peer review is not conducted as part of the licensing/certification process.

(f) The States shall develop procedures for the implementation of this section and such procedures shall be developed in consultation with the State Medical Director for Substance Abuse Services.

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§ 96.137 Payment schedule.

(a) The Block Grant money that may be spent for §§ 96.124(c) and (e), 96.127 and 96.128 is governed by this section which ensures that the grant will be the “payment of last resort.” The entities that receive funding under the Block Grant and provides services required by the above-referenced sections shall make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to:

(1) Collect reimbursement for the costs of providing such services to persons who are entitled to insurance benefits under the Social Security Act, including programs under title XVIII and title XIX, any State compensation program, any other public assistance program for medical expenses, any grant program, any private health insurance, or any other benefit program; and

(2) Secure from patients or clients payments for services in accordance with their ability to pay.

APPENDIX A TO PART 96—UNIFORM DEFINITIONS OF SERVICES

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2. Case Management Services
3. Congregate Meals
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5. Day Care Services—Adults
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- 26. Special Services for Youth Involved in or At Risk of Involvement in Criminal Activity
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- 28. Transportation Services
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UNIFORM DEFINITIONS OF SERVICES

1. Adoption Services

Adoption services are those services or activities provided to assist in bringing about the adoption of a child. Component services and activities may include, but are not limited to, counseling the biological parent(s), recruitment of adoptive homes, and pre- and post-placement training and/or counseling.

2. Case Management Services

Case management services are services or activities for the arrangement, coordination, and monitoring of services to meet the needs of individuals and families. Component services and activities may include individual service plan development; counseling; monitoring, developing, securing, and coordinating services; monitoring and evaluating client progress; and assuring that clients' rights are protected.

3. Congregate Meals

Congregate meals are those services or activities designed to prepare and serve one or more meals a day to individuals in central dining areas in order to prevent institutionalization, malnutrition, and feelings of isolation. Component services or activities may include the cost of personnel, equipment, and food; assessment of nutritional and dietary needs; nutritional education and counseling; socialization; and other services such as transportation and information and referral.

4. Counseling Services

Counseling services are those services or activities that apply therapeutic processes to personal, family, situational, or occupational problems in order to bring about a positive resolution of the problem or improved individual or family functioning or circumstances. Problem areas may include family and marital relationships, parent-child problems, or drug abuse.

5. Day Care Services—Adults

Day care services for adults are those services or activities provided to adults who require care and supervision in a protective setting for a portion of a 24-hour day. Component services or activities may include opportunity for social interaction, companionship and self-education; health support or assistance in obtaining health services; counseling; recreation and general leisure time

activities; meals; personal care services; plan development; and transportation.

6. Day Care Services—Children

Day care services for children (including infants, pre-schoolers, and school age children) are services or activities provided in a setting that meets applicable standards of state and local law, in a center or in a home, for a portion of a 24-hour day. Component services or activities may include a comprehensive and coordinated set of appropriate developmental activities for children, recreation, meals and snacks, transportation, health support services, social service counseling for parents, plan development, and licensing and monitoring of child care homes and facilities.

7. Education and Training Services

Education and training services are those services provided to improve knowledge or daily living skills and to enhance cultural opportunities. Services may include instruction or training in, but are not limited to, such issues as consumer education, health education, community protection and safety education, literacy education, English as a second language, and General Educational Development (G.E.D.). Component services or activities may include screening, assessment and testing; individual or group instruction; tutoring; provision of books, supplies and instructional material; counseling; transportation; and referral to community resources.

8. Employment Services

Employment services are those services or activities provided to assist individuals in securing employment or acquiring or learning skills that promote opportunities for employment. Component services or activities may include employment screening, assessment, or testing; structured job skills and job seeking skills; specialized therapy (occupational, speech, physical); special training and tutoring, including literacy training and pre-vocational training; provision of books, supplies and instructional material; counseling, transportation; and referral to community resources.

9. Family Planning Services

Family planning services are those educational, comprehensive medical or social services or activities which enable individuals, including minors, to determine freely the number and spacing of their children and to select the means by which this may be achieved. These services and activities include a broad range of acceptable and effective methods and services to limit or enhance fertility, including contraceptive methods (including natural family planning

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and abstinence), and the management of infertility (including referral to adoption). Specific component services and activities may include preconceptional counseling, education, and general reproductive health care, including diagnosis and treatment of infections which threaten reproductive capability. Family planning services do not include pregnancy care (including obstetric or prenatal care).

10. Foster Care Services for Adults

Foster care services for adults are those services or activities that assess the need and arrange for the substitute care and alternate living situation of adults in a setting suitable to the individual's needs. Individuals may need such services because of social, physical or mental disabilities, or as a consequence of abuse or neglect. Care may be provided in a community-based setting, or such services may arrange for institutionalization when necessary. Component services or activities include assessment of the individual's needs; case planning and case management to assure that the individual receives proper care in the placement; counseling to help with personal problems and adjusting to new situations; assistance in obtaining other necessary supportive services; determining, through periodic reviews, the continued appropriateness of and need for placement; and recruitment and licensing of foster care homes and facilities.

11. Foster Care Services for Children

Foster care services for children are those services or activities associated with the provision of an alternative family life experience for abused, neglected or dependent children, between birth and the age of majority, on the basis of a court commitment or a voluntary placement agreement signed by the parent or guardian. Services may be provided to children in foster family homes, foster homes of relatives, group homes, emergency shelters, residential facilities, child care institutions, pre-adoptive homes or supervised independent living situation. Component services or activities may include assessment of the child's needs; case planning and case management to assure that the child receives proper care in the placement; medical care as an integral but subordinate part of the service; counseling of the child, the child's parents, and the foster parents; referral and assistance in obtaining other necessary supportive services; periodical reviews to determine the continued appropriateness and need for placement; and recruitment and licensing of foster homes and child care institutions.

12. Health Related and Home Health Services

Health related and home health services are those in-home or out-of-home services or

activities designed to assist individuals and families to attain and maintain a favorable condition of health. Component services and activities may include providing an analysis or assessment of an individual's health problems and the development of a treatment plan; assisting individuals to identify and understand their health needs; assisting individuals to locate, provide or secure, and utilize appropriate medical treatment, preventive medical care, and health maintenance services, including in-home health services and emergency medical services; and providing follow-up services as needed.

13. Home Based Services

Home based services are those in-home services or activities provided to individuals or families to assist with household or personal care activities that improve or maintain adequate family well-being. These services may be provided for reasons of illness, incapacity, frailty, absence of a caretaker relative, or to prevent abuse and neglect of a child or adult. Major service components include homemaker services, chore services, home maintenance services, and household management services. Component services or activities may include protective supervision of adults and/or children to help prevent abuse, temporary non-medical personal care, house-cleaning, essential shopping, simple household repairs, yard maintenance, teaching of homemaking skills, training in self-help and self-care skills, assistance with meal planning and preparation, sanitation, budgeting, and general household management.

14. Home Delivered Meals

Home-delivered meals are those services or activities designed to prepare and deliver one or more meals a day to an individual's residence in order to prevent institutionalization, malnutrition, and feelings of isolation. Component services or activities may include the cost of personnel, equipment, and food; assessment of nutritional and dietary needs; nutritional education and counseling; socialization services; and information and referral.

15. Housing Services

Housing services are those services or activities designed to assist individuals or families in locating, obtaining, or retaining suitable housing. Component services or activities may include tenant counseling; helping individuals and families to identify and correct substandard housing conditions on behalf of individuals and families who are unable to protect their own interests; and assisting individuals and families to understand leases, secure utilities, make moving arrangements and minor renovations.

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16. Independent and Transitional Living Services

Independent and transitional living services are those services and activities designed to help older youth in foster care or homeless youth make the transition to independent living, or to help adults make the transition from an institution, or from homelessness, to independent living. Component services or activities may include educational and employment assistance, training in daily living skills, and housing assistance. Specific component services and activities may include supervised practice living and post-foster care services.

17. Information and Referral Services

Information and referral services are those services or activities designed to provide information about services provided by public and private service providers and a brief assessment of client needs (but not diagnosis and evaluation) to facilitate appropriate referral to these community resources.

18. Legal Services

Legal services are those services or activities provided by a lawyer or other person(s) under the supervision of a lawyer to assist individuals in seeking or obtaining legal help in civil matters such as housing, divorce, child support, guardianship, paternity, and legal separation. Component services or activities may include receiving and preparing cases for trial, provision of legal advice, representation at hearings, and counseling.

19. Pregnancy and Parenting Services for Young Parents

Pregnancy and parenting services are those services or activities for married or unmarried adolescent parents and their families designed to assist young parents in coping with the social, emotional, and economic problems related to pregnancy and in planning for the future. Component services or activities may include securing necessary health care and living arrangements; obtaining legal services; and providing counseling, child care education, and training in and development of parenting skills.

20. Prevention and Intervention Services

Prevention and intervention services are those services or activities designed to provide early identification and/or timely intervention to support families and prevent or ameliorate the consequences of, abuse, neglect, or family violence, or to assist in making arrangement for alternate placements or living arrangements where necessary. Such services may also be provided to prevent the removal of a child or adult from the home. Component services and activities may include investigation; assessment and/or eval-

uation of the extent of the problem; counseling, including mental health counseling or therapy as needed; developmental and parenting skills training; respite care; and other services including supervision, case management, and transportation.

21. Protective Services for Adults

Protective services for adults are those services or activities designed to prevent or remedy abuse, neglect or exploitation of adults who are unable to protect their own interests. Examples of situations that may require protective services are injury due to maltreatment or family violence; lack of adequate food, clothing or shelter; lack of essential medical treatment or rehabilitation services; and lack of necessary financial or other resources. Component services or activities may include investigation; immediate intervention; emergency medical services; emergency shelter; developing case plans; initiation of legal action (if needed); counseling for the individual and the family; assessment/evaluation of family circumstances; arranging alternative or improved living arrangements; preparing for foster placement, if needed; and case management and referral to service providers.

22. Protective Services for Children

Protective services for children are those services or activities designed to prevent or remedy abuse, neglect, or exploitation of children who may be harmed through physical or mental injury, sexual abuse or exploitation, and negligent treatment or maltreatment, including failure to be provided with adequate food, clothing, shelter, or medical care. Component services or activities may include immediate investigation and intervention; emergency medical services; emergency shelter; developing case plans; initiation of legal action (if needed); counseling for the child and the family; assessment/evaluation of family circumstances; arranging alternative living arrangement; preparing for foster placement, if needed; and case management and referral to service providers.

23. Recreational Services

Recreational services are those services or activities designed to provide, or assist individuals to take advantage of, individual or group activities directed towards promoting physical, cultural, and/or social development.

24. Residential Treatment Services

Residential treatment services provide short-term residential care and comprehensive treatment and services for children or adults whose problems are so severe or are such that they cannot be cared for at home or in foster care and need the specialized

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services provided by specialized facilities. Component services and activities may include diagnosis and psychological evaluation; alcohol and drug detoxification services; individual, family, and group therapy and counseling; remedial education and GED preparation; vocational or pre-vocational training; training in activities of daily living; supervised recreational and social activities; case management; transportation; and referral to and utilization of other services.

25. Special Services for Persons With Developmental or Physical Disabilities, or Persons With Visual or Auditory Impairments

Special services for persons with developmental or physical disabilities, or persons with visual or auditory impairments, are services or activities to maximize the potential of persons with disabilities, help alleviate the effects of physical, mental or emotional disabilities, and to enable these persons to live in the least restrictive environment possible. Component services or activities may include personal and family counseling; respite care; family support; recreation; transportation; aid to assist with independent functioning in the community; and training in mobility, communication skills, the use of special aids and appliances, and self-sufficiency skills. Residential and medical services may be included only as an integral, but subordinate, part of the services.

26. Special Services for Youth Involved in or at Risk of Involvement With Criminal Activity

Special services for youth involved in or at risk of involvement with criminal activity are those services or activities for youth who are, or who may become, involved with the juvenile justice system and their families. Components services or activities are designed to enhance family functioning and/or modify the youth's behavior with the goal of developing socially appropriate behavior and may include counseling, intervention therapy, and residential and medical services if included as an integral but subordinate part of the service.

27. Substance Abuse Services

Substance abuse services are those services or activities that are primarily designed to deter, reduce, or eliminate substance abuse or chemical dependence. Except for initial detoxification services, medical and residential services may be included but only as an integral but subordinate part of the service. Component substance abuse services or activities may include a comprehensive range of personal and family counseling methods, methadone treatment for opiate abusers, or detoxification treatment for alcohol abusers. Services may be provided in alternative liv-

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ing arrangements such as institutional settings and community-based halfway houses.

28. Transportation Services

Transportation services are those services or activities that provide or arrange for the travel, including travel costs, of individuals in order to access services, or obtain medical care or employment. Component services or activities may include special travel arrangements such as special modes of transportation and personnel to accompany or assist individuals or families to utilize transportation.

29. Other Services

Other Services are services that do not fall within the definitions of the preceding 28 services. The definition used by the State for each of these services should appear elsewhere in the annual report.

[58 FR 60128, Nov. 15, 1993]

**APPENDIX B TO PART 96—SSBG
REPORTING FORM AND INSTRUCTIONS**

Instructions

This form must be used by states as the reporting instrument to satisfy the requirements of 45 CFR 96.74(a) (1) through (4). Following are instructions on how to complete the form:

General

1. Enter the name of the state submitting the form.
2. Enter the fiscal year for which the form is being submitted. Either the state or federal fiscal year may be used.
3. Enter the month and year of the beginning and end of the fiscal year—e.g., 07/91 to 06/92.

Services

4. The "service" column contains a list of services that are to be used for national reporting. This list in no way mandates how a state is to design its program of services under the SSBG, but rather is to be used only to obtain nationally comparable statistics. If the services that your state provides reasonably fit the uniform service definitions in appendix A, use them. In cases where no fit is possible between the state services and the services on the form, use item number 29—the other services category. Please list all services reported under item 29, using a separate sheet if necessary. The state's definition of these services must appear in the state's annual report.

Recipient Data

In reporting the following data:

- Each state should use its own definitions of the terms “adult” and “child.” These definitions should be described elsewhere in the annual report. If the definitions of adult and child vary by services, all such definitions must be included.

- States should, if possible, consider as the “recipient” of the service the individual to whom the service is provided. This means that the child would be considered the recipient of child day care services, even if such services are provided to allow the child’s adult caretaker to pursue employment. Similarly, an adult who receives counseling services should be considered as the recipient of that service, even if the service is provided as part of a child’s protective services plan. In cases where each member of a family, for example, receives an individual service such as counseling, each family member should be considered as a separate recipient.

- States should, if possible, consider as a service, i.e., a count of one, any service provided to a single recipient for the duration of the reporting period (one year), or any fraction thereof. In cases where an individual received a service during the reporting period, then discontinued the service, and then received the service again, the individual should only be counted once, if possible.

- The criteria applied in determining eligibility for each service—such as income eligibility guidelines, sliding fee scales, the effect of public assistance benefits, and any requirements for enrollment in school or training programs—should be described elsewhere in the annual report.

5. Under “Number of Recipients—Adults” enter the number of adults who have received each service funded in whole or part under the SSBG.

6. Under “Number of Recipients—Children” enter the number of children who have received each service funded in whole or part under the SSBG.

7. Under “Number of Recipients—Total” enter the total number of recipients of each service. This should be the sum of the adults and children reported in the preceding “adult” and “children” columns.

Expenditure Data

8. Under “Expenditures—Total \$” enter all funds that the state expends on each service. This should include SSBG funds as well as funds from other federal sources, state funds, and local funds. A listing of the sources of these funds, and the amounts allocated, should appear elsewhere in the annual report.

9. Under “Expenditures—SSBG \$” enter the total SSBG funds expended for each service. This column should be totaled, and the sum placed at the bottom of the column in the “Totals” box.

10. Under “Expenditures—Per Adult” enter the average amount of SSBG funds expended on each adult recipient of each service.

11. Under “Expenditures—Per Child” enter the average amount of SSBG funds expended on each child recipient of each service.

12. Item 30 in the “Total SSBG \$” column should contain other expenditures and income as follows:

a. “Transfers In” should contain funds transferred from other federal block grants to the SSBG program. A listing of the source(s) of block grant funds and their amounts should appear elsewhere in the annual report.

b. “Transfers Out” should show funds transferred from the SSBG program to other federal block grants. A listing of the program(s) to which SSBG funds were transferred, and the amounts, should appear elsewhere in the annual report.

c. “Carry Forward” should show funds the state intends to carry over from the reporting fiscal year to the following fiscal year. The SSBG statute permits states two years to expend SSBG funds.

d. “Carry Over” should show funds carried from a previous fiscal year into the current reporting year.

e. “Administrative Costs” should show all other non-service use of SSBG funds—e.g., funds expended for training, licensing activities, or overhead costs.

f. This column should be totaled, and the sum placed at the bottom of the column in the “Totals” box.

13. Under “Provisions Method—Public/Private” enter a check mark on “X” in the appropriate column(s) to indicate whether a service was provided by public agencies or private agencies. In some cases, a given service may have been provided by both methods, in which case both columns would be checked for that service.

14. Enter the name, title, and telephone number of a contact person who can answer questions about the data.

15. Code Column:

Six of the columns on this form have a “C” column to the right of them. These are “Code” columns to permit a state to indicate, for expenditure data, whether each cell of data is A (actual), E (estimated), or S (sampled), and for recipient data, whether the data is based on an unduplicated (U) or duplicated (D) count of recipients. These codes will permit the Department to determine the relative degree of statistical validity of the data. Actual recipient counts and expenditure amounts must be used when available. If actual counts are not available, sampling and/or estimating may be used to derive the numbers in this report. A description of the sampling and/or estimation methods used to derive any data must appear elsewhere in the annual report.

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Report Submission Using PC Diskettes

States with personal computer (PC) equipment may submit this data using PC diskettes in addition to the hardcopy form which will be included in the complete annual report. Diskettes may be either 5¼" or 3½"; data may be submitted using Lotus 1-2-3, Quattro Pro, dBase III or IV, Wordstar, Word Perfect, or ASCII formats. Use of Lotus 1-2-3 is preferred, but any of the other formats listed may be used. If a state wishes to use a

format other than one listed here, please call Bryant Tudor on (202) 401-5535 or Frank Burns on (202) 401-5536, or write to the Office of Community Services, Administration for Children and Families, Fourth Floor—East Wing, 370 L'Enfant Promenade, SW., Washington, DC 10447. Use of diskettes can greatly reduce transcription errors and also facilitate processing of the data once received. We anticipate that many states will want to avail themselves of this method of reporting.

ANNUAL REPORT OF SERVICES FUNDED BY THE SOCIAL SERVICES BLOCK GRANT (SSBG) FOR FISCAL YEAR 19__														
STATE:			Report Covers Period of:			Mo./Yr.			Mo./Yr.			Provision Method		
Contact: _____			Title: _____			Date: _____			Number of Recipients			Expenditures		
Service	Adults	Children	C	Total	Total \$	C	SSBG \$	C	Per Adult	Per Child	C	Public	Private	
1 Adoption Services														
2 Case Management														
3 Congregate Meals														
4 Counseling Services														
5 Day Care - Adults														
6 Day Care - Children														
7 Educ./Training Services														
8 Employment Services														
9 Family Planning Services														
10 Foster Care Svs. - Adults														
11 Foster Care Svs. - Children														
12 Health Related Services														
13 Home Based Services														
14 Home Delivered Meals														
15 Housing Services														
16 Inden./Trans. Living Svs.														
17 Info. & Referral Services														
18 Legal Services														
19 Pregnancy & Parenting														
20 Prevention/Intervention														
21 Protective Svs. - Adults														
22 Protective Svs. - Children														
23 Recreation Services														
24 Residential Treatment														
25 Spec. Svs. - Youth at Risk														
26 Special Svs. - Disabled														
27 Substance Abuse Services														
28 Transportation														
29 Other Services														
30 Other Expenditures														
a. Transfers In														
b. Transfers Out														
c. Carry Forward														
d. Carry Over														
e. Administrative Costs														
TOTAL														

PART 97—CONSOLIDATION OF GRANTS TO THE INSULAR AREAS

Sec.

97.10 What is a consolidated grant?

97.11 Which jurisdictions may apply for a consolidated grant?

97.12 Which grants may be consolidated?

97.13 How does an insular area apply for a consolidated grant?

97.14 How will grant awards be made?

97.15 For what purposes can grant funds be used?

97.16 What fiscal, matching and administrative requirements apply to grantees?

AUTHORITY: Sec. 501, Pub. L. 95–134, as amended, 48 U.S.C. 1469a.

SOURCE: 47 FR 56468, Dec. 16, 1982, unless otherwise noted.

§ 97.10 What is a consolidated grant?

As used in this part, a *consolidated grant* means a grant award to an insular area, the funds of which are derived from the allocations under two or more of the programs specified in § 97.12.

§ 97.11 Which jurisdictions may apply for a consolidated grant?

The following jurisdictions (insular areas), as appropriate with respect to each block and formula grant program, may apply for a consolidated grant under this part: the Virgin Islands; Guam; American Samoa, the Commonwealth of the Northern Mariana Islands; and the Trust Territory of the Pacific Islands (the Republic of Palau). In addition, the Federated States of Micronesia and the Republic of the Marshall Islands may apply for a consolidated grant for certain PHS programs as indicated in § 97.12.

[56 FR 38346, Aug. 13, 1991]

§ 97.12 Which grants may be consolidated?

(a) These regulations apply to the consolidation of grants under the programs listed in paragraphs (b) and (c) of this section and to any additional program(s) as determined by the Secretary. The list of programs will be periodically updated in the Code of Federal Regulations through publication in the FEDERAL REGISTER.

(b) Block Grants.

(1) Preventive Health and Health Services, 42 U.S.C. 300w–300w–10.¹

(2) Alcohol and Drug Abuse and Mental Health Services, 42 U.S.C. 300x–300x–9.²

(3) Maternal and Child Health Services, 42 U.S.C. 701–709.³

(4) Social Services, 42 U.S.C. 1397–1397f.

(5) Community Services, 42 U.S.C. 9901–9912.

(6) Low-Income Home Energy Assistance, 42 U.S.C. 8621–8629.

(7) Community Youth Activity, 42 U.S.C. 11841.⁴

(c) Other Grants.

(1) Child Welfare Services, 42 U.S.C. 620, *et seq.*

(2) Developmental Disabilities, 42 U.S.C. 6021–6030.

(3) Aging Supportive Services and Senior Centers, 42 U.S.C. 3030d.

(4) Congregate Meals for the Elderly, 42 U.S.C. 3030e.

(5) Home Delivered Meals for the Elderly, 42 U.S.C. 3030f.

(6) Child Abuse and Neglect State Grants, 42 U.S.C. 5103(b).

(7) Dependent Care Planning and Development State Grants, 42 U.S.C. 9871, *et seq.*

(8) Family Violence Prevention and Services, 42 U.S.C. 10401, *et seq.*

(9) Children's Justice Act, 42 U.S.C. 5101, *et seq.*

(10) Child Development Associate Scholarship Assistance Act, 42 U.S.C. 10901, *et seq.*

(11) Emergency Community Services Homeless, 42 U.S.C. 11301.

(12) Community Food and Nutrition, 42 U.S.C. 9910a.

(13) Protection and Advocacy for Mentally Ill Individuals, 42 U.S.C. 9501.

(14) Projects for Assistance in Transition from Homelessness, 42 U.S.C. 290 (cc–21) *et seq.*

[56 FR 38346, Aug. 13, 1991]

¹ Certain Public Health Service programs for which the Federated States of Micronesia and the Republic of the Marshall Islands may apply for a consolidated grant.

² See footnote 1 in § 97.12(a)(1).

³ See footnote 1 in § 97.12(a)(1).

⁴ See footnote 1 in § 97.12(a)(1).

§ 97.13 How does an insular area apply for a consolidated grant?

(a) An insular area may apply for a consolidated grant in lieu of filing an individual application for any of the programs listed in § 97.12 for which the insular area is eligible.

(b) The chief executive officer or his designee may submit a consolidated grant application at any time prior to expenditure of the funds proposed for consolidation. The application must specify the amount of funds proposed for consolidation, the titles of the programs that are the sources of funds that are to be consolidated and the titles of the programs under whose statutory authority the funds are to be expended.

(c) The application must contain the assurances, certifications, and other information required by the statutes and regulations applicable to those programs under which funds will be expended. If any of the requirements for these latter programs are substantially the same, they may be met by a single assurance, certification, or narrative, as appropriate. The application need not meet the application or other requirements for programs which are sources of funds for the consolidated grant but under whose authority no funds will be expended.

(d) If after receiving a consolidated grant, an insular area wishes to use funds for a purpose authorized by an eligible program that is not included in the consolidated grant, or by an eligible program that was included in the grant but was not intended as a program under which funds would be expended, the insular area must submit an amended application indicating the proposed change and containing the assurances, certifications and other information applicable to that program.

§ 97.14 How will grant awards be made?

The Secretary, or his designee, will award a consolidated grant to each insular area that applies for a consolidated grant and meets the requirements of this part and of the statutes and regulations applicable to the programs under whose authority the consolidated grant funds will be expended. As long as the amount requested does

not exceed the amount for which the insular area is eligible under the programs that are being consolidated, the amount of the award will equal the amount requested in the application.

§ 97.15 For what purposes can grant funds be used?

Funds awarded under a consolidated grant must be used for purposes authorized by the statutes and regulations of the programs included in the consolidated grant. In its application for a consolidated grant the insular area is to indicate the amount of funds that will be allocated to the eligible programs.

§ 97.16 What fiscal, matching and administrative requirements apply to grantees?

(a) An insular area receiving a consolidated grant must comply with the statutes and regulations applicable to the programs under which the funds are to be used, except as otherwise provided in this part.

(b) In regard to programs included in a consolidated grant, an insular area need not comply with any of the statutory or regulatory provisions requiring recipients to match federal funds with their own or other funds.

(c) A single report may be submitted in lieu of any individual reports that may be required under the programs included in a consolidated grant.

PART 98—CHILD CARE AND DEVELOPMENT FUND**Subpart A—Goals, Purposes and Definitions**

Sec.

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98.2 Definitions.

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AUTHORITY: 42 U.S.C. 618, 9858.

SOURCE: 63 FR 39981, July 24, 1998, unless otherwise noted.

Subpart A—Goals, Purposes and Definitions

§ 98.1 Purposes.

(a) The purposes of the CCDF are:

(1) To allow each State maximum flexibility in developing child care programs and policies that best suit the needs of children and parents within that State;

(2) To promote parental choice to empower working parents to make their own decisions regarding the child care services that best suits their family's needs;

(3) To encourage States to provide consumer education information to help parents make informed choices about child care services and to promote involvement by parents and family members in the development of their children in child care settings;

(4) To assist States in delivering high-quality, coordinated early childhood care and education services to maximize parents' options and support parents trying to achieve independence from public assistance;

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(5) To assist States in improving the overall quality of child care services and programs by implementing the health, safety, licensing, training, and oversight standards established in this subchapter and in State law (including State regulations);

(6) To improve child care and development of participating children; and

(7) To increase the number and percentage of low-income children in high-quality child care settings.

(b) The purpose of this part is to provide the basis for administration of the Fund. These regulations provide that State, Territorial, and Tribal Lead Agencies:

(1) Maximize parental choice of safe, healthy and nurturing child care settings through the use of certificates and through grants and contracts, and by providing parents with information about child care programs;

(2) Include in their programs a broad range of child care providers, including center-based care, family child care, in home care, care provided by relatives and sectarian child care providers;

(3) Improve the quality and supply of child care and before- and after-school care services that meet applicable requirements and promote healthy child development and learning and family economic stability;

(4) Coordinate planning and delivery of services at all levels, including Federal, State, Tribal, and local;

(5) Design flexible programs that provide for the changing needs of recipient families and engage families in their children's development and learning;

(6) Administer the CCDF responsibly to ensure that statutory requirements are met and that adequate information regarding the use of public funds is provided;

(7) Design programs that provide uninterrupted service to families and providers, to the extent allowed under the statute, to support parental education, training, and employment and continuity of care that minimizes disruptions to children's learning and development;

(8) Provide a progression of training and professional development opportunities for caregivers, teachers, and directors to increase their effectiveness in supporting children's development

and learning and strengthen and retain (including through financial incentives and compensation improvements) the child care workforce.

[81 FR 67573, Sept. 30, 2016]

§ 98.2 Definitions.

For the purpose of this part and part 99:

The Act refers to the Child Care and Development Block Grant Act of 1990, section 5082 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508, as amended and codified at 42 U.S.C. 9858 *et seq.*

ACF means the Administration for Children and Families;

Application is a request for funding that includes the information required at § 98.13;

Assistant Secretary means the Assistant Secretary for Children and Families, Department of Health and Human Services;

Caregiver means an individual who provides child care services directly to an eligible child on a person-to-person basis;

Categories of care means center-based child care, family child care, and in home care;

Center-based child care provider means a provider licensed or otherwise authorized to provide child care services for fewer than 24 hours per day per child in a non-residential setting, unless care in excess of 24 hours is due to the nature of the parent(s)' work;

Child care certificate means a certificate (that may be a check, or other disbursement) that is issued by a grantee directly to a parent who may use such certificate only as payment for child care services or as a deposit for child care services if such a deposit is required of other children being cared for by the provider, pursuant to § 98.30. Nothing in this part shall preclude the use of such certificate for sectarian child care services if freely chosen by the parent. For the purposes of this part, a child care certificate is assistance to the parent, not assistance to the provider;

Child Care and Development Fund (CCDF) means the child care programs conducted under the provisions of the Child Care and Development Block

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Grant Act, as amended. The Fund consists of Discretionary Funds authorized under section 658B of the amended Act, and Mandatory and Matching Funds appropriated under section 418 of the Social Security Act;

Child care provider that receives assistance means a child care provider that receives Federal funds under the CCDF pursuant to grants, contracts, or loans, but does not include a child care provider to whom Federal funds under the CCDF are directed only through the operation of a certificate program;

Child care services, for the purposes of § 98.50, means the care given to an eligible child by an eligible child care provider;

Child experiencing homelessness means a child who is homeless as defined in section 725 of Subtitle VII–B of the McKinney-Vento Act (42 U.S.C. 11434a);

Child with a disability means:

(1) A child with a disability, as defined in section 602 of the Individuals with Disabilities Education Act (20 U.S.C. 1401);

(2) A child who is eligible for early intervention services under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*);

(3) A child who is less than 13 years of age and who is eligible for services under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); and

(4) A child with a disability, as defined by the State, Territory or Tribe involved;

Construction means the erection of a facility that does not currently exist;

The Department means the Department of Health and Human Services;

Director means a person who has primary responsibility for the daily operations and management for a child care provider, which may include a family child care provider, and which may serve children from birth to kindergarten entry and children in school-age child care;

Discretionary funds means the funds authorized under section 658B of the Child Care and Development Block Grant Act. The Discretionary funds were formerly referred to as the Child Care and Development Block Grant;

Eligible child means an individual who meets the requirements of § 98.20;

Eligible child care provider means:

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(1) A center-based child care provider, a family child care provider, an in-home child care provider, or other provider of child care services for compensation that—

(i) Is licensed, regulated, or registered under applicable State or local law as described in § 98.40; and

(ii) Satisfies State and local requirements, including those referred to in § 98.41 applicable to the child care services it provides; or

(2) A child care provider who is 18 years of age or older who provides child care services only to eligible children who are, by marriage, blood relationship, or court decree, the grandchild, great grandchild, siblings (if such provider lives in separate residence), niece, or nephew of such provider, and complies with any applicable requirements that govern child care provided by the relative involved;

English learner means an individual who is an English learner, as defined in section 8101 of the Elementary and Secondary Education Act of 1965 or who is limited English proficient, as defined in section 637 of the Head Start Act (42 U.S.C. 9832);

Facility means real property or modular unit appropriate for use by a grantee to carry out a child care program;

Family child care provider means one or more individual(s) who provide child care services for fewer than 24 hours per day per child, in a private residence other than the child's residence, unless care in excess of 24 hours is due to the nature of the parent(s)' work;

Indian Tribe means any Indian Tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. § 1601 *et seq.*) that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians;

In-home child care provider means an individual who provides child care services in the child's own home;

Lead Agency means the State, territorial or tribal entity, or joint inter-agency office, designated or established under §§ 98.10 and 98.16(a) to which a

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grant is awarded and that is accountable for the use of the funds provided. The Lead Agency is the entire legal entity even if only a particular component of the entity is designated in the grant award document;

Licensing or regulatory requirements means requirements necessary for a provider to legally provide child care services in a State or locality, including registration requirements established under State, local or tribal law;

Liquidation period means the applicable time period during which a fiscal year's grant shall be liquidated pursuant to the requirements at § 98.60.;

Major renovation means any renovation that has a cost equal to or exceeding \$350,000 in CCDF funds for child care centers and \$50,000 in CCDF funds for family child care homes, which amount shall be adjusted annually for inflation and published on the Office of Child Care website. If renovation costs exceed these thresholds and do not include:

- (1) Structural changes to the foundation, roof, floor, exterior or load-bearing walls of a facility, or the extension of a facility to increase its floor area; or

- (2) Extensive alteration of a facility such as to significantly change its function and purpose for direct child care services, even if such renovation does not include any structural change; and improve the health, safety, and/or quality of child care, then it shall not be considered major renovation;

Mandatory funds means the general entitlement child care funds described at section 418(a)(1) of the Social Security Act;

Matching funds means the remainder of the general entitlement child care funds that are described at section 418(a)(2) of the Social Security Act;

Modular unit means a portable structure made at another location and moved to a site for use by a grantee to carry out a child care program;

Obligation period means the applicable time period during which a fiscal year's grant shall be obligated pursuant to § 98.60;

Parent means a parent by blood, marriage or adoption and also means a legal guardian, or other person standing *in loco parentis*;

The Plan means the Plan for the implementation of programs under the CCDF;

Program period means the time period for using a fiscal year's grant and does not extend beyond the last day to liquidate funds;

Programs refers generically to all activities under the CCDF, including child care services and other activities pursuant to § 98.50 as well as quality activities pursuant to § 98.53;

Provider means the entity providing child care services;

The regulation refers to the actual regulatory text contained in parts 98 and 99 of this chapter;

Real property means land, including land improvements, structures and appurtenances thereto, excluding movable machinery and equipment;

Secretary means the Secretary of the Department of Health and Human Services;

Sectarian organization or sectarian child care provider means religious organizations or religious providers generally. The terms embrace any organization or provider that engages in religious conduct or activity or that seeks to maintain a religious identity in some or all of its functions. There is no requirement that a sectarian organization or provider be managed by clergy or have any particular degree of religious management, control, or content;

Sectarian purposes and activities means any religious purpose or activity, including but not limited to religious worship or instruction;

Services for which assistance is provided means all child care services funded under the CCDF, either as assistance directly to child care providers through grants, contracts, or loans, or indirectly as assistance to parents through child care certificates;

Sliding fee scale means a system of cost-sharing by a family based on income and size of the family, in accordance with § 98.45(1);

State means any of the States and the District of Columbia, and includes Territories and Tribes unless otherwise specified;

Teacher means a lead teacher, teacher, teacher assistant, or teacher aide who is employed by a child care provider for compensation on a regular

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basis, or a family child care provider, and whose responsibilities and activities are to organize, guide, and implement activities in a group or individual basis, or to assist a teacher or lead teacher in such activities, to further the cognitive, social, emotional, and physical development of children from birth to kindergarten entry and children in school-age child care;

Territory means the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Marianas Islands;

Territory mandatory funds means the child care funds set aside at section 418(a)(3)(C) of the Social Security Act (42 U.S.C. 618(a)(3)(C)) for payments to the Territories;

Tribal mandatory funds means the child care funds set aside at section 418(a)(3)(B) of the Social Security Act (42 U.S.C. 618(a)(3)(B)) for payments to Indian Tribes and tribal organizations;

Tribal organization means the recognized governing body of any Indian Tribe, or any legally established organization of Indians, including a consortium, which is controlled, sanctioned, or chartered by such governing body or which is democratically elected by the adult members of the Indian community to be served by such organization and which includes the maximum participation of Indians in all phases of its activities: Provided, that in any case where a contract is let or grant is made to an organization to perform services benefitting more than one Indian Tribe, the approval of each such Indian Tribe shall be a prerequisite to the letting or making of such contract or grant; and

Types of providers means the different classes of providers under each category of care. For the purposes of the CCDF, types of providers include non-profit providers, for-profit providers, sectarian providers and relatives who provide care.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67573, Sept. 30, 2016; 89 FR 15411, Mar. 1, 2024; 89 FR 52396, June 24, 2024]

§ 98.3 Effect on State law.

(a) Nothing in the Act or this part shall be construed to supersede or modify any provision of a State constitution or State law that prohibits the ex-

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penditure of public funds in or by sectarian organizations, except that no provision of a State constitution or State law shall be construed to prohibit the expenditure in or by sectarian institutions of any Federal funds provided under this part.

(b) If a State law or constitution would prevent CCDF funds from being expended for the purposes provided in the Act, without limitation, then States shall segregate State and Federal funds.

Subpart B—General Application Procedures

§ 98.10 Lead Agency responsibilities.

The Lead Agency (which may be an appropriate collaborative agency), or a joint interagency office, as designated or established by the Governor of the State (or by the appropriate Tribal leader or applicant), shall:

(a) Administer the CCDF program, directly or through other governmental or non-governmental agencies, in accordance with § 98.11;

(b) Apply for funding under this part, pursuant to § 98.13;

(c) Consult with appropriate representatives of local government in developing a Plan to be submitted to the Secretary pursuant to § 98.14(b);

(d) Hold at least one public hearing in accordance with § 98.14(c);

(e) Coordinate CCDF services pursuant to § 98.12; and

(f) Consult, collaborate, and coordinate in the development of the State Plan in a timely manner with Indian Tribes or tribal organizations in the State (at the option of the Tribe or tribal organization).

[63 FR 39981, July 24, 1998, as amended at 81 FR 67574, Sept. 30, 2016]

§ 98.11 Administration under contracts and agreements.

(a) The Lead Agency has broad authority to administer the program through other governmental or non-governmental agencies. In addition, the Lead Agency can use other public or private local agencies to implement the program; however:

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(1) The Lead Agency shall retain overall responsibility for the administration of the program, as defined in paragraph (b) of this section;

(2) The Lead Agency shall serve as the single point of contact for issues involving the administration of the grantee's CCDF program; and

(3) Administrative and implementation responsibilities undertaken by agencies other than the Lead Agency shall be governed by written agreements that specify the mutual roles and responsibilities of the Lead Agency and the other agencies in meeting the requirements of this part. The contents of the written agreement may vary based on the role the agency is asked to assume or the type of project undertaken, but must include, at a minimum, tasks to be performed, a schedule for completing tasks, a budget which itemizes categorical expenditures consistent with CCDF requirements at § 98.65(h), and indicators or measures to assess performance.

(b) In retaining overall responsibility for the administration of the program, the Lead Agency shall:

(1) Determine the basic usage and priorities for the expenditure of CCDF funds;

(2) Promulgate all rules and regulations governing overall administration of the Plan;

(3) Submit all reports required by the Secretary;

(4) Ensure that the program complies with the approved Plan and all Federal requirements;

(5) Oversee the expenditure of funds by subrecipients and contractors, in accordance with 75 CFR parts 351 to 353;

(6) Monitor programs and services;

(7) Fulfill the responsibilities of any subgrantee in any: disallowance under subpart G; complaint or compliance action under subpart J; or hearing or appeal action under part 99 of this chapter; and

(8) Ensure that all State and local or non-governmental agencies through which the State administers the program, including agencies and contractors that determine individual eligibility, operate according to the rules established for the program.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67574, Sept. 30, 2016]

§ 98.12 Coordination and consultation.

The Lead Agency shall:

(a) Coordinate the provision of services for which assistance is provided under this part with the agencies listed in § 98.14(a).

(b) Consult, in accordance with § 98.14(b), with representatives of general purpose local government during the development of the Plan; and

(c) Coordinate, to the maximum extent feasible, per § 98.10(f) with any Indian Tribes in the State receiving CCDF funds in accordance with subpart I of this part.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67574, Sept. 30, 2016]

§ 98.13 Applying for Funds.

The Lead Agency of a State or Territory shall apply for Child Care and Development funds by providing the following:

(a) The amount of funds requested at such time and in such manner as prescribed by the Secretary.

(b) The following assurances or certifications:

(1) An assurance that the Lead Agency will comply with the requirements of the Act and this part;

(2) A lobbying certification that assures that the funds will not be used for the purpose of influencing pursuant to 45 CFR part 93, and, if necessary, a Standard Form LLL (SF-LLL) that discloses lobbying payments;

(3) An assurance that the Lead Agency provides a drug-free workplace pursuant to 45 CFR 76.600, or a statement that such an assurance has already been submitted for all HHS grants;

(4) A certification that no principals have been debarred pursuant to 2 CFR 180.300;

(5) Assurances that the Lead Agency will comply with the applicable provisions regarding nondiscrimination at 45 CFR part 80 (implementing title VI of the Civil Rights Act of 1964, as amended), 45 CFR part 84 (implementing section 504 of the Rehabilitation Act of 1973, as amended), 45 CFR part 86 (implementing title IX of the Education Amendments of 1972, as amended) and 45 CFR part 91 (implementing the Age Discrimination Act of 1975, as amended), and;

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(6) Assurances that the Lead Agency will comply with the applicable provisions of Public Law 103-277, Part C—Environmental Tobacco Smoke, also known as the Pro-Children Act of 1994, regarding prohibitions on smoking.

(c) The Child Care and Development Fund Plan, at times and in such manner as required in § 98.17; and

(d) Such other information as specified by the Secretary.

[63 FR 39981, July 24, 1998, as amended at 89 FR 15412, Mar. 1, 2024]

§ 98.14 Plan process.

In the development of each Plan, as required pursuant to § 98.17, the Lead Agency shall:

(a)(1) Coordinate the provision of child care services funded under this part with other Federal, State, and local child care and early childhood development programs (including such programs for the benefit of Indian children, infants and toddlers, children with disabilities, children experiencing homelessness, and children in foster care) to expand accessibility and continuity of care as well as full-day services. The Lead Agency shall also coordinate the provision of services with the State, and if applicable, tribal agencies responsible for:

(i) Public health, including the agency responsible for immunizations;

(ii) Employment services/workforce development;

(iii) Public education (including agencies responsible for prekindergarten services, if applicable, and early intervention and preschool services provided under Part B and C of the Individuals with Disabilities Education Act (20 U.S.C. 1400));

(iv) Providing Temporary Assistance for Needy Families;

(v) Child care licensing;

(vi) Head Start collaboration, as authorized by the Head Start Act (42 U.S.C. 9831 *et seq.*);

(vii) State Advisory Council on Early Childhood Education and Care (designated or established pursuant to the Head Start Act (42 U.S.C. 9831 *et seq.*) or similar coordinating body;

(viii) Statewide after-school network or other coordinating entity for out-of-school time care (if applicable);

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(ix) Emergency management and response;

(x) Child and Adult Care Food Program (CACFP) authorized by the National School Lunch Act (42 U.S.C. 1766) and other relevant nutrition programs;

(xi) Services for children experiencing homelessness, including State Coordinators of Education for Homeless Children and Youth (EHCY State Coordinators) and, to the extent practicable, local liaisons designated by Local Educational Agencies (LEAs) in the State as required by the McKinney-Vento Act (42 U.S.C. 11432) and Continuum of Care grantees;

(xii) Medicaid and the State children's health insurance programs (42 U.S.C. 1396 *et seq.*, 1397aa *et seq.*);

(xiii) Mental health services; and

(xiv) Child care resources and referral agencies, child care consumer education organizations, and providers of early childhood education training and professional development.

(2) Provide a description of the results of the coordination with each of these agencies in the CCDF Plan.

(3) If the Lead Agency elects to combine funding for CCDF services with any other early childhood program, provide a description in the CCDF Plan of how the Lead Agency will combine and use the funding.

(4) Demonstrate in the CCDF Plan how the State, Territory, or Tribe encourages partnerships among its agencies, other public agencies, Indian Tribes and Tribal organizations, and private entities, including faith-based and community-based organizations, to leverage existing service delivery systems for child care and development services and to increase the supply and quality of child care and development services and to increase the supply and quality of child care services for children who are less than 13 years of age, such as by implementing voluntary shared service alliance models.

(b) Consult with appropriate representatives of local governments;

(c)(1) Hold at least one hearing in the State, after at least 20 days of statewide public notice, to provide to the public an opportunity to comment on the provision of child care services under the Plan.

(2) The hearing required by paragraph (c)(1) shall be held before the Plan is submitted to ACF, but no earlier than nine months before the Plan becomes effective.

(3) In advance of the hearing required by this section, the Lead Agency shall make available to the public the content of the Plan as described in § 98.16 that it proposes to submit to the Secretary, which shall include posting the Plan content on a Web site.

(d) Make the submitted and final Plan, any Plan amendments, and any approved requests for temporary relief (in accordance with § 98.19) publicly available on a Web site.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67574, Sept. 30, 2016]

§ 98.15 Assurances and certifications.

(a) The Lead Agency shall include the following assurances in its CCDF Plan:

(1) Upon approval, it will have in effect a program that complies with the provisions of the CCDF Plan, and that is administered in accordance with the Child Care and Development Block Grant Act of 1990, as amended, section 418 of the Social Security Act, and all other applicable Federal laws and regulations;

(2) The parent(s) of each eligible child within the area served by the Lead Agency who receives or is offered child care services for which financial assistance is provided is given the option either:

(i) To enroll such child with a child care provider that has a grant or contract for the provision of the service; or

(ii) To receive a child care certificate as defined in § 98.2;

(3) In cases in which the parent(s), pursuant to § 98.30, elects to enroll their child with a provider that has a grant or contract with the Lead Agency, the child will be enrolled with the eligible provider selected by the parent to the maximum extent practicable;

(4) In accordance with § 98.30, the child care certificate offered to parents shall be of a value commensurate with the subsidy value of child care services provided under a grant or contract;

(5) With respect to State and local regulatory requirements (or tribal reg-

ulatory requirements), health and safety requirements, payment rates, and registration requirements, State or local (or tribal) rules, procedures or other requirements promulgated for the purpose of the CCDF will not significantly restrict parental choice from among categories of care or types of providers, pursuant to § 98.30(f).

(6) That if expenditures for pre-Kindergarten services are used to meet the maintenance-of-effort requirement, the State has not reduced its level of effort in full-day/full-year child care services, pursuant to § 98.55(h)(1).

(7) Training and professional development requirements comply with § 98.44 and are applicable to caregivers, teaching staff, and directors working for child care providers of services for which assistance is provided under the CCDF.

(8) To the extent practicable, enrollment and eligibility policies support the fixed costs of providing child care services by delinking provider payment rates from an eligible child's occasional absences in accordance with § 98.45(m);

(9) The State will maintain or implement early learning and developmental guidelines that are developmentally appropriate for all children from birth to kindergarten entry, describing what such children should know and be able to do, and covering the essential domains of early childhood development (cognition, including language arts and mathematics; social, emotional and physical development; and approaches toward learning) for use statewide by child care providers and caregivers. Such guidelines shall—

(i) Be research-based and developmentally, culturally, and linguistically appropriate, building in a forward progression, and aligned with entry to kindergarten;

(ii) Be implemented in consultation with the State educational agency and the State Advisory Council on Early Childhood Education and Care (designated or established pursuant to section 642B(b)(1)(A)(i) of the Head Start Act (42 U.S.C. 9837b(b)(1)(A)(i)) or similar coordinating body, and in consultation with child development and content experts; and

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(iii) Be updated as determined by the State.

(10) Funds received by the State to carry out this subchapter will not be used to develop or implement an assessment for children that—

(i) Will be the primary or sole basis for a child care provider being determined to be ineligible to participate in the program carried out under this subchapter;

(ii) Will be used as the primary or sole basis to provide a reward or sanction for an individual provider;

(iii) Will be used as the primary or sole method for assessing program effectiveness; or

(iv) Will be used to deny children eligibility to participate in the program carried out under this subchapter.

(11) To the extent practicable and appropriate, any code or software for child care information systems or information technology that a Lead Agency or other agency expends CCDF funds to develop must be made available upon request to other public agencies, including public agencies in other States, for their use in administering child care or related programs.

(b) The Lead Agency shall include the following certifications in its CCDF Plan:

(1) The State has developed the CCDF Plan in consultation with the State Advisory Council on Early Childhood Education and Care (designated or established pursuant to section 642B(b)(1)(A)(i) of the Head Start Act (42 U.S.C. 9837b(b)(1)(A)(i))) or similar coordinating body, pursuant to § 98.14(a)(1)(vii);

(2) In accordance with § 98.31, the Lead Agency has procedures in place to ensure that providers of child care services for which assistance is provided under the CCDF, afford parents unlimited access to their children and to the providers caring for their children, during the normal hours of operations and whenever such children are in the care of such providers;

(3) As required by § 98.32, the State maintains a record of substantiated parental complaints and makes information regarding such complaints available to the public on request;

(4) It will collect and disseminate to parents of eligible children, the general

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public and, where applicable, child care providers, consumer education information that will promote informed child care choices, information on access to other programs for which families may be eligible, and information on developmental screenings, as required by § 98.33;

(5) In accordance with § 98.33(a), that the State makes public, through a consumer-friendly and easily accessible Web site, the results of monitoring and inspection reports, as well as the number of deaths, serious injuries, and instances of substantiated child abuse that occurred in child care settings;

(6) There are in effect licensing requirements applicable to child care services provided within the State, pursuant to § 98.40;

(7) There are in effect within the State (or other area served by the Lead Agency), under State or local (or tribal) law, requirements designed to protect the health and safety of children that are applicable to child care providers that provide services for which assistance is made available under the CCDF, pursuant to § 98.41;

(8) In accordance with § 98.42(a), procedures are in effect to ensure that child care providers of services for which assistance is provided under the CCDF comply with all applicable State or local (or tribal) health and safety requirements;

(9) Caregivers, teachers, and directors of child care providers comply with the State's, Territory's, or Tribe's procedures for reporting child abuse and neglect as required by section 106(b)(2)(B)(i) of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5106a(b)(2)(B)(i)), if applicable, or other child abuse reporting procedures and laws in the service area, as required by § 98.41(e);

(10) There are in effect monitoring policies and practices pursuant to § 98.42;

(11) Payment rates for the provision of child care services, in accordance with § 98.45, are sufficient to ensure equal access for eligible children to comparable child care services in the State or sub-State area that are provided to children whose parents are not eligible to receive assistance under this

program or under any other Federal or State child care assistance programs;

(12) Payment practices of child care providers of services for which assistance is provided under the CCDF reflect generally accepted payment practices of child care providers that serve children who do not receive CCDF assistance, pursuant to § 98.45(m); and

(13) There are in effect policies to govern the use and disclosure of confidential and personally identifiable information about children and families receiving CCDF assistance and child care providers receiving CCDF funds.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67575, Sept. 30, 2016; 89 FR 15412, Mar. 1, 2024]

§ 98.16 Plan provisions.

A CCDF Plan shall contain the following:

(a) Specification of the Lead Agency whose duties and responsibilities are delineated in § 98.10;

(b) A description of processes the Lead Agency will use to monitor administrative and implementation responsibilities undertaken by agencies other than the Lead Agency including descriptions of written agreements, monitoring and auditing procedures, and indicators or measures to assess performance pursuant to § 98.11(a)(3);

(c) The assurances and certifications listed under § 98.15;

(d)(1) A description of how the CCDF program will be administered and implemented, if the Lead Agency does not directly administer and implement the program;

(2) Identification of the public or private entities designated to receive private donated funds and the purposes for which such funds will be expended, pursuant to § 98.55(f);

(e) A description of the coordination and consultation processes involved in the development of the Plan and the provision of services, including a description of public-private partnership activities that promote business involvement in meeting child care needs pursuant to § 98.14;

(f) A description of the public hearing process, pursuant to § 98.14(c);

(g) Definitions of the following terms for purposes of determining eligibility, pursuant to §§ 98.20(a) and 98.46:

(1) Special needs child;

(2) Physical or mental incapacity (if applicable);

(3) Attending (a job training or educational program);

(4) Job training and educational program;

(5) Residing with;

(6) Working;

(7) Protective services (if applicable), including whether children in foster care are considered in protective services for purposes of child care eligibility; and whether respite care is provided to custodial parents of children in protective services.

(8) Very low income; and

(9) In loco parentis;

(h) A description and demonstration of eligibility determination and redetermination processes to promote continuity of care for children and stability for families receiving CCDF services, including:

(1) An eligibility redetermination period of no less than 12 months in accordance with § 98.21(a);

(2) A graduated phase-out for families whose income exceeds the Lead Agency's threshold to initially qualify for CCDF assistance, but does not exceed 85 percent of State median income, pursuant to § 98.21(b);

(3) Processes that take into account irregular fluctuation in earnings, pursuant to § 98.21(c);

(4) Processes to incorporate additional eligible children in the family size in accordance with § 98.21(d);

(5) Procedures and policies for presumptive eligibility in accordance with § 98.21(e), including procedures for tracking the number of presumptively eligible children;

(6) Procedures and policies to ensure that parents are not required to unduly disrupt their education, training, or employment to complete initial eligibility determination or re-determination, pursuant to § 98.21(f);

(7) Processes for using eligibility for other programs to verify eligibility for CCDF in accordance with § 98.21(g);

(8) Limiting any requirements to report changes in circumstances in accordance with § 98.21(h);

(9) Policies that take into account children's development and learning

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when authorizing child care services pursuant to § 98.21(i); and,

(10) Other policies and practices such as timely eligibility determination and processing of applications;

(i) For child care services pursuant to § 98.50:

(1) A description of such services and activities;

(2) Any limits established for the provision of in-home care and the reasons for such limits pursuant to § 98.30(e)(1)(iii);

(3) A list of political subdivisions in which such services and activities are offered, if such services and activities are not available throughout the entire service area;

(4) A description of how the Lead Agency will meet the needs of certain families specified at § 98.50(e);

(5) Any eligibility criteria, priority rules, and definitions established pursuant to §§ 98.20 and 98.46;

(j) A description of the activities to provide comprehensive consumer and provider education, including the posting of monitoring and inspection reports, pursuant to § 98.33, to increase parental choice, and to improve the quality of child care, pursuant to § 98.53;

(k) A description of the sliding fee scale(s) (including any factors other than income and family size used in establishing the fee scale(s)) that provide(s) for cost-sharing by the families that receive child care services for which assistance is provided under the CCDF and how co-payments are affordable for families, pursuant to § 98.45(l). This shall include a description of the criteria established by the Lead Agency, if any, for waiving contributions for families;

(l) A description of the health and safety requirements, applicable to all providers of child care services for which assistance is provided under the CCDF, in effect pursuant to § 98.41, and any exemptions to those requirements for relative providers made in accordance with § 98.42(c);

(m) A description of child care standards for child care providers of services for which assistance is provided under the CCDF, in accordance with § 98.41(d), that includes group size limits, child-

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staff ratios, and required qualifications for caregivers, teachers, and directors;

(n) A description of monitoring and other enforcement procedures in effect to ensure that child care providers comply with applicable health and safety requirements pursuant to § 98.42;

(o) A description of criminal background check requirements, policies, and procedures in accordance with § 98.43, including a description of the requirements, policies, and procedures in place to respond to other States', Territories', and Tribes' requests for background check results in order to accommodate the 45 day timeframe;

(p) A description of training and professional development requirements for caregivers, teaching staff, and directors of providers of services for which assistance is provided in accordance with § 98.44;

(q) A description of the child care certificate payment system(s), including the form or forms of the child care certificate, pursuant to § 98.30(c);

(r) Payment rates and a summary of the facts, including a local market rate survey or alternative methodology relied upon to determine that the rates provided are sufficient to ensure equal access pursuant to § 98.45;

(s) A detailed description of the State's hotline for complaints, its process for substantiating and responding to complaints, whether or not the State uses monitoring as part of its process for responding to complaints for both CCDF and non-CCDF providers, how the State maintains a record of substantiated parental complaints, and how it makes information regarding those complaints available to the public on request, pursuant to § 98.32;

(t) A detailed description of the procedures in effect for affording parents unlimited access to their children whenever their children are in the care of the provider, pursuant to § 98.31;

(u) A detailed description of the licensing requirements applicable to child care services provided, any exemption to licensing requirements that is applicable to child care providers of services for which assistance is provided under the CCDF and a demonstration of why such exemption does

not endanger the health, safety, or development of children, and a description of how such licensing requirements are effectively enforced, pursuant to § 98.40;

(v) Pursuant to § 98.33(f), the definitions or criteria used to implement the exception, provided in section 407(e)(2) of the Social Security Act (42 U.S.C. 607(e)(2)), to individual penalties in the TANF work requirement applicable to a single custodial parent caring for a child under age six;

(w)(1) When any Matching funds under § 98.55(b) are claimed, a description of the efforts to ensure that pre-Kindergarten programs meet the needs of working parents;

(2) When State pre-Kindergarten expenditures are used to meet more than 10% of the amount required at § 98.55(c)(1), or for more than 10% of the funds available at § 98.55(b), or both, a description of how the State will coordinate its pre-Kindergarten and child care services to expand the availability of child care;

(x) A description of the supply of child care available regardless of subsidy participation relative to the population of children requiring child care, including care for infants and toddlers, children with disabilities as defined by the Lead Agency, children who receive care during nontraditional hours, and children in underserved geographic areas, including the data sources used to identify shortages in the supply of child care providers;

(y) A description of the Lead Agency's strategies and the actions it will take to address the supply shortages identified in paragraph (x) of this section and improve parent choice specifically for families eligible to participate in CCDF, including:

(1) For families needing care during nontraditional hours, which may include strategies such as higher payment rates, engaging with home-based child care networks, partnering with employers that have employees working nontraditional hours, and grants or contracts for direct services;

(2) For families needing infant and toddler care, which must include grants or contracts for direct services pursuant to § 98.30(b) and described further in paragraph (z) of this section

and may include additional strategies such as enhanced payment rates, training and professional development opportunities for the child care workforce, and engaging with staffed family child care networks and/or child care provider membership organizations;

(3) For families needing care for children with disabilities, which must include grants or contracts for direct services pursuant to § 98.30(b) and described further in paragraph (z) of this section and may include additional strategies such as enhanced payment rates, training and professional development opportunities for the child care workforce, and engaging with staffed family child care networks and/or child care provider membership organizations;

(4) For families in underserved geographic areas, which must include grants or contracts for direct services pursuant to § 98.30(b) and described further in paragraph (z) of this section and may include additional strategies such as enhanced payment rates, training and professional development opportunities for the child care workforce, and engaging with staffed family child care networks and/or child care provider membership organizations; and,

(5) A method of tracking progress toward goals to increase supply and support equal access and parental choice;

(z) A description of how the Lead Agency will use grants or contracts for direct services to achieve supply building goals for children in underserved geographic areas, infants and toddlers, children with disabilities as defined by the Lead Agency, and, at Lead Agency option, children who receive care during nontraditional hours. This must include a description of the proportion of the shortages for these groups would be filled by contracted or grant funded slots. Lead Agencies must continue to provide CCDF families the option to choose a certificate for the purposes of acquiring care;

(aa) A description of how the Lead Agency will improve the quality of child care services for children in underserved geographic areas, infants and toddlers, children with disabilities as

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defined by the Lead Agency, and children who receive care during nontraditional hours;

(bb) A description of how the Lead Agency prioritizes increasing access to high-quality child care and development services for children of families in areas that have significant concentrations of poverty and unemployment and that do not have sufficient numbers of such programs, pursuant to § 98.46;

(cc) A description of how the Lead Agency develops and implements strategies to strengthen the business practices of child care providers to expand the supply, and improve the quality of, child care services;

(dd) A demonstration of how the State, Territory or Tribe will address the needs of children, including the need for safe child care, before, during and after a state of emergency declared by the Governor or a major disaster or emergency (as defined by section 102 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5122) through a Statewide Disaster Plan (or Disaster Plan for a Tribe's service area) that:

(1) For a State, is developed in collaboration with the State human services agency, the State emergency management agency, the State licensing agency, the State health department or public health department, local and State child care resource and referral agencies, and the State Advisory Council on Early Childhood Education and Care (designated or established pursuant to section 642B(b)(I)(A)(i) of the Head Start Act (42 U.S.C. 9837b(b)(1)(A)(i))) or similar coordinating body; and

(2) Includes the following components:

(i) Guidelines for continuation of child care subsidies and child care services, which may include the provision of emergency and temporary child care services during a disaster, and temporary operating standards for child care after a disaster;

(ii) Coordination of post-disaster recovery of child care services; and

(iii) Requirements that child care providers of services for which assistance is provided under the CCDF, as well as other child care providers as de-

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termined appropriate by the State, Territory or Tribe, have in place:

(A) Procedures for evacuation, relocation, shelter-in-place, lock-down, communication and reunification with families, continuity of operations, accommodations of infants and toddlers, children with disabilities, and children with chronic medical conditions; and

(B) Procedures for staff and volunteer emergency preparedness training and practice drills, including training requirements for child care providers of services for which assistance is provided under CCDF at § 98.41(a)(1)(vii);

(ee) A description of generally-accepted payment practices applicable to providers of child care services for which assistance is provided under this part, pursuant to § 98.45(m), including practices to ensure timely payment for services, to delink provider payments from children's occasional absences to the extent practicable, cover mandatory fees, and pay based on a full or part-time basis;

(ff) A description of internal controls to ensure integrity and accountability, processes in place to investigate and recover fraudulent payments and to impose sanctions on clients or providers in response to fraud, and procedures in place to document and verify eligibility, pursuant to § 98.68;

(gg) A description of how the Lead Agency will provide outreach and services to eligible families with limited English proficiency and persons with disabilities and facilitate participation of child care providers with limited English proficiency and disabilities in the subsidy system;

(hh) A description of policies to prevent suspension, expulsion, and denial of services due to behavior of children birth to age five in child care and other early childhood programs receiving assistance under this part, which must be disseminated as part of consumer and provider education efforts in accordance with § 98.33(b)(1)(v);

(ii) Designation of a State, territorial, or tribal entity to which child care providers must submit reports of any serious injuries or deaths of children occurring in child care, in accordance with § 98.42(b)(4);

(jj) A description of how the Lead Agency will support child care providers in the successful engagement of families in children's learning and development;

(kk) A description of how the Lead Agency will respond to complaints submitted through the national hotline and website, required in section 658L(b) of the CCDBG Act of 2014 (42 U.S.C.9858j(b)), including the designee responsible for receiving and responding to such complaints regarding both licensed and license-exempt child care providers; and

(ll) Such other information as specified by the Secretary.

[81 FR 67576, Sept. 30, 2016, as amended at 89 FR 15412, Mar. 1, 2024; 89 FR 52396, June 24, 2024]

§ 98.17 Period covered by Plan.

(a) For States, Territories, and Indian Tribes the Plan shall cover a period of three years.

(b) The Lead Agency shall submit a new Plan prior to the expiration of the time period specified in paragraph (a) of this section, at such time as required by the Secretary in written instructions.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67578, Sept. 30, 2016]

§ 98.18 Approval and disapproval of Plans and Plan amendments.

(a) *Plan approval.* The Assistant Secretary will approve a Plan that satisfies the requirements of the Act and this part. Plans will be approved not later than the 90th day following the date on which the Plan submittal is received, unless a written agreement to extend that period has been secured.

(b) *Plan amendments.* (1) Approved Plans shall be amended whenever a substantial change in the program occurs. A Plan amendment shall be submitted within 60 days of the effective date of the change. Plan amendments will be approved or denied not later than the 90th day following the date on which the amendment is received, unless a written agreement to extend that period has been secured.

(2) Lead Agencies must ensure advanced written notice is provided to affected parties (*i.e.*, parents and child care providers) of substantial changes

in the program that adversely affect eligibility, payment rates, and/or sliding fee scales.

(c) *Appeal of disapproval of a Plan or Plan amendment.* (1) An applicant or Lead Agency dissatisfied with a determination of the Assistant Secretary pursuant to paragraphs (a) or (b) of this section with respect to any Plan or amendment may, within 60 days after the date of receipt of notification of such determination, file a petition with the Assistant Secretary asking for reconsideration of the issue of whether such Plan or amendment conforms to the requirements for approval under the Act and pertinent Federal regulations.

(2) Within 30 days after receipt of such petition, the Assistant Secretary shall notify the applicant or Lead Agency of the time and place at which the hearing for the purpose of reconsidering such issue will be held.

(3) Such hearing shall be held not less than 30 days, nor more than 90 days, after the notification is furnished to the applicant or Lead Agency, unless the Assistant Secretary and the applicant or Lead Agency agree in writing on another time.

(4) Action pursuant to an initial determination by the Assistant Secretary described in paragraphs (a) and (b) of this section that a Plan or amendment is not approvable shall not be stayed pending the reconsideration, but in the event that the Assistant Secretary subsequently determines that the original decision was incorrect, the Assistant Secretary shall certify restitution forthwith in a lump sum of any funds incorrectly withheld or otherwise denied. The hearing procedures are described in part 99 of this chapter.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67578, Sept. 30, 2016]

§ 98.19 Requests for temporary waivers.

(a) *Requests for relief.* The Secretary may temporarily waive one or more of the requirements contained in the Act or this part, with the exception of State Match and Maintenance of Effort requirements for a State, consistent with the conditions described in section 658I(c)(1) of the Act (42 U.S.C.

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9858g(c)(1)), provided that the waiver request:

(1) Describes circumstances that prevent the State, Territory, or Tribe from complying with any statutory or regulatory requirements of this part;

(2) By itself, contributes to or enhances the State's, Territory's, or Tribe's ability to carry out the purposes of the Act and this part;

(3) Will not contribute to inconsistency with the purposes of the Act or this part, and;

(4) Meets the requirements set forth in paragraphs (b) through (g) of this section.

(b) *Types.* Types of waivers include:

(1) *Transitional and legislative waivers.* Lead Agencies may apply for temporary waivers meeting the requirements described in paragraph (a) of this section that would provide transitional relief from conflicting or duplicative requirements preventing implementation, or an extended period of time in order for a State, territorial or tribal legislature to enact legislation to implement the provisions of this subchapter. Such waivers are:

(i) Limited to a two-year period;

(ii) May not be extended, notwithstanding paragraph (f) of this section;

(iii) Are designed to provide States, Territories and Tribes at most one full legislative session to enact legislation to implement the provisions of the Act or this part, and;

(iv) Are conditional, dependent on progress towards implementation, and may be terminated by the Secretary at any time in accordance with paragraph (e) of this section.

(2) *Waivers for extraordinary circumstances.* States, Territories and Tribes may apply for waivers meeting the requirements described in paragraph (a) of this section, in cases of extraordinary circumstances, which are defined as temporary circumstances or situations, such as a natural disaster or financial crisis. Such waivers are:

(i) Limited to an initial period of no more than 2 years from the date of approval;

(ii) May be extended, in accordance with paragraph (f) of this section, for at most one additional year from the date of approval of the extension, and;

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(iii) May be terminated by the Secretary at any time in accordance with paragraph (e) of this section.

(c) *Contents.* Waiver requests must be submitted to the Secretary in writing and:

(1) Indicate which type of waiver, as detailed in paragraph (b) of this section, the State, Territory or Tribe is requesting;

(2) Detail each sanction or provision of the Act or regulations that the State, Territory or Tribe seeks relief from;

(3) Describe how a waiver from that sanction or provision will, by itself, improve delivery of child care services for children; and

(4) Certify and describe how the health, safety, and well-being of children served through assistance received under this part will not be compromised as a result of the waiver.

(d) *Notification.* Within 90 days after receipt of the waiver request or, if additional follow up information has been requested, the receipt of such information, the Secretary will notify the Lead Agency of the approval or disapproval of the request.

(e) *Termination.* The Secretary shall terminate approval of a request for a waiver authorized under the Act or this section if the Secretary determines, after notice and opportunity for a hearing based on the rules of procedure in part 99 of this chapter, that the performance of a State, Territory or Tribe granted relief under this section has been inadequate, or if such relief is no longer necessary to achieve its original purposes.

(f) *Renewal.* Where permitted, the Secretary may approve or disapprove a request from a State, Territory or Tribe for renewal of an existing waiver under the Act or this section for a period no longer than one year. A State, Territory or Tribe seeking to renew their waiver approval must inform the Secretary of this intent no later than 30 days prior to the expiration date of the waiver. The State, Territory or Tribe shall re-certify in its extension request the provisions in paragraph (a) of this section, and shall also explain the need for additional time of relief from such sanction(s) or provisions.

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(g) *Restrictions.* The Secretary may not:

(1) Permit Lead Agencies to alter the federal eligibility requirements for eligible children, including work requirements, job training, or educational program participation, that apply to the parents of eligible children under this part;

(2) Waive anything related to the Secretary's authority under this part; or

(3) Require or impose any new or additional requirements in exchange for receipt of a waiver if such requirements are not specified in the Act.

[81 FR 67578, Sept. 30, 2016, as amended at 89 FR 15413, Mar. 1, 2024]

Subpart C—Eligibility for Services

§ 98.20 A child's eligibility for child care services.

(a) To be eligible for services under § 98.50, a child shall, at the time of eligibility determination or redetermination:

(1)(i) Be under 13 years of age; or,

(ii) At the option of the Lead Agency, be under age 19 and physically or mentally incapable of caring for himself or herself, or under court supervision;

(2)(i) Reside with a family whose income does not exceed 85 percent of the State's median income (SMI), which must be based on the most recent SMI data that is published by the Bureau of the Census, for a family of the same size; and

(ii) Whose family assets do not exceed \$1,000,000 (as certified by such family member); and

(3)(i) Reside with a parent or parents who are working or attending a job training or educational program; or

(ii) Receive, or need to receive, protective services, which may include specific populations of vulnerable children as identified by the Lead Agency, and reside with a parent or parents other than the parent(s) described in paragraph (a)(3)(i) of this section.

(A) At grantee option, the requirements in paragraph (a)(2) of this section may be waived for families eligible for child care pursuant to this paragraph, if determined to be necessary on a case-by-case basis.

(B) At grantee option, the waiver provisions in paragraph (a)(3)(ii)(A) of this section apply to children in foster care when defined in the Plan, pursuant to § 98.16(g)(7).

(b) A grantee or other administering agency may establish eligibility conditions or priority rules in addition to those specified in this section and § 98.46, which shall be described in the Plan pursuant to § 98.16(i)(5), so long as they do not:

(1) Discriminate against children on the basis of race, national origin, ethnic background, sex, religious affiliation, or disability;

(2) Limit parental rights provided under subpart D of this part;

(3) Violate the provisions of this section, § 98.46, or the Plan. In particular, such conditions or priority rules may not be based on a parent's preference for a category of care or type of provider. In addition, such additional conditions or rules may not be based on a parent's choice of a child care certificate; or

(4) Impact eligibility other than at the time of eligibility determination or redetermination.

(c) For purposes of implementing the citizenship eligibility verification requirements mandated by title IV of the Personal Responsibility and Work Opportunity Reconciliation Act, 8 U.S.C. 1601 *et seq.*, only the citizenship and immigration status of the child, who is the primary beneficiary of the CCDF benefit, is relevant. Therefore, a Lead Agency or other administering agency may not condition a child's eligibility for services under § 98.50 based upon the citizenship or immigration status of their parent or the provision of any information about the citizenship or immigration status of their parent.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67579, Sept. 30, 2016]

§ 98.21 Eligibility determination processes.

(a) A Lead Agency shall re-determine a child's eligibility for child care services no sooner than 12 months following the initial determination or most recent redetermination, subject to the following:

(1) During the period of time between determinations or redeterminations, if

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the child met all of the requirements in § 98.20(a) on the date of the most recent eligibility determination or redetermination, the child shall be considered eligible and will receive services at least at the same level, regardless of:

(i) A change in family income, if that family income does not exceed 85 percent of SMI for a family of the same size; or

(ii) A temporary change in the ongoing status of the child's parent as working or attending a job training or educational program. A temporary change shall include, at a minimum:

(A) Any time-limited absence from work for an employed parent due to reasons such as need to care for a family member or an illness;;

(B) Any interruption in work for a seasonal worker who is not working between regular industry work seasons;

(C) Any student holiday or break for a parent participating in training or education;

(D) Any reduction in work, training or education hours, as long as the parent is still working or attending training or education;

(E) Any other cessation of work or attendance at a training or education program that does not exceed three months or a longer period of time established by the Lead Agency;

(F) Any change in age, including turning 13 years old during the eligibility period; and

(G) Any change in residency within the State, Territory, or Tribal service area.

(2)(i) Lead Agencies have the option, but are not required, to discontinue assistance due to a parent's loss of work or cessation of attendance at a job training or educational program that does not constitute a temporary change in accordance with paragraph (a)(1)(ii) of this section. However, if the Lead Agency exercises this option, it must continue assistance at least at the same level for a period of not less than three months after each such loss or cessation in order for the parent to engage in job search and resume work, or resume attendance at a job training or educational activity.

(ii) At the end of the minimum three-month period of continued assistance, if the parent is engaged in a qualifying

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work, education, or training activity with income below 85% of SMI, assistance cannot be terminated and the child must continue receiving assistance until the next scheduled re-determination, or at Lead Agency option, for an additional minimum 12-month eligibility period.

(iii) If a Lead Agency chooses to initially qualify a family for CCDF assistance based on a parent's status of seeking employment or engaging in job search, the Lead Agency has the option to end assistance after a minimum of three months if the parent has still not found employment, although assistance must continue if the parent becomes employed during the job search period.

(3) Lead Agencies cannot increase family co-payment amounts, established in accordance with § 98.45(k), within the minimum 12-month eligibility period except as described in paragraph (b)(3) of this section.

(4) Because a child meeting eligibility requirements at the most recent eligibility determination or redetermination is considered eligible between redeterminations as described in paragraph (a)(1) of this section, any payment for such a child shall not be considered an error or improper payment under subpart K of this part due to a change in the family's circumstances.

(5) Notwithstanding paragraph (a)(1), the Lead Agency may discontinue assistance prior to the next re-determination in limited circumstances where there have been:

(i) Excessive unexplained absences despite multiple attempts by the Lead Agency or designated entity to contact the family and provider, including prior notification of possible discontinuation of assistance;

(A) If the Lead Agency chooses this option, it shall define the number of unexplained absences that shall be considered excessive;

(B) [Reserved]

(ii) A change in residency outside of the State, Territory, or Tribal service area; or

(iii) Substantiated fraud or intentional program violations that invalidate prior determinations of eligibility.

(b)(1) Lead Agencies that establish family income eligibility at a level less than 85 percent of SMI for a family of the same size (in order for a child to initially qualify for assistance) must provide a graduated phase-out by implementing two-tiered eligibility thresholds, with the second tier of eligibility (used at the time of eligibility re-determination) set at:

(i) 85 percent of SMI for a family of the same size; or

(ii) An amount lower than 85 percent of SMI for a family of the same size, but above the Lead Agency's initial eligibility threshold, that:

(A) Takes into account the typical household budget of a low income family; and

(B) Provides justification that the second eligibility threshold is:

(1) Sufficient to accommodate increases in family income over time that are typical for low-income workers and that promote and support family economic stability; and

(2) Reasonably allows a family to continue accessing child care services without unnecessary disruption.

(2) At re-determination, a child shall be considered eligible (pursuant to paragraph (a) of this section) if their parents, at the time of redetermination, are working or attending a job training or educational program even if their income exceeds the Lead Agency's income limit to initially qualify for assistance, as long as their income does not exceed the second tier of the eligibility described in (b)(1);

(3) A family meeting the conditions described in paragraph (b)(2) of this section shall be eligible for services pursuant to the conditions described in § 98.20 and all other paragraphs of this section, with the exception of the co-payment restrictions at paragraph (a)(3) of this section. To help families transition off of child care assistance, Lead Agencies may gradually adjust co-pay amounts for families whose children are determined eligible under the graduated phase-out conditions described in paragraph (b)(2) and may require additional reporting on changes in family income as described in paragraph (h)(3) of this section, provided such requirements do not constitute an undue burden, pursuant to conditions

described in paragraphs (h)(2)(ii) and (iii) of this section.

(c) The Lead Agency shall establish processes for initial determination and redetermination of eligibility that take into account irregular fluctuation in earnings, including policies that ensure temporary increases in income, including temporary increases that result in monthly income exceeding 85 percent of SMI (calculated on a monthly basis), do not affect eligibility or family co-payments.

(d) The Lead Agency shall establish policies and processes to incorporate additional eligible children in the family size (*e.g.*, siblings or foster siblings), including ensuring a minimum of 12 months of eligibility between eligibility determination and redetermination as described in paragraph (a) of this section for children previously determined eligible and for new children who are determined eligible, without placing undue reporting burden on families.

(e) At a Lead Agency's option, a child may be considered presumptively eligible for up to three months and begin to receive child care subsidy prior to full documentation and eligibility determination:

(1) The Lead Agency may issue presumptive eligibility prior to full documentation of a child's eligibility if the Lead Agency first obtains a less burdensome minimum verification requirement from the family.

(2) If, after full documentation is provided, a child is determined to be ineligible, the Lead Agency shall ensure that a child care provider is paid and shall not recover funds paid or owed to a child care provider for services provided as a result of the presumptive eligibility determination except in cases of fraud or intentional program violation by the provider.

(3) Any CCDF payment made on behalf of a presumptively eligible child prior to the final eligibility determination shall not be considered an error or improper payment under subpart K of this part and will not be subject to disallowance so long as the payment was not for a service period longer than the period of presumptive eligibility.

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(4) If a child is determined to be eligible, the period of presumptive eligibility will apply to the minimum of 12 months of eligibility prior to re-determination described in paragraph (a) of this section.

(5) The Secretary may deny the use of federal funds for direct services under presumptive eligibility for Lead Agencies under a corrective action plan for error rate reporting pursuant to § 98.102(c).

(f) The Lead Agency shall establish procedures and policies to ensure parents, especially parents receiving assistance through the Temporary Assistance for Needy Families (TANF) program are not required to unduly disrupt their education, training, or employment in order to complete the eligibility determination or re-determination process, including the use of online applications and other measures, to the extent practicable.

(g) At the Lead Agency's option, enrollment in other benefit programs or documents or verification used for other benefit programs may be used to verify eligibility as appropriate according to § 98.68(c) for CCDF, such as:

(1) Benefit programs with income eligibility requirements aligned with the income eligibility at § 98.20(a)(2)(i) may be used to verify a family's income eligibility; and

(2) Benefit programs with other eligibility requirements aligned with § 98.20(a)(3) may verify:

(i) A family's work or attendance at a job training or educational program;

(ii) A family's status as receiving, or need to receive, protective services; or

(iii) Other information needed for eligibility.

(h) The Lead Agency shall specify in the Plan any requirements for parents to notify the Lead Agency of changes in circumstances during the minimum 12-month eligibility period, and describe efforts to ensure such requirements do not place an undue burden on eligible families that could impact continued eligibility between redeterminations.

(1) The Lead Agency must require families to report a change at any point during the minimum 12-month period, limited to:

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(i) If the family's income exceeds 85% of SMI, taking into account irregular income fluctuations; or

(ii) At the option of the Lead Agency, the family has experienced a non-temporary cessation of work, training, or education.

(2) Any additional requirements the Lead Agency chooses, at its option, to impose on parents to provide notification of changes in circumstances to the Lead Agency or entities designated to perform eligibility functions shall not constitute an undue burden on families. Any such requirements shall:

(i) Limit notification requirements to items that impact a family's eligibility (*e.g.*, only if income exceeds 85 percent of SMI, or there is a non-temporary change in the status of the child's parent as working or attending a job training or educational program) or those that enable the Lead Agency to contact the family or pay providers;

(ii) Not require an office visit in order to fulfill notification requirements; and

(iii) Offer a range of notification options (*e.g.*, phone, email, online forms, extended submission hours) to accommodate the needs of parents;

(3) During a period of graduated phase-out, the Lead Agency may require additional reporting on changes in family income in order to gradually adjust family co-payments, if desired, as described in paragraph (b)(3) of this section.

(4) Lead Agencies must allow families the option to voluntarily report changes on an ongoing basis.

(i) Lead Agencies are required to act on this information provided by the family if it would reduce the family's co-payment or increase the family's subsidy.

(ii) Lead Agencies are prohibited from acting on information that would reduce the family's subsidy unless the information provided indicates the family's income exceeds 85 percent of SMI for a family of the same size, taking into account irregular income fluctuations, or, at the option of the Lead Agency, the family has experienced a non-temporary change in the work, training, or educational status.

(i) Lead Agencies must take into consideration children's development and

learning and promote continuity of care when authorizing child care services.

(j) Lead Agencies are not required to limit authorized child care services strictly based on the work, training, or educational schedule of the parent(s) or the number of hours the parent(s) spend in work, training, or educational activities.

[81 FR 67579, Sept. 30, 2016, as amended at 89 FR 15413, Mar. 1, 2024; 89 FR 52397, June 24, 2024; 89 FR 85071, Oct. 25, 2024]

Subpart D—Program Operations (Child Care Services)—Parental Rights and Responsibilities

§ 98.30 Parental choice.

(a) The parent or parents of an eligible child who receives or is offered child care services shall be offered a choice:

(1) To enroll the child with an eligible child care provider that has a grant or contract for the provision of such services, if such services are available; or

(2) To receive a child care certificate as defined in § 98.2. Such choice shall be offered any time that child care services are made available to a parent.

(b)(1) Lead Agencies shall increase parent choice by providing some portion of the delivery of direct services via grants or contracts, including at a minimum for children in underserved geographic areas, infants and toddlers, and children with disabilities.

(2) When a parent elects to enroll the child with a provider that has a grant or contract for the provision of child care services, the child will be enrolled with the provider selected by the parent to the maximum extent practicable.

(c) In cases in which a parent elects to use a child care certificate, such certificate:

(1) Will be issued directly to the parent;

(2) Shall be of a value commensurate with the subsidy value of the child care services provided under paragraph (a)(1) of this section;

(3) May be used as a deposit for child care services if such a deposit is re-

quired of other children being cared for by the provider;

(4) May be used for child care services provided by a sectarian organization or agency, including those that engage in religious activities, if those services are chosen by the parent;

(5) May be expended by providers for any sectarian purpose or activity that is part of the child care services, including sectarian worship or instruction;

(6) Shall not be considered a grant or contract to a provider but shall be considered assistance to the parent.

(d) Child care certificates shall be made available to any parents offered child care services.

(e)(1) For child care services, certificates under paragraph (a)(2) of this section shall permit parents to choose from a variety of child care categories, including:

(i) Center-based child care;

(ii) Family child care; and

(iii) In-home child care, with limitations, if any, imposed by the Lead Agency and described in its Plan at § 98.16(1)(2). Under each of the above categories, care by a sectarian provider may not be limited or excluded.

(2) Lead Agencies shall provide information regarding the range of provider options under paragraph (e)(1) of this section, including care by sectarian providers and relatives, to families offered child care services.

(f) With respect to State and local regulatory requirements under § 98.40, health and safety requirements under § 98.41, and payment rates under § 98.45, CCDF funds will not be available to a Lead Agency if State or local rules, procedures or other requirements promulgated for purposes of the CCDF significantly restrict parental choice by:

(1) Expressly or effectively excluding:

(i) Any category of care or type of provider, as defined in § 98.2; or

(ii) Any type of provider within a category of care; or

(2) Having the effect of limiting parental access to or choice from among such categories of care or types of providers, as defined in § 98.2, with the exception of in-home care; or

(3) Excluding a significant number of providers in any category of care or of any type as defined in § 98.2.

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(g) As long as provisions at paragraph (f) of this section are met, parental choice provisions shall not be construed as prohibiting a Lead Agency from establishing policies that require providers of child care services for which assistance is provided under this part to meet higher standards of quality, such as those identified in a quality rating and improvement system or other transparent system of quality indicators.

(h) Parental choice provisions shall not be construed as prohibiting a Lead Agency from providing parents with information and incentives that encourage the selection of high-quality child care.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67580, Sept. 30, 2016; 89 FR 15413, Mar. 1, 2024]

§ 98.31 Parental access.

The Lead Agency shall have in effect procedures to ensure that providers of child care services for which assistance is provided afford parents unlimited access to their children, and to the providers caring for their children, during normal hours of provider operation and whenever the children are in the care of the provider. The Lead Agency shall provide a detailed description in the Plan of such procedures.

[81 FR 67581, Sept. 30, 2016]

§ 98.32 Parental complaints.

The State shall:

(a) Establish or designate a hotline or similar reporting process for parents to submit complaints about child care providers;

(b) Maintain a record of substantiated parent complaints;

(c) Make information regarding such parental complaints available to the public on request; and

(d) The Lead Agency shall provide a detailed description in the Plan of how:

(1) Complaints are substantiated and responded to, including whether or not the State uses monitoring as part of its process for responding to complaints for both CCDF and non-CCDF providers; and,

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(2) A record of substantiated complaints is maintained and is made available.

[81 FR 67581, Sept. 30, 2016]

§ 98.33 Consumer and provider education.

The Lead Agency shall:

(a) Certify that it will collect and disseminate consumer education information to parents of eligible children, the general public, and providers through a consumer-friendly and easily accessible Web site that ensures the widest possible access to services for families who speak languages other than English and persons with disabilities, including:

(1) Lead Agency processes, including:

(i) The process for licensing child care providers pursuant to § 98.40;

(ii) The process for conducting monitoring and inspections of child care providers pursuant to § 98.42;

(iii) Policies and procedures related to criminal background checks for child care providers pursuant to § 98.43; and

(iv) The offenses that prevent individuals from serving as child care providers.

(2) A localized list of all licensed child care providers, and, at the discretion of the Lead Agency, all eligible child care providers (other than an individual who is related to all children for whom child care services are provided), differentiating between licensed and license-exempt providers, searchable by zip code;

(3) The quality of a provider as determined by the Lead Agency through a quality rating and improvement system or other transparent system of quality indicators, if such information is available for the provider;

(4) Results of monitoring and inspection reports for all eligible and licensed child care providers (other than an individual who is related to all children for whom child care services are provided), including those required at § 98.42 and those due to major substantiated complaints about failure to comply with provisions at § 98.41 and Lead Agency child care policies. Lead Agencies shall post in a timely manner full monitoring and inspection reports, either in plain language or with a plain

language summary, for parents and child care providers to understand, and shall establish a process for correcting inaccuracies in the reports. Such results shall include:

- (i) Information on the date of such inspection;
- (ii) Areas of compliance and non-compliance;
- (iii) Information on corrective action taken by the State and child care provider, where applicable;
- (iv) Any health and safety violations, including any fatalities and serious injuries occurring at the provider, prominently displayed on the report or summary; and
- (v) A minimum of 3 years of results where available.

(5) Aggregate data for each year for eligible providers including:

- (i) Number of deaths (for each provider category and licensing status);
 - (ii) Number of serious injuries (for each provider category and licensing status);
 - (iii) Instances of substantiated child abuse that occurred in child care settings; and,
 - (iv) Total number of children in care (for each provider category and licensing status).
- (6) Referrals to local child care resource and referral organizations.
- (7) Directions on how parents can contact the Lead Agency or its designee and other programs to help them understand information included on the Web site.

(8) The sliding fee scale for parent co-payments pursuant to § 98.45(1), including the co-payment amount a family may expect to pay and policies for waiving co-payments.

(b) Certify that it will collect and disseminate, through resource and referral organizations or other means as determined by the State, including, but not limited to, through the Web site described in paragraph (a) of this section, to parents of eligible children and the general public, and where applicable providers, information about:

- (1) The availability of the full diversity of child care services to promote informed parental choice, including information about:
 - (i) The availability of child care services under this part and other pro-

grams for which families may be eligible, as well as the availability of financial assistance to obtain child care services;

(ii) Other programs for which families that receive assistance under this part may be eligible, including:

(A) Temporary Assistance for Needy Families (TANF) (42 U.S.C. 601 *et seq.*);

(B) Head Start and Early Head Start (42 U.S.C. 9831 *et seq.*);

(C) Low-Income Home Energy Assistance Program (LIHEAP) (42 U.S.C. 8621 *et seq.*);

(D) Supplemental Nutrition Assistance Program (SNAP) (7 U.S.C. 2011 *et seq.*);

(E) Special supplemental nutrition program for women, infants, and children (42 U.S.C. 1786);

(F) Child and Adult Care Food Program (CACFP) (42 U.S.C. 1766);

(G) Medicaid and the State children's health insurance programs (42 U.S.C. 1396 *et seq.*, 1397aa *et seq.*);

(iii) Programs carried out under section 619 and part C of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1419, 1431 *et seq.*);

(iv) Research and best practices concerning children's development, meaningful parent and family engagement, and physical health and development, particularly healthy eating and physical activity; and

(v) State policies regarding social emotional behavioral health of children which may include positive behavioral health intervention and support models for birth to school-age or age-appropriate, and policies to prevent suspension and expulsion of children birth to age five in child care and other early childhood programs, as described in the Plan pursuant to § 98.16(ee), receiving assistance under this part.

(c) Provide information on developmental screenings to parents as part of the intake process for families receiving assistance under this part, and to providers through training and education, including:

- (1) Information on existing resources and services the State can make available in conducting developmental screenings and providing referrals to services when appropriate for children who receive assistance under this part, including the coordinated use of the

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Early and Periodic Screening, Diagnosis, and Treatment program (42 U.S.C. 1396 *et seq.*) and developmental screening services available under section 619 and part C of the Individuals with Disabilities Education Act (20 U.S.C. 1419, 1431 *et seq.*); and

(2) A description of how a family or eligible child care provider may utilize the resources and services described in paragraph (c)(1) of this section to obtain developmental screenings for children who receive assistance under this part who may be at risk for cognitive or other developmental delays, which may include social, emotional, physical, or linguistic delays.

(d) For families that receive assistance under this part, provide specific information about the child care provider selected by the parent, including health and safety requirements met by the provider pursuant to § 98.41, any licensing or regulatory requirements met by the provider, date the provider was last inspected, any history of violations of these requirements, and any voluntary quality standards met by the provider. Information must also describe how CCDF subsidies are designed to promote equal access in accordance with § 98.45, how to submit a complaint through the hotline at § 98.32(a), and how to contact local resource and referral agencies or other community-based supports that assist parents in finding and enrolling in quality child care.

(e) Provide linkages to databases related to paragraph (a) to HHS for implementing a national Web site and other uses as determined by the Secretary.

(f) Inform parents who receive TANF benefits about the requirement at section 407(e)(2) of the Social Security Act (42 U.S.C. 607(e)(2)) that the TANF agency make an exception to the individual penalties associated with the work requirement for any single custodial parent who has a demonstrated inability to obtain needed child care for a child under six years of age. The information may be provided directly by the Lead Agency, or, pursuant to § 98.11, other entities, and shall include:

(1) The procedures the TANF agency uses to determine if the parent has a

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demonstrated inability to obtain needed child care;

(2) The criteria or definitions applied by the TANF agency to determine whether the parent has a demonstrated inability to obtain needed child care, including:

- (i) “Appropriate child care”;
- (ii) “Reasonable distance”;
- (iii) “Unsuitability of informal child care”;
- (iv) “Affordable child care arrangements”;

(3) The clarification that assistance received during the time an eligible parent receives the exception referred to in paragraph (f) of this section will count toward the time limit on Federal benefits required at section 408(a)(7) of the Social Security Act (42 U.S.C. 608(a)(7)).

(g) Include in the triennial Plan the definitions or criteria the TANF agency uses in implementing the exception to the work requirement specified in paragraph (f) of this section.

[81 FR 67581, Sept. 30, 2016, as amended at 89 FR 15414, Mar. 1, 2024]

§ 98.34 Parental rights and responsibilities.

Nothing under this part shall be construed or applied in any manner to infringe on or usurp the moral and legal rights and responsibilities of parents or legal guardians.

Subpart E—Program Operations (Child Care Services)—Lead Agency and Provider Requirements

§ 98.40 Compliance with applicable State and local regulatory requirements.

(a) Lead Agencies shall:

(1) Certify that they have in effect licensing requirements applicable to child care services provided within the area served by the Lead Agency;

(2) Describe in the Plan exemption(s) to licensing requirements, if any, for child care services for which assistance is provided, and a demonstration for how such exemption(s) do not endanger the health, safety, or development of children who receive services from such providers. Lead Agencies must provide the required description and

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demonstration for any exemptions based on:

- (i) Provider category, type, or setting;
- (ii) Length of day;
- (iii) Providers not subject to licensing because the number of children served falls below a State-defined threshold; and
- (iv) Any other exemption to licensing requirements; and

(3) Provide a detailed description in the Plan of the requirements under paragraph (a)(1) of this section and of how they are effectively enforced.

(b)(1) This section does not prohibit a Lead Agency from imposing more stringent standards and licensing or regulatory requirements on child care providers of services for which assistance is provided under the CCDF than the standards or requirements imposed on other child care providers.

(2) Any such additional requirements shall be consistent with the safeguards for parental choice in § 98.30(f).

[63 FR 39981, July 24, 1998, as amended at 81 FR 67582, Sept. 30, 2016]

§ 98.41 Health and safety requirements.

(a) Each Lead Agency shall certify that there are in effect, within the State (or other area served by the Lead Agency), under State, local or tribal law, requirements (appropriate to provider setting and age of children served) that are designed, implemented, and enforced to protect the health and safety of children. Such requirements must be applicable to child care providers of services for which assistance is provided under this part. Such requirements, which are subject to monitoring pursuant to § 98.42, shall:

(1) Include health and safety topics consisting of, at a minimum:

(i) The prevention and control of infectious diseases (including immunizations); with respect to immunizations, the following provisions apply:

(A) As part of their health and safety provisions in this area, Lead Agencies shall assure that children receiving services under the CCDF are age-appropriately immunized. Those health and safety provisions shall incorporate (by reference or otherwise) the latest recommendation for childhood immuniza-

tions of the respective State, territorial, or tribal public health agency.

(B) Notwithstanding this paragraph (a)(1)(i), Lead Agencies may exempt:

(1) Children who are cared for by relatives (defined as grandparents, great grandparents, siblings (if living in a separate residence), aunts, and uncles), provided there are no other unrelated children who are cared for in the same setting.

(2) Children who receive care in their own homes, provided there are no other unrelated children who are cared for in the home.

(3) Children whose parents object to immunization on religious grounds.

(4) Children whose medical condition contraindicates immunization.

(C) Lead Agencies shall establish a grace period that allows children experiencing homelessness and children in foster care to receive services under this part while providing their families (including foster families) a reasonable time to take any necessary action to comply with immunization and other health and safety requirements.

(1) The length of such grace period shall be established in consultation with the State, Territorial or Tribal health agency.

(2) Any payment for such child during the grace period shall not be considered an error or improper payment under subpart K of this part.

(3) The Lead Agency may also, at its option, establish grace periods for other children who are not experiencing homelessness or in foster care.

(4) Lead Agencies must coordinate with licensing agencies and other relevant State, Territorial, Tribal, and local agencies to provide referrals and support to help families of children receiving services during a grace period comply with immunization and other health and safety requirements;

(ii) Prevention of sudden infant death syndrome and use of safe sleeping practices;

(iii) Administration of medication, consistent with standards for parental consent;

(iv) Prevention and response to emergencies due to food and allergic reactions;

(v) Building and physical premises safety, including identification of and

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protection from hazards, bodies of water, and vehicular traffic;

(vi) Prevention of shaken baby syndrome, abusive head trauma, and child maltreatment;

(vii) Emergency preparedness and response planning for emergencies resulting from a natural disaster, or a man-caused event (such as violence at a child care facility), within the meaning of those terms under section 602(a)(1) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5195a(a)(1)) that shall include procedures for evacuation, relocation, shelter-in-place and lock down, staff and volunteer emergency preparedness training and practice drills, communication and reunification with families, continuity of operations, and accommodation of infants and toddlers, children with disabilities, and children with chronic medical conditions;

(viii) Handling and storage of hazardous materials and the appropriate disposal of biocontaminants;

(ix) Appropriate precautions in transporting children, if applicable;

(x) Pediatric first aid and cardiopulmonary resuscitation;

(xi) Recognition and reporting of child abuse and neglect, in accordance with the requirement in paragraph (e) of this section; and

(xii) May include requirements relating to:

(A) Nutrition (including age-appropriate feeding);

(B) Access to physical activity;

(C) Caring for children with special needs; or

(D) Any other subject area determined by the Lead Agency to be necessary to promote child development or to protect children's health and safety.

(2) Include minimum health and safety training on the topics above, as described in § 98.44.

(b) Lead Agencies may not set health and safety standards and requirements other than those required in paragraph (a) of this section that are inconsistent with the parental choice safeguards in § 98.30(f).

(c) The requirements in paragraph (a) of this section shall apply to all providers of child care services for which assistance is provided under this part, within the area served by the Lead

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Agency, except the relatives specified at § 98.42(c).

(d) Lead Agencies shall describe in the Plan standards for child care services for which assistance is provided under this part, appropriate to strengthening the adult and child relationship in the type of child care setting involved, to provide for the safety and developmental needs of the children served, that address:

(1) Group size limits for specific age populations;

(2) The appropriate ratio between the number of children and the number of caregivers, in terms of age of children in child care; and

(3) Required qualifications for caregivers in child care settings as described at § 98.44(a)(4).

(e) Lead Agencies shall certify that caregivers, teachers, and directors of child care providers within the State or service area will comply with the State's, Territory's, or Tribe's child abuse reporting requirements as required by section 106(b)(2)(B)(i) of the Child Abuse and Prevention and Treatment Act (42 U.S.C. 5106a(b)(2)(B)(i)) or other child abuse reporting procedures and laws in the service area.

[81 FR 67582, Sept. 30, 2016]

§ 98.42 Enforcement of licensing and health and safety requirements.

(a) Each Lead Agency shall certify in the Plan that procedures are in effect to ensure that child care providers of services for which assistance is made available in accordance with this part, within the area served by the Lead Agency, comply with all applicable State, local, or tribal health and safety requirements, including those described in § 98.41.

(b) Each Lead Agency shall certify in the Plan it has monitoring policies and practices applicable to all child care providers and facilities eligible to deliver services for which assistance is provided under this part. The Lead Agency shall:

(1) Ensure individuals who are hired as licensing inspectors are qualified to inspect those child care providers and facilities and have received training in related health and safety requirements appropriate to provider setting and age

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of children served. Training shall include, but is not limited to, those requirements described in § 98.41, and all aspects of the State, Territory, or Tribe's licensure requirements;

(2) Require inspections of child care providers and facilities, performed by licensing inspectors (or qualified inspectors designated by the Lead Agency), as specified below:

(i) For licensed child care providers and facilities,

(A) Not less than one pre-licensure inspection for compliance with health, safety, and fire standards, and

(B) Not less than annually, an unannounced inspection for compliance with all child care licensing standards, which shall include an inspection for compliance with health and safety, (including, but not limited to, those requirements described in § 98.41) and fire standards (inspectors may inspect for compliance with all three standards at the same time); and

(ii) For license-exempt child care providers and facilities that are eligible to provide services for which assistance is made available in accordance with this part, an annual inspection for compliance with health and safety (including, but not limited to, those requirements described in § 98.41), and fire standards;

(iii) Coordinate, to the extent practicable, monitoring efforts with other Federal, State, and local agencies that conduct similar inspections.

(iv) The Lead Agency may, at its option:

(A) Use differential monitoring or a risk-based approach to design annual inspections, provided that the contents covered during each monitoring visit is representative of the full complement of health and safety requirements;

(B) Develop alternate monitoring requirements for care provided in the child's home that are appropriate to the setting; and

(3) Ensure the ratio of licensing inspectors to such child care providers and facilities is maintained at a level sufficient to enable the State, Territory, or Tribe to conduct effective inspections on a timely basis in accordance with the applicable Federal, State, Territory, Tribal, and local law;

(4) Require child care providers to report to a designated State, Territorial, or Tribal entity any serious injuries or deaths of children occurring in child care.

(c) For the purposes of this section and § 98.41, Lead Agencies may exclude grandparents, great grandparents, siblings (if such providers live in a separate residence), aunts, or uncles, from the term "child care providers." If the Lead Agency chooses to exclude these providers, the Lead Agency shall provide a description and justification in the CCDF Plan, pursuant to § 98.16(l), of requirements, if any, that apply to these providers.

[81 FR 67583, Sept. 30, 2016]

§ 98.43 Criminal background checks.

(a)(1) States, Territories, and Tribes, through coordination of the Lead agency with other State, territorial, and tribal agencies, shall have in effect:

(i) Requirements, policies, and procedures to require and conduct background checks, and make a determination of eligibility for child care staff members (including prospective child care staff members) of all licensed, regulated, or registered child care providers and all child care providers eligible to deliver services for which assistance is provided under this part as described in paragraph (a)(2) of this section;

(ii) Licensing, regulation, and registration requirements, as applicable, that prohibit the employment of child care staff members as described in paragraph (c) of this section; and

(iii) Requirements, policies, and procedures in place to respond as expeditiously as possible to other States', Territories', and Tribes' requests for background check results in order to accommodate the 45 day timeframe required in paragraph (e)(1) of this section.

(2) In this section:

(i) Child care provider means a center based child care provider, a family child care provider, or another provider of child care services for compensation and on a regular basis that:

(A) Is not an individual who is related to all children for whom child care services are provided; and

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(B) Is licensed, regulated, or registered under State law or eligible to receive assistance provided under this subchapter; and

(ii) Child care staff member means an individual (other than an individual who is related to all children for whom child care services are provided):

(A) Who is employed by a child care provider for compensation, including contract employees or self-employed individuals;

(B) Whose activities involve the care or supervision of children for a child care provider or unsupervised access to children who are cared for or supervised by a child care provider; or

(C) Any individual residing in a family child care home who is age 18 and older.

(b) A criminal background check for a child care staff member under paragraph (a) of this section shall include:

(1) A Federal Bureau of Investigation fingerprint check using Next Generation Identification;

(2) A search of the National Crime Information Center's National Sex Offender Registry; and

(3) A search of the following registries, repositories, or databases in the State where the child care staff member resides and each State where such staff member resided during the preceding five years:

(i) State criminal registry or repository, with the use of fingerprints being:

(A) Required in the State where the staff member resides;

(B) Optional in other States;

(ii) State sex offender registry or repository; and

(iii) State-based child abuse and neglect registry and database.

(c)(1) The State, Territory, or Tribe in coordination with the Lead Agency shall find a child care staff member ineligible for employment for services for which assistance is made available in accordance with this part, if such individual:

(i) Refuses to consent to the criminal background check described in paragraph (b) of this section;

(ii) Knowingly makes a materially false statement in connection with such criminal background check;

(iii) Is registered, or is required to be registered, on a State sex offender reg-

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istry or repository or the National Sex Offender Registry; or

(iv) Has been convicted of a felony consisting of:

(A) Murder, as described in section 1111 of title 18, United States Code;

(B) Child abuse or neglect;

(C) A crime against children, including child pornography;

(D) Spousal abuse;

(E) A crime involving rape or sexual assault;

(F) Kidnapping;

(G) Arson;

(H) Physical assault or battery; or

(I) Subject to paragraph (e)(4) of this section, a drug-related offense committed during the preceding 5 years; or

(v) Has been convicted of a violent misdemeanor committed as an adult against a child, including the following crimes: child abuse, child endangerment, and sexual assault, or of any misdemeanor involving child pornography.

(2) A child care provider described in paragraph (a)(2)(i) of this section shall be ineligible for assistance provided in accordance with this subchapter if the provider employs a staff member who is ineligible for employment under paragraph (c)(1) of this section.

(d)(1) A child care provider covered by paragraph (a)(2)(i) of this section shall submit a request, to the appropriate State, Territorial, or Tribal agency, defined clearly on the State or Territory Web site described in paragraph (g) of this section, for a criminal background check described in paragraph (b) of this section, for each child care staff member (including prospective child care staff members) of the provider.

(2) Subject to paragraph (d)(3) of this section, the provider shall submit such a request:

(i) Prior to the date an individual becomes a child care staff member of the provider; and

(ii) Not less than once during each 5-year period for any existing staff member.

(3) A child care provider shall not be required to submit a request under paragraph (d)(2) of this section for a child care staff member if:

(i) The staff member received qualifying results from a background check

described in paragraph (b) of this section;

(A) Within 5 years before the latest date on which such a submission may be made; and

(B) While employed by or seeking employment by another child care provider within the State;

(ii) The State provided to the first provider a qualifying background check result, consistent with this subchapter, for the staff member; and

(iii) The staff member is employed by a child care provider within the State, or has been separated from employment from a child care provider within the State for a period of not more than 180 consecutive days.

(4) A prospective staff member may begin work for a child care provider described in paragraph (a)(2)(i) of this section after receiving qualifying results for either the check described at paragraph (b)(1) or (b)(3)(i) of this section in the State where the prospective staff member resides. Pending completion of all background check components in paragraph (b) of this section, the staff member must be supervised at all times by an individual who received a qualifying result on a background check described in paragraph (b) of this section within the past five years.

(e) *Background check results.* (1) The State, Territory, or Tribe shall carry out the request of a child care provider for a criminal background check as expeditiously as possible, but not to exceed 45 days after the date on which the provider submitted the request, and shall provide the results of the criminal background check to such provider and to the current or prospective staff member.

(2) States, Territories, and Tribes shall ensure the privacy of background check results by:

(i) Providing the results of the criminal background check to the provider in a statement that indicates whether a child care staff member (including a prospective child care staff member) is eligible or ineligible for employment described in paragraph (c)(1) of this section, without revealing any disqualifying crime or other related information regarding the individual.

(ii) If the child care staff member is ineligible for such employment due to

the background check, the State, Territory, or Tribe will, when providing the results of the background check, include information related to each disqualifying crime, in a report to the staff member or prospective staff member, along with information on the opportunity to appeal, described in paragraph (e)(3) of this section.

(iii) No State, Territory, or Tribe shall publicly release or share the results of individual background checks, except States and Tribes may release aggregated data by crime as listed under paragraph (c)(1)(iv) of this section from background check results, as long as such data is not personally identifiable information.

(3) States, Territories, and Tribes shall provide for a process by which a child care staff member (including a prospective child care staff member) may appeal the results of a criminal background check conducted under this section to challenge the accuracy or completeness of the information contained in such member's criminal background report. The State, Territory, and Tribe shall ensure that:

(i) Each child care staff member is given notice of the opportunity to appeal;

(ii) A child care staff member will receive clear instructions about how to complete the appeals process if the child care staff member wishes to challenge the accuracy or completeness of the information contained in such member's criminal background report;

(iii) If the staff member files an appeal, the State, Territory, or Tribe will attempt to verify the accuracy of the information challenged by the child care staff member, including making an effort to locate any missing disposition information related to the disqualifying crime;

(iv) The appeals process is completed in a timely manner for each child care staff member; and

(v) Each child care staff member shall receive written notice of the decision. In the case of a negative determination, the decision should indicate the State's efforts to verify the accuracy of information challenged by the child care staff member, as well as any additional appeals rights available to the child care staff member.

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(4) States, Territories, and Tribes may allow for a review process through which the State, Territory, or Tribe may determine that a child care staff member (including a prospective child care staff member) disqualified for a crime specified in paragraph (c)(1)(iv)(I) of this section is eligible for employment described in paragraph (c)(1) of this section, notwithstanding paragraph (c)(2) of this section. The review process shall be consistent with title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*);

(5) Nothing in this section shall be construed to create a private right of action if a provider has acted in accordance with this section.

(f) *Fees for background checks.* Fees that a State, Territory, or Tribe may charge for the costs of processing applications and administering a criminal background check as required by this section shall not exceed the actual costs for the processing and administration.

(g) *Transparency.* The State or Territory must ensure that its policies and procedures under this section, including the process by which a child care provider or other State or Territory may submit a background check request, are published in the Web site of the State or Territory as described in § 98.33(a) and the Web site of local lead agencies.

(h) *Disqualification for other crimes.* (1) Nothing in this section shall be construed to prevent a State, Territory, or Tribe from disqualifying individuals as child care staff members based on their conviction for crimes not specifically listed in paragraph (c)(1) of this section that bear upon the fitness of an individual to provide care for and have responsibility for the safety and well-being of children.

(2) Nothing in this section shall be construed to alter or otherwise affect the rights and remedies provided for child care staff members or prospective staff members residing in a State that disqualifies individuals as child care staff members for crimes not specifically provided for under this section.

[81 FR 67584, Sept. 30, 2016, as amended at 89 FR 15414, Mar. 1, 2024]

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§ 98.44 Training and professional development.

(a) The Lead Agency must describe in the Plan the State or Territory framework for training, professional development, and postsecondary education for caregivers, teachers, and directors, including those working in school-age care, that:

(1) Is developed in consultation with the State Advisory Council on Early Childhood Education and Care (designated or established pursuant to section 642B(b)(1)(A)(i) of the Head Start Act (42 U.S.C. 9837b(b)(1)(A)(i))) or similar coordinating body;

(2) May engage training and professional development providers, including higher education in aligning training and education opportunities with the State's framework;

(3) Addresses professional standards and competencies, career pathways, advisory structure, articulation, and workforce information and financing;

(4) Establishes qualifications in accordance with § 98.41(d)(3) designed to enable child care and school-age care providers that provide services for which assistance is provided in accordance with this part to promote the social, emotional, physical, and cognitive development of children and improve the knowledge and skills of caregivers, teachers and directors in working with children and their families;

(5) Includes professional development conducted on an ongoing basis, providing a progression of professional development (which may include encouraging the pursuit of postsecondary education);

(6) Reflects current research and best practices relating to the skills necessary for caregivers, teachers, and directors to meet the developmental needs of participating children and engage families, including culturally and linguistically appropriate practices; and

(7) Improves the quality, diversity, stability, and retention (including financial incentives and compensation improvements) of caregivers, teachers, and directors.

(b) The Lead Agency must describe in the Plan its established requirements for pre-service or orientation (to be completed within three months) and

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ongoing professional development for caregivers, teachers, and directors of child care providers of services for which assistance is provided under the CCDF that, to the extent practicable, align with the State framework:

(1) Accessible pre-service or orientation training in health and safety standards appropriate to the setting and age of children served that addresses:

(i) Each of the requirements relating to matters described in § 98.41(a)(1)(i) through (xi) and specifying critical health and safety training that must be completed before caregivers, teachers, and directors are allowed to care for children unsupervised;

(ii) At the Lead Agency option, matters described in § 98.41(a)(1)(xii); and

(iii) Child development, including the major domains (cognitive, social, emotional, physical development and approaches to learning);

(2) Ongoing, accessible professional development, aligned to a progression of professional development, including the minimum annual requirement for hours of training and professional development for eligible caregivers, teachers and directors, appropriate to the setting and age of children served, that:

(i) Maintains and updates health and safety training standards described in § 98.41(a)(1)(i) through (xi), and at the Lead Agency option, in § 98.41(a)(1)(xii);

(ii) Incorporates knowledge and application of the State's early learning and developmental guidelines for children birth to kindergarten (where applicable);

(iii) Incorporates social-emotional behavior intervention models for children birth through school-age, which may include positive behavior intervention and support models including preventing and reducing expulsions and suspensions of preschool-aged and school-aged children;

(iv) To the extent practicable, are appropriate for a population of children that includes:

(A) Different age groups;

(B) English learners;

(C) Children with developmental delays and disabilities; and

(D) Native Americans, including Indians, as the term is defined in section 4

of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b) (including Alaska Natives within the meaning of that term), and Native Hawaiians (as defined in section 6207 of the Elementary and Secondary Education Act of 1965);

(v) To the extent practicable, awards continuing education units or is credit-bearing; and

(vi) Shall be accessible to caregivers, teachers, and directors supported through Indian tribes or tribal organizations that receive assistance under this subchapter.

[81 FR 67585, Sept. 30, 2016]

§ 98.45 Equal access.

(a) The Lead Agency shall certify that the payment rates for the provision of child care services under this part are sufficient to ensure equal access, for eligible families in the area served by the Lead Agency, to child care services comparable to those provided to families not eligible to receive CCDF assistance or child care assistance under any other Federal, State, or tribal programs.

(b) The Lead Agency shall provide in the Plan a summary of the data and facts relied on to determine that its payment rates ensure equal access. At a minimum, the summary shall include facts showing:

(1) How a choice of the full range of providers is made available, and the extent to which child care providers participate in the CCDF subsidy system and any barriers to participation including barriers related to payment rates and practices, based on information obtained in accordance with paragraph (d)(2) of this section;

(2) How payment rates are adequate and have been established based on the most recent market rate survey or alternative methodology conducted in accordance with paragraph (c) of this section;

(3) How base payment rates enable providers to meet health, safety, quality, and staffing requirements in accordance with paragraphs (f)(1)(ii)(A) and (f)(2)(ii) of this section;

(4) How the Lead Agency took the cost of higher quality into account in accordance with paragraph (f)(2)(iii) of this section, including how payment

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rates for higher-quality care, as defined by the Lead Agency using a quality rating and improvement system or other system of quality indicators, relate to the estimated cost of care at each level of quality;

(5) How co-payments based on a sliding fee scale are affordable and do not exceed 7 percent of income for all families, as stipulated at paragraph (1) of this section; if applicable, a rationale for the Lead Agency's policy on whether child care providers may charge additional amounts to families above the required family co-payment, including a demonstration that the policy promotes affordability and access; analysis of the interaction between any such additional amounts with the required family co-payments, and of the ability of subsidy payment rates to provide access to care without additional fees; and data on the extent to which CCDF providers charge such additional amounts (based on information obtained in accordance with paragraph (d)(2) of this section);

(6) How the Lead Agency's payment practices support equal access to a range of providers by providing stability of funding and encouraging more child care providers to serve children receiving CCDF subsidies, in accordance with paragraph (m) of this section;

(7) How and on what factors the Lead Agency differentiates payment rates; and

(8) Any additional facts the Lead Agency considered in determining that its payment rates ensure equal access.

(c) The Lead Agency shall demonstrate in the Plan that it has developed and conducted, not earlier than two years before the date of the submission of the Plan, either:

(1) A statistically valid and reliable survey of the market rates for child care services; or

(2) An alternative methodology, such as a cost estimation model, that has been:

- (i) Proposed by the Lead Agency; and
- (ii) Approved in advance by ACF.

(d) The Lead Agency must:

(1) Ensure that the market rate survey or alternative methodology reflects variations by geographic loca-

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tion, category of provider, and age of child;

(2) Track through the market rate survey or alternative methodology, or through a separate source, information on the extent to which:

(i) Child care providers are participating in the CCDF subsidy program and any barriers to participation, including barriers related to payment rates and practices; and

(ii) CCDF child care providers charge amounts to families more than the required family co-payment (under paragraph (1) of this section) in instances where the provider's price exceeds the subsidy payment, including data on the size and frequency of any such amounts.

(e) Prior to conducting the market rate survey or alternative methodology, the Lead Agency must consult with:

(1) The State Advisory Council on Early Childhood Education and Care (designated or established pursuant to section 642B(b)(1)(A)(i) of the Head Start Act (42 U.S.C. 9837b(b)(1)(A)(i)) or similar coordinating body, local child care program administrators, local child care resource and referral agencies, and other appropriate entities; and

(2) Organizations representing child care caregivers, teachers, and directors.

(f) After conducting the market rate survey or alternative methodology, the Lead Agency must:

(1) Prepare a detailed report containing the results, and make the report widely available, including by posting it on the Internet, not later than 30 days after the completion of the report. The report must include:

(i) The results of the market rate survey or alternative methodology;

(ii) The estimated cost of care necessary (including any relevant variation by geographic location, category of provider, or age of child) to support:

(A) Child care providers' implementation of the health, safety, quality, and staffing requirements at §§98.41 through 98.44; and

(B) Higher-quality care, as defined by the Lead Agency using a quality rating

and improvement system or other system of quality indicators, at each level;

(iii) The Lead Agency's response to stakeholder views and comments; and,

(iv) The data and summary required at paragraph (d)(2)(ii) of this section.

(2) Set payment rates for CCDF assistance:

(i) In accordance with the results of the most recent market rate survey or alternative methodology conducted pursuant to paragraph (c) of this section;

(ii) With base payment rates established at least at a level sufficient for child care providers to meet health, safety quality, and staffing requirements in accordance with paragraph (f)(1)(ii)(A) of this section;

(iii) Taking into consideration the cost of providing higher-quality child care services, including consideration of the information at each level of higher quality required by paragraph (f)(1)(ii)(B) of this section;

(iv) Taking into consideration the views and comments of the public obtained in accordance with paragraph (e) and through other processes determined by the Lead Agency; and

(v) Without, to the extent practicable, reducing the number of families receiving CCDF assistance.

(g) To facilitate parent choice, increase program quality, build supply, and better reflect the cost of providing care, it is permissible for a Lead Agency to pay an eligible child care provider the Lead Agency's established payment rate at paragraph (a) of this section, which may be more than the price charged to children not receiving CCDF subsidies.

(h) A Lead Agency may not establish different payment rates based on a family's eligibility status, such as TANF status.

(i) Payment rates under paragraph (a) of this section shall be consistent with the parental requirements in § 98.30

(j) Nothing in this section shall be construed to create a private right of action if the Lead Agency acts in accordance with the Act and this part.

(k) Nothing in this part shall be construed to prevent a Lead Agency from

differentiating payment rates on the basis of such factors as:

(1) Geographic location of child care providers (such as location in an urban or rural area);

(2) Age or particular needs of children (such as the needs of children with disabilities, children served by child protective services, and children experiencing homelessness);

(3) Whether child care providers provide services during the weekend or other non-traditional hours; or

(4) The Lead Agency's determination that such differential payment rates may enable a parent to choose high-quality child care that best fits the parents' needs.

(1) Lead Agencies shall establish, and periodically revise, by rule, a sliding fee scale(s) for families that receive CCDF child care services that:

(1) Helps families afford child care and enables choice of a range of child care options;

(2) Is based on income and the size of the family and may be based on other factors as appropriate, but may not be based on the cost of care or amount of subsidy payment;

(3) Provides for affordable family co-payments that are not a barrier to families receiving assistance under this part, not to exceed 7 percent of income for all families, regardless of the number of children in care who may be receiving CCDF assistance; and

(4) At Lead Agency discretion, allows for co-payments to be waived for families whose incomes are at or below 150 percent of the poverty level for a family of the same size, that have children who are in foster or kinship care or otherwise receive or need to receive protective services, that are experiencing homelessness, that have children who have a disability as defined at § 98.2, that are enrolled in Head Start or Early Head Start (42 U.S.C. 9831 *et seq.*), or that meet other criteria established by the Lead Agency.

(m) The Lead Agency shall demonstrate in the Plan that it has established payment practices applicable to all CCDF child care providers that reflect generally accepted payment practices of child care providers that serve children who do not receive CCDF subsidies, which must include (unless the

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Lead Agency can demonstrate that such practices are not generally-accepted for a type of child care setting);

(1) Ensure timeliness of payment to child care providers by paying in advance of or at the beginning of the delivery of child care services to children receiving assistance under this part;

(2) Support the fixed costs of providing child care services by delinking provider payments from a child's occasional absences by:

(i) Basing payment on a child's authorized enrollment; or,

(ii) An alternative approach for which the Lead Agency provides a justification in its Plan that the requirements at paragraph (m)(2)(i) of this section are not practicable, including evidence that the alternative approach will not undermine the stability of child care programs.

(3) Pay providers on a part-time or full-time basis (rather than paying for hours of service or smaller increments of time); and

(4) Pay for reasonable mandatory registration fees that the provider charges to private-paying parents.

(n) The Lead Agency shall demonstrate in the Plan that it has established payment practices applicable to all CCDF providers that:

(1) Ensure child care providers receive payment for any services in accordance with a written payment agreement or authorization for services that includes, at a minimum, information regarding payment policies, including rates, schedules, any fees charged to providers, and the dispute resolution process required by paragraph (n)(3);

(2) Ensure child care providers receive prompt notice of changes to a family's eligibility status that may impact payment, and that such notice is sent to providers no later than the day the Lead Agency becomes aware that such a change will occur;

(3) Include timely appeal and resolution processes for any payment inaccuracies and disputes;

(4) May include taking precautionary measures when a provider is suspected of fiscal mismanagement; and

(5) Ensure the total payment received by CCDF child care providers is not reduced by the determination of afford-

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able family co-payment as described in the sliding fee scale at § 98.45(l).

[81 FR 67586, Sept. 30, 2016, as amended at 89 FR 15414, Mar. 1, 2024]

§ 98.46 Priority for child care services.

(a) Lead Agencies shall give priority for services provided under § 98.50(a) to:

(1) Children of families with very low family income (considering family size);

(2) Children with special needs, which may include any vulnerable populations as defined by the Lead Agency; and

(3) Children experiencing homelessness.

(b) Lead Agencies shall prioritize increasing access to high-quality child care and development services for children of families in areas that have significant concentrations of poverty and unemployment and that do not have a sufficient number of such programs.

[81 FR 67587, Sept. 30, 2016]

§ 98.47 List of providers.

If a Lead Agency does not have a registration process for child care providers who are unlicensed or unregulated under State, local, or tribal law, it is required to maintain a list of the names and addresses of unlicensed or unregulated providers of child care services for which assistance is provided under this part.

[63 FR 39981, July 24, 1998. Redesignated at 81 FR 67584, Sept. 30, 2016]

§ 98.48 Nondiscrimination in admissions on the basis of religion.

(a) Child care providers (other than family child care providers, as defined in § 98.2) that receive assistance through grants and contracts under the CCDF shall not discriminate in admissions against any child on the basis of religion.

(b) Paragraph (a) of this section does not prohibit a child care provider from selecting children for child care slots that are not funded directly (i.e., through grants or contracts to providers) with assistance provided under the CCDF because such children or their family members participate on a regular basis in other activities of the

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organization that owns or operates such provider.

(c) Notwithstanding paragraph (b) of this section, if 80 percent or more of the operating budget of a child care provider comes from Federal or State funds, including direct or indirect assistance under the CCDF, the Lead Agency shall assure that before any further CCDF assistance is given to the provider,

(1) The grant or contract relating to the assistance, or

(2) The admission policies of the provider specifically provide that no person with responsibilities in the operation of the child care program, project, or activity will discriminate, on the basis of religion, in the admission of any child.

[63 FR 39981, July 24, 1998. Redesignated at 81 FR 67584, Sept. 30, 2016]

§ 98.49 Nondiscrimination in employment on the basis of religion.

(a) In general, except as provided in paragraph (b) of this section, nothing in this part modifies or affects the provision of any other applicable Federal law and regulation relating to discrimination in employment on the basis of religion.

(1) Child care providers that receive assistance through grants or contracts under the CCDF shall not discriminate, on the basis of religion, in the employment of caregivers as defined in § 98.2.

(2) If two or more prospective employees are qualified for any position with a child care provider, this section shall not prohibit the provider from employing a prospective employee who is already participating on a regular basis in other activities of the organization that owns or operates the provider.

(3) Paragraphs (a)(1) and (2) of this section shall not apply to employees of child care providers if such employees were employed with the provider on November 5, 1990.

(b) Notwithstanding paragraph (a) of this section, a sectarian organization may require that employees adhere to the religious tenets and teachings of such organization and to rules forbidding the use of drugs or alcohol.

(c) Notwithstanding paragraph (b) of this section, if 80 percent or more of

the operating budget of a child care provider comes from Federal and State funds, including direct and indirect assistance under the CCDF, the Lead Agency shall assure that, before any further CCDF assistance is given to the provider,

(1) The grant or contract relating to the assistance, or

(2) The employment policies of the provider specifically provide that no person with responsibilities in the operation of the child care program will discriminate, on the basis of religion, in the employment of any individual as a caregiver, as defined in § 98.2.

[63 FR 39981, July 24, 1998. Redesignated at 81 FR 67584, Sept. 30, 2016]

Subpart F—Use of Child Care and Development Funds

§ 98.50 Child care services.

(a) Direct child care services shall be provided:

(1) To eligible children, as described in § 98.20;

(2) Using a sliding fee scale, as described in § 98.45(1);

(3) Using funding methods provided for in § 98.30 including grants or contracts for slots for children in underserved geographic areas, for infants and toddlers, and children with disabilities. Grants solely to improve the quality of child care services like those in (b) of this section would not satisfy the requirements at § 98.30(b); and

(4) Based on the priorities in § 98.46.

(b) Of the aggregate amount of funds expended by a State or Territory (*i.e.*, Discretionary, Mandatory, and Federal and State share of Matching funds):

(1) No less than nine percent shall be used for activities designed to improve the quality of child care services and increase parental options for, and access to, high-quality child care as described at § 98.53; and

(2) No less than three percent shall be used to carry out activities at § 98.53(a)(4) as such activities relate to the quality of care for infants and toddlers.

(3) Nothing in this section shall preclude the State or Territory from reserving a larger percentage of funds to carry out activities described in paragraphs (b)(1) and (2) of this section.

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(4) Amounts reserved pursuant to this subsection may not be used to satisfy requirements at § 98.30(b).

(c) Funds expended from each fiscal year's allotment on quality activities pursuant to paragraph (b) of this section:

(1) Must be in alignment with an assessment of the Lead Agency's need to carry out such services and care as required at § 98.53(a);

(2) Must include measurable indicators of progress in accordance with § 98.53(g); and

(3) May be provided directly by the Lead Agency or through grants or contracts with local child care resource and referral organizations or other appropriate entities.

(d) Of the aggregate amount of funds expended (*i.e.*, Discretionary, Mandatory, and Federal and State share of Matching Funds), no more than five percent may be used for administrative activities as described at § 98.54.

(e) Not less than 70 percent of the State and Territory Mandatory and Federal and State share of State Matching Funds shall be used to meet the child care needs of families who:

(1) Are receiving assistance under a State program under Part A of title IV of the Social Security Act;

(2) Are attempting through work activities to transition off such assistance program; and

(3) Are at risk of becoming dependent on such assistance program.

(f) From Discretionary amounts provided for a fiscal year, the Lead Agency shall:

(1) Reserve the minimum amount required under paragraph (b) of this section for quality activities, and the funds for administrative costs described at paragraph (d) of this section; and

(2) From the remainder, use not less than 70 percent to fund direct services (provided by the Lead Agency).

(g) Of the funds remaining after applying the provisions of paragraphs (a) through (f) of this section, the Lead Agency shall spend a substantial portion of funds to provide direct child care services to low-income families who are working or attending training or education.

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(h) Pursuant to § 98.16(i)(4), the Plan shall specify how the State will meet the child care needs of families described in paragraph (e) of this section.

[81 FR 67587, Sept. 30, 2016, as amended at 89 FR 15415, Mar. 1, 2024; 89 FR 52397, June 24, 2024]

§ 98.51 Services for children experiencing homelessness.

Lead Agencies shall expend funds on activities that improve access to quality child care services for children experiencing homelessness, including:

(a) The use of procedures to permit enrollment (after an initial eligibility determination) of children experiencing homelessness while required documentation is obtained;

(1) If, after full documentation is provided, a family experiencing homelessness is found ineligible,

(i) The Lead Agency shall pay any amount owed to a child care provider for services provided as a result of the initial eligibility determination; and

(ii) Any CCDF payment made prior to the final eligibility determination shall not be considered an error or improper payment under subpart K of this part;

(2) [Reserved]

(b) Training and technical assistance for providers and appropriate Lead Agency (or designated entity) staff on identifying and serving children experiencing homelessness and their families; and

(c) Specific outreach to families experiencing homelessness.

[81 FR 67588, Sept. 30, 2016]

§ 98.52 Child care resource and referral system.

(a) A Lead Agency may expend funds to establish or support a system of local or regional child care resource and referral organizations that is coordinated, to the extent determined appropriate by the Lead Agency, by a statewide public or private nonprofit, community-based or regionally based, lead child care resource and referral organization.

(b) If a Lead Agency uses funds as described in paragraph (a) of this section,

the local or regional child care resource and referral organizations supported shall, at the direction of the Lead Agency:

(1) Provide parents in the State with consumer education information referred to in § 98.33 (except as otherwise provided in that paragraph), concerning the full range of child care options (including faith-based and community-based child care providers), analyzed by provider, including child care provided during nontraditional hours and through emergency child care centers, in their political subdivisions or regions;

(2) To the extent practicable, work directly with families who receive assistance under this subchapter to offer the families support and assistance, using information described in paragraph (b)(1) of this section, to make an informed decision about which child care providers they will use, in an effort to ensure that the families are enrolling their children in the most appropriate child care setting to suit their needs and one that is of high quality (as determined by the Lead Agency);

(3) Collect data and provide information on the coordination of services and supports, including services under section 619 and part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431, *et seq.*), for children with disabilities (as defined in section 602 of such Act (20 U.S.C. 1401));

(4) Collect data and provide information on the supply of and demand for child care services in political subdivisions or regions within the State and submit such information to the State;

(5) Work to establish partnerships with public agencies and private entities, including faith-based and community-based child care providers, to increase the supply and quality of child care services in the State; and

(6) As appropriate, coordinate their activities with the activities of the State Lead Agency and local agencies that administer funds made available in accordance with this part.

[81 FR 67588, Sept. 30, 2016]

§ 98.53 Activities to improve the quality of child care.

(a) The Lead Agency must expend funds from each fiscal year's allotment on quality activities pursuant to §§ 98.50(b) and 98.83(g) in accordance with an assessment of need by the Lead Agency. Such funds must be used to carry out at least one of the following quality activities to improve the quality of child care services for all children, regardless of CCDF receipt, in accordance with paragraph (e) of this section:

(1) Supporting the training, professional development, and postsecondary education of the child care workforce as part of a progression of professional development through activities such as those included at § 98.44, in addition to:

(i) Offering training, professional development, and postsecondary education opportunities for child care caregivers, teachers and directors that:

(A) Relate to the use of scientifically based, developmentally-appropriate, culturally-appropriate, and age-appropriate strategies to promote the social, emotional, physical, and cognitive development of children, including those related to nutrition and physical activity; and

(B) Offer specialized training, professional development, and postsecondary education for caregivers, teachers and directors caring for those populations prioritized at § 98.44(b)(2)(iv), and children with disabilities;

(ii) Incorporating the effective use of data to guide program improvement and improve opportunities for caregivers, teachers and directors to advance on their progression of training, professional development, and postsecondary education;

(iii) Including effective, age-appropriate behavior management strategies and training, including positive behavior interventions and support models for birth to school-age, that promote positive social and emotional development and reduce challenging behaviors, including reducing suspensions and expulsions of children under age five for such behaviors;

(iv) Providing training and outreach on engaging parents and families in culturally and linguistically appropriate ways to expand their knowledge,

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skills, and capacity to become meaningful partners in supporting their children's positive development;

(v) Providing training corresponding to the nutritional and physical activity needs of children to promote healthy development;

(vi) Providing training or professional development for caregivers, teachers and directors regarding the early neurological development of children; and

(vii) Connecting child care caregivers, teachers, and directors with available Federal and State financial aid that would assist these individuals in pursuing relevant postsecondary education, or delivering financial resources directly through programs that provide scholarships and compensation improvements for education attainment and retention.

(2) Improving upon the development or implementation of the early learning and development guidelines at § 98.15(a)(9) by providing technical assistance to eligible child care providers in order to enhance the cognitive, physical, social, and emotional development and overall well-being of participating children.

(3) Developing, implementing, or enhancing a tiered quality rating and improvement system for child care providers and services to meet consumer education requirements at § 98.33, which may:

(i) Support and assess the quality of child care providers in the State, Territory, or Tribe;

(ii) Build on licensing standards and other regulatory standards for such providers;

(iii) Be designed to improve the quality of different types of child care providers and services;

(iv) Describe the safety of child care facilities;

(v) Build the capacity of early childhood programs and communities to promote parents' and families' understanding of the early childhood system and the rating of the program in which the child is enrolled;

(vi) Provide, to the maximum extent practicable, financial incentives and other supports designed to expand the full diversity of child care options and

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help child care providers improve the quality of services; and

(vii) Accommodate a variety of distinctive approaches to early childhood education and care, including but not limited to, those practiced in faith-based settings, community-based settings, child centered settings, or similar settings that offer a distinctive approach to early childhood development.

(4) Improving the supply and quality of child care programs and services for infants and toddlers through activities, which may include:

(i) Establishing or expanding high-quality community or neighborhood based family and child development centers, which may serve as resources to child care providers in order to improve the quality of early childhood services provided to infants and toddlers from low-income families and to help eligible child care providers improve their capacity to offer high-quality, age-appropriate care to infants and toddlers from low-income families;

(ii) Establishing or expanding the operation of community or neighborhood-based family child care networks;

(iii) Promoting and expanding child care providers' ability to provide developmentally appropriate services for infants and toddlers through, but not limited to:

(A) Training and professional development for caregivers, teachers and directors, including coaching and technical assistance on this age group's unique needs from statewide networks of qualified infant-toddler specialists; and

(B) Improved coordination with early intervention specialists who provide services for infants and toddlers with disabilities under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431. *et seq.*);

(iv) If applicable, developing infant and toddler components within the Lead Agency's quality rating and improvement system described in paragraph (a)(3) of this section for child care providers for infants and toddlers, or the development of infant and toddler components in the child care licensing regulations or early learning and development guidelines;

(v) Improving the ability of parents to access transparent and easy to understand consumer information about high-quality infant and toddler care as described at § 98.33; and

(vi) Carrying out other activities determined by the Lead Agency to improve the quality of infant and toddler care provided, and for which there is evidence that the activities will lead to improved infant and toddler health and safety, infant and toddler cognitive and physical development, or infant and toddler well-being, including providing health and safety training (including training in safe sleep practices, first aid, and cardiopulmonary resuscitation for providers and caregivers).

(5) Establishing or expanding a statewide system of child care resource and referral services.

(6) Facilitating compliance with Lead Agency requirements for inspection, monitoring, training, and health and safety, and with licensing standards.

(7) Evaluating and assessing the quality and effectiveness of child care programs and services offered, including evaluating how such programs positively impact children.

(8) Supporting child care providers in the voluntary pursuit of accreditation by a national accrediting body with demonstrated, valid, and reliable program standards of high-quality.

(9) Supporting Lead Agency or local efforts to develop or adopt high-quality program standards relating to health, mental health, nutrition, physical activity, and physical development.

(10) Carrying out other activities, including implementing consumer education provisions at § 98.33, determined by the Lead Agency to improve the quality of child care services provided, and for which measurement of outcomes relating to improvement of provider preparedness, child safety, child well-being, or entry to kindergarten is possible.

(b) Lead Agencies are strongly encouraged to engage families and providers with direct experience in the child care subsidy system to improve the quality of child care and child care subsidy policy. Lead Agencies may expend quality funds to support such engagement including:

(1) Planning and implementing an engagement strategy to solicit and implement feedback from families, child care providers, and staff who have direct experience with the child care subsidy program and/or quality improvement activities;

(2) Compensating participating parents, child care providers, and child care staff for their time and for expenses incurred as a result of their participation (*i.e.* transportation, child care); and

(3) Hiring parents, child care providers, or child care staff to serve as subject matter experts in the development or refinement of subsidy policy and quality initiatives.

(c) Pursuant to § 98.16(j), the Lead Agency shall describe in its Plan the activities it will fund under this section.

(d) Non-Federal expenditures required by § 98.55(c) (*i.e.*, the maintenance-of effort amount) are not subject to the requirement at paragraph (a) of this section.

(e) Activities to improve the quality of child care services are not restricted to activities affecting children meeting eligibility requirements under § 98.20 or to child care providers of services for which assistance is provided under this part.

(f) Unless expressly authorized by law, targeted funds for quality improvement and other set asides that may be included in appropriations law may not be used towards meeting the quality expenditure minimum requirement at § 98.50(b).

(g) States shall annually prepare and submit reports, including a quality progress report and expenditure report, to the Secretary, which must be made publicly available and shall include:

(1) An assurance that the State was in compliance with requirements at § 98.50(b) in the preceding fiscal year and information about the amount of funds reserved for that purpose;

(2) A description of the activities carried out under this section to comply with § 98.50(b);

(3) The measures the State will use to evaluate its progress in improving the quality of child care programs and services in the State, and data on the

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extent to which the State had met these measures;

(4) A report describing any changes to State regulations, enforcement mechanisms, or other State policies addressing health and safety based on an annual review and assessment of serious child injuries and any deaths occurring in child care programs serving children receiving assistance under this part, and in other regulated and unregulated child care centers and family child care homes, to the extent possible; and

(5) A description of how the Lead Agency responded to complaints submitted through the national hotline and Web site, required in section 658L(b) of the CCDBG Act (42 U.S.C. 9858j(b)).

[81 FR 67588, Sept. 30, 2016, as amended at 89 FR 15415, Mar. 1, 2024; 89 FR 52397, June 24, 2024]

§ 98.54 Administrative costs.

(a) Not more than five percent of the aggregate funds expended by the Lead Agency from each fiscal year's allotment, including the amounts expended in the State pursuant to § 98.55(b), shall be expended for administrative activities. These activities may include but are not limited to:

(1) Salaries and related costs of the staff of the Lead Agency or other agencies engaged in the administration and implementation of the program pursuant to § 98.11. Program administration and implementation include the following types of activities:

(i) Planning, developing, and designing the Child Care and Development Fund program;

(ii) Providing local officials and the public with information about the program, including the conduct of public hearings;

(iii) Preparing the application and Plan;

(iv) Developing agreements with administering agencies in order to carry out program activities;

(v) Monitoring program activities for compliance with program requirements;

(vi) Preparing reports and other documents related to the program for submission to the Secretary;

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(vii) Maintaining substantiated complaint files in accordance with the requirements of § 98.32;

(viii) Coordinating the provision of Child Care and Development Fund services with other Federal, State, and local child care, early childhood development programs, and before-and after-school care programs;

(ix) Coordinating the resolution of audit and monitoring findings;

(x) Evaluating program results; and

(xi) Managing or supervising persons with responsibilities described in paragraphs (a)(1)(i) through (x) of this section;

(2) Travel costs incurred for official business in carrying out the program;

(3) Administrative services, including such services as accounting services, performed by grantees or subgrantees or under agreements with third parties;

(4) Audit services as required at § 98.65;

(5) Other costs for goods and services required for the administration of the program, including rental or purchase of equipment, utilities, and office supplies; and

(6) Indirect costs as determined by an indirect cost agreement or cost allocation plan pursuant to § 98.57.

(b) The following activities do not count towards the five percent limitation on administrative expenditures in paragraph (a) of this section:

(1) Establishment and maintenance of computerized child care information systems;

(2) Establishing and operating a certificate program;

(3) Eligibility determination and re-determination;

(4) Preparation/participation in judicial hearings;

(5) Child care placement;

(6) Recruitment, licensing, inspection of child care providers;

(7) Training for Lead Agency or sub recipient staff on billing and claims processes associated with the subsidy program;

(8) Reviews and supervision of child care placements;

(9) Activities associated with payment rate setting;

(10) Resource and referral services; and

(11) Training for child care staff.

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(c) The five percent limitation at paragraph (a) of this section applies only to the States and Territories. The amount of the limitation at paragraph (a) of this section does not apply to Tribes or tribal organizations.

(d) Non-Federal expenditures required by § 98.55(c) (*i.e.*, the maintenance-of-effort amount) are not subject to the five percent limitation at paragraph (a) of this section.

(e) If a Lead Agency enters into agreements with sub-recipients for operation of the CCDF program, the amount of the contract or grant attributable to administrative activities as described in this section shall be counted towards the five percent limit.

[63 FR 39981, July 24, 1998. Redesignated and amended at 81 FR 67588, 67590, Sept. 30, 2016]

§ 98.55 Matching fund requirements.

(a) Federal matching funds are available for expenditures in a State based upon the formula specified at § 98.63(a).

(b) Expenditures in a State under paragraph (a) of this section will be matched at the Federal medical assistance rate for the applicable fiscal year for allowable activities, as described in the approved State Plan, that meet the goals and purposes of the Act.

(c) In order to receive Federal matching funds for a fiscal year under paragraph (a) of this section:

(1) States shall also expend an amount of non-Federal funds for child care activities in the State that is at least equal to the State's share of expenditures for fiscal year 1994 or 1995 (whichever is greater) under sections 402(g) and (i) of the Social Security Act as these sections were in effect before October 1, 1995; and

(2) The expenditures shall be for allowable services or activities, as described in the approved State Plan if appropriate, that meet the goals and purposes of the Act.

(3) All Mandatory Funds are obligated in accordance with § 98.60(d)(2)(i).

(d) The same expenditure may not be used to meet the requirements under both paragraphs (b) and (c) of this section in a fiscal year.

(e) An expenditure in the State for purposes of this subpart may be:

(1) Public funds when the funds are:

(i) Appropriated directly to the Lead Agency specified at § 98.10, or transferred from another public agency to that Lead Agency and under its administrative control, or certified by the contributing public agency as representing expenditures eligible for Federal match;

(ii) Not used to match other Federal funds; and

(iii) Not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds; or

(2) Donated from private sources when the donated funds:

(i) Are donated without any restriction that would require their use for a specific individual, organization, facility or institution;

(ii) Do not revert to the donor's facility or use;

(iii) Are not used to match other Federal funds;

(iv) Shall be certified both by the Lead Agency and by the donor (if funds are donated directly to the Lead Agency) or the Lead Agency and the entity designated by the State to receive donated funds pursuant to paragraph (f) of this section (if funds are donated directly to the designated entity) as available and representing funds eligible for Federal match; and

(v) Shall be subject to the audit requirements in § 98.65 of these regulations.

(f) Donated funds need not be transferred to or under the administrative control of the Lead Agency in order to qualify as an expenditure eligible to receive Federal match under this section. They may be given to the public or private entities designated by the State to implement the child care program in accordance with § 98.11 provided that such entities are identified and designated in the State Plan to receive donated funds in accordance with § 98.16(d)(2).

(g) The following are not counted as an eligible State expenditure under this part:

(1) In-kind contributions; and

(2) Family contributions to the cost of care as required by § 98.45(1).

(h) Public pre-kindergarten (pre-K) expenditures:

(1) May be used to meet the maintenance-of-effort requirement only if the

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State has not reduced its expenditures for full-day/full-year child care services; and

(2) May be eligible for Federal match if the State includes in its Plan, as provided in § 98.16(w), a description of the efforts it will undertake to ensure that pre-K programs meet the needs of working parents.

(3) In any fiscal year, a State may use public pre-K funds for up to 20% of the funds serving as maintenance-of-effort under this subsection. In addition, in any fiscal year, a State may use other public pre-K funds as expenditures serving as State matching funds under this subsection; such public pre-K funds used as State expenditures may not exceed 30% of the amount of a State's expenditures required to draw down the State's full allotment of Federal matching funds available under this subsection.

(4) If applicable, the CCDF Plan shall reflect the State's intent to use public pre-K funds in excess of 10%, but not for more than 20% of its maintenance-of-effort or 30% of its State matching funds in a fiscal year. Also, the Plan shall describe how the State will coordinate its pre-K and child care services to expand the availability of child care.

(i) Matching funds are subject to the obligation and liquidation requirements at § 98.60(d)(4).

[63 FR 39981, July 24, 1998, as amended at 72 FR 27979, May 18, 2007. Redesignated and amended at 81 FR 67588, 67590, Sept. 30, 2016; 89 FR 52397, June 24, 2024]

§ 98.56 Restrictions on the use of funds.

(a) *General.* (1) Funds authorized under section 418 of the Social Security Act and section 658B of the Child Care and Development Block Grant Act, and all funds transferred to the Lead Agency pursuant to section 404(d) of the Social Security Act, shall be expended consistent with these regulations. Funds transferred pursuant to section 404(d) of the Social Security Act shall be treated as Discretionary Funds;

(2) Funds shall be expended in accordance with applicable State and local laws, except as superseded by § 98.3.

(b) *Construction.* (1) For State and local agencies and nonsectarian agen-

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cies or organizations, no funds shall be expended for the purchase or improvement of land, or for the purchase, construction, or permanent improvement of any building or facility. However, funds may be expended for minor remodeling, and for upgrading child care facilities to assure that providers meet State and local child care standards, including applicable health and safety requirements. Improvements or upgrades to a facility which are not specified under the definitions of construction or major renovation at § 98.2 may be considered minor remodeling and are, therefore, not prohibited.

(2) For sectarian agencies or organizations, the prohibitions in paragraph (b)(1) of this section apply; however, funds may be expended for minor remodeling only if necessary to bring the facility into compliance with the health and safety requirements established pursuant to § 8.41.

(3) Tribes and tribal organizations are subject to the requirements at § 98.84 regarding construction and renovation.

(c) *Tuition.* Funds may not be expended for students enrolled in grades 1 through 12 for:

(1) Any service provided to such students during the regular school day;

(2) Any service for which such students receive academic credit toward graduation; or

(3) Any instructional services that supplant or duplicate the academic program of any public or private school.

(d) *Sectarian purposes and activities.* Funds provided under grants or contracts to providers may not be expended for any sectarian purpose or activity, including sectarian worship or instruction. Assistance provided to parents through certificates is not a grant or contract. Funds provided through child care certificates may be expended for sectarian purposes or activities, including sectarian worship or instruction when provided as part of the child care services.

(e) *Non-Federal share for other Federal programs.* The CCDF may not be used as the non-Federal share for other Federal

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grant programs, unless explicitly authorized by statute.

[63 FR 39981, July 24, 1998. Redesignated and amended at 81 FR 67588, 67590, Sept. 30, 2016]

§ 98.57 Cost allocation.

(a) The Lead Agency and subgrantees shall keep on file cost allocation plans or indirect cost agreements, as appropriate, that have been amended to include costs allocated to the CCDF.

(b) Subgrantees that do not already have a negotiated indirect rate with the Federal government should prepare and keep on file cost allocation plans or indirect cost agreements, as appropriate.

(c) Approval of the cost allocation plans or indirect cost agreements is not specifically required by these regulations, but these plans and agreements are subject to review.

[63 FR 39981, July 24, 1998. Redesignated at 81 FR 67588, Sept. 30, 2016]

Subpart G—Financial Management

§ 98.60 Availability of funds.

(a) The CCDF is available, subject to the availability of appropriations, in accordance with the apportionment of funds from the Office of Management and Budget as follows:

(1) Discretionary Funds are available to States, Territories, and Tribes;

(2) State Mandatory and Matching Funds are available to States;

(3) Territory Mandatory Funds are available to Territories; and

(4) Tribal Mandatory Funds are available to Tribes.

(b) Subject to the availability of appropriations, in accordance with relevant statutory provisions and the apportionment of funds from the Office of Management and Budget, the Secretary:

(1) May withhold a portion of the CCDF funds made available for a fiscal year for the provision of technical assistance, for research, evaluation, and demonstration, and for a national toll free hotline and Web site;

(2) Will award the remaining CCDF funds to grantees that have an approved application and Plan.

(c) The Secretary may make payments in installments, and in advance or by way of reimbursement, with necessary adjustments due to overpayments or underpayments.

(d) The following obligation and liquidation provisions apply to States and Territories:

(1) Discretionary Fund allotments shall be obligated in the fiscal year in which funds are awarded or in the succeeding fiscal year. Unliquidated obligations as of the end of the succeeding fiscal year shall be liquidated within one year.

(2)(i) Mandatory Funds for States requesting Matching Funds per § 98.55 shall be obligated in the fiscal year in which the funds are granted and are available until expended.

(ii) Mandatory Funds for States that do not request Matching Funds are available until expended.

(3) Mandatory Funds for Territories shall be obligated in the fiscal year in which funds are granted and liquidated no later than the end of the succeeding fiscal year.

(4) Both the Federal and non-Federal share of the Matching Fund shall be obligated in the fiscal year in which the funds are granted and liquidated no later than the end of the succeeding fiscal year.

(5) Except for paragraph (d)(6) of this section, determination of whether funds have been obligated and liquidated will be based on:

(i) State or local law; or,

(ii) If there is no applicable State or local law, the regulation at 2 CFR 200.1, Expenditures and Obligations.

(6) Obligations may include subgrants or contracts that require the payment of funds to a third party (e.g., subgrantee or contractor). However, the following are not considered third party subgrantees or contractors:

(i) A local office of the Lead Agency;

(ii) Another entity at the same level of government as the Lead Agency; or

(iii) A local office of another entity at the same level of government as the Lead Agency.

(7) In instances where the Lead Agency issues child care certificates, funds for child care services provided through

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a child care certificate will be considered obligated when a child care certificate is issued to a family in writing that indicates:

(i) The amount of funds that will be paid to a child care provider or family, and

(ii) The specific length of time covered by the certificate, which is limited to the date established for redetermination of the family's eligibility, but shall be no later than the end of the liquidation period.

(8) In instances where third party agencies issue child care certificates, the obligation of funds occurs upon entering into agreement through a subgrant or contract with such agency, rather than when the third party issues certificates to a family.

(9) Any funds not obligated during the obligation period specified in paragraph (d) of this section will revert to the Federal government. Any funds not liquidated by the end of the applicable liquidation period specified in paragraph (d) of this section will also revert to the Federal government.

(e) The following obligation and liquidation provisions apply to Tribal Discretionary and Tribal Mandatory Funds:

(1) Tribal grantees shall obligate all funds by the end of the fiscal year following the fiscal year for which the grant is awarded. Any funds not obligated during this period will revert to the Federal government.

(2) Obligations that remain unliquidated at the end of the succeeding fiscal year shall be liquidated within the next fiscal year. Any tribal funds that remain unliquidated by the end of this period will also revert to the Federal government.

(f) Cash advances shall be limited to the minimum amounts needed and shall be timed to be in accord with the actual, immediate cash requirements of the State Lead Agency, its subgrantee or contractor in carrying out the purpose of the program in accordance with 31 CFR part 205.

(g) Funds that are returned (e.g., loan repayments, funds deobligated by cancellation of a child care certificate, unused subgrantee funds) as well as program income (e.g., contributions made by families directly to the Lead

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Agency or subgrantee for the cost of care where the Lead Agency or subgrantee has made a full payment to the child care provider) shall,

(1) if received by the Lead Agency during the applicable obligation period, described in paragraphs (d) and (e) of this section, be used for activities specified in the Lead Agency's approved plan and must be obligated by the end of the obligation period; or

(2) if received after the end of the applicable obligation period described at paragraphs (d) and (e) of this section, be returned to the Federal government.

(h) Repayment of loans made to child care providers as part of a quality improvement activity pursuant to § 98.53, may be made in cash or in services provided in-kind. Payment provided in-kind shall be based on fair market value. All loans shall be fully repaid.

(i) Lead Agencies shall recover child care payments that are the result of fraud. These payments shall be recovered from the party responsible for committing the fraud.

[63 FR 39981, July 24, 1998, as amended at 81 FR 3020, Jan. 20, 2016; 81 FR 67591, Sept. 30, 2016; 89 FR 15415, Mar. 1, 2024; 89 FR 52397, June 24, 2024; 89 FR 80071, Oct. 2, 2024]

§ 98.61 Allotments from the Discretionary Fund.

(a) To the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico an amount equal to the funds appropriated for the Child Care and Development Block Grant, less amounts reserved for technical assistance, research, and the national hotline and Web site, pursuant to § 98.60(b), and amounts reserved for the Territories and Tribes, pursuant to § 98.60(b) and paragraphs (b) and (c) of this section, shall be allotted based upon the formula specified in section 658O(b) of the Act (42 U.S.C. 9858m(b)).

(b) For the U.S. Territories of Guam, American Samoa, the Virgin Islands of the United States, and the Commonwealth of the Northern Mariana Islands an amount up to one-half of one percent of the amount appropriated for the Child Care and Development Block Grant shall be reserved.

(1) Funds shall be allotted to these Territories based upon the following factors:

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(i) A Young Child factor—the ratio of the number of children in the Territory under five years of age to the number of such children in all Territories; and

(ii) An Allotment Proportion factor—determined by dividing the per capita income of all individuals in all the Territories by the per capita income of all individuals in the Territory.

(A) Per capita income shall be:

(1) Equal to the average of the annual per capita incomes for the most recent period of three consecutive years for which satisfactory data are available at the time such determination is made; and

(2) Determined every two years.

(B) Per capita income determined, pursuant to paragraph (b)(1)(ii)(A) of this section, will be applied in establishing the allotment for the fiscal year for which it is determined and for the following fiscal year.

(C) If the Allotment Proportion factor determined at paragraph (b)(1)(ii) of this section:

(1) Exceeds 1.2, then the Allotment Proportion factor of the Territory shall be considered to be 1.2; or

(2) Is less than 0.8, then the Allotment Proportion factor of the Territory shall be considered to be 0.8.

(2)(i) The formula used in calculating a Territory's allotment is as follows:

$$\frac{YCF_t \times APF_t}{\sum (YCF_t \times APF_t)} \times \text{Territories at paragraph (a) of this section.}$$

(ii) For purposes of the formula specified at paragraph (b)(2)(i) of this section, the term "YCF_t" means the Territory's Young Child factor as defined at paragraph (b)(1)(i) of this section.

(iii) For purposes of the formula specified at paragraph (b)(2)(i) of this section, the term "APF_t" means the Territory's Allotment Proportion factor as defined at paragraph (b)(1)(ii) of this section.

(c) For Indian Tribes and tribal organizations, including any Alaskan Native Village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*) not less than two percent of the amount appropriated for the Child Care

and Development Block Grant shall be reserved.

(1) Except as specified in paragraph (c)(2) of this section, grants to individual tribal grantees will be equal to the sum of:

(i) A base amount as set by the Secretary; and

(ii) An additional amount per Indian child under age 13 (or such similar age as determined by the Secretary from the best available data), which is determined by dividing the amount of funds available, less amounts set aside for eligible Tribes, pursuant to paragraph (c)(1)(i) of this section, by the number of all Indian children living on or near tribal reservations or other appropriate area served by the tribal grantee, pursuant to § 98.80(e).

(2) Grants to Tribes with fewer than 50 Indian children that apply as part of a consortium, pursuant to § 98.80(b)(1), are equal to the sum of:

(i) A portion of the base amount, pursuant to paragraph (c)(1)(i) of this section, that bears the same ratio as the number of Indian children in the Tribe living on or near the reservation, or other appropriate area served by the tribal grantee, pursuant to § 98.80(e), does to 50; and

(ii) An additional amount per Indian child, pursuant to paragraph (c)(1)(ii) of this section.

(3) Tribal consortia will receive grants that are equal to the sum of the individual grants of their members.

(d) All funds reserved for Territories at paragraph (b) of this section will be allotted to Territories, and all funds reserved for Tribes at paragraph (c) of this section will be allotted to tribal grantees. Any funds that are returned by the Territories after they have been allotted will revert to the Federal government.

(e) For other organizations, up to \$2,000,000 may be reserved from the tribal funds reserved at paragraph (c) of this section. From this amount the Secretary may award a grant to a Native Hawaiian Organization, as defined in section 4009(4) of the Augustus F. Hawkins-Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988 (20 U.S.C. 4909(4)) and to a private non-profit organization established for the purpose

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of serving youth who are Indians or Native Hawaiians. The Secretary will establish selection criteria and procedures for the award of grants under this subsection by notice in the FEDERAL REGISTER.

(f) Lead Agencies shall expend any funds that may be set-aside for targeted activities pursuant to annual appropriations law as directed by the Secretary.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67591, Sept. 30, 2016]

§ 98.62 Allotments from the Mandatory Fund.

(a) Each of the 50 States and the District of Columbia will be allocated from the funds appropriated under section 418(a)(3)(A) of the Social Security Act, less the amounts reserved for technical assistance pursuant to § 98.60(b)(1) an amount of funds equal to the greater of:

(1) the Federal share of its child care expenditures under subsections (g) and (i) of section 402 of the Social Security Act (as in effect before October 1, 1995) for fiscal year 1994 or 1995 (whichever is greater); or

(2) the average of the Federal share of its child care expenditures under the subsections referred to in subparagraph (a)(1) of this section for fiscal years 1992 through 1994.

(b) For Indian Tribes and tribal organizations will be allocated from the funds appropriated under section 418(a)(3)(B) of the Social Security Act shall be allocated according to the formula at paragraph (c) of this section. In Alaska, only the following 13 entities shall receive allocations under this subpart, in accordance with the formula at paragraph (c) of this section:

(1) The Metlakatla Indian Community of the Annette Islands Reserve;

(2) Arctic Slope Native Association;

(3) Kawerak, Inc.;

(4) Maniilaq Association;

(5) Association of Village Council Presidents;

(6) Tanana Chiefs Conference;

(7) Cook Inlet Tribal Council;

(8) Bristol Bay Native Association;

(9) Aleutian and Pribilof Islands Association;

(10) Chugachmuit;

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(11) Tlingit and Haida Central Council;

(12) Kodiak Area Native Association; and

(13) Copper River Native Association.

(c)(1) Grants to individual Tribes with 50 or more Indian children, and to Tribes with fewer than 50 Indian children that apply as part of a consortium pursuant to § 98.80(b)(1), will be equal to an amount per Indian child under age 13 (or such similar age as determined by the Secretary from the best available data), which is determined by dividing the amount of funds available, by the number of Indian children in each Tribe's service area pursuant to § 98.80(e).

(2) Tribal consortia will receive grants that are equal to the sum of the individual grants of their members.

(d) The Territories will be allocated from the funds appropriated under section 418(a)(3)(C) of the Social Security Act based upon the following factors:

(1) A Young Child factor—the ratio of the number of children in the Territory under five years of age to the number of such children in all Territories; and

(2) An Allotment Proportion factor—determined by dividing the per capita income of all individuals in all the Territories by the per capita income of all individuals in the Territory.

(i) Per capita income shall be:

(A) Equal to the average of the annual per capita incomes for the most recent period of three consecutive years for which satisfactory data are available at the time such determination is made; and

(B) Determined every two years.

(ii) [Reserved]

[63 FR 39981, July 24, 1998, as amended at 89 FR 15415, Mar. 1, 2024]

§ 98.63 Allotments from the Matching Fund.

(a) To each of the 50 States and the District of Columbia there is allocated an amount equal to its share of the total available under section 418(a)(3) of the Social Security Act. That amount is based on the same ratio as the number of children under age 13 residing in the State bears to the national total of children under age 13. The number of children under 13 is derived from the best data available to

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the Secretary for the second preceding fiscal year.

(b) For purposes of this section, the amounts available under section 418(a)(3) of the Social Security Act (42 U.S.C. 618(a)(3)) excludes the amounts reserved and allocated under § 98.60(b)(1) for technical assistance, research and evaluation, and the national toll-free hotline and Web site and under § 98.62(a) and (b) for the Mandatory Fund.

(c) Amounts under this section are available pursuant to the requirements at § 98.55(c).

[63 FR 39981, July 24, 1998, as amended at 81 FR 67591, Sept. 30, 2016]

§ 98.64 Reallotment and redistribution of funds.

(a) According to the provisions of this section State and Tribal Discretionary Funds are subject to reallotment, and State Matching Funds and Territory Mandatory Funds are subject to redistribution. State funds are reallotted or redistributed only to States as defined for the original allocation. Tribal funds are reallotted only to Tribes. Mandatory Funds granted to Territories are redistributed only to Territories. Discretionary Funds granted to the Territories are not subject to reallotment. Any Discretionary funds granted to the Territories that are returned after they have been allotted will revert to the Federal Government.

(b) Any portion of a State's Discretionary Fund allotment that is not required to carry out its Plan, in the period for which the allotment is made available, shall be reallotted to other States in proportion to the original allotments. For purposes of this paragraph the term "State" means the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico. The other Territories and the Tribes may not receive reallotted State Discretionary Funds.

(1) Each year, the State shall report to the Secretary either the dollar amount from the previous year's grant that it will be unable to obligate by the end of the obligation period or that all funds will be obligated during such time. Such report shall be postmarked by April 1st.

(2) Based upon the reallotment reports submitted by States, the Secretary will reallot funds.

(i) If the total amount available for reallotment is \$25,000 or more, funds will be reallotted to States in proportion to each State's allotment for the applicable fiscal year's funds, pursuant to § 98.61(a).

(ii) If the amount available for reallotment is less than \$25,000, the Secretary will not reallot any funds, and such funds will revert to the Federal government.

(iii) If an individual reallotment amount to a State is less than \$500, the Secretary will not issue the award, and such funds will revert to the Federal government.

(3) If a State does not submit a reallotment report by the deadline for report submittal, either:

(i) The Secretary will determine that the State does not have any funds available for reallotment; or

(ii) In the case of a report postmarked after April 1st, any funds reported to be available for reallotment shall revert to the Federal government.

(4) States receiving reallotted funds shall obligate and expend these funds in accordance with § 98.60. The reallotment of funds does not extend the obligation period or the program period for expenditure of such funds.

(c)(1) Any portion of the Matching Fund granted to a State that is not obligated in the period for which the grant is made shall be redistributed. Funds, if any, will be redistributed on the request of, and only to, those other States that have met the requirements of § 98.55(c) in the period for which the grant was first made. For purposes of this paragraph (c)(1), the term "State" means the 50 States and the District of Columbia. Territorial and tribal grantees may not receive redistributed Matching Funds.

(2) Matching Funds allotted to a State under § 98.63(a), but not granted, shall also be redistributed in the manner described in paragraph (1) of this section.

(3) The amount of Matching Funds granted to a State that will be made available for redistribution will be based on the State's financial report to

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ACF for the Child Care and Development Fund (ACF-696) and is subject to the monetary limits at paragraph (b)(2) of this section.

(4) A State eligible to receive redistributed Matching Funds shall also use the ACF-696 to request its share of the redistributed funds, if any.

(5) A State's share of redistributed Matching Funds is based on the same ratio as the number of children under 13 residing in the State to the number of children residing in all States eligible to receive and that request the redistributed Matching Funds.

(6) Redistributed funds are considered part of the grant for the fiscal year in which the redistribution occurs.

(d) Any portion of a Tribe's allotment of Discretionary Funds that is not required to carry out its Plan, in the period for which the allotment is made available, shall be reallocated to other tribal grantees in proportion to their original allotments. States and Territories may not receive reallocated tribal funds.

(1) Each year, the Tribe shall report to the Secretary either the dollar amount from the previous year's grant that it will be unable to obligate by the end of the obligation period or that all funds will be obligated during such time. Such report shall be postmarked by a deadline established by the Secretary.

(2) Based upon the reallocation reports submitted by Tribes, the Secretary will reallocate Tribal Discretionary Funds among the other Tribes.

(i) If the total amount available for reallocation is \$25,000 or more, funds will be reallocated to other tribal grantees in proportion to each Tribe's original allotment for the applicable fiscal year pursuant to § 98.62(c).

(ii) If the total amount available for reallocation is less than \$25,000, the Secretary will not reallocate any funds, and such funds will revert to the Federal government.

(iii) If an individual reallocation amount to an applicant Tribe is less than \$500, the Secretary will not issue the award, and such funds will revert to the Federal government.

(3) If a Tribe does not submit a reallocation report by the deadline for report submittal, either:

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(i) The Secretary will determine that Tribe does not have any funds available for reallocation; or

(ii) In the case of a report received after the deadline established by the Secretary, any funds reported to be available for reallocation shall revert to the Federal government.

(4) Tribes receiving reallocated funds shall obligate and expend these funds in accordance with § 98.60. The reallocation of funds does not extend the obligation period or the program period for expenditure of such funds.

(e)(1) Any portion of the Mandatory Funds that are not obligated in the period for which the grant is made shall be redistributed. Territory Mandatory Funds, if any, will be redistributed on the request of, and only to, those other Territories that have obligated their entire Territory Mandatory Fund allocation in full for the period for which the grant was first made.

(2) The amount of Mandatory Funds granted to a Territory that will be made available for redistribution will be based on the Territory's financial report to ACF for the Child Care and Development Fund (ACF-696) and is subject to the monetary limits at paragraph (b)(2) of this section.

(3) A Territory eligible to receive redistributed Mandatory Funds shall also use the ACF-696 to request its share of the redistributed funds, if any.

(4) A Territory's share of redistributed Mandatory Funds is based on the same ratio as § 98.62(d).

(5) Redistributed funds are considered part of the grant for the fiscal year in which the redistribution occurs.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67591, Sept. 30, 2016; 89 FR 15416, Mar. 1, 2024]

§ 98.65 Audits and financial reporting.

(a) Each Lead Agency shall have an audit conducted after the close of each program period in accordance with 2 CFR part 200, subpart F, and the Single Audit Act Amendments of 1996.

(b) Lead Agencies are responsible for ensuring that subgrantees are audited in accordance with appropriate audit requirements.

(c) Not later than 30 days after the completion of the audit, Lead Agencies

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shall submit a copy of their audit report to the legislature of the State or, if applicable, to the Tribal Council(s). Lead Agencies shall also submit a copy of their audit report to the HHS Inspector General for Audit Services, as well as to their cognizant agency, if applicable.

(d) Any amounts determined through an audit not to have been expended in accordance with these statutory or regulatory provisions, or with the Plan, and that are subsequently disallowed by the Department shall be repaid to the Federal government, or the Secretary will offset such amounts against any other CCDF funds to which the Lead Agency is or may be entitled.

(e) Lead Agencies shall provide access to appropriate books, documents, papers and records to allow the Secretary to verify that CCDF funds have been expended in accordance with the statutory and regulatory requirements of the program, and with the Plan.

(f) The audit required in paragraph (a) of this section shall be conducted by an agency that is independent of the State, Territory or Tribe as defined by generally accepted government auditing standards issued by the Comptroller General, or a public accountant who meets such independent standards.

(g) Lead Agencies shall submit financial reports, in a manner specified by ACF, quarterly for each fiscal year until funds are expended.

(h) At a minimum, a State or territorial Lead Agency's quarterly report shall include the following information on expenditures under CCDF grant funds, including Discretionary (which includes reallocated funding and any funds transferred from the TANF block grant), Mandatory, and Matching Funds (which includes redistributed funding); and State Matching and Maintenance-of-Effort (MOE) Funds:

- (1) Child care administration;
- (2) Quality activities, including any sub-categories of quality activities as required by ACF;
- (3) Direct services for both grant or contracted slots and certificates;
- (4) Non-direct services, including:
 - (i) Establishment and maintenance of computerized child care information systems;

(ii) Certificate program cost/eligibility determination;

(iii) All other non-direct services; and

(5) Such other information as specified by the Secretary.

(i) Tribal Lead Agencies shall submit financial reports annually in a manner specified by ACF.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67591, Sept. 30, 2016; 89 FR 15416, Mar. 1, 2024; 89 FR 80071, Oct. 2, 2024]

§ 98.66 Disallowance procedures.

(a) Any expenditures not made in accordance with the Act, the implementing regulations, or the approved Plan, will be subject to disallowance.

(b) If the Department, as the result of an audit or a review, finds that expenditures should be disallowed, the Department will notify the Lead Agency of this decision in writing.

(c)(1) If the Lead Agency agrees with the finding that amounts were not expended in accordance with the Act, these regulations, or the Plan, the Lead Agency shall fulfill the provisions of the disallowance notice and repay any amounts improperly expended; or

(2) The Lead Agency may appeal the finding:

(i) By requesting reconsideration from the Assistant Secretary, pursuant to paragraph (f) of this section; or

(ii) By following the procedure in paragraph (d) of this section.

(d) A Lead Agency may appeal the disallowance decision to the Departmental Appeals Board in accordance with 45 CFR part 16.

(e) The Lead Agency may appeal a disallowance of costs that the Department has determined to be unallowable under an award. A grantee may not appeal the determination of award amounts or disposition of unobligated balances.

(f) The Lead Agency's request for reconsideration in (c)(2)(i) of this section shall be postmarked no later than 30 days after the receipt of the disallowance notice. A Lead Agency may request an extension within the 30-day time frame. The request for reconsideration, pursuant to (c)(2)(i) of this section, need not follow any prescribed form, but it shall contain:

- (1) The amount of the disallowance;

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(2) The Lead Agency's reasons for believing that the disallowance was improper; and

(3) A copy of the disallowance decision issued pursuant to paragraph (b) of this section.

(g)(1) Upon receipt of a request for reconsideration, pursuant to (c)(2)(i) of this section, the Assistant Secretary or the Assistant Secretary's designee will inform the Lead Agency that the request is under review.

(2) The Assistant Secretary or the designee will review any material submitted by the Lead Agency and any other necessary materials.

(3) If the reconsideration decision is adverse to the Lead Agency's position, the response will include a notification of the Lead Agency's right to appeal to the Departmental Appeals Board, pursuant to paragraph (d) of this section.

(h) If a Lead Agency refuses to repay amounts after a final decision has been made, the amounts will be offset against future payments to the Lead Agency.

(i) The appeals process in this section is not applicable if the disallowance is part of a compliance review, pursuant to § 98.90, the findings of which have been appealed by the Lead Agency.

(j) Disallowances under the CCDF program are subject to interest regulations at 45 CFR part 30. Interest will begin to accrue from the date of notification.

§ 98.67 Fiscal requirements.

(a) Lead Agencies shall expend and account for CCDF funds in accordance with their own laws and procedures for expending and accounting for their own funds.

(b) Unless otherwise specified in this part, contracts that entail the expenditure of CCDF funds shall comply with the laws and procedures generally applicable to expenditures by the contracting agency of its own funds.

(c) Fiscal control and accounting procedures shall be sufficient to permit:

(1) Preparation of reports required by the Secretary under this subpart and under subpart H; and

(2) The tracing of funds to a level of expenditure adequate to establish that such funds have not been used in violation of the provisions of this part.

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§ 98.68 Program integrity.

(a) Lead Agencies are required to describe in their Plan effective internal controls that are in place to ensure integrity and accountability, while maintaining continuity of services, in the CCDF program. These shall include:

(1) Processes to ensure sound fiscal management;

(2) Processes to identify areas of risk;

(3) Processes to train child care providers and staff of the Lead Agency and other agencies engaged in the administration of CCDF about program requirements and integrity; and

(4) Regular evaluation of internal control activities.

(b) Lead Agencies are required to describe in their Plan the processes that are in place to:

(1) Identify fraud or other program violations, which may include, but are not limited to the following:

(i) Record matching and database linkages;

(ii) Review of attendance and billing records;

(iii) Quality control or quality assurance reviews; and

(iv) Staff training on monitoring and audit processes.

(2) Investigate and recover fraudulent payments and to impose sanctions on clients or providers in response to fraud.

(c) Lead Agencies must describe in their Plan the procedures that are in place for documenting and verifying that children receiving assistance under this part meet eligibility criteria at the time of eligibility determination and redetermination. Because a child meeting eligibility requirements at the most recent eligibility determination or redetermination is considered eligible during the period between redeterminations as described in § 98.21(a)(1):

(1) The Lead Agency shall pay any amount owed to a child care provider for services provided for such a child during this period under a payment agreement or authorization for services; and

(2) Any CCDF payment made for such a child during this period shall not be considered an error or improper payment under subpart K of this part due

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to a change in the family's circumstances, as set forth at § 98.21(a).

[81 FR 67591, Sept. 30, 2016]

Subpart H—Program Reporting Requirements

§ 98.70 Reporting requirements.

(a) Quarterly Case-level Report—

(1) State and territorial Lead Agencies that receive assistance under the CCDF shall prepare and submit to the Department, in a manner specified by the Secretary, a quarterly case-level report of monthly family case-level data. Data shall be collected monthly and submitted quarterly. States may submit the data monthly if they choose to do so.

(2) The information shall be reported for the three-month federal fiscal period preceding the required report. The first report shall be submitted no later than August 31, 1998, and quarterly thereafter. The first report shall include data from the third quarter of FFY 1998 (April 1998 through June 1998). States and Territorial Lead Agencies which choose to submit case-level data monthly must submit their report for April 1998 no later than July 30, 1998. Following reports must be submitted every thirty days thereafter.

(3) State and territorial Lead Agencies choosing to submit data based on a sample shall submit a sampling plan to ACF for approval 60 days prior to the submission of the first quarterly report. States are not prohibited from submitting case-level data for the entire population receiving CCDF services.

(4) Quarterly family case-level reports to the Secretary shall include the information listed in § 98.71(a).

(b) Annual Report—

(1) State and territorial Lead Agencies that receive assistance under CCDF shall prepare and submit to the Secretary an annual report. The report shall be submitted, in a manner specified by the Secretary, by December 31 of each year and shall cover the most recent federal fiscal year (October through September).

(2) The first annual aggregate report shall be submitted no later than De-

cember 31, 1997, and every twelve months thereafter.

(3) Biennial reports to Congress by the Secretary shall include the information listed in § 98.71(b).

(c) Tribal Annual Report—

(1) Tribal Lead Agencies that receive assistance under CCDF shall prepare and submit to the Secretary an annual aggregate report.

(2) The report shall be submitted in the manner specified by the Secretary by December 31 of each year and shall cover services for children and families served with CCDF funds during the preceding Federal Fiscal Year.

(3) Biennial reports to Congress by the Secretary shall include the information listed in § 98.71(c).

(d) State and territorial Lead Agencies shall make the following reports publicly available on a Web site in a timely manner:

(1) Annual administrative data reports under paragraph (b) of this section;

(2) Quarterly financial reports under § 98.65(g); and

(3) Annual quality progress reports under § 98.53(g).

[63 FR 39981, July 24, 1998, as amended at 81 FR 67592, Sept. 30, 2016; 89 FR 52397, June 24, 2024]

§ 98.71 Content of report.

(a) At a minimum, a State or territorial Lead Agency's quarterly case-level report to the Secretary, as required in § 98.70, shall include the following information on services provided under CCDF grant funds, including Federal Discretionary (which includes any funds transferred from the TANF Block Grant), Mandatory, and Matching Funds; and State Matching and Maintenance-of-Effort (MOE) Funds:

(1) The total monthly family income and family size used for determining eligibility;

(2) Zip code of residence of the family and zip code of the location of the child care provider;

(3) Gender and month/year of birth of children;

(4) Ethnicity and race of children;

(5) Whether the head of the family is a single parent

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(6) The sources of family income and assistance from employment (including self-employment), cash or other assistance under the Temporary Assistance for Needy Families program under Part A of title IV of the Social Security Act (42 U.S.C. 609(a)(7)), cash or other assistance under a State program for which State spending is counted toward the maintenance of effort requirement under section 409(a)(7) of the Social Security Act, housing assistance, assistance under the Food Stamp Act of 1977, and other assistance programs;

(7) The month/year child care assistance to the family started;

(8) The type(s) of child care in which the child was enrolled (such as family child care, in-home care, or center-based child care);

(9) Whether the child care provider was a relative;

(10) The total monthly child care co-payment by the family;

(11) [Reserved]

(12) The total expected dollar amount per month to be received by the provider for each child;

(13) The total hours per month of such care;

(14) Unique identifier of the head of the family unit receiving child care assistance, and of the child care provider;

(15) Reasons for receiving care;

(16) Whether the family is experiencing homelessness;

(17) Whether the parent(s) are in the military service;

(18) Whether the child has a disability;

(19) Primary language spoken at home;

(20) Date of the child care provider's most recent health, safety and fire inspection meeting the requirements of § 98.42(b)(2);

(21) Indicator of the quality of the child care provider; and

(22) Any additional information that the Secretary shall require.

(b) At a minimum, a State or territorial Lead Agency's annual aggregate report to the Secretary, as required in § 98.70(b), shall include the following information on services provided through all CCDF grant funds, including Federal Discretionary (which includes any funds transferred from the TANF Block Grant), Mandatory, and Matching

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Funds; and State Matching and MOE Funds:

(1) The number of child care providers that received funding under CCDF as separately identified based on the types of providers listed in section 658P(5) of the amended Child Care and Development Block Grant Act;

(2) The number of children served by payments through certificates or vouchers, contracts or grants, and cash under public benefit programs, listed by the primary type of child care services provided during the last month of the report period (or the last month of service for those children leaving the program before the end of the report period);

(3) The manner in which consumer education information was provided to parents and the number of parents to whom such information was provided;

(4) The total number (without duplication) of children and families served under CCDF;

(5) For Lead Agencies implementing presumptive eligibility in accordance with § 98.21(e):

(i) The number of presumptively eligible children ultimately determined fully eligible;

(ii) The number of presumptively eligible children for whom the family does not complete the documentation for full eligibility verification; and,

(iii) The number of presumptively eligible children who are determined not to be eligible after full verification;

(6) The number of child fatalities by type of care; and

(7) Any additional information that the Secretary shall require.

(c) A Tribal Lead Agency's annual report as required in § 98.70(c), shall include such information as the Secretary shall require.

[81 FR 67592, Sept. 30, 2016, as amended at 89 FR 15416, Mar. 1, 2024]

Subpart I—Indian Tribes

§ 98.80 General procedures and requirements.

An Indian Tribe or tribal organization (as described in subpart G of these regulations) may be awarded grants to plan and carry out programs for the purpose of increasing the availability, affordability, and quality of child care

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and childhood development programs subject to the following conditions:

(a) An Indian Tribe applying for or receiving CCDF funds shall be subject to the requirements under this part as specified in this section based on the size of the awarded funds. The Secretary shall establish thresholds for Tribes' total CCDF allotments pursuant to §§ 98.61(c) and 98.62(b) to be divided into three categories:

- (1) Large allocations;
- (2) Medium allocations; and
- (3) Small allocations.

(b) An Indian Tribe applying for or receiving CCDF funds shall:

(1) Have at least 50 children under 13 years of age (or such similar age, as determined by the Secretary from the best available data) in order to be eligible to operate a CCDF program. This limitation does not preclude an Indian Tribe with fewer than 50 children under 13 years of age from participating in a consortium that receives CCDF funds; and

(2) Demonstrate its current service delivery capability, including skills, personnel, resources, community support, and other necessary components to satisfactorily carry out the proposed program.

(c) A consortium representing more than one Indian Tribe may be eligible to receive CCDF funds on behalf of a particular Tribe if:

(1) The consortium adequately demonstrates that each participating Tribe authorizes the consortium to receive CCDF funds on behalf of each Tribe or tribal organization in the consortium;

(2) The consortium consists of Tribes that each meet the eligibility requirements for the CCDF program as defined in this part, or that would otherwise meet the eligibility requirements if the Tribe or tribal organization had at least 50 children under 13 years of age;

(3) All the participating consortium members are in geographic proximity to one another (including operation in a multi-State area) or have an existing consortium arrangement; and

(4) The consortium demonstrates that it has the managerial, technical and administrative staff with the ability to administer government funds, manage a CCDF program and comply

with the provisions of the Act and of this part.

(d) The awarding of a grant under this section shall not affect the eligibility of any Indian child to receive CCDF services provided by the State or States in which the Indian Tribe is located.

(e) For purposes of the CCDF, the determination of the number of children in the Tribe, pursuant to paragraph (b)(1) of this section, shall include Indian children living on or near reservations, with the exception of Tribes in Alaska, California and Oklahoma.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67592, Sept. 30, 2016]

§ 98.81 Application and Plan procedures.

(a) In order to receive CCDF funds, a Tribal Lead Agency shall apply for funds pursuant to § 98.13, except that the requirement at § 98.13(b)(2) does not apply.

(b) Tribal Lead Agencies with large and medium allocations shall submit a CCDF Plan, as described at § 98.16, with the following additions and exceptions:

(1) The Plan shall include the basis for determining family eligibility.

(i) If the Tribe's median income is below a certain level established by the Secretary, then, at the Tribe's option, any Indian child in the Tribe's service area shall be considered eligible to receive CCDF funds, regardless of the family's income, work, or training status, provided that provision for services still goes to those with the highest need.

(ii) The basis for determining family eligibility may be determined by the Tribe notwithstanding family income or assets as described in § 98.20(a)(2).

(2) For purposes of determining eligibility, the following terms shall also be defined:

(i) Indian child; and

(ii) Indian reservation or tribal service area.

(3) The Tribal Lead Agency shall also assure that:

(i) The applicant shall coordinate, to the maximum extent feasible, with the Lead Agency in the State in which the applicant shall carry out CCDF programs or activities, pursuant to § 98.82; and

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(ii) In the case of an applicant located in a State other than Alaska, California, or Oklahoma, CCDF programs and activities shall be carried out on an Indian reservation for the benefit of Indian children, pursuant to § 98.83(b).

(4) The Plan shall include any information, as prescribed by the Secretary, necessary for determining the number of children in accordance with §§ 98.61(c), 98.62(c), and 98.80(b)(1).

(5) The Plan shall include a description of the Tribe's payment rates, how they are established, and how they support quality including, where applicable, cultural and linguistic appropriateness.

(6) The Plan is not subject to the following requirements:

(i) The early learning and developmental guidelines requirement at § 98.15(a)(9);

(ii) The certification to develop the CCDF Plan in consultation with the State Advisory Council at § 98.15(b)(1);

(iii) The licensing requirements applicable to child care services at §§ 98.15(b)(6) and § 98.16(u);

(iv) The identification of the public or private entities designated to receive private funds at § 98.16(d)(2);

(v) A definition of very low income at § 98.16(g)(8);

(vi) A description at § 98.16(i)(4) of how the Lead Agency will meet the needs of certain families specified at § 98.50(e);

(vii) The description of the sliding fee scale at § 98.16(k);

(viii) The description of the market rate survey or alternative methodology at § 98.16(r);

(ix) The description relating to Matching Funds at § 98.16(w);

(x) The description of how the Lead Agency uses grants or contracts for supply building at § 98.16(z);

(xi) The description of how the Lead Agency prioritizes increasing access to high-quality child care in areas with high concentration of poverty at § 98.16(aa); and

(xii) The description of provider payment practices at § 98.16(ee).

(7) In its initial Plan, an Indian Tribe shall describe its current service delivery capability pursuant to § 98.80(b)(2).

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(8) A consortium shall also provide the following:

(i) A list of participating or constituent members, including demonstrations from these members pursuant to § 98.80(c)(1);

(ii) A description of how the consortium is coordinating services on behalf of its members, pursuant to § 98.83(c)(1); and

(iii) As part of its initial Plan, the additional information required at § 98.80(c)(4).

(9) Plans for Tribal Lead Agencies with medium allocations are not subject to the following requirements unless the Tribe chooses to include such services, and, therefore, the associated requirements, in its program:

(i) The assurance at § 98.15(a)(2) regarding options for services;

(ii) A description of any limits established for the provision of in-home care at § 98.16(i)(2), or

(iii) A description of the child care certificate payment system(s) at § 98.16(q).

(c) Tribal Lead Agencies with small allocations shall submit an abbreviated CCDF Plan, as described by the Secretary.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67593, Sept. 30, 2016; 89 FR 15416, Mar. 1, 2024; 89 FR 90608, Nov. 18, 2024]

§ 98.82 Coordination.

Tribal applicants shall coordinate the development of the Plan and the provision of services, to the extent practicable, as required by §§ 98.12 and 98.14 and:

(a) To the maximum extent feasible, with the Lead Agency in the State or States in which the applicant will carry out the CCDF program; and

(b) With other Federal, State, local, and tribal child care and childhood development programs.

[81 FR 67593, Sept. 30, 2016]

§ 98.83 Requirements for tribal programs.

(a) The grantee shall designate an agency, department, or unit to act as the Tribal Lead Agency to administer the CCDF program.

(b) With the exception of Alaska, California, and Oklahoma, programs and activities for the benefit of Indian

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children shall be carried out on or near an Indian reservation.

(c) In the case of a tribal grantee that is a consortium:

(1) A brief description of the direct child care services funded by CCDF for each of their participating Tribes shall be provided by the consortium in their three-year CCDF Plan; and

(2) Variations in CCDF programs or requirements and in child care licensing, regulatory and health and safety requirements shall be specified in written agreements between the consortium and the Tribe.

(3) If a Tribe elects to participate in a consortium arrangement to receive one part of the CCDF (*e.g.*, Discretionary Funds), it may not join another consortium or apply as a direct grantee to receive the other part of the CCDF (*e.g.*, Tribal Mandatory Funds).

(4) If a Tribe relinquishes its membership in a consortium at any time during the fiscal year, CCDF funds awarded on behalf of the member Tribe will remain with the tribal consortium to provide direct child care services to other consortium members for that fiscal year.

(d)(1) Tribal Lead Agencies shall not be subject to:

(i) The requirements to use grants or contracts to build supply for certain populations at § 98.30(b);

(ii) The requirement to produce a consumer education website at § 98.33(a). Tribal Lead Agencies still must collect and disseminate the provider-specific consumer education information described at § 98.33(a) through (d), but may do so using methods other than a website;

(iii) The requirement to have licensing applicable to child care services at § 98.40;

(iv) The requirement for a training and professional development framework at § 98.44(a);

(v) The market rate survey or alternative methodology described at § 98.45(b)(2) and the related requirements at § 98.45(c), (d), (e), and (f);

(vi) The requirement for a sliding fee scale at § 98.45(l);

(vii) The requirement to have provider payment practices that reflect generally accepted payment practices at § 98.45(m);

(viii) The requirement that Lead Agencies shall give priority for services to children of families with very low family income at § 98.46(a)(1);

(ix) The requirement that Lead Agencies shall prioritize increasing access to high-quality child care in areas with significant concentrations of poverty and unemployment at § 98.46(b);

(x) The requirements to use grants or contracts at § 98.50(a)(3);

(xi) The requirements about Mandatory and Matching Funds at § 98.50(e);

(xii) The requirement to complete the quality progress report at § 98.53(g);

(xiii) The requirement that Lead Agencies shall expend no more than five percent from each year's allotment on administrative costs at § 98.54(a); and

(xiv) The Matching fund requirements at §§ 98.55 and 98.63.

(2) Tribal Lead Agencies with large, medium, and small allocations shall be subject to the provision at § 98.42(b)(2) to require inspections of child care providers and facilities, unless a Tribal Lead Agency describes an alternative monitoring approach in its Plan and provides adequate justification for the approach.

(3) Tribal Lead Agencies with large, medium, and small allocations shall be subject to the requirement at § 98.43 to conduct comprehensive criminal background checks, unless the Tribal Lead Agency describes an alternative background check approach in its Plan and provides adequate justification for the approach.

(e) Tribal Lead Agencies with medium and small allocations shall not be subject to the requirement for certificates at § 98.30(a) and (d).

(f) Tribal Lead Agencies with small allocations must spend their CCDF funds in alignment with the goals and purposes described in § 98.1. These Tribes shall have flexibility in how they spend their CCDF funds and shall be subject to the following requirements:

(1) The health and safety requirements described in § 98.41;

(2) The monitoring requirements at §§ 98.42 and 98.83(d)(2); and

(3) The background checks requirements described in §§ 98.43 and 98.83(d)(3);

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(4) The requirements to spend funds on activities to improve the quality of child care described in §§98.83(g) and 98.53;

(5) The use of funds requirements at §98.56 and cost allocation requirement at §98.57;

(6) The financial management requirements at subpart G of this part that are applicable to Tribes;

(7) The reporting requirements at subpart H of this part that are applicable to Tribes;

(8) The eligibility definitions at §98.81(b)(2);

(9) The 15 percent limitation on administrative activities at §98.83(i);

(10) The monitoring, non-compliance, and complaint provisions at subpart J of this part; and

(11) Any other requirement established by the Secretary.

(g) Of the aggregate amount of funds expended (*i.e.*, Discretionary and Mandatory Funds):

(1) For Tribal Lead Agencies with large, medium, and small allocations, no less than nine percent shall be used for activities designed to improve the quality of child care services and increase parental options for, and access to, high-quality child care as described at §98.53; and

(2) For Tribal Lead Agencies with large and medium allocations, no less than three percent shall be used to carry out activities at §98.53(a)(4) as such activities relate to the quality of care for infants and toddlers.

(3) Nothing in this section shall preclude the Tribal Lead Agencies from reserving a larger percentage of funds to carry out activities described in paragraph (g)(1) and (2) of this section.

(h) The base amount of any tribal grant is not subject to the administrative cost limitation at paragraph (i) of this section, the direct services requirement at §98.50(f)(2), or the quality expenditure requirement at §98.53(a). The base amount may be expended for any costs consistent with the purposes and requirements of the CCDF.

(i) Not more than 15 percent of the aggregate CCDF funds expended by the Tribal Lead Agency from each fiscal year's (including amounts used for construction and renovation in accordance with §98.84, but not including the base

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amount provided under paragraph (h) of this section) shall be expended for administrative activities. Amounts used for construction and major renovation in accordance with §98.84 are not considered administrative costs.

(j)(1) CCDF funds are available for costs incurred by the Tribal Lead Agency only after the funds are made available by Congress for Federal obligation unless costs are incurred for planning activities related to the submission of an initial CCDF Plan.

(2) Federal obligation of funds for planning costs, pursuant to paragraph (j)(1) of this section, is subject to the actual availability of the appropriation.

[81 FR 67593, Sept. 30, 2016, as amended at 82 FR 3186, Jan. 11, 2017; 89 FR 15416, Mar. 1, 2024; 89 FR 52397, June 24, 2024; 89 FR 85071, Oct. 25, 2024]

§ 98.84 Construction and renovation of child care facilities.

(a) Upon requesting and receiving approval from the Secretary, Tribal Lead Agencies may use amounts provided under §§98.61(c) and 98.62(b) to make payments for construction or major renovation of child care facilities (including paying the cost of amortizing the principal and paying interest on loans).

(b) To be approved by the Secretary, a request shall be made in accordance with uniform procedures established by program instruction and, in addition, shall demonstrate that:

(1) Adequate facilities are not otherwise available to enable the Tribal Lead Agency to carry out child care programs;

(2) The lack of such facilities will inhibit the operation of child care programs in the future; and

(3) The use of funds for construction or major renovation will not result in a decrease in the level of child care services provided by the Tribal Lead Agency as compared to the level of services provided by the Tribal Lead Agency in the preceding fiscal year. The Secretary shall waive this requirement if:

(i) The Secretary determines that the decrease in the level of child care services provided by the Indian tribe or tribal organization is temporary; and

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(ii) The Indian tribe or tribal organization submits to the Secretary a plan that demonstrates that after the date on which the construction or renovation is completed:

(A) The level of direct child care services will increase; or

(B) The quality of child care services will improve.

(c)(1) Tribal Lead Agency may use CCDF funds for reasonable and necessary planning costs associated with assessing the need for construction or renovation or for preparing a request, in accordance with the uniform procedures established by program instruction, to spend CCDF funds on construction or major renovation.

(2) A Tribal Lead Agency may only use CCDF funds to pay for the costs of an architect, engineer, or other consultant for a project that is subsequently approved by the Secretary. If the project later fails to gain the Secretary's approval, the Tribal Lead Agency must pay for the architectural, engineering or consultant costs using non-CCDF funds.

(d) Tribal Lead Agencies that receive approval from the Secretary to use CCDF funds for construction or major renovation shall comply with the following:

(1) Federal share requirements and use of property requirements at 2 CFR 200.311;

(2) Transfer and disposition of property requirements at 2 CFR 200.311(d);

(3) Title requirements at 2 CFR 200.311(a);

(4) Cost principles and allowable cost requirements at subpart E of 2 CFR parts 200 and 300;

(5) Program income requirements at 2 CFR 200.307;

(6) Procurement procedures at 2 CFR 200.317 through 200.327; and

(7) Any additional requirements established by program instruction, including requirements concerning:

(i) The recording of a Notice of Federal Interest in the property;

(ii) Rights and responsibilities in the event of a grantee's default on a mortgage;

(iii) Insurance and maintenance;

(iv) Submission of plans, specifications, inspection reports, and other legal documents; and

(v) Modular units.

(e) In lieu of obligation and liquidation requirements at § 98.60(e), Tribal Lead Agencies shall obligate CCDF funds used for construction or major renovation by the end of the second fiscal year following the fiscal year for which the grant is awarded. Tribal construction and major renovation funds must be liquidated at the end of the second succeeding fiscal year following this obligation deadline. Any Tribal construction and major renovation funds that remain unliquidated by the end of this period will revert to the Federal government.

(f) Tribal Lead Agencies may expend funds, without requesting approval pursuant to paragraph (a) of this section, for minor renovation.

(g) A new tribal grantee (i.e., one that did not receive CCDF funds the preceding fiscal year) may spend no more than an amount equivalent to its Tribal Mandatory allocation on construction and renovation. A new tribal grantee must spend an amount equivalent to its Discretionary allocation on activities other than construction or renovation (i.e., direct services, quality activities, or administrative costs).

(h) A construction or renovation project that requires and receives approval by the Secretary must include as part of the construction and renovation costs:

(1) planning costs as allowed at § 98.84(c);

(2) labor, materials and services necessary for the functioning of the facility; and

(3) initial equipment for the facility. Equipment means items which are tangible, nonexpendable personal property having a useful life of more than five years.

[63 FR 39981, July 24, 1998, as amended at 81 FR 3020, Jan. 20, 2016; 81 FR 67594, Sept. 30, 2016; 89 FR 15417, Mar. 1, 2024; 89 FR 80071, Oct. 2, 2024]

Subpart J—Monitoring, Non-compliance and Complaints

§ 98.90 Monitoring.

(a) The Secretary will monitor programs funded under the CCDF for compliance with:

(1) The Act;

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(2) The provisions of this part; and
(3) The provisions and requirements set forth in the CCDF Plan approved under § 98.18;

(b) If a review or investigation reveals evidence that the Lead Agency, or an entity providing services under contract or agreement with the Lead Agency, has failed to substantially comply with the Plan or with one or more provisions of the Act or implementing regulations, the Secretary will issue a preliminary notice to the Lead Agency of possible non-compliance. The Secretary shall consider comments received from the Lead Agency within 60 days (or such longer period as may be agreed upon between the Lead Agency and the Secretary).

(c) Pursuant to an investigation conducted under paragraph (a) of this section, a Lead Agency shall make appropriate books, documents, papers, manuals, instructions, and records available to the Secretary, or any duly authorized representatives, for examination or copying on or off the premises of the appropriate entity, including subgrantees and contractors, upon reasonable request.

(d)(1) Lead Agencies and subgrantees shall retain all CCDF records, as specified in paragraph (c) of this section, and any other records of Lead Agencies and subgrantees that are needed to substantiate compliance with CCDF requirements, for the period of time specified in paragraph (e) of this section.

(2) Lead Agencies and subgrantees shall provide through an appropriate provision in their contracts that their contractors will retain and permit access to any books, documents, papers, and records of the contractor that are directly pertinent to that specific contract.

(e) *Length of retention period.* (1) Except as provided in paragraph (e)(2) of this section, records specified in paragraph (c) of this section shall be retained for three years from the day the Lead Agency or subgrantee submits the Financial Reports required by the Secretary, pursuant to § 98.65(g), for the program period.

(2) If any litigation, claim, negotiation, audit, disallowance action, or other action involving the records has been started before the expiration of

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the three-year retention period, the records shall be retained until completion of the action and resolution of all issues that arise from it, or until the end of the regular three-year period, whichever is later.

§ 98.91 Non-compliance.

(a) If after reasonable notice to a Lead Agency, pursuant to § 98.90 or § 98.93, a final determination is made that:

(1) There has been a failure by the Lead Agency, or by an entity providing services under contract or agreement with the Lead Agency, to comply substantially with any provision or requirement set forth in the Plan approved under § 98.16; or

(2) If in the operation of any program for which funding is provided under the CCDF, there is a failure by the Lead Agency, or by an entity providing services under contract or agreement with the Lead Agency, to comply substantially with any provision of the Act or this part, the Secretary will provide to the Lead Agency a written notice of a finding of non-compliance. This notice will be issued within 60 days of the preliminary notification in § 98.90(b), or within 60 days of the receipt of additional comments from the Lead Agency, whichever is later, and will provide the opportunity for a hearing, pursuant to part 99.

(b) The notice in paragraph (a) of this section will include all relevant findings, as well as any penalties or sanctions to be applied, pursuant to § 98.92.

(c) Issues subject to review at the hearing include the finding of non-compliance, as well as any penalties or sanctions to be imposed pursuant to § 98.92.

§ 98.92 Penalties and sanctions.

(a) Upon a final determination that the Lead Agency has failed to substantially comply with the Act, the implementing regulations, or the Plan, one of the following penalties will be applied:

(1) The Secretary will disallow any improperly expended funds;

(2) An amount equal to or less than the improperly expended funds will be

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deducted from the administrative portion of the State allotment for the following fiscal year; or

(3) A combination of the above options will be applied.

(b) In addition to imposing the penalties described in paragraph (a) of this section, the Secretary may impose other appropriate sanctions, including:

(1) Disqualification of the Lead Agency from the receipt of further funding under the CCDF; or

(2)(i) A penalty of not more than four percent of the funds allotted under § 98.61 (i.e., the Discretionary Funds) for a Fiscal Year shall be withheld if the Secretary determines that the Lead Agency has failed to implement a provision of the Act, these regulations, or the Plan required under § 98.16;

(ii) This penalty will be withheld no earlier than the second full quarter following the quarter in which the Lead Agency was notified of the proposed penalty;

(iii) This penalty will not be applied if the Lead Agency corrects the failure or violation before the penalty is to be applied or if it submits a plan for corrective action that is acceptable to the Secretary; or

(iv) The Lead Agency may show cause to the Secretary why the amount of the penalty, if applied, should be reduced.

(3)(i) A penalty of five percent of the funds allotted under § 98.61 (i.e., the Discretionary Funds) for a Fiscal Year shall be withheld for any For Fiscal Year the Secretary determines that the Lead Agency has failed to give priority for service in accordance with § 98.46(a);

(ii) This penalty will be withheld no earlier than the first full Fiscal Year following the determination to apply the penalty;

(iii) This penalty will not be applied if the Lead Agency corrects its failure to comply and amends its CCDF Plan within six months of being notified of the failure; and

(iv) The Secretary may waive a penalty for one year in the event of extraordinary circumstances, such as a natural disaster.

(4)(i) A penalty of five percent of the funds allotted under § 98.61 (i.e., the Discretionary Funds) for a Fiscal Year shall be withheld for any Fiscal Year

that the Secretary determines that the State, Territory, or Tribe has failed to comply substantially with the criminal background check requirements at § 98.43;

(ii) This penalty will be withheld no earlier than the first full Fiscal Year following the determination to apply the penalty; and

(iii) This penalty will not be applied if the State, Territory, or Tribe corrects the failure before the penalty is to be applied or if it submits a plan for corrective action that is acceptable to the Secretary.

(c) If a Lead Agency is subject to additional sanctions as provided under paragraph (b) of this section, specific identification of any additional sanctions being imposed will be provided in the notice provided pursuant to § 98.91.

(d) Nothing in this section, or in § 98.90 or § 98.91, will preclude the Lead Agency and the Department from informally resolving a possible compliance issue without following all of the steps described in §§ 98.90, 98.91 and 98.92. Penalties and/or sanctions, as described in paragraphs (a) and (b) of this section, may nevertheless be applied, even though the issue is resolved informally.

(e) It is at the Secretary's sole discretion to choose the penalty to be imposed under paragraphs (a) and (b) of this section.

[63 FR 39981, July 24, 1998, as amended at 81 FR 67594, Sept. 30, 2016]

§ 98.93 Complaints.

(a) This section applies to any complaint (other than a complaint alleging violation of the nondiscrimination provisions) that a Lead Agency has failed to use its allotment in accordance with the terms of the Act, the implementing regulations, or the Plan. The Secretary is not required to consider a complaint unless it is submitted as required by this section. Complaints with respect to discrimination should be referred to the Office of Civil Rights of the Department.

(b) Complaints with respect to the CCDF shall be submitted in writing to the Assistant Secretary for Children and Families. The complaint shall identify the provision of the Plan, the Act, or this part that was allegedly

violated, specify the basis for alleging the violation(s), and include all relevant information known to the person submitting it.

(c) The Department shall promptly furnish a copy of any complaint to the affected Lead Agency. Any comments received from the Lead Agency within 60 days (or such longer period as may be agreed upon between the Lead Agency and Department) shall be considered by the Department in responding to the complaint. The Department will conduct an investigation of complaints, where appropriate.

(d) The Department will provide a written response to complaints within 180 days after receipt. If a final resolution cannot be provided at that time, the response will state the reasons why additional time is necessary.

(e) Complaints that are not satisfactorily resolved through communication with the Lead Agency will be pursued through the process described in § 98.90.

[63 FR 39981, Sept. 24, 1998, as amended at 81 FR 67595, Sept. 30, 2016]

Subpart K—Error Rate Reporting

SOURCE: 72 FR 50898, Sept. 5, 2007, unless otherwise noted.

§ 98.100 Error Rate Report.

(a) *Applicability*—The requirements of this subpart apply to the fifty States, the District of Columbia and Puerto Rico.

(b) *Generally*—States, the District of Columbia and Puerto Rico shall calculate, prepare and submit to the Department, a report of errors occurring in the administration of CCDF grant funds, at times and in a manner specified by the Secretary in instructions. States, the District of Columbia and Puerto Rico must use this report to calculate their error rates, which is defined as the percentage of cases with an error (expressed as the total number of cases with an error compared to the total number of cases); the percentage of cases with an improper payment (expressed as the total number of cases with an improper payment compared to the total number of cases); the percentage of improper payments (expressed as the total amount of improper pay-

ments in the sample compared to the total dollar amount of payments made in the sample); the average amount of improper payment; and the estimated annual amount of improper payments. The report also will provide strategies for reducing their error rates and allow States, the District of Columbia and Puerto Rico to set target error rates for the next cycle.

(c) *Error Defined*—For purposes of this subpart, an “error” shall mean any violation or misapplication of statutory, contractual, administrative, or other legally applicable requirements governing the administration of CCDF grant funds, regardless of whether such violation results in an improper payment.

(d) *Improper Payment Defined*—For purposes of this subpart, “improper payment.”

(1) Means any payment of CCDF grant funds 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 governing the administration of CCDF grant funds; and

(2) Includes any payment of CCDF grant funds to an ineligible recipient, any payment of CCDF grant funds for an ineligible service, any duplicate payment of CCDF grant funds and payments of CCDF grant funds for services not received. Because a child meeting eligibility requirements at the most recent eligibility determination or redetermination is considered eligible between redeterminations as described in § 98.21(a)(1), any payment for such a child shall not be considered an error or improper payment due to a change in the family’s circumstances, as set forth at § 98.21(a) and (b).

(e) *Costs of Preparing the Error Rate Report*—Provided the error rate calculations and reports focus on client eligibility, expenses incurred by the States, the District of Columbia and Puerto Rico in complying with this rule, including preparation of required reports, shall be considered a cost of direct service related to eligibility determination and therefore is not subject to the five percent limitation on CCDF

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administrative costs pursuant to § 98.54(a).

[72 FR 50898, Sept. 5, 2007, as amended at 81 FR 67595, Sept. 30, 2016]

§ 98.101 Case Review Methodology.

(a) *Case Reviews and Sampling*—In preparing the error reports required by this subpart, States, the District of Columbia and Puerto Rico shall conduct comprehensive reviews of case records using a methodology established by the Secretary. For purposes of the case reviews, States, the District of Columbia and Puerto Rico shall select a random sample of case records which is estimated to achieve the calculation of an estimated annual amount of improper payments with a 90 percent confidence interval of ± 5.0 percent.

(b) *Methodology and Forms*—States, the District of Columbia and Puerto Rico must prepare and submit forms issued by the Secretary, following the accompanying instructions setting forth the methodology to be used in conducting case reviews and calculating the error rates.

(c) *Reporting Frequency and Cycle*—States, the District of Columbia and Puerto Rico shall conduct case reviews and submit error rate reports to the Department according to a staggered three-year cycle established by the Secretary such that each State, the District of Columbia, and Puerto Rico will be selected once, and only once, in every three years.

(d) *Access to Federal Staff*—States, the District of Columbia and Puerto Rico must provide access to Federal staff to participate and provide oversight in case reviews and error rate calculations, including access to forms related to determining error rates.

(e) *Record Retention*—Records pertinent to the case reviews and submission of error rate reports shall be retained for a period of five years from the date of submission of the applicable error rate report or, if the error rate report was revised, from the date of submission of the revision. Records must be made available to Federal staff upon request.

§ 98.102 Content of Error Rate Reports.

(a) *Baseline Submission Report*—At a minimum, States, the District of Columbia and Puerto Rico shall submit an initial error rate report to the Department, as required in § 98.100, which includes the following information on errors and resulting improper payments occurring in the administration of CCDF grant funds, including Federal Discretionary Funds (which includes any funds transferred from the TANF Block Grant), Mandatory and Matching Funds and State Matching and Maintenance-of-Effort (MOE Funds):

(1) Percentage of cases with an error (regardless of whether such error resulted in an over or under payment), expressed as the total number of cases in the sample with an error compared to the total number of cases in the sample;

(2) Percentage of cases with an improper payment (both over and under payments), expressed as the total number of cases in the sample with an improper payment compared to the total number of cases in the sample;

(3) Percentage of improper payments (both over and under payments), expressed as the total dollar amount of improper payments in the sample compared to the total dollar amount of payments made in the sample;

(4) Average amount of improper payments (gross over and under payments, divided by the total number of cases in the sample that had an improper payment (both over and under payments));

(5) Estimated annual amount of improper payments (which is a projection of the results from the sample to the universe of cases statewide during the 12-month review period) calculated by multiplying the percentage of improper payments by the total dollar amount of child care payments that the State, the District of Columbia or Puerto Rico paid during the 12-month review period;

(6) For each category of data listed above, targets for errors and improper payments in the next reporting cycle;

(7) Summary of methodology used to arrive at estimate, including fieldwork preparation, sample generation, record review and error rate computation processes;

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(8) Discussion of the causes of improper payments identified and actions that will be taken to correct those causes in order to reduce the error rates;

(9) Description of the information systems and other infrastructure that assist the State, the District of Columbia and Puerto Rico in identifying and reducing improper payments, or if the State, the District of Columbia or Puerto Rico does not have these tools, a description of actions that will be taken to acquire the necessary information systems and other infrastructure; and

(10) Such other information as specified by the Secretary.

(b) *Standard Report*—At a minimum, the State, the District of Columbia and Puerto Rico shall submit an error rate report to the Department, as required in § 98.100, made subsequent to the baseline submission report as set forth in § 98.102(a) which includes the following information on errors and resulting improper payments occurring in the administration of CCDF grant funds, including Federal Discretionary Funds (which includes any funds transferred from the TANF Block Grant), Mandatory and Matching Funds and State Matching and Maintenance-of-Effort (MOE Funds):

(1) All the information reported in the baseline submission, as set forth in § 98.102(a), updated for the current cycle;

(2) For each category of data listed in § 98.102(a)(1) through (5), States, the District of Columbia and Puerto Rico must include data and targets from the prior cycle in addition to data from the current cycle and targets for the next cycle;

(3) Description of whether the State, the District of Columbia or Puerto Rico met error rate targets set in the prior cycle and, if not, an explanation of why not;

(4) Discussion of the causes of improper payments identified in the prior cycle and actions that were taken to correct those causes, in addition to a discussion on the causes of improper payments identified in the current cycle and actions that will be taken to correct those causes in order to reduce the error rates; and

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(5) Such other information as specified by the Secretary.

(c) Any Lead Agency with an improper payment rate that exceeds a threshold established by the Secretary must submit to the Assistant Secretary for approval a comprehensive corrective action plan, as well as subsequent reports describing progress in implementing the plan.

(1) The corrective action plan must be submitted within 60 days of the deadline for submitting the Lead Agency's standard error rate report required by paragraph (b) of this section.

(2) The corrective action plan must include the following:

(i) Identification of a senior accountable official;

(ii) Root causes of error as identified on the Lead Agency's most recent ACF-404 and other root causes identified;

(iii) Detailed descriptions of actions to reduce improper payments and the name and/or title of the individual responsible for ensuring actions are completed;

(iv) Milestones to indicate progress towards action completion and error reduction goals;

(v) A timeline for completing each action of the plan within 1 year, and for reducing the improper payment rate below the threshold established by the Secretary; and

(vi) Targets for future improper payment rates.

(3) Subsequent progress reports including updated corrective action plans must be submitted as requested by the Assistant Secretary until the Lead Agency's improper payment rate no longer exceeds the threshold.

(4) Failure to carry out actions as described in the approved corrective action plan or to fulfill requirements in this paragraph (c) will be grounds for a penalty or sanction under § 98.92.

[72 FR 50898, Sept. 5, 2007, as amended at 81 FR 67595, Sept. 30, 2016; 89 FR 15417, Mar. 1, 2024]

PART 99—PROCEDURE FOR HEARINGS FOR THE CHILD CARE AND DEVELOPMENT FUND

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- 99.31 Posthearing briefs.
- 99.32 Decisions following hearing.
- 99.33 Effective date of Assistant Secretary's decision.

AUTHORITY: 42 U.S.C. 618, 9858.

SOURCE: 57 FR 34428, Aug. 4, 1992, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 99 appear at 63 FR 39998, July 24, 1998.

Subpart A—General

§ 99.1 Scope of rules.

(a) The rules of procedure in this section govern the practice for hearings afforded by the Department to Lead Agencies pursuant to § 98.18(c) or § 98.91, and the practice relating to the decisions of such hearings.

(b) Nothing in this part is intended to preclude or limit negotiations between the Department and the Lead Agency, whether before, during, or after the hearing, to resolve the issues which 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 part, except as expressly provided herein.

§ 99.2 Presiding officer.

(a) (1) The presiding officer at a hearing shall be the Assistant Secretary or the Assistant Secretary's designee.

(2) The designation of the presiding officer shall be in writing. A copy of the designation shall be served on all parties.

(b) The presiding officer, for all hearings, shall be bound by all applicable laws and regulations.

§ 99.3 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 Assistant Secretary. Inquiries may be made at the Administration for Children and Families, 370 L'Enfant Promenade SW., Washington, DC 20447.

§ 99.4 Suspension of rules.

With notice to all parties, the Assistant Secretary for Children and Families or the presiding officer, with respect to pending matters, may modify or waive any rule in this part upon determination that no party will be unduly prejudiced and the ends of justice will thereby be served.

§ 99.5 Filing and service of papers.

(a) An original and two copies of all papers in the proceedings shall be filed with the presiding officer. For exhibits and transcripts of testimony, only the originals need be filed.

(b) All papers in the proceedings shall be served on all parties by personal delivery or by certified mail. Service on the party's designated attorney will be deemed service on the party.

Subpart B—Preliminary Matters—Notice and Parties

§ 99.11 Notice of hearing or opportunity for hearing.

Proceedings commence when the Assistant Secretary mails a notice of

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hearing or opportunity for hearing to the Lead Agency. The notice shall state the time and place for the hearing, and the issues which will be considered. A copy of the notice shall be published in the FEDERAL REGISTER.

§ 99.12 Time of hearing.

The hearing shall be scheduled not less than 30 days nor more than 90 days after the date of the notice of the hearing furnished to the applicant or Lead Agency, unless otherwise agreed to, in writing, by the parties.

§ 99.13 Place.

The hearing shall be held in the city in which the regional office of the Department responsible for oversight of the Lead Agency is located or in such other place as the Assistant Secretary determines, considering both the circumstances of the case and the convenience and necessity of the parties or their representatives.

§ 99.14 Issues at hearing.

(a) The Assistant Secretary may, prior to a hearing under § 98.91 of this part, notify the Lead Agency in writing of additional issues which will be considered at the hearing. Such notice shall be published in the FEDERAL REGISTER. If such notice is received by the Lead Agency less than 20 days before the date of the hearing, a postponement of the hearing shall be granted at the request of the Lead Agency or any other party. The hearing shall be held on a date 20 days after such notice was received, or on such later date as agreed to by the Assistant Secretary.

(b) If, as a result of negotiations between the Department and the Lead Agency, the submittal of a Plan amendment, a change in the Lead Agency program, or other action by the Lead Agency, any issue is resolved in whole or in part, but new or modified issues are presented, as specified by the Assistant Secretary, the hearing shall proceed on such new or modified issues. A notice of such new or modified issues shall be published in the FEDERAL REGISTER. If such notice is received by the Lead Agency less than 20 days before the date of the hearing, a postponement of the hearing shall be granted at the request of the Lead

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Agency or any other party. The hearing shall be held on a date 20 days after such notice was received, or on such later date as agreed to by the Assistant Secretary.

(c)(1) If, at any time, the Assistant Secretary finds that the Lead Agency has come into compliance with Federal statutes and regulations on any issue, in whole or in part, the Assistant Secretary shall remove such issue from the proceedings, in whole or in part, as may be appropriate. If all issues are removed, the Assistant Secretary shall terminate the hearing.

(2) Prior to the removal of any issue from the hearing, in whole or in part, the Assistant Secretary shall provide all parties other than the Department and the Lead Agency (see § 99.15(b)) with written notice of the intention, and the reasons for it. Such notice shall include a copy of the proposed CCDF Plan provision on which the Lead Agency and Assistant Secretary have settled. The parties shall have 15 days from the receipt of such notice to file their views or any information on the merits of the proposed Plan provision and the merits of the Assistant Secretary's reasons for removing the issue from the hearing.

(d) The issues considered at the hearing shall be limited to those issues of which the Lead Agency is notified, as provided in paragraph (a) of this section, and new or modified issues described in paragraph (b) of this section; they shall not include issues or parts of issues removed from the proceedings pursuant to paragraph (c) of this section.

§ 99.15 Request to participate in hearing.

(a) The Department and the Lead Agency are parties to the hearing without making a specific request to participate.

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

(2) Any individual or group wishing to participate as a party shall file a petition with the presiding officer within 15 days after notice of the hearing has been published in the FEDERAL REGISTER and shall serve a copy on each party of record at that time, in accordance with § 99.5(b). Such petition shall concisely state:

- (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.

(3) Any party may, within 5 days of receipt of such petition, file comments on it.

(4) The presiding officer shall promptly determine whether each petitioner has the requisite interest in the proceedings and shall permit or deny participation accordingly. Where petitions to participate as parties are made by individuals or groups with common interests, at the presiding officer's discretion, the presiding officer may request that all such petitioners designate a single representative or may recognize one or more of such petitioners to represent all such petitioners. The presiding officer shall give each petitioner written notice of the decision on the petition, and if the petition is denied, the presiding officer shall briefly state the grounds for denial. If the petition is denied, the presiding officer may recognize the petitioner as an *amicus curiae*.

(c)(1) Any interested person or organization wishing to participate as an *amicus curiae* shall file a petition with the presiding officer before the commencement of the hearing. Such petition shall concisely state:

- (i) The petitioner's interest in the hearing;
- (ii) Who will represent the petitioner; and
- (iii) The issues on which petitioner intends to present argument.

An *amicus curiae* is not a party but may participate as provided in this paragraph.

(2) The presiding officer may grant the petition upon finding that the petitioner has a legitimate interest in the proceedings, that such participation

will not unduly delay the outcome, and it may contribute materially to the proper disposition of the issues.

(3) An *amicus curiae* may present a brief oral statement at the hearing, at the point in the proceedings specified by the presiding officer. The *amicus curiae* may submit a written statement of position to the presiding officer prior to the beginning of a hearing and shall serve a copy on each party. The *amicus curiae* may also submit a brief or written statement at such time as the parties submit briefs and shall serve a copy on each party.

Subpart C—Hearing Procedures

§ 99.21 Authority of presiding officer.

(a) The presiding officer shall have the duty to conduct a fair hearing, to avoid delay, maintain order, and make a record of the proceedings. The presiding officer shall have all powers necessary to accomplish these ends, including, but not limited to, the power to:

(1) Change the date, time, and place of the hearing, upon due notice to the parties. This authority includes the power to continue the hearing in whole or in part;

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

(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 all pending 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 therein;

(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 in matters pending;

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(10) If the presiding officer is the Assistant Secretary, make a final decision;

(11) If the presiding officer is not the Assistant Secretary, certify the entire record including the recommended findings and proposed decision to the Assistant Secretary; and

(12) Take any action authorized by the rules in this part 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.

§ 99.22 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; and

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

§ 99.23 Discovery.

The Department, the Lead Agency, and any individuals or groups recognized as parties shall have the right to conduct discovery (including depositions) against opposing parties. Rules 26–37 of the Federal Rules of Civil Procedure shall apply to such proceedings; there will be no fixed rule on priority of discovery. Upon written motion, the presiding officer shall promptly rule upon any objection to such discovery action initiated pursuant to this section. The presiding officer shall also have 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 pre-

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vent undue delay in the conduct of the hearing. Upon the failure of any party to make discovery, the presiding officer may, at the presiding officer's discretion, issue any order and impose any sanction (other than contempt orders) authorized by rule 37 of the Federal Rules of Civil Procedure.

§ 99.24 Evidentiary purpose.

The purpose of the hearing is to receive factual evidence and expert opinion testimony related to the issues in the proceeding. Argument will not be received in evidence; rather, it should be presented in statements, memoranda, or briefs, as determined by the presiding officer. Brief opening statements, which shall be limited to statement of the party's position and what the party intends to prove, may be made at hearings.

§ 99.25 Evidence.

(a) Testimony. Testimony shall be given orally under oath or affirmation by witnesses at the hearing. Witnesses shall be available at the hearing for cross-examination by all parties.

(b) Stipulations and exhibits. Two or more parties may agree to stipulations of fact. Such stipulations, or any exhibit proposed by any party, shall be exchanged at the prehearing conference or otherwise prior to the hearing if the presiding officer so requires.

(c) Rules of evidence. Technical rules of evidence shall not apply to hearings conducted pursuant to this part, but rules or principles designed to assure production of the most credible evidence available and to subject testimony to test by cross-examination shall be applied where reasonably necessary by the presiding officer. A witness may be cross-examined on any matter material to the proceeding without regard to the scope of direct examination. The presiding officer may exclude irrelevant, immaterial, or unduly repetitious evidence. All documents and other evidence offered or taken for the record shall be open to examination by the parties, and opportunity shall be given to refute facts and arguments advanced on either side of the issues.

§ 99.26 Unsponsored written material.

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

§ 99.27 Official transcript.

The Department will designate the official reporter for all hearings. The official transcripts of testimony taken, together with any stipulations, exhibits, briefs, or memoranda of law filed therewith shall be filed with the Department. Transcripts of testimony in hearings may be obtained from the official reporter by the parties and the public at rates not to exceed the maximum rates fixed by the contract between the Department and the reporter. Upon notice to all parties, the presiding officer may authorize corrections to the transcript which involve matters of substance.

§ 99.28 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, shall constitute the exclusive record for decision.

Subpart D—Posthearing Procedures, Decisions

§ 99.31 Posthearing briefs.

The presiding officer shall fix the time for filing posthearing briefs, which may contain proposed findings of fact and conclusions of law. The presiding officer shall also fix the time for reply briefs, if permitted.

§ 99.32 Decisions following hearing.

(a) If the Assistant Secretary is the presiding officer, the Assistant Secretary shall issue the decision within 60 days after the time for submission of posthearing briefs has expired.

(b)(1) If the presiding officer is not the Assistant Secretary, the presiding officer shall certify the entire record, including the recommended findings

and proposed decision, to the Assistant Secretary within 60 days after the time for submission of posthearing briefs has expired. The Assistant Secretary shall serve a copy of the recommended findings and proposed decision upon all parties, and amici, if any.

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

(3) The Assistant Secretary shall thereupon review the recommended decision and, within 45 days after the receipt of the exceptions to the recommended findings and proposed decision, issue the decision.

(c) The decision of the Assistant Secretary under this section shall be the final decision of the Secretary and shall constitute “final agency action” within the meaning of 5 U.S.C. 704. The Assistant Secretary’s decision shall be promptly served on all parties, and amici, if any.

§ 99.33 Effective date of Assistant Secretary’s decision.

If, in the case of a hearing pursuant to § 98.18(b) of this chapter, the Assistant Secretary concludes that a Plan amendment does not comply with the Federal statutes and regulations, the decision that further payments will not be made to the Lead Agency, or payments will be limited to categories under other parts of the CCDF Plan not affected, shall specify the effective date for the withholding of Federal funds.

PART 100—INTERGOVERNMENTAL REVIEW OF DEPARTMENT OF HEALTH AND HUMAN SERVICES PROGRAMS AND ACTIVITIES

Sec.

100.1 What is the purpose of these regulations?

100.2 What definitions apply to these regulations?

100.3 What programs and activities of the Department are subject to these regulations?

100.4 [Reserved]

100.5 What is the Secretary’s obligation with respect to Federal interagency coordination?

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- 100.6 What procedures apply to the selection of programs and activities under these regulations?
- 100.7 How does the Secretary communicate with state and local officials concerning the Department's programs and activities?
- 100.8 How does the Secretary provide states an opportunity to comment on proposed Federal financial assistance and direct Federal development?
- 100.9 How does the Secretary receive and respond to comments?
- 100.10 How does the Secretary make efforts to accommodate intergovernmental concerns?
- 100.11 What are the Secretary's obligations in interstate situations?
- 100.12 How may a state simplify, consolidate, or substitute federally required state plans?
- 100.13 May the Secretary waive any provision of these regulations?

AUTHORITY: Executive Order 12372, July 14, 1982 (47 FR 30959), as amended April 8, 1983 (48 FR 15887); sec. 401, Intergovernmental Cooperation Act of 1968, as amended (31 U.S.C. 6506); sec. 204, Demonstration Cities and Metropolitan Development Act of 1966, as amended (42 U.S.C. 3334).

SOURCE: 48 FR 29200, June 24, 1983, unless otherwise noted.

§ 100.1 What is the purpose of these regulations?

(a) The regulations in this part implement Executive Order 12372, "Intergovernmental Review of Federal Programs," issued July 14, 1982 and amended on April 8, 1983. These regulations also implement applicable provisions of section 401 of the Intergovernmental Cooperation Act of 1968 and section 204 of the Demonstration Cities and Metropolitan Development Act of 1966.

(b) These regulations are intended to foster an intergovernmental partnership and a strengthened Federalism by relying on state processes and on state, areawide, regional and local coordination for review of proposed Federal financial assistance and direct Federal development.

(c) These regulations are intended to aid the internal management of the Department, and are not intended to create any right or benefit enforceable at law by a party against the Department or its officers.

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§ 100.2 What definitions apply to these regulations?

Department means the U.S. Department of Health and Human Services (HHS).

Order means Executive Order 12372, issued July 14, 1982, and amended April 8, 1983 and titled "Intergovernmental Review of Federal Programs."

Secretary means the Secretary of HHS or an official or employee of the Department acting for the Secretary under a delegation of authority.

State means any of the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the U.S. Virgin Islands, or the Trust Territory of the Pacific Islands.

§ 100.3 What programs and activities of the Department are subject to these regulations?

The Secretary publishes in the FEDERAL REGISTER a list of the Department's programs and activities that are subject to these regulations and identifies which of these are subject to the requirements of section 204 of the Demonstration Cities and Metropolitan Development Act.

§ 100.4 [Reserved]

§ 100.5 What is the Secretary's obligation with respect to Federal inter-agency coordination?

The Secretary, to the extent practicable, consults with and seeks advice from all other substantially affected Federal departments and agencies in an effort to assure full coordination between such agencies and the Department regarding programs and activities covered under these regulations.

§ 100.6 What procedures apply to the selection of programs and activities under these regulations?

(a) A state may select any program or activity published in the FEDERAL REGISTER in accordance with § 100.3 of this part for intergovernmental review under these regulations. Each state, before selecting programs and activities, shall consult with local elected officials.

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(b) Each state that adopts a process shall notify the Secretary of the Department's programs and activities selected for that process.

(c) A state may notify the Secretary of changes in its selections at any time. For each change, the state shall submit to the Secretary an assurance that the state has consulted with local elected officials regarding the change. The Department may establish deadlines by which states are required to inform the Secretary of changes in their program selections.

(d) The Secretary uses a state's process as soon as feasible, depending on individual programs and activities, after the Secretary is notified of its selections.

§ 100.7 How does the Secretary communicate with state and local officials concerning the Department's programs and activities?

(a) For those programs and activities selected by a state process under § 100.6, the Secretary, to the extent permitted by law:

(1) Uses the state process to determine views of state and local elected officials; and,

(2) Communicates with state and local elected officials, through the state process, as early in a program planning cycle as is reasonably feasible to explain specific plans and actions.

(b) The Secretary provides notice to directly affected state, areawide, regional, and local entities in a state of proposed Federal financial assistance or direct Federal development if:

(1) The state has not adopted a process under the Order; or

(2) The assistance or development involves a program or activity not selected for the state process.

This notice may be made by publication in the FEDERAL REGISTER or other appropriate means, which the Department in its discretion deems appropriate.

§ 100.8 How does the Secretary provide states an opportunity to comment on proposed Federal financial assistance and direct Federal development?

(a) Except in unusual circumstances, the Secretary gives state processes or

directly affected state, areawide, regional and local officials and entities:

(1) At least 30 days from the date established by the Secretary to comment on proposed direct Federal development or Federal financial assistance in the form of noncompeting continuation awards; and

(2) At least 60 days from the date established by the Secretary to comment on proposed direct Federal development or Federal financial assistance other than noncompeting continuation awards.

(b) This section also applies to comments in cases in which the review, coordination, and communication with the Department have been delegated.

(c) Applicants for programs and activities subject to section 204 of the Demonstration Cities and Metropolitan Act shall allow areawide agencies a 60-day opportunity for review and comment.

§ 100.9 How does the Secretary receive and respond to comments?

(a) The Secretary follows the procedures in § 100.10 if:

(1) A state office or official is designated to act as a single point of contact between a state process and all Federal agencies, and

(2) That office or official transmits a state process recommendation for a program selected under § 100.6.

(b)(1) The single point of contract is not obligated to transmit comments from state, areawide, regional or local officials and entities where there is no state process recommendation.

(2) If a state process recommendation is transmitted by a single point of contact, all comments from state, areawide, regional, and local officials and entities that differ from it must also be transmitted.

(c) If a state has not established a process, or is unable to submit a state process recommendation, state, areawide, regional and local officials and entities may submit comments either to the applicant or to the Department.

(d) If a program or activity is not selected for review under a state process, state, areawide, regional and local officials and entities may submit comments either to the applicant or to the

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Department. In addition, if a state process recommendation for a non-selected program or activity is transmitted to the Department by the single point of contact, the Secretary follows the procedures of § 100.10 of this part.

(e) The Secretary considers comments which do not constitute a state process recommendation submitted under these regulations and for which the Secretary is not required to apply the procedures of § 100.10 of this part, when such comments are provided by a single point of contact, by the applicant, or directly to the Department by a commenting party.

(f) If an applicant receives comments under § 100.9(a)(2), (c) or (d) of this part, it must forward such comments to the Department with its application materials.

§ 100.10 How does the Secretary make efforts to accommodate intergovernmental concerns?

(a) If a state process provides a state process recommendation to the Department through its single point of contact, the Secretary either:

- (1) Accepts the recommendation;
- (2) Reaches a mutually agreeable solution with the state process; or
- (3) Provides the single point of contact with such written explanation of the decision as the Secretary in this or her discretion deems appropriate. The Secretary may also supplement the written explanation by providing the explanation to the single point of contact by telephone, other telecommunication, or other means.

(b) In any explanation under paragraph (a)(3) of this section, the Secretary informs the single point of contact that:

- (1) The Department will not implement its decision for at least ten days after the single point of contact receives the explanation; or
- (2) The Secretary has reviewed the decision and determined that, because of unusual circumstances, the waiting period of at least ten days is not feasible.
- (c) For purposes of computing the waiting period under paragraph (b)(1) of this section, a single point of contact is presumed to have received writ-

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ten explanation 5 days after the date such notification is dated.

§ 100.11 What are the Secretary's obligations in interstate situations?

(a) The Secretary is responsible for:

(1) Identifying proposed Federal financial assistance and direct Federal development that have an impact on interstate areas;

(2) Notifying appropriate officials and entities in states which have adopted a process and which select the Department's program or activity.

(3) Making efforts to identify and notify the affected state, areawide, regional, and local officials and entities in those states that have not adopted a process under the Order or do not select the Department's program or activity;

(4) Responding pursuant to § 100.10 of this part if the Secretary receives a recommendation from a designated areawide agency transmitted by a single point of contact, in cases in which the review, coordination, and communication with the Department have been delegated.

(b) The Secretary uses the procedures in § 100.10 if a state process provides a state process recommendation to the Department through a single point of contact.

§ 100.12 How may a state simplify, consolidate, or substitute federally required state plans?

(a) As used in this section:

(1) *Simplify* means that a state may develop its own format, choose its own submission date, and select the planning period for a state plan.

(2) *Consolidate* means that a state may meet statutory and regulatory requirements by combining two or more plans into one document and that the state can select the format, submission date, and planning period for the consolidated plan.

(3) *Substitute* means that a state may use a plan or other document that it has developed for its own purposes to meet Federal requirements.

(b) If not inconsistent with law, a state may decide to try to simplify, consolidate, or substitute federally required state plans without prior approval by the Secretary.

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(c) The Secretary reviews each state plan that a state has simplified, consolidated, or substituted and accepts the plan only if its contents meet Federal requirements.

§ 100.13 May the Secretary waive any provision of these regulations?

In an emergency, the Secretary may waive any provision of these regulations.

PART 101—HEALTH RESOURCES PRIORITIES AND ALLOCATIONS SYSTEM (HRPAS)

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APPENDIX 1 TO PART 101

AUTHORITY: Defense Production Act of 1950, as amended (50 U.S.C. 4501, *et seq.*), and Executive Order 13603 (77 FR 16651, 3 CFR, March 16, 2012).

SOURCE: 89 FR 9025, Feb. 9, 2024, unless otherwise noted.

Subpart A—General

§ 101.1 Purpose.

This part provides guidance and procedures for use of Defense Production Act (DPA) of 1950 section 101 priorities and allocations authority with respect to health resources necessary or appropriate to promote the national defense. The guidance and procedures in this part are consistent with the guidance and procedures provided in other regulations that form the Federal Priorities and Allocations System (FPAS). Guidance and procedures for use of the DPA priorities and allocations authority with respect to other types of resources are provided for: food resources, food resource facilities, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer in 7 CFR part 789; all forms of energy in 10 CFR part 217; all forms of civil transportation in 49 CFR part 33; and all other materials,

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services, and facilities, including construction materials in 15 CFR part 700.

§ 101.2 Priorities and allocations authority.

(a) Section 201 of Executive Order (E.O.) 13603, delegates the President's priorities and allocations authority under section 101 of the DPA. Section 101 of the DPA provides the President with authority to require acceptance and priority performance of contracts and orders (other than contracts of employment) to promote the national defense over performance of any other contracts or orders, and to allocate materials, services, and facilities as deemed necessary or appropriate to promote the national defense to a number of agencies. Section 201 of E.O. 13603 delegates the President's authority to specific agencies as follows:

(1) The Secretary of Agriculture with respect to food resources, food resource facilities, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer;

(2) The Secretary of Energy with respect to all forms of energy;

(3) The Secretary of Health and Human Services with respect to health resources;

(4) The Secretary of Transportation with respect to all forms of civil transportation;

(5) The Secretary of Defense with respect to water resources; and

(6) The Secretary of Commerce for all other materials, services, and facilities, including construction materials.

(b) Section 202 of E.O. 13603 states that the authority delegated in section 201, except as provided in section 201(e) of E.O. 13603, may be used only to support programs that have been determined in writing as necessary or appropriate to promote the national defense:

(1) By the Secretary of Defense with respect to military production and construction, military assistance to foreign nations, military use of civil transportation, stockpiles managed by the Department of Defense, space, and directly related activities.

(2) By the Secretary of Energy with respect to energy production and construction, distribution, and use, and directly related activities; and

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(3) By the Secretary of Homeland Security with respect to all other national defense programs, including civil defense and continuity of Government.

(c) Section 201(e) of E.O. 13603 provides that each department that is delegated allocations authority under section 201(a) of E.O. 13603 may use this authority with respect to control of the general distribution of any material (including applicable services) in the civilian market only after:

(1) Making the finding required under section 101(b) of the DPA; and

(2) The finding has been approved by the President.

§ 101.3 Program eligibility.

Certain programs to promote the national defense are approved for priorities and allocations support. These include programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity. Other eligible programs include emergency preparedness activities conducted pursuant to title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), and critical infrastructure protection and restoration.

Subpart B—Definitions

§ 101.20 Definitions.

The following definitions pertain to all sections of this part:

Allocation means the control of the distribution of materials, services, or facilities for a purpose deemed necessary or appropriate to promote the national defense.

Allocation order means an official action to control the distribution of materials, services, or facilities for a purpose deemed necessary or appropriate to promote the national defense.

Allotment means an official action that specifies the maximum quantity or use of a material, service, or facility authorized for a specific use to promote the national defense.

Approved program means a program determined by the Secretary of Defense, the Secretary of Energy, or the Secretary of Homeland Security to be

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necessary or appropriate to promote the national defense, under the authority of the Defense Production Act and in accordance with section 202 of E.O. 13603.

Construction means the erection, addition, extension, or alteration of any building, structure, or project, using materials or products which are to be an integral and permanent part of the building, structure, or project. Construction does not include maintenance and repair.

Critical infrastructure means any systems and assets, whether physical or cyber-based, so vital to the United States that the degradation or destruction of such systems and assets would have a debilitating impact on national security, including, but not limited to, national economic security and national public health or safety.

Defense Production Act or *DPA* means the Defense Production Act of 1950, as amended (50 U.S.C. 4501 *et seq.*).

Delegate agency means a Federal Government agency authorized by delegation from the Department of Health and Human Services (HHS) to place priority ratings on contracts or orders needed to support approved programs.

Directive means an official action that requires a person to take or refrain from taking certain actions in accordance with its provisions.

Emergency preparedness means all those activities and measures designed or undertaken to prepare for or minimize the effects of a hazard upon the civilian population, to deal with the immediate emergency conditions which would be created by the hazard, and to effectuate emergency repairs to, or the emergency restoration of, vital utilities and facilities destroyed or damaged by the hazard. "Emergency Preparedness" includes the following:

(1) Measures to be undertaken in preparation for anticipated hazards (including the establishment of appropriate organizations, operational plans, and supporting agreements, the recruitment and training of personnel, the conduct of research, the procurement and stockpiling of necessary materials and supplies, the provision of suitable warning systems, the construction or preparation of shelters, shelter areas, and control centers, and,

when appropriate, the nonmilitary evacuation of the civilian population).

(2) Measures to be undertaken during a hazard (including the enforcement of passive defense regulations prescribed by duly established military or civil authorities, the evacuation of personnel to shelter areas, the control of traffic and panic, and the control and use of lighting and civil communications).

(3) Measures to be undertaken following a hazard (including activities for firefighting; rescue; emergency medical, health and sanitation services; monitoring for specific dangers of special weapons; unexploded bomb reconnaissance; essential debris clearance; emergency welfare measures; and immediately essential emergency repair or restoration of damaged vital facilities).

Facilities includes all types of buildings, structures, or other improvements to real property (but excluding farms, churches or other places of worship, and private dwelling houses), and services relating to the use of any such building, structure, or other improvement.

Farm equipment means equipment, machinery, and repair parts manufactured for use on farms in connection with the production or preparation for market use of food resources.

Fertilizer means any product or combination of products that contain one or more of the elements nitrogen, phosphorous, and potassium for use as a plant nutrient.

Food resource facilities means plants, machinery, vehicles (including on farm), and other facilities required for the production, processing, distribution, and storage (including cold storage) of food resources, and for the domestic distribution of farm equipment and fertilizer (excluding transportation thereof).

Food resources means all commodities and products, (simple, mixed, or compound), or complements to such commodities or products, that are capable of being ingested by other human beings or animals, irrespective of other uses to which such commodities or products may be put, at all stages of processing from the raw commodity to the products thereof in vendible form

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for human or animal consumption. “Food resources” also means potable water packaged in commercially marketable containers, all starches, sugars, vegetable and animal or marine fats and oils, seed, cotton, hemp, and flax fiber, but does not mean any such material after it loses its identity as an agricultural commodity or agriculture product.

Hazard means an emergency or disaster resulting from:

- (1) A natural disaster; or
- (2) An accidental or man-caused event.

Health resources means drugs, biological products, medical devices, materials, facilities, health supplies, services and equipment required to diagnose, mitigate, or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population.

Homeland Security includes efforts—

- (1) To prevent terrorist attacks within the United States;
- (2) To reduce the vulnerability of the United States to terrorism;
- (3) To minimize damage from a terrorist attack in the United States; and
- (4) To recover from a terrorist attack in the United States.

Industrial resource means all materials, services, and facilities, including construction materials, the authority for which has not been delegated to other agencies under E.O. 13603. The term “Industrial resource” does not include food resources, food resource facilities, livestock resources, veterinary resources, and the domestic distribution of farm equipment and commercial fertilizer; all forms of energy; health resources; all forms of civil transportation; and water resources.

Item means any raw, in process, or manufactured material, article, commodity, supply, equipment, component, accessory, part, assembly, or product of any kind, technical information, process, or service.

Maintenance and Repair and/or Operating Supplies (MRO) includes the following—

- (1) “*Maintenance*” is the upkeep necessary to continue any plant, facility, or equipment in working condition;
- (2) “*Repair*” is the restoration of any plant, facility, or equipment to work-

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ing condition when it has been rendered unsafe or unfit for service by wear and tear, damage, or failure of parts;

(3) “*Operating Supplies*” are any resources carried as operating supplies according to a person’s established accounting practice. “Operating Supplies” may include hand tools and expendable tools, jigs, dies, fixtures used on production equipment, lubricants, cleaners, chemicals, and other expendable items; and

(4) *MRO* does not include items produced or obtained for sale to other persons or for installation upon or attachment to the property of another person, or items required for the production of such items; items needed for the replacement of any plant, facility, or equipment; or items for the improvement of any plant, facility, or equipment by replacing items which are still in working condition with items of a new or different kind, quality, or design.

Materials includes—

(1) Any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and

(2) Any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items.

National defense means programs for military and energy production or construction, military or critical infrastructure assistance to any foreign nation, homeland security, stockpiling, space, and any directly related activity. Such term includes emergency preparedness activities conducted pursuant to title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121, *et seq.*) and critical infrastructure protection and restoration.

Official action means an action taken by HHS under the authority of the DPA, E.O. 13603, and this part or another regulation under the FPAS. Such actions include the issuance of Rating Authorizations, Directives, Set Asides, Allotments, Letters of Understanding,

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and Demands for Information, Inspection Authorizations, and Administrative Subpoenas.

Person includes any individual, corporation, partnership, association, or any other organized group of persons, or legal successor or representative thereof; or any State or local government or agency thereof; and for purposes of administration of this part, includes the Federal Government and any authorized foreign government or international organization or agency thereof, delegated authority as provided in this part.

Priority rating is an identifying code assigned by HHS, a Delegate Agency or authorized person placed on all rated orders for health resources and consisting of the rating symbol and program identification symbol.

Program Identification Symbols is an abbreviation used to indicate which approved program is supported by a rated order.

Rated order means a prime contract, a subcontract, or a purchase order in support of an approved program issued in accordance with the provisions of this part.

Resource department means any agency delegated priorities and allocations authority as specified in §101.2.

Secretary means the Secretary of HHS.

Services includes any effort that is needed for or incidental to—

(1) The development, production, processing, distribution, delivery, or use of a health resource.

(2) The construction of facilities.

(3) Other national defense programs and activities.

Set-aside means an official action that requires a person to reserve materials, services, or facilities capacity in anticipation of the receipt of rated orders.

Stafford Act means title VI (Emergency Preparedness) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended (42 U.S.C. 5121 *et seq.*).

Water resources means all usable water, from all sources, within the jurisdiction of the United States, that can be managed, controlled, and allocated to meet emergency requirements, except “water resources” do not

include usable water that qualifies as “food resources”.

Working day means any day that the recipient of an order is open for business.

Subpart C—Placement of Rated Orders

§ 101.30 Delegations of authority.

(a) The priorities and allocations authorities of the President under section 101 of the DPA with respect to health resources have been delegated to the Secretary under E.O. 13603. The Secretary may re-delegate the Secretary's priorities authorities under the DPA to authorize a Delegate Agency to assign priority ratings to orders for health resources needed for use in approved programs.

(b) Pursuant to 87 FR 58363 published in the FEDERAL REGISTER on September 26, 2022, the Secretary delegated to the Assistant Secretary for Preparedness and Response (the ASPR) within the Administration for Strategic Preparedness and Response (ASPR), the authority under section 201 of E.O. 13603 to exercise priorities authority under section 101 of the DPA. This delegation authorized the ASPR, on behalf of the Secretary, to approve DO—[M1–M9] priority rating requests for health resources that promote the national defense, though this delegation excludes the authority to approve all priorities provisions for health resources that require DX—[M1–M9] priority ratings.

§ 101.31 Priority ratings.

(a) *Levels of priority.* (1) There are two levels of priority established by the HRPAS, identified by the rating symbols “DO” and “DX”.

(2) All DO rated orders have equal priority with each other and take precedence over unrated orders. All DX rated orders have equal priority with each other and take precedence over DO rated orders and unrated orders. (For resolution of conflicts among rated orders of equal priority, see §101.34(c).

(3) In addition, a Directive regarding priority treatment for a given item issued by HHS for that item takes precedence over any DX rated order,

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DO rated order, or unrated order, as stipulated in the Directive. (For a full discussion of Directives, see § 101.62.)

(b) *Priority ratings.* A priority rating is an identifying code assigned by a Delegate Agency or authorized person placed on all rated orders for health resources. It consists of the rating symbol and the program identification symbol.

§ 101.32 Elements of a rated order.

(a) Each rated order must include:

(1) The appropriate priority rating (e.g., DO-[M1-M9 or DX—[—[M1-M9];

(2) A required delivery date or dates. The words “immediately” or “as soon as possible” do not constitute a delivery date. A “requirements contract,” “basic ordering agreement,” “prime vendor contract,” or similar procurement document bearing a priority rating may contain no specific delivery date or dates and may provide for the furnishing of items or service from time-to-time or within a stated period against specific purchase orders, such as “calls,” “requisitions,” and “delivery orders.” These purchase orders must specify a required delivery date or dates and are to be considered as rated as of the date of their receipt by the supplier and not as of the date of the original procurement document;

(3) The written signature on a manually placed order, or the digital signature or name on an electronically placed order, of an individual authorized to sign rated orders for the person placing the order. The signature or use of the name certifies that the rated order is authorized under this part and that the requirements of this part are being followed; and

(4) A statement that reads in substance:

(b) This is a rated order certified for national defense use, and you are required to follow all the provisions of the Health Resources Priorities and Allocations System regulation at 45 CFR part 101.

(c) Additional element required for certain emergency preparedness rated orders. If the rated order is placed in support of emergency preparedness requirements and expedited action is necessary and appropriate to meet these requirements, the following

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statement must be included in the order: “This rated order is placed for the purpose of emergency preparedness. It must be accepted or rejected within [Insert a time limit no less than the minimum applicable time limit specified in § 101.33(e)].”

§ 101.33 Acceptance and rejection of rated orders.

(a) *Mandatory acceptance.* (1) Except as otherwise specified in this section, a person shall accept every rated order received and must fill such orders regardless of any other rated or unrated orders that have been accepted.

(2) A person shall not discriminate against rated orders in any manner such as by charging higher prices or by imposing different terms and conditions than for comparable unrated orders.

(b) *Mandatory rejection.* Unless otherwise directed by HHS for a rated order involving health resources:

(1) A person shall not accept a rated order for delivery on a specific date if unable to fill the order by that date. However, the person must inform the customer of the earliest date on which delivery can be made and offer to accept the order on the basis of that date. Scheduling conflicts with previously accepted lower rated or unrated orders are not sufficient reason for rejection under this section.

(2) A person shall not accept a DO rated order for delivery on a date which would interfere with delivery of any previously accepted DO or DX rated orders. However, the person must offer to accept the order based on the earliest delivery date otherwise possible.

(3) A person shall not accept a DX rated order for delivery on a date which would interfere with delivery of any previously accepted DX rated orders but must offer to accept the order based on the earliest delivery date otherwise possible.

(4) If a person is unable to fill all of the rated orders of equal priority status received on the same day, the person must accept, based upon the earliest delivery dates, only those orders which can be filled, and reject the other orders. For example, a person must accept order A requiring delivery

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on December 15 before accepting order B requiring delivery on December 31. However, the person must offer to accept the rejected orders based on the earliest delivery dates otherwise possible.

(c) *Optional rejection.* Unless otherwise directed by HHS for a rated order involving health resources, rated orders may be rejected in any of the following cases as long as a supplier does not discriminate among customers:

(1) If the person placing the order is unwilling or unable to meet regularly established terms of sale or payment;

(2) If the order is for an item not supplied or for a service not capable of being performed;

(3) If the order is for an item or service produced, acquired, or provided only for the supplier's own use for which no orders have been filled for two years prior to the date of receipt of the rated order. If, however, a supplier has sold some of these items or provided similar services, the supplier is obligated to accept rated orders up to that quantity or portion of production or service, whichever is greater, sold or provided within the past two years;

(4) If the person placing the rated order, other than the U.S. Government, makes the item or performs the service being ordered;

(5) If acceptance of a rated order or performance against a rated order would violate any other regulation, official action, or order of the HHS issued under the authority of the DPA or another relevant statute.

(d) *Customer notification requirements.*

(1) Except as provided in paragraph (e) of this section, a person must accept or reject a rated order in writing or electronically within fifteen (15) working days after receipt of a DO-rated order and within ten (10) working days after receipt of a DX-rated order. If the order is rejected, the person must give reasons in writing or electronically for the rejection.

(2) If a person has accepted a rated order and subsequently finds that shipment or performance will be delayed, the person must notify the customer immediately, give the reasons for the delay, and advise of a new shipment or performance date. If notification is given verbally, written (hard copy) or

electronic confirmation must be provided within one (1) working day of the verbal notice.

(e) *Exception for emergency response conditions.* If the rated order is placed for the purpose of emergency preparedness, and expedited action is necessary or appropriate to meet these requirements and the order includes the statement as set forth in § 101.32(a)(4)(b), a person must accept or reject a rated order and transmit the acceptance or rejection in writing or in an electronic format within the time frame specified in the rated order (usually within two working days after receipt of the order). The minimum times for acceptance or rejection that such orders may specify are six (6) hours after receipt if the order is issued by an authorized person in response to a hazard that has occurred; or twelve (12) hours after receipt if the order is issued by an authorized person to prepare for an imminent hazard.

§ 101.34 Preferential scheduling.

(a) A person must schedule operations, including the acquisition of all needed production items or services, in a timely manner to satisfy the delivery requirements of each rated order. Modifying production or delivery schedules is necessary only when required delivery dates for rated orders cannot otherwise be met.

(b) DO rated orders must be given production preference over unrated orders, if necessary, to meet required delivery dates, even if this requires the diversion of items being processed or ready for delivery or services being performed against unrated orders. Similarly, DX rated orders must be given preference over DO rated orders and unrated orders. (Examples: If a person receives a DO rated order with a delivery date of June 3 and if meeting that date would mean delaying production or delivery of an item for an unrated order, the unrated order must be delayed. If a DX rated order is received calling for delivery on July 15 and a person has a DO rated order requiring delivery on June 2 and operations can be scheduled to meet both deliveries, there is no need to alter production schedules to give any additional preference to the DX rated

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order. However, if business operations cannot be altered to meet both the June 2 and July 15 delivery dates, then the DX rated order must be given priority over the DO rated order.)

(c)(1) If a person finds that delivery or performance against any accepted rated orders conflicts with the delivery or performance against other accepted rated orders of equal priority status, the person shall give precedence to the conflicting orders in the sequence in which they are to be delivered or performed (not to the receipt dates). If the conflicting orders are scheduled to be delivered or performed on the same day, the person shall give precedence to those orders that have the earliest receipt dates.

(2) If a person is unable to resolve rated order delivery or performance conflicts under this section, the person should promptly seek special priorities assistance as provided in §§101.40 through 101.44. If the person's customer objects to the rescheduling of delivery or performance of a rated order, the customer should promptly seek special priorities assistance as provided in §§101.40 through 101.44. For any rated order against which delivery or performance will be delayed, the person must notify the customer as provided in §101.33(d)(2).

(d) If a person is unable to purchase needed production items in time to fill a rated order by its required delivery date, the person must fill the rated order by using inventoried production items. A person who uses inventoried items to fill a rated order may replace those items with the use of a rated order as provided in §101.37(b).

§ 101.35 Extension of priority ratings.

(a) A person must use rated orders with suppliers to obtain items or services needed to fill a rated order. The person must use the priority rating indicated on the customer's rated order, except as otherwise provided in this part or as directed by HHS.

(b) The priority rating must be included on each successive order placed to obtain items or services needed to fill a customer's rated order. This continues from contractor to subcontractor to supplier throughout the entire procurement chain.

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§ 101.36 Changes or cancellations of priority ratings and rated orders.

(a) The priority rating on a rated order may be changed or canceled by:

(1) An official action of HHS; or

(2) Written notification from the person who placed the rated order (including a Delegate Agency).

(b) If an unrated order is amended to make it a rated order, or a DO rating is changed to a DX rating, the supplier must give the appropriate preferential treatment to the order as of the date the change is received by the supplier.

(c) An amendment to a rated order that significantly alters a supplier's original production or delivery schedule shall constitute a new rated order as of the date of its receipt. The supplier must accept or reject the amended order according to the provisions of §101.33.

(d) The following amendments do not constitute a new rated order: a change in shipping destination; a reduction in the total amount of the order; an increase in the total amount of the order which has negligible impact upon deliveries; a minor variation in size or design (prior to the start of production); or a change which is agreed upon between the supplier and the customer.

(e) If a person no longer needs items or services to fill a rated order, any rated orders placed with suppliers for the items or services, or the priority rating on those orders, must be canceled.

(f) When a priority rating is added to an unrated order, or is changed or canceled, all suppliers must be promptly notified in writing.

§ 101.37 Use of rated orders.

(a) A person must use rated orders to obtain:

(1) Items which will be physically incorporated into other items to fill rated orders, including that portion of such items normally consumed or converted into scrap or by-products in the course of processing;

(2) Containers or other packaging materials required to make delivery of the finished items against rated orders;

(3) Services, other than contracts of employment, needed to fill rated orders;

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(4) MRO needed to produce the finished items to fill rated orders.

(b) A person may use a rated order to replace inventoried items (including finished items) if such items were used to fill rated orders, as follows:

(1) The order must be placed within 90 days of the date of use of the inventory.

(2) A DO rating symbol and the program identification symbol indicated on the customer's rated order must be used on the order. A DX rating may not be used even if the inventory was used to fill a DX rated order.

(3) If the priority ratings on rated orders from one customer or several customers contain different program identification symbols, the rated orders may be combined.

(c) A person may combine DX and DO rated orders from one customer or several customers if the items or services covered by each level of priority are identified separately and clearly.

(d) Combining rated and unrated orders.

(1) A person may combine rated and unrated order quantities on one purchase order provided that:

(i) The rated quantities are separately and clearly identified; and

(ii) The four elements of a rated order, as required by § 101.32, are included on the order with the statement required in § 101.32(a)(4) modified to read in substance: "This purchase order contains rated order quantities certified for national defense use, and you are required to follow all applicable provisions of the Health Resources Priorities and Allocations System regulations at 45 CFR part 101 only as it pertains to the rated quantities".

(2) A supplier must accept or reject the rated portion of the purchase order as provided in § 101.33 and give preferential treatment only to the rated quantities as required by this part. This part may not be used to require preferential treatment for the unrated portion of the order.

(3) Any supplier who believes that rated and unrated orders are being combined in a manner contrary to the intent of this part or in a fashion that causes undue or exceptional hardship may submit a request for adjustment or exception under § 101.80.

(e) A person may place a rated order for the minimum commercially procurable quantity even if the quantity needed to fill a rated order is less than that minimum. However, a person must combine rated orders as provided in paragraph (c) of this section, if possible, to obtain minimum procurable quantities.

(f) A person is not required to place a priority rating on an order for less than one-half of the Simplified Acquisition Threshold (as established in the Federal Acquisition Regulation (FAR) (see 48 CFR 2.101) or in other authorized acquisition regulatory or management systems) whichever amount is greater, provided that delivery can be obtained in a timely fashion without the use of the priority rating.

§ 101.38 Limitations on placing rated orders.

(a) *General limitations.* (1) A person may not place a DO or DX rated order pursuant to this part unless the person in receipt of the rated order has been explicitly authorized to do so by HHS or a Delegate Agency or is otherwise permitted to do so by this part.

(2) Rated orders may not be used to obtain:

(i) Delivery on a date earlier than needed;

(ii) A greater quantity of the item or services than needed, except to obtain a minimum procurable quantity. Separate rated orders may not be placed solely for the purpose of obtaining minimum procurable quantities on each order;

(iii) Items or services in advance of the receipt of a rated order, except as specifically authorized by HHS (see § 101.41(c) for information on obtaining authorization for a priority rating in advance of a rated order);

(iv) Items that are not needed to fill a rated order, except as specifically authorized by HHS, or as otherwise permitted by this part; or

(v) Any of the following items unless specific priority rating authority has been obtained from HHS, a Delegate Agency, or the Department of Commerce, as appropriate:

(A) Items for plant improvement, expansion, or construction, unless they will be physically incorporated into a

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construction project covered by a rated order; or

(B) Production or construction equipment or items to be used for the manufacture of production equipment. [For information on requesting priority rating authority, see § 101.41.]

(C) Any items related to the development of chemical or biological warfare capabilities or the production of chemical or biological weapons unless such development or production has been authorized by the President or the Secretary of Defense. This provision does not however prohibit the use of the priority and allocations authority to acquire or produce qualified countermeasures that are necessary to treat, identify, or prevent harm from any biological or chemical agent that may pose a public health threat affecting national security.

(b) *Jurisdictional limitations.* Unless authorized by the resource agency with jurisdiction, the provisions of this part are not applicable to the following resources:

(1) Food resources, food resource facilities, livestock resources, veterinary resources, plant health resources, and the domestic distribution of farm equipment and commercial fertilizer (Resource agency with jurisdiction—Department of Agriculture);

(2) All forms of energy (Resource agency with jurisdiction—Department of Energy);

(3) All forms of civil transportation (Resource agency with jurisdiction—Department of Transportation);

(4) Water resources (Resource agency with jurisdiction—Department of Defense/U.S. Army Corps of Engineers);

(5) All materials, services, and facilities, including construction materials (industrial resources) for which the authority has not been delegated to other agencies under E.O. 13603 (Resource agency with jurisdiction—Department of Commerce);

(6) The priorities and allocations authority of this part may not be applied to communications services (Resource agency with jurisdiction—National Communications System under E.O. 13618 of July 6, 2012).

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Subpart D—Special Priorities Assistance

§ 101.40 General provisions.

(a) Once a priority rating has been authorized pursuant to this part, further action by HHS is generally not needed. However, from time-to-time, production or delivery problems will arise in connection with rated orders for health resources as covered under this part. In this event, a person should immediately contact ASPR for guidance, as specified in § 101.93. ASPR serves as the lead policy office for emergency preparedness and response operations on behalf of HHS and manages the Department's delegated DPA authorities. If ASPR is unable to resolve the problem or to authorize the use of a priority rating and believes additional assistance is warranted, ASPR may forward the request to another agency with resource jurisdiction, such as the Department of Commerce, as appropriate, for action. Special priorities assistance is provided to alleviate problems that do arise.

(b) Special priorities assistance is available for any reason consistent with this part. Generally, special priorities assistance is provided to expedite deliveries, resolve delivery conflicts, place rated orders, locate suppliers, or to verify information supplied by customers and vendors. Special priorities assistance may also be used to request rating authority for items that are not normally eligible for priority treatment.

§ 101.41 Requests for priority rating authority.

(a) *Rating authority for items or services not normally rated.* If a rated order is likely to be delayed because a person is unable to obtain items or services not normally rated under this part, the person may request the authority to use a priority rating in ordering the needed items or services.

(b) *Rating authority for production or construction equipment.* (1) A request for priority rating authority for production or construction equipment must be submitted to the U.S. Department of Commerce on Form BIS-999.

(2) When the use of a priority rating is authorized for the procurement of

production or construction equipment, a rated order may be used either to purchase or to lease such equipment. However, in the latter case, the equipment may be leased only from a person engaged in the business of leasing such equipment or from a person willing to lease rather than sell.

(c) *Rating authority in advance of a rated prime contract.* (1) In certain cases, and upon specific request HHS may authorize a person to place a priority rating on an order to a supplier in advance of the issuance of a rated prime contract. In these instances, the person requesting advance-rating authority must obtain sponsorship of the request from HHS or the appropriate Delegate Agency. The person shall also assume any business risk associated with the placing of rated orders in the event the rated prime contract is not issued.

(2) The person must state the following in the request: It is understood that the authorization of a priority rating in advance of our receiving a rated prime contract from the Department of Health and Human Services (HHS) and our use of that priority rating with our suppliers in no way commits HHS or any other government agency to enter into a contract or order or to expend funds. Further, we understand that the Federal Government shall not be liable for any cancellation charges, termination costs, or other damages that may accrue if a rated prime contract is not eventually placed and, as a result, we must subsequently cancel orders placed with the use of the priority rating authorized as a result of this request.

(3) In reviewing requests for rating authority in advance of a rated prime contract, HHS will consider, among other things, the following criteria:

- (i) The probability that the prime contract will be awarded;
 - (ii) The impact of the resulting rated orders on suppliers and on other authorized programs;
 - (iii) Whether the contractor is the sole source;
 - (iv) Whether the item being produced has a long lead time;
 - (v) The time period for which the rating is being requested;
- (4) HHS may require periodic reports on the use of the rating authority

granted under paragraph (c) of this section.

(5) If a rated prime contract is not issued, the person shall promptly notify all suppliers who have received rated orders pursuant to the advanced rating authority that the priority rating on those orders is cancelled.

§ 101.42 Examples of assistance.

(a) While special priorities assistance may be provided for any reason in support of this part, it is usually provided in situations where:

- (1) A person is experiencing difficulty in obtaining delivery against a rated order by the required delivery date; or
- (2) A person cannot locate a supplier for an item or service needed to fill a rated order.

(b) Other examples of special priorities assistance include:

- (1) Ensuring that rated orders receive preferential treatment by suppliers;
- (2) Resolving production or delivery conflicts between various rated orders;
- (3) Assisting in placing rated orders with suppliers;
- (4) Verifying the urgency of rated orders; and
- (5) Determining the validity of rated orders.

§ 101.43 Criteria for assistance.

Requests for special priorities assistance should be timely, *i.e.*, the request has been submitted promptly and enough time exists for HHS, or the Delegate Agency to affect a meaningful resolution to the problem, and must establish that:

- (a) There is an urgent need for the item; and
- (b) The applicant has made a reasonable effort to resolve the problem.

§ 101.44 Instances where assistance may not be provided.

Special priorities assistance is provided at the discretion of HHS or the Delegate Agency when it is determined that such assistance is warranted to meet the objectives of this part. Examples where assistance may not be provided include situations when a person is attempting to:

- (a) Secure a price advantage;
- (b) Obtain delivery prior to the time required to fill a rated order;

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- (c) Gain competitive advantage;
- (d) Disrupt an industry apportionment program in a manner designed to provide a person with an unwarranted share of scarce items; or
- (e) Overcome a supplier's regularly established terms of sale or conditions of doing business.

Subpart E—Allocation Actions

§ 101.50 Policy.

- (a) Allocation orders will:
 - (1) Only be used when there is insufficient supply of a material, service, or facility to satisfy national defense supply requirements through the use of the priorities authority or when the use of the priorities authority would cause a severe and prolonged disruption in the supply of materials, services, or facilities available to support normal U.S. economic activities; and
 - (2) Not be used to ration materials or services at the retail level.
- (b) Allocation orders, when used, will be distributed equitably among the suppliers of the materials, services, or facilities being allocated and not require any person to relinquish a disproportionate share of the civilian market.

§ 101.51 General procedures.

Before the Department of Health and Human Services uses its allocations authority to address a supply problem within its resource jurisdiction, it will develop a plan that includes:

- (a) A copy of the written determination made in accordance with section 202 of Executive Order 13603, that the program or programs that would be supported by the allocation action are necessary or appropriate to promote the national defense.
- (b) A detailed description of the situation to include any unusual events or circumstances that have created the requirement for an allocation action;
- (c) A statement of the specific objective(s) of the allocation action;
- (d) A list of the materials, services, or facilities to be allocated;
- (e) A list of the sources of the materials, services, or facilities that will be subject to the allocation action;
- (f) A detailed description of the provisions that will be included in the al-

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location orders, including the type(s) of allocation orders, the percentages or quantity of capacity or output to be allocated for each purpose, and the duration of the allocation action (*i.e.*, anticipated start and end dates);

(g) An evaluation of the impact of the proposed allocation action on the civilian market; and

(h) Proposed actions, if any, to mitigate disruptions to civilian market operations.

§ 101.52 Controlling the general distribution of a material in the civilian market.

No allocation action taken by HHS may be used to control the general distribution of a material in the civilian market, unless the Secretary has:

- (a) Made a written finding that:
 - (1) Such material is a scarce and critical material essential to the national defense, and
 - (2) The requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship;
- (b) Submitted the finding for the President's approval through the Assistant to the President and National Security Advisor and the Assistant to the President for Homeland Security and Counterterrorism; and
- (c) The President has approved the finding.

§ 101.53 Types of allocation orders.

There are three types of allocation orders available for communicating allocation actions.

(a) *Set-aside*. An official action that requires a person to reserve materials, services, or facilities capacity in anticipation of the receipt of rated orders.

(b) *Directive*. An official action that requires a person to take or refrain from taking certain actions in accordance with its provisions. A directive can require a person to: Stop or reduce production of an item; prohibit the use of selected materials, services, or facilities; or divert the use of materials, services, or facilities from one purpose to another; and

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(c) *Allotment*. An official action that specifies the maximum quantity of a material, service, or facility authorized for a specific use to promote the national defense.

§ 101.54 Elements of an allocation order.

Allocation orders may be issued directly to the affected persons or by constructive notice through publication in the FEDERAL REGISTER. This section describes the elements that each order must include.

(a) Each allocation order must include:

(1) A detailed description of the required allocation action(s), including its relationship to any received DX rated orders, DO rated orders, and unrated orders;

(2) Specific start and end calendar dates for each required allocation action;

(3) The written signature on a manually placed order or the digital signature on an electronically placed order of the Secretary of HHS.

(b)(1) Elements to be included in orders issued directly to affected persons:

(2) A statement that reads in substance: “This is an allocation order certified for national defense use. [Insert the name of the person receiving the order] is required to comply with this order, in accordance with the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR part 101);

(c)(1) Elements to be included in an allocation order that gives constructive notice through publication in the FEDERAL REGISTER:

(2) A statement that reads in substance: “This is an allocation order certified for national defense use. [Insert the name(s) of the person(s) to whom the order applies or a description of the class of persons to whom the order applies] is (are) required to comply with this order, in accordance with the provisions of the Health Resources Priorities and Allocations System regulation (45 CFR part 101).

§ 101.55 Mandatory acceptance of an allocation order.

(a) Except as otherwise specified in this section (see paragraph (c) of this

section), a person shall accept and comply with every allocation order received.

(b) A person shall not discriminate against an allocation order in any manner such as by charging higher prices for materials, services, or facilities covered by the order or by imposing terms and conditions for contracts and orders involving allocated materials, services, or facilities that differ from the person’s terms and conditions for contracts and orders for the materials, services, or facilities prior to receiving the allocation order.

(c) If a person is unable to comply fully with the required action(s) specified in an allocation order, the person must notify the ASPR, as specified in § 101.93, immediately, explain the extent to which compliance is possible, and give the reasons why full compliance is not possible. If notification is given verbally, then written or electronic confirmation must be provided within one (1) working day. Such notification does not release the person from complying with the order to the fullest extent possible, until the person is notified by HHS that the order has been changed or cancelled.

§ 101.56 Changes or cancellations of an allocation order.

An allocation order may be changed or canceled by an official action of HHS. Notice of such changes or cancellations may be provided directly to persons to whom the order being cancelled or modified applies or constructive notice may be provided by publication in the FEDERAL REGISTER.

Subpart F—Official Actions

§ 101.60 General provisions.

(a) HHS may take specific official actions to implement the provisions of this part.

(b) These official actions include, but are not limited to, Rating Authorizations, Directives, and Letters of Understanding (See § 101.20.)

§ 101.61 Rating Authorizations.

(a) A Rating Authorization is an official action granting specific priority rating authority that:

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(1) Permits a person to place a priority rating on an order for an item or service not normally ratable under this part; or

(2) Authorizes a person to modify a priority rating on a specific order or series of contracts or orders.

(b) To request priority rating authority, see § 101.41.

§ 101.62 Directives.

(a) A Directive is an official action that requires a person to take or refrain from taking certain actions in accordance with its provisions.

(b) A person must comply with each Directive issued. However, a person may not use or extend a Directive to obtain any items from a supplier, unless expressly authorized to do so in the Directive.

(c) A Directive takes precedence over all DX rated orders, DO rated orders, and unrated orders previously or subsequently received, unless a contrary instruction appears in the Directive.

§ 101.63 Letters of Understanding.

(a) A Letter of Understanding is an official action that may be issued in resolving special priorities assistance cases to reflect an agreement reached by all parties including HHS, the Department of Commerce (if applicable), a Delegate Agency (if applicable), the supplier, and the customer.

(b) A Letter of Understanding is not used to alter scheduling between rated orders, to authorize the use of priority ratings, to impose restrictions under this part. Rather, Letters of Understanding are used to confirm production or shipping schedules that do not require modifications to other rated orders.

Subpart G—Compliance

§ 101.70 General provisions.

(a) HHS may take specific official actions for any reason necessary or appropriate to the enforcement or the administration of the Defense Production Act and other applicable statutes, this part, or an official action. Such actions include Administrative Subpoenas, Demands for Information, and Inspection Authorizations.

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(b) Any person who places or receives a rated order or an allocation order must comply with the provisions of this part.

(c) Willful violation of the provisions of title I or section 705 of the DPA and other applicable statutes, this part, or an official action of HHS is a criminal act, punishable as provided in the DPA and other applicable statutes, and as set forth in § 101.74.

§ 101.71 Audits and investigations.

(a) Audits and investigations are official examinations of books, records, documents, other writings, and information to ensure that the provisions of the DPA and other applicable statutes, this part, and official actions have been properly followed. An audit or investigation may also include interviews and a systems evaluation to detect problems or failures in the implementation of this part.

(b) When undertaking an audit or investigation, HHS shall:

(1) Define the scope and purpose in the official action given to the person under investigation; and

(2) Have ascertained that the information sought, or other adequate and authoritative data are not available from any Federal or other responsible agency.

(c) In administering this part, HHS may issue the following documents that constitute official actions:

(1) *Administrative Subpoenas.* An Administrative Subpoena requires a person to appear as a witness before an official designated by HHS to testify under oath on matters of which that person has knowledge relating to the enforcement or the administration of the DPA and other applicable statutes, this part, or official actions. An Administrative Subpoena may also require the production of books, papers, records, documents and physical objects or property.

(2) *Demands for Information.* A Demand for Information requires a person to furnish to a duly authorized representative of HHS any information necessary or appropriate to the enforcement or the administration of the DPA and other applicable statutes, this part, or official actions.

(3) *Inspection Authorizations.* An Inspection Authorization requires a person to permit a duly authorized representative of HHS to interview the person's employees or agents, to inspect books, records, documents, other writings, and information, including electronically-stored information, in the person's possession or control at the place where that person usually keeps them or otherwise, and to inspect a person's property when such interviews and inspections are necessary or appropriate to the enforcement or the administration of the DPA and related statutes, this part, or official actions.

(d) The production of books, records, documents, other writings, and information will not be required at any place other than where they are usually kept, if, prior to the return date specified in the Administrative Subpoena or Demand for Information, a duly authorized official of HHS is furnished with copies of such material that are certified under oath to be true copies. As an alternative, a duly authorized representative of HHS may enter into a stipulation with a person as to the content of the material.

(e) An Administrative Subpoena, Demand for Information, or Inspection Authorization shall include the name, title, or official position of the person to be served, the evidence sought to be adduced, and its general relevance to the scope and purpose of the audit, investigation, or other inquiry. If employees or agents are to be interviewed; if books, records, documents, other writings, or information are to be produced; or if property is to be inspected; the Administrative Subpoena, Demand for Information, or Inspection Authorization will describe them with particularity.

(f) Service of documents shall be made in the following manner:

(1) Service of a Demand for Information or Inspection Authorization shall be made personally, or by Certified Mail-Return Receipt Requested at the person's last known address. Service of an Administrative Subpoena shall be made personally. Personal service may also be made by leaving a copy of the document with someone at least 18

years old at the person's last known dwelling or place of business.

(2) Service upon other than an individual may be made by serving a partner, corporate officer, or a managing or general agent authorized by appointment or by law to accept service of process. If an agent is served, a copy of the document shall be mailed to the person named in the document.

(3) Any individual 18 years of age or over may serve an Administrative Subpoena, Demand for Information, or Inspection Authorization. When personal service is made, the individual making the service shall prepare an affidavit as to the manner in which service was made and the identity of the person served, and return the affidavit, and in the case of subpoenas, the original document, to the issuing officer. In case of failure to make service, the reasons for the failure shall be stated on the original document.

§ 101.72 Compulsory process.

(a) If a person refuses to permit a duly authorized representative of HHS to have access to any premises or to the source of information necessary to the administration or the enforcement of the DPA and other applicable statutes, this part, or official actions, HHS, through its authorized representative may seek compulsory process. Compulsory process means the institution of appropriate legal action, including ex parte application for an inspection warrant or its equivalent, in any forum of appropriate jurisdiction.

(b) Compulsory process may be sought in advance of an audit, investigation, or other inquiry, if, in the judgment of the Secretary there is reason to believe that a person will refuse to permit an audit, investigation, or other inquiry, or that other circumstances exist which make such process desirable or necessary.

§ 101.73 Notification of failure to comply.

(a) At the conclusion of an audit, investigation, or other inquiry, or at any other time, HHS may inform the person in writing of HHS' position regarding that person's non-compliance with the requirements of the DPA and other

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applicable statutes, this part, or an official action.

(b) In cases where HHS determines that failure to comply with the provisions of the DPA and other applicable statutes, this part, or an official action was inadvertent, the person may be informed in writing of the particulars involved and the corrective action to be taken. Failure to take corrective action may then be construed as a willful violation of the DPA and other applicable statutes, this part, or an official action.

§ 101.74 Violations, penalties, and remedies.

(a) Willful violation of the provisions of the DPA, and related statutes (when applicable), this part, or an official action, is a crime and upon conviction, a person may be punished by fine or imprisonment, or both. The maximum penalties provided by the DPA are a \$10,000 fine, or one year in prison, or both.

(b) The Government may also seek an injunction from a court of appropriate jurisdiction to prohibit the continuance of any violation of, or to enforce compliance with, the DPA, this part, or an official action.

(c) In order to secure the effective enforcement of the DPA and other applicable statutes, this part, and official actions, the following are prohibited:

(1) No person may solicit, influence, or permit another person to perform any act prohibited by, or to omit any act required by, the DPA and other applicable statutes, this part, or an official action.

(2) No person may conspire or act in concert with any other person to perform any act prohibited by, or to omit any act required by, the DPA and other applicable statutes, this part, or an official action.

(3) No person shall deliver any item if the person knows or has reason to believe that the item will be accepted, re-delivered, held, or used in violation of the DPA and other applicable statutes, this part, or an official action. In such instances, the person must immediately notify HHS that, in accordance with this provision, delivery has not been made.

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§ 101.75 Compliance conflicts.

If compliance with any provision of the DPA and other applicable statutes, this part, or an official action would prevent a person from filling a rated order or from complying with another provision of the DPA and other applicable statutes, this part, or an official action, the person must immediately notify HHS, as specified in § 101.93, for resolution of the conflict.

Subpart H—Adjustments, Exceptions, and Appeals

§ 101.80 Adjustments or exceptions.

(a) A person may submit a request to HHS for an adjustment or exception on the ground that:

(1) A provision of this part or an official action results in an undue or exceptional hardship on that person not suffered generally by others in similar situations and circumstances; or

(2) The consequences of following a provision of this part or an official action are contrary to the intent of the DPA and other applicable statutes, or this part.

(b) Each request for adjustment or exception must be in writing and contain a complete statement of all the facts and circumstances related to the provision of this part or official action from which adjustment is sought and a full and precise statement of the reasons why relief should be provided.

(c) The submission of a request for adjustment or exception shall not relieve any person from the obligation of complying with the provision of this part or official action in question while the request is being considered unless such interim relief is granted in writing by the Secretary or the Secretary's designated representative.

(d) A decision of the Secretary or the Secretary's designated representative under this section may be appealed to the Secretary. (For information on the appeal procedure, see § 101.81.)

§ 101.81 Appeals.

(a) Any person whose request for adjustment or exception was denied by the Secretary or the Secretary's designated representative under § 101.80, may appeal to the Secretary who,

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through the Secretary's designated representative, shall review and reconsider the denial.

(b)(1) Except as provided in paragraph (b)(2) of this section, an appeal must be received by the Secretary no later than 45 business days after receipt of a written notice of denial. After this 45-business day period, an appeal may be accepted at the discretion of the Secretary.

(2) For requests for adjustment or exception involving rated orders placed for the purpose of emergency preparedness (see §101.33(e)), an appeal must be received by the Secretary, no later than 15 business days after receipt of a written notice of denial. Contract performance under the order shall not be stayed pending resolution of the appeal.

(c) Each appeal must be in writing and contain a complete statement of all the facts and circumstances related to the action appealed from and a full and precise statement of the reasons the decision should be modified or reversed.

(d) In addition to the written materials submitted in support of an appeal, an appellant may request, in writing, an opportunity for an informal hearing. This request may be granted or denied at the discretion of the Secretary or the Secretary's designated representative.

(e) When a hearing is granted, the Secretary may designate an HHS employee to act as the Secretary's representative and hearing officer to conduct the hearing and to prepare a report. The hearing officer shall determine all procedural questions and impose such time or other limitations deemed reasonable. In the event that the hearing officer decides that a printed transcript is necessary, all expenses shall be borne by the appellant.

(f) When determining an appeal, the Secretary may consider all information submitted during the appeal as well as any recommendations, reports, or other relevant information and documents available to HHS or consult with any other persons or groups.

(g) The submission of an appeal under this section shall not relieve any person from the obligation of complying with the provision of this part or offi-

cial action in question while the appeal is being considered unless such relief is granted in writing by the Secretary.

Subpart I—Miscellaneous Provisions

§ 101.90 Protection against claims.

A person shall not be held liable for damages or penalties for any act or failure to act resulting directly or indirectly from compliance with any provision of this part, or an official action, notwithstanding that such provision or action shall subsequently be declared invalid by judicial or other competent authority.

§ 101.91 Records and reports.

(a) Persons are required to make and preserve for at least three years, accurate and complete records of any transaction covered by this part or an official action.

(b) Records must be maintained in sufficient detail to permit the determination, upon examination, of whether each transaction complies with the provisions of this part or any official action. However, this part does not specify any method or system to be used.

(c) Records required to be maintained by this part must be made available for examination on demand by duly authorized representatives of HHS as provided in §101.71.

(d) In addition, persons must develop, maintain, and submit any other records and reports to HHS that may be required for the administration of the DPA and other applicable statutes, and this part.

(e) DPA section 705(d), as implemented by E.O. 13603, provides that information obtained under this section which the Secretary deems confidential, or with reference to which a request for confidential treatment is made by the person furnishing such information, shall not be published or disclosed unless the Secretary determines that the withholding of this information is contrary to the interest of the national defense. Information required to be submitted to HHS in connection with the enforcement or administration of the DPA, this part, or

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an official action, is deemed to be confidential under DPA section 705(d) and shall be handled in accordance with applicable Federal law.

§ 101.92 Applicability of this part and official actions.

(a) This part and all official actions, unless specifically stated otherwise, apply to transactions in any state, territory, or possession of the United States and the District of Columbia.

(b) This part and all official actions apply not only to deliveries to other persons but also include deliveries to affiliates and subsidiaries of a person and deliveries from one branch, division, or section of a single entity to another branch, division, or section under common ownership or control.

(c) This part shall not be construed to affect any administrative actions taken by HHS, or any outstanding contracts or orders placed pursuant to any of the regulations, orders, schedules, or delegations of authority previously issued by HHS pursuant to authority granted to HHS, by the President under the DPA and E.O. 13603. Such actions, contracts, or orders shall continue in full force and effect under this part unless modified or terminated by proper authority.

§ 101.93 Communications.

All communications concerning this part, including requests for copies of the part and explanatory information, requests for guidance or clarification, and requests for adjustment or exception shall be addressed to the Administration for Strategic Preparedness and Response, U.S. Department of Health and Human Services, Washington, DC 20201. Ref: HRPAS, or email aspr.dpa@hhs.gov.

45 CFR Subtitle A (10–1–25 Edition)

Program identification symbol	Approved program	Agency
M2	Strategic National Stockpile.	Department of Health and Human Services.
M3	Biodefense and Related Medical Countermeasures.	Department of Health and Human Services.
M4	ASPR Critical Infrastructure Protection Program.	Department of Health and Human Services.

PART 102—ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION

Sec.

102.1 Applicability.

102.2 Applicability date.

102.3 Penalty adjustment and table.

AUTHORITY: Pub. L. 101–410, Sec. 701 of Pub. L. 114–74, 31 U.S.C. 3801–3812.

SOURCE: 81 FR 61565, Sept. 6, 2016, unless otherwise noted.

§ 102.1 Applicability.

This part applies to each statutory provision under the laws administered by the Department of Health and Human Services concerning the civil monetary penalties which may be assessed or enforced by an agency pursuant to Federal law or is assessed or enforced pursuant to civil judicial actions in the Federal courts or administrative proceedings. The regulations cited in this part supersede existing HHS regulations setting forth civil monetary penalty amounts. If applicable, the HHS agencies responsible for specific civil monetary penalties will amend their regulations to reflect the adjusted amounts and/or a cross-reference to 45 CFR part 102 in separate actions as soon as practicable.

§ 102.2 Applicability date.

The increased penalty amounts set forth in the right-most column of the table in Section 102.3, “Maximum Adjusted Penalty (\$)”, apply to all civil monetary penalties which are assessed after August 1, 2016, including those penalties whose associated violations occurred after November 2, 2015.

APPENDIX 1 TO PART 101

Program identification symbol	Approved program	Agency
M1	Emergency Support Function 8 Public Health and Medical Services.	Department of Health and Human Services.

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§ 102.3 Penalty adjustment and table.

The adjusted statutory penalty provisions and their applicable amounts are set out in the following table. The

right-most column in the table, “Maximum Adjusted Penalty (\$)”, provides the maximum adjusted civil penalty amounts. The civil monetary penalty amounts are adjusted annually.

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
21 U.S.C.:						
333(b)(2)(A)		FDA	Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	2023	123,965	127,983
333(b)(2)(B)		FDA	Penalty for violation related to drug samples resulting in a conviction of any representative of manufacturer or distributor after the second conviction in any 10-yr period.	2023	2,479,282	2,559,636
333(b)(3)		FDA	Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	2023	247,929	255,964
333(f)(1)(A)		FDA	Penalty for any person who violates a requirement related to devices for each such violation.	2023	33,483	34,568
		FDA	Penalty for aggregate of all violations related to devices in a single proceeding.	2023	2,232,281	2,304,629
333(f)(2)(A)		FDA	Penalty for any individual who introduces or delivers for introduction into interstate commerce food that is adulterated per 21 U.S.C. 342(a)(2)(B) or any individual who does not comply with a recall order under 21 U.S.C. 350i.	2023	94,128	97,179
		FDA	Penalty in the case of any other person (other than an individual) for such introduction or delivery of adulterated food.	2023	470,640	485,893
		FDA	Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	2023	941,280	971,787

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333(f)(3)(A)		FDA	Penalty for all violations adjudicated in a single proceeding for any person who violates 21 U.S.C. 331(j) by failing to submit the certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification; by failing to submit clinical trial information under 42 U.S.C. 282(j); or by submitting clinical trial information under 42 U.S.C. 282(j) that is false or misleading in any particular under 42 U.S.C. 282(j)(5)(D).	2023	14,262	14,724
333(f)(3)(B)		FDA	Penalty for each day any above violation is not corrected after a 30-day period following notification until the violation is corrected.	2023	14,262	14,724
333(f)(4)(A)(i)		FDA	Penalty for any responsible person that violates a requirement of 21 U.S.C. 355(o) (post-marketing studies, clinical trials, labeling), 21 U.S.C. 355(p) (risk evaluation and mitigation (REMS)), or 21 U.S.C. 355-1 (REMS).	2023	356,580	368,137
		FDA	Penalty for aggregate of all such above violations in a single proceeding.	2023	1,426,319	1,472,546
333(f)(4)(A)(ii)		FDA	Penalty for REMS violation that continues after written notice to the responsible person for the first 30-day period (or any portion thereof) the responsible person continues to be in violation.	2023	356,580	368,137
		FDA	Penalty for REMS violation that continues after written notice to responsible person doubles for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2023	1,426,319	1,472,546
		FDA	Penalty for aggregate of all such above violations adjudicated in a single proceeding.	2023	14,263,186	14,725,456

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
333(f)(9)(A)		FDA	Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	2023	20,678	21,348
		FDA	Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	2023	1,378,541	1,423,220
333(f)(9)(B)(i)(I)		FDA	Penalty per violation related to violations of tobacco requirements.	2023	344,636	355,806
		FDA	Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	2023	1,378,541	1,423,220
333(f)(9)(B)(i)(II)		FDA	Penalty in the case of a violation of tobacco product requirements that continues after written notice to such person, for the first 30-day period (or any portion thereof) the person continues to be in violation.	2023	344,636	355,806
		FDA	Penalty for violation of tobacco product requirements that continues after written notice to such person shall double for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2023	1,378,541	1,423,220
		FDA	Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	2023	13,785,420	14,232,205

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333(f)(9)(B)(ii)(I)	FDA		Penalty for any person who either does not conduct post-market surveillance and studies to determine impact of a modified risk tobacco product for which the HHS Secretary has provided them an order to sell, or who does not submit a protocol to the HHS Secretary after being notified of a requirement to conduct post-market surveillance of such tobacco products. Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	2023	344,636	355,806
	FDA			2023	1,378,541	1,423,220
333(f)(9)(B)(ii)(II)	FDA		Penalty for violation of modified risk tobacco product post-market surveillance that continues after written notice to such person for the first 30-day period (or any portion thereof) that the person continues to be in violation.	2023	344,636	355,806
	FDA			2023	1,378,541	1,423,220
			Penalty for post-notice violation of modified risk tobacco product post-market surveillance shall double for every 30-day period thereafter that the tobacco product requirement violation continues for any 30-day period, but may not exceed penalty amount for any 30-day period.			
			Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	2023	13,785,420	14,232,205
333(g)(1)	FDA		Penalty for any person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading for the first such violation in any 3-year period.	2023	356,580	368,137
			Penalty for each subsequent above violation in any 3-year period.	2023	713,160	736,274

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
333 note		FDA	Penalty to be applied for violations of 21 U.S.C. 387f(d)(5) or of violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR part 1140) with respect to a retailer with an approved training program in the case of a second regulation violation within a 12-month period.	2023	345	356
		FDA	Penalty in the case of a third violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	687	709
		FDA	Penalty in the case of a fourth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	2,757	2,846
		FDA	Penalty in the case of a fifth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 36-month period.	2023	6,892	7,115
		FDA	Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2023	13,785	14,232

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FDA	Penalty to be applied for violations of 21 U.S.C. 387f(d)(5) or of violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR part 1140) with respect to a retailer that does not have an approved training program in the case of the first regulation violation.	2023	345	356
FDA	Penalty in the case of a second violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 12-month period.	2023	687	709
FDA	Penalty in the case of a third violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	1,379	1,424
FDA	Penalty in the case of a fourth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2023	2,757	2,846
FDA	Penalty in the case of a fifth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 36-month period.	2023	6,892	7,115
FDA	Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2023	13,785	14,232

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
335b(a)		FDA	Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	2023	525,406	542,434
		FDA	Penalty in the case of any other person (other than an individual) per above violation.	2023	2,101,618	2,169,731
360pp(b)(1)		FDA	Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	2023	3,446	3,558
		FDA	Penalty imposed for any related series of violations of requirements relating to electronic products.	2023	1,174,680	1,212,751
42 U.S.C.				2023	270,180	278,937
262(d)		FDA	Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	2023	21,018	21,699
263b(h)(3)		FDA	Penalty for failure to obtain a mammography certificate as required.	2023	270,180	278,937
300aa–28(b)(1)		FDA	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	2023		

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256b(d)(1)(B)(vi)		HRSA	Penalty for each instance of overcharging a 340B covered entity.	2023	6,813	7,034
299c-3(d)		AHRQ	Penalty for using or disclosing identifiable information obtained in the course of activities undertaken pursuant to Title IX of the Public Health Service Act, for a purpose other than that for which the information was supplied, without consent to do so.	2023	17,717	18,291
653(l)(2)	45 CFR 303.21(f)	ACF	Penalty for Misuse of Information in the National Directory of New Hires.	2023	1,818	1,877
262a(i)(1)	42 CFR 1003.910	OIG	Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	2023	410,932	424,250
	42 CFR 1003.1410	OIG	Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	2023	821,868	848,505
300jj-51		OIG	Penalty per violation for committing information blocking.	2023	1,252,992	1,293,601
1320a-7a(a)	42 CFR 1003.210(a)(1)	OIG	Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	2023	24,164	24,947
		OIG	Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	2023	24,164	24,947
	42 CFR 1003.210(a)(2)	OIG	Penalty for knowingly giving or causing to be presented to a participating provider or supplier false or misleading information that could reasonably be expected to influence a discharge decision.	2023	36,246	37,421
	42 CFR 1003.210(a)(3)	OIG	Penalty for an excluded party retaining ownership or control interest in a participating entity.	2023	24,164	24,947

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
	42 CFR 1003.1010	OIG	Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	2023	24,164	24,947
	42 CFR 1003.210(a)(4)	OIG	Penalty for employing or contracting with an excluded individual.	2023	24,164	24,947
	42 CFR 1003.310(a)(3)	OIG	Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.	2023	120,816	124,732
	42 CFR 1003.210(a)(1)	OIG	Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	2023	24,164	24,947
	42 CFR 1003.210(a)(6)	OIG	Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.	2023	120,816	124,732
	42 CFR 1003.210(a)(8)	OIG	Penalty for knowing of an overpayment and failing to report and return.	2023	24,164	24,947
	42 CFR 1003.210(a)(7)	OIG	Penalty for making or using a false record or statement that is material to a false or fraudulent claim.	2023	68,128	70,336
	42 CFR 1003.210(a)(9)	OIG	Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	2023	36,246	37,421

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1320a-7a(b)		OIG	Penalty for payments by a hospital or critical access hospital to induce a physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2023	6,040	6,236
		OIG	Penalty for physicians who knowingly receive payments from a hospital or critical access hospital to induce such physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2023	6,040	6,236
1320a-7a(o)	42 CFR 1003.210(a)(10)	OIG	Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	2023	12,081	12,473
	42 CFR 1003.710(a)(1)	OIG	Penalty for knowingly presenting or causing to be presented a false or fraudulent specified claim under a grant, contract, or other agreement for which the Secretary provides funding.	2023	11,784	12,166
	42 CFR 1003.710(a)(2)	OIG	Penalty for knowingly making, using, or causing to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document required to directly or indirectly receive or retain funds provided pursuant to grant, contract, or other agreement.	2023	58,921	60,831
	42 CFR 1003.710(a)(3)	OIG	Penalty for Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent specified claim under grant, contract, or other agreement.	2023	58,921	60,831

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
	42 CFR 1003.710(a)(4)	OIG	Penalty for knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit funds or property with respect to grant, contract, or other agreement, or knowingly conceals or improperly avoids or decreases any such obligation, per each false record or statement.	2023	61,458	63,450
			Penalty for knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit funds or property with respect to grant, contract, or other agreement, or knowingly conceals or improperly avoids or decreases any such obligation, per each false record or statement.	2023	12,308	12,707
	42 CFR 1003.710(a)(5)	OIG	Penalty for failure to grant timely access, upon reasonable request, to the I.G. for purposes of audits, investigations, evaluations, or other statutory functions of I.G. in matters involving grants, contracts, or other agreements.	2023	17,677	18,250
1320a–7e(b)(6)(A)	42 CFR 1003.810	OIG	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner.	2023	46,102	47,596
1320b–10(b)(1)	42 CFR 1003.610(a)	OIG	Penalty for the misuse of words, symbols, or emblems in communications in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	2023	12,397	12,799

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1320b-10(b)(2)	42 CFR 1003.610(a)	OIG	Penalty for the misuse of words, symbols, or emblems in a broadcast or telecast in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS.	2023	61,982	63,991
1395i-3(b)(3)(B)(iii)(1)	42 CFR 1003.210(a)(11)	OIG	Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	2023	2,586	2,670
1395i-3(b)(3)(B)(iii)(2)	42 CFR 1003.210(a)(11)	OIG	Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment.	2023	12,924	13,343
1395i-3(g)(2)(A)	42 CFR 1003.1310	OIG	Penalty for any individual who notifies or causes to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	2023	5,171	5,339
1395w-27(g)(2)(A)	42 CFR 1003.410	OIG	Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services.	2023	47,061	48,586
		OIG	Penalty for a Medicare Advantage organization that charges excessive premiums.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2023	184,412	190,389
		OIG	Penalty per individual who does not enroll as a result of a Medicare Advantage organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2023	27,661	28,557

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
		OIG	Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	2023	184,412	190,389
		OIG	Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	2023	46,102	47,596
		OIG	Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	2023	46,102	47,596
		OIG	Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w–27(g)(1)(A)–(J).	2023	46,102	47,596

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1395w-141(i)(3)		OIG	Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds.	2023	16,108	16,630
1395cc(g)	42 CFR 1003.210(a)(5)	OIG	Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities.	2023	6,266	6,469
1395dd(d)(1)	42 CFR 1003.510	OIG	Penalty for a hospital with 100 beds or more or responsible physician dumping patients needing emergency medical care.	2023	129,232	133,420
		OIG	Penalty for a hospital with less than 100 beds dumping patients needing emergency medical care.	2023	64,618	66,712
1395mm(i)(6)(B)(i)	42 CFR 1003.410	OIG	Penalty for a HMO or competitive medical plan if such plan substantially fails to provide medically necessary, required items or services.	2023	64,618	66,712
		OIG	Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	2023	64,618	66,712
		OIG	Penalty for a HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions.	2023	258,464	266,841
		OIG	Penalty for a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	2023	37,190	38,395
		OIG	Penalty per individual not enrolled in a plan as a result of a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in the future.	2023	258,464	266,841
		OIG	Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	2023		

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
		OIG	Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	2023	64,618	66,712
		OIG	Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	2023	64,618	66,712
		OIG	Penalty for HMO that employs or contracts with excluded individual or entity.	2023	59,316	61,238
1395nn(g)(3)	42 CFR 1003.310	OIG	Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals.	2023	29,899	30,868
1395nn(g)(4)	42 CFR 1003.310	OIG	Penalty for circumvention schemes in violation of the Stark Law's restrictions on physician self-referrals.	2023	199,338	205,799
1395ss(d)(1)	42 CFR 1003.1110	OIG	Penalty for a material misrepresentation regarding Medigap compliance policies.	2023	12,397	12,799
1395ss(d)(2)	42 CFR 1003.1110	OIG	Penalty for selling Medigap policy under false pretense.	2023	12,397	12,799
1395ss(d)(3)(A)(ii)	42 CFR 1003.1110	OIG	Penalty for an issuer that sells health insurance policy that duplicates benefits.	2023	55,808	57,617
		OIG	Penalty for someone other than issuer that sells health insurance that duplicates benefits.	2023	33,483	34,568
1395ss(d)(4)(A)	42 CFR 1003.1110	OIG	Penalty for using mail to sell a non-approved Medigap insurance policy.	2023	12,397	12,799

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1396b(m)(5)(B)(i)	42 CFR 1003.410	OIG	Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services.	2023	61,982	63,991
		OIG	Penalty for a Medicaid MCO that charges excessive premiums.	2023	61,982	63,991
		OIG	Penalty for a Medicaid MCO that improperly expels or refuses to re-enroll a beneficiary.	2023	247,929	255,964
		OIG	Penalty per individual who does not enroll as a result of a Medicaid MCO's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2023	37,190	38,395
		OIG	Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	2023	247,929	255,964
		OIG	Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	2023	61,982	63,991
		OIG	Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	2023	55,808	57,617
1396r(b)(3)(B)(ii)(I)	42 CFR 1003.210(a)(11)	OIG	Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment.	2023	2,586	2,670
1396r(b)(3)(B)(ii)(II)	42 CFR 1003.210(a)(11)	OIG	Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment.	2023	12,924	13,343
1396r(g)(2)(A)(I)	42 CFR 1003.1310	OIG	Penalty for notifying or causing to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted.	2023	5,171	5,339
1396r-8(b)(3)(B)	42 CFR 1003.1210	OIG	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug.	2023	223,229	230,464

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1396r–8(b)(3)(C)(i)	42 CFR 1003.1210	OIG	Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement.	2023	22,324	23,048
1396r–8(b)(3)(C)(ii)	42 CFR 1003.1210	OIG	Penalty for knowing provision of false information by drug manufacturer with rebate agreement.	2023	223,229	230,464
1396t(i)(3)(A)	42 CFR 1003.1310	OIG	Penalty for notifying home and community-based providers or settings of survey.	2023	4,465	4,610
11131(c)	42 CFR 1003.810	OIG	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank.	2023	27,018	27,894
11137(b)(2)	42 CFR 1003.810	OIG	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank.	2023	27,018	27,894
299b–22(f)(1)	42 CFR 3.404	OCR	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act.	2023	14,960	15,445
1320(d)–5(a)	45 CFR 160.404(b)(1)(i), (ii).	OCR	Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions.	2023	187	193
1320(d)–5(a)	45 CFR 160.404(b)(2)(i)(A), (B).	OCR OCR	Calendar Year Cap	2023 2023	47,061	48,586
			Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the covered entity or business associate did not know and, by exercising reasonable diligence, would not have known that the covered entity or business associate violated such a provision.			
			Minimum	2023	137	141
			Maximum	2023	68,928	71,162
			Calendar Year Cap	2023	2,067,813	2,134,831

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45 CFR 160.404(b)(2)(ii)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA ad- ministrative simplification provision in which it is established that the violation was due to reasonable cause and not to willful neglect.	2023		
			2023	1,379	1,424
			2023	68,928	71,162
			2023	2,067,813	2,134,831
45 CFR 160.404(b)(2)(iii)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA ad- ministrative simplification provision in which it is established that the violation was due to willful neglect and was corrected during the 30- day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred.	2023		
			2023	13,785	14,232
			2023	68,928	71,162
			2023	2,067,813	2,134,831
45 CFR 160.404(b)(2)(iv)(A), (B).	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA ad- ministrative simplification provision in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the viola- tion occurred.	2023		
			2023	68,928	71,162
			2023	2,067,813	2,134,831
			2023	323	333
42 U.S.C. 300gg-18, 42 U.S.C. 1302	CMS	Penalty for a hospital's non-compli- ance with making public standard charges for hospital items and services. Per Day (Maximum)	2023	5,926	6,118
			2023		
			2023		
			2023		

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
CARES Act, Public Law 116–136, section 3202(b)(2).	45 CFR 180.90(c)(2)(i) ..	CMS	Per day penalty for a hospital's non-compliance with making public standard charges for hospital items and services.		328	339
	45 CFR 180.90(c)(2)(ii)(A).	CMS	Per day penalty for hospitals with equal to or less than 30 beds.		323	333
	45 CFR 180.90(c)(2)(ii)(B).	CMS	Per day, per bed penalty for hospitals having at least 31 and up to and including 550 beds.		11	11
	45 CFR 180.90(c)(2)(ii)(C).	CMS	Per day penalty for hospitals having greater than 550 beds.		2,926	3,021
	45 CFR 182.70	CMS	Penalty for a provider's non-compliance with price transparency requirements regarding diagnostic tests for COVID–19.	2023		
263a(h)(2)(B) & 1395w–2(b)(2)(A)(i).	42 CFR 493.1834(d)(2)(i).	CMS	Per Day (Maximum)	2023	323	333
			Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy.	2023		
42 CFR 493.1834(d)(2)(ii).			Minimum	2023	7,562	7,807
			Maximum	2023	24,793	25,597
			Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy.	2023		
			Minimum	2023	125	129
			Maximum	2023	7,437	7,678
42 CFR 493.1834(d)(2)(iii).		CMS	Penalty for a clinical laboratory's failure to meet SARS-CoV–2 test reporting requirements.	2023		
			First day of noncompliance	2023		
			Each additional day of noncompliance.	2023		

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300gg-15(f)	45 CFR 147.200(e)	CMS	Failure to provide the Summary of Benefits and Coverage.	2023	1,362	1,406
300gg-18	45 CFR 158.606	CMS	Penalty for violations of regulations related to the medical loss ratio reporting and rebating.	2023	136	140
	45 CFR 180.90	CMS	Price against hospital identified by CMS as noncompliant according to § 182.50 with respect to price transparency requirements regarding diagnostic tests for COVID-19.	2023		
42 U.S.C. 300gg-118 note, 300gg-134.		CMS	Penalties for failure to comply with No Surprises Act requirements on providers, facilities, providers of air ambulance services.	2023	11,445	11,816
1320a-7h(b)(1)	42 CFR 402.105(d)(5), 42 CFR 403.912(a) & (c).	CMS	Penalty for manufacturer or group purchasing organization failing to report information required under 42 U.S.C. 1320a-7h(a), relating to physician ownership or investment interests.	2023		
			Minimum	2023	1,362	1,406
			Maximum	2023	13,625	14,067
			Calendar Year Cap	2023	204,384	211,008
1320a-7h(b)(2)	42 CFR 402.105(h), 42 CFR 403.912(b) & (c).	CMS	Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 U.S.C. 1320a-7h(a), relating to physician ownership or investment interests.	2023		
			Minimum	2023	13,625	14,067
			Maximum	2023	136,258	140,674
			Calendar Year Cap	2023	1,362,567	1,406,728
		CMS	Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	2023	136,258	140,674
1320a-7j(h)(3)(A)	42 CFR 488.446(a)(1), (2), & (3).	CMS	Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	2023	681	703
			Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	2023	2,045	2,111

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1320a–8(a)(1)		CMS	Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure. Penalty for an entity knowingly making a false statement or representation of material fact in the determination of the amount of benefits or payments related to old-age, survivors, and disability insurance benefits, special benefits for certain World War II veterans, or supplemental security income for the aged, blind, and disabled. Penalty for violation of 42 U.S.C. 1320a–8(a)(1) if the violator is a person who receives a fee or other income for services performed in connection with determination of the benefit amount or the person is a physician or other health care provider who submits evidence in connection with such a determination.	2023	4,087	4,219
				2023	9,966	10,289
				2023	9,399	9,704
1320a–8(a)(3)		CMS	Penalty for a representative payee (under 42 U.S.C. 405(j), 1007, or 1383(a)(2)) converting any part of a received payment from the benefit programs described in the previous civil monetary penalty to a use other than for the benefit of the beneficiary.	2023	7,805	8,058

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1320b-25(c)(1)(A)	CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility.	2023	272,514	281,346
1320b-25(c)(2)(A)	CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility if such failure exacerbates the harm to the victim of the crime or results in the harm to another individual.	2023	408,769	422,017
1320b-25(d)(2)	CMS	Penalty for a long-term care facility that retaliates against any employee because of lawful acts done by the employee, or files a complaint or report with the State professional disciplinary agency against an employee or nurse for lawful acts done by the employee or nurse.	2023	272,514	281,346
1395b-7(b)(2)(B)	CMS	Penalty for any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.	2023	184	190
1395i-3(h)(2)(B)(iii)(I)	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements.	2023		
		Minimum	2023	129	133
		Maximum	2023	7,752	8,003
	CMS	Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility.	2023		
		Minimum	2023	2,586	2,670
		Maximum	2023	25,847	26,685

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
	42 CFR 488.408(e)(1)(iii).	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements. Minimum	2023		
			Maximum	2023	7,884	8,140
	42 CFR 488.408(e)(1)(iv).	CMS	Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility. Minimum	2023	25,847	26,685
			Maximum	2023	2,586	2,670
	42 CFR 488.408(e)(2)(ii)	CMS	Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy. Per Day (Minimum)	2023	25,847	26,685
			Per Day (Maximum)	2023	2,586	2,670
			Per Instance (Minimum)	2023	25,847	26,685
	42 CFR 488.438(a)(1)(i)	CMS	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day. Minimum	2023		
			Maximum	2023	7,884	8,140
	42 CFR 488.438(a)(1)(ii)	CMS	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day. Minimum	2023	25,847	26,685
			Maximum	2023		
	42 CFR 488.438(a)(2) ...	CMS	Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements. Minimum	2023	129	133
				2023	7,752	8,003
				2023	2,586	2,670

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1395i-6(c)(5)(B)(i)	42 CFR 488.447	CMS	Maximum	2023	25,847	26,685
			Penalty imposed for failure to comply with infection control weekly reporting requirements at 42 CFR 483.80(g)(1) and (2).	2023		
			First occurrence	2023	1,158	1,196
			Incremental increases for each subsequent occurrence.	2023	579	598
	42 CFR 488.1245	CMS	Penalty for noncompliance by hospice program with requirements specified in section 1395x(dd) of 42 U.S.C.	2023	10,775	11,124
	42 CFR 488.1245(b)(2)(iii).	CMS	Adjustment to penalties. Maximum penalty assessment for each day a hospice is not in substantial compliance with one or more conditions of participation.	2023	10,775	11,124
	42 CFR 488.1245(b)(3)	CMS	Penalty imposed for hospice condition-level deficiency that is immediate jeopardy. These amounts represent the upper range of penalty.			
			Minimum	2023	9,158	9,455
	42 CFR 488.1245(b)(3)(i).	CMS	Maximum	2023	10,775	11,124
			Penalty imposed for hospice condition-level deficiency that is immediate jeopardy. These amounts represent the upper range of penalty.	2023	10,775	11,124
	42 CFR 488.1245(b)(3)(ii).	CMS	Penalty imposed for hospice condition-level deficiency that is immediate jeopardy. These amounts represent the upper range of penalty.	2023	9,697	10,011
	42 CFR 488.1245(b)(3)(iii).	CMS	Penalty imposed for hospice condition-level deficiency that is immediate jeopardy. These amounts represent the upper range of penalty.	2023	9,158	9,455

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
	42 CFR 488.1245(b)(4)	CMS	Penalty imposed for hospice repeat or condition-level deficiency or both that does not constitute immediate jeopardy but is directly related to poor quality patient care outcomes. These amounts represent the middle range of penalty. Minimum Maximum	2023 2023	1,616 9,158	1,668 9,455
	42 CFR 488.1245(b)(5)	CMS	Penalty imposed for hospice repeat or condition-level deficiency or both that does not constitute immediate jeopardy and are related predominantly to structure or process-oriented conditions rather than directly related to patient outcomes. These amounts represent the lower range of penalty. Minimum Maximum	2023 2023	539 4,310	556 4,450
	42 CFR 488.1245(b)(6)	CMS	Penalty range imposed for per instance of hospice noncompliance. Minimum Maximum	2023 2023	1,077 10,775	1,112 11,124
	42 CFR 488.1245(d)(1)(ii).	CMS	Penalty for each per instance of hospice noncompliance, maximum per day per hospice program.	2023	10,775	11,124
1395(h)(5)(D)	42 CFR 402.105(d)(2)(i)	CMS	Penalty for knowingly, willfully, and repeatedly billing for a clinical diagnostic laboratory test other than on an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435

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1395(i)(6)		CMS	Penalty for knowingly and willfully presenting or causing to be presented a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved. Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	2023	4,960	5,121
1395(q)(2)(B)(i)	42 CFR 402.105(a)	CMS	Penalty for any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	4,745	4,899
1395m(a)(11)(A)	42 CFR 402.1(c)(4), 402.105(d)(2)(ii).	CMS	Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395m(a)(18)(B)	42 CFR 402.1(c)(5), 402.105(d)(2)(iii).	CMS	Penalty for any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge for radiologist services. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395m(b)(5)(C)	42 CFR 402.1(c)(6), 402.105(d)(2)(iv).	CMS		2023	18,825	19,435

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1395m(h)(3)	42 CFR 402.1(c)(8), 402.105(d)(2)(vi).	CMS	Penalty for any supplier of prosthetic devices, orthotics, and prosthetics that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(a)(11)(A), that is in the same manner as 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395m(j)(2)(A)(iii)		CMS	Penalty for any supplier of durable medical equipment including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully distributes a certificate of medical necessity in violation of Section 1834(j)(2)(A)(i) of the Act or fails to provide the information required under Section 1834(j)(2)(A)(ii) of the Act.	2023	1,993	2,058

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1395m(j)(4)	42 CFR 402.1(c)(10), 402.105(d)(2)(vii).	CMS	Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for series billed other than on an assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395m-1(a)	42 CFR 414.504(e)	CMS	Penalty for an applicable entity that has failed to report or made a misrepresentation or omission in reporting applicable information with respect to a clinical diagnostic laboratory test.	2023	12,551	12,958
	42 CFR 402.1(c)(31), 402.105(d)(3).	CMS	Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395m(l)(6)	42 CFR 402.1(c)(32), 402.105(d)(4).	CMS	Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1395u(b)(18)(B)	42 CFR 402.1(c)(11), 402.105(d)(2)(viii).	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395u(j)(2)(B)	42 CFR 402.1(c)	CMS	Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 U.S.C. 1320a–7a(a)).	2023	18,825	19,435
1395u(k)	42 CFR 402.1(c)(12), 402.105(d)(2)(ix), 1834A(a)(9) and 42 CFR 414.504(e).	CMS	Penalty for any physician who knowingly and willfully presents or causes to be presented a claim for bill for an assistant at a cataract surgery performed on or after March 1, 1987, for which payment may not be made because of section 1862(a)(15). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435

1395u(l)(3)	42 CFR 402.1(c)(13), 402.105(d)(2)(x).	CMS	Penalty for any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality under 1842(l)(1)(A). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395u(m)(3)	42 CFR 402.1(c)(14), 402.105(d)(2)(xi).	CMS	Penalty for any nonparticipating physician charging more than \$500 who does not accept payment for an elective surgical procedure on an assignment related basis and who knowingly and willfully fails to disclose the required information regarding charges and coinsurance amounts and fails to refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435
1395u(n)(3)	42 CFR 402.1(c)(15), 402.105(d)(2)(xii).	CMS	Penalty for any physician who knowingly, willfully, and repeatedly bills one or more beneficiaries for purchased diagnostic tests any amount other than the payment amount specified by the Act. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a)).	2023	18,825	19,435

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1395u(o)(3)(B)	42 CFR 414.707(b)	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services pertaining to drugs or biologics by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435
1395u(p)(3)(A)		CMS	Penalty for any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis codes upon CMS or Medicare administrative contractor request for payment or bill not submitted on an assignment-related basis.	2023	4,960	5,121
1395w–3a(d)(4)(A)	42 CFR 414.806	CMS	Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	2023	16,108	16,630
1395w–4(g)(1)(B)	42 CFR 402.1(c)(17), 402.105(d)(2)(xii).	CMS	Penalty for any nonparticipating physician, supplier, or other person that furnishes physician services not on an assignment-related basis who either knowingly and willfully bills or collects in excess of the statutorily-defined limiting charge or fails to make a timely refund or adjustment. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a–7a(a)).	2023	18,825	19,435

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1395w-4(g)(3)(B)	42 CFR 402.1(c)(18), 402.105(d)(2)(xiv).	CMS	Penalty for any person that knowingly and willfully bills for statutorily defined State-plan approved physicians' services on any other basis than an assignment-related basis for a Medicare/Medicaid dual eligible beneficiary. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7(a)).	2023	18,825	19,435
1395w-27(g)(3)(A); 1857(g)(3); 1860D- 12(b)(3)(E).	42 CFR 422.760(b); 42 CFR 423.760(b).	CMS	Penalty for each termination determination the Secretary makes that is the result of actions by a Medicare Advantage organization or Part D sponsor that has adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.	2023	46,102	47,596
1395w-27(g)(3)(B); 1857(g)(3); 1860D- 12(b)(3)(E).		CMS	Penalty for each week beginning after the initiation of civil money penalty procedures by the Secretary because a Medicare Advantage organization or Part D sponsor has failed to carry out a contract, or has carried out a contract inconsistently with regulations.	2023	18,442	19,040
1395w-27(g)(3)(D); 1857(g)(3); 1860D- 12(b)(3)(E).		CMS	Penalty for a Medicare Advantage organization or Part D sponsor's early termination of its contract.	2023	171,257	176,807
1395y(b)(3)(C)	42 CFR 411.103(b)	CMS	Penalty for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits not to enroll under a group health plan or large group health plan which would be a primary plan.	2023	11,162	11,524

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1395y(b)(5)(C)(ii)	42 CFR 402.1(c)(20), 42 CFR 402.105(b)(2).	CMS	Penalty for any non-governmental employer that, before October 1, 1998, willfully or repeatedly failed to provide timely and accurate information requested relating to an employee's group health insurance coverage.	2023	1,818	1,877
1395y(b)(6)(B)	42 CFR 402.1(c)(20), 402.105(a).	CMS	Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	2023	3,988	4,117
1395y(b)(7)(B)(i)	42 CFR 402.1(c)(21), 402.105(a).	CMS	Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	2023	1,428	1,474
1395y(b)(8)(E)		CMS	Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.	2023	1,428	1,474
1395nn(g)(5)	42 CFR 411.361	CMS	Penalty for any person that fails to report information required by HHS under Section 1877(f) concerning ownership, investment, and compensation arrangements.	2023	23,727	24,496

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1395pp(h)	42 CFR 402.1(c)(23), 402.105(d)(2)(xv).	CMS	Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 1395u(j)(2) and 1320a-7a(a)).	2023	18,825	19,435
1395ss(a)(2)	402.102(f)(1)	CMS	Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	2023	64,617	66,711
1395ss(d)(3)(A)(vi) (II)	42 CFR 402.1(c)(25), 402.105(e), 402.105(f)(2).	CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	2023	33,483	34,568
1395ss(d)(3)(B)(iv)		CMS	Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	2023	55,808	57,617
		CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	2023	33,483	34,568
		CMS	Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	2023	55,808	57,617
1395ss(p)(6)	42 CFR 402.1(c)(25), 402.105(e).	CMS	Penalty for someone other than issuer that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute.	2023	33,483	34,568

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
	42 CFR 402.1(c)(25), 405402.105(f)(2).	CMS	Penalty for an issuer that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute.	2023	55,808	57,617
1395ss(p)(9)(C)	42 CFR 402.1(c)(26), 402.105(e), 402.105(f)(3), (4).	CMS	Penalty for someone other than issuer that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2023	33,483	34,568
	402.105(f)(3),(4)	CMS	Penalty for an issuer that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2023	55,808	57,617
1395ss(q)(5)(C)	402.105(f)(5)	CMS	Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	2023	55,808	57,617
1395ss(r)(6)(A)	402.105(f)(6)	CMS	Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B).	2023	55,808	57,617

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1395ss(s)(4)	42 CFR 402.1(c)(29), 402.105(c).	CMS	Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a preceding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	2023	23,692	24,460
1395ss(t)(2)	42 CFR 402.1(c)(30), 402.105(f)(7).	CMS	Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	2023	55,808	57,617
1395ss(v)(4)(A)		CMS	Penalty someone other than issuer who sells, issues, or renews a medigap Rx policy to an individual who is a Part D enrollee.	2023	24,163	24,946
		CMS	Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	2023	40,272	41,577
1395bbb(c)(1)	42 CFR 488.725(c)	CMS	Penalty for any individual who notifies or causes to be notified a home health agency of the time or date on which a survey of such agency is to be conducted.	2023	5,171	5,339
1395bbb(f)(2)(A)(i)	42 CFR 488.845(b)(2)(iii) 42 CFR 488.845(b)(3)– (6); and 42 CFR 488.845(d)(1)(ii). 42 CFR 488.845(b)(3) ...	CMS	Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements.	2023	24,793	25,597
		CMS	Penalty per day for home health agency's noncompliance (Upper Range).	2023		
			Minimum	2023	21,074	21,757
			Maximum	2023	24,793	25,597
	42 CFR 488.845(b)(3)(i)	CMS	Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm.	2023	24,793	25,597

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
	42 CFR 488.845(b)(3)(ii)	CMS	Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm.	2023	22,313	23,036
	42 CFR 488.845(b)(3)(iii).	CMS	Penalty for an isolated incident of noncompliance in violation of established HHA policy.	2023	21,074	21,757
	42 CFR 488.845(b)(4) ...	CMS	Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range). Minimum Maximum	2023 2023 2023	3,720 21,074	3,841 21,757
	42 CFR 488.845(b)(5) ...	CMS	Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (Lower Range). Minimum Maximum	2023 2023 2023	1,240 2,479	1,280 2,559
	42 CFR 488.845(b)(6) ...	CMS	Penalty imposed for instance of noncompliance that may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey. Penalty for each day of noncompliance (Minimum). Penalty for each day of noncompliance (Maximum). Penalty for each day of noncompliance (Maximum).	2023 2023 2023	2,479 24,793 24,793	2,559 25,597 25,597

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1395eee(e)(6)(B); 1396u-4(e)(6)(B).	42 CFR 460.46	CMS	Penalty for PACE organization that discriminates in enrollment or disenrollment, or engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, on the basis of health status or the need for services.	2023	46,102	47,596
		CMS	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.	2023		
			Minimum	2023	17,370	17,933
			Maximum	2023	115,802	119,555
		CMS	Penalty for a PACE organization that charges excessive premiums.	2023	46,102	47,596
		CMS	Penalty for a PACE organization misrepresenting or falsifying information to CMS or the State.	2023	184,412	190,389
		CMS	Penalty for any other violation specified in 42 CFR 460.40.	2023	46,102	47,596
	42 CFR 488.408(d)(1)(iii).	CMS	Penalty per day for a nursing facility's failure to meet a Category 2 Certification.	2023		
			Minimum	2023	129	133
			Maximum	2023	7,752	8,003
1396r(h)(3)(C)(ii)(I)	42 CFR 488.408(d)(1)(iv).	CMS	Penalty per instance for a nursing facility's failure to meet Category 2 certification.	2023		
			Minimum	2023	2,586	2,670
			Maximum	2023	25,847	26,685
	42 CFR 488.408(e)(1)(iii).	CMS	Penalty per day for a nursing facility's failure to meet Category 3 certification.	2023		
			Minimum	2023	7,884	8,140
			Maximum	2023	25,847	26,685
	42 CFR 488.408(e)(1)(iv).	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification.	2023		
			Minimum	2023	2,586	2,670
			Maximum	2023	25,847	26,685
				2023		

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1396r(f)(2)(B)(iii)(I)(c)	42 CFR 488.408(e)(2)(ii)	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy. Minimum	2023		
			Maximum	2023	2,586	2,670
	42 CFR 488.438(a)(1)(i)	CMS	Penalty per day for nursing facility's failure to meet certification (Upper Range). Minimum	2023	25,847	26,685
			Maximum	2023		
	42 CFR 488.438(a)(1)(ii)	CMS	Penalty per day for nursing facility's failure to meet certification (Lower Range). Minimum	2023	7,884	8,140
			Maximum	2023	25,847	26,685
	42 CFR 488.438(a)(2) ...	CMS	Penalty per instance for nursing facility's failure to meet certification. Minimum	2023	129	133
			Maximum	2023	7,752	8,003
	42 CFR 488.447	CMS	Penalty imposed for failure to comply with infection control weekly reporting requirements at 42 CFR 483.80(g)(1) and (2). First occurrence (Minimum)	2023	2,586	2,670
			Incremental increases for each subsequent occurrence.	2023	25,847	26,685
1396r(f)(2)(B)(iii)(I)(c)	42 CFR 483.151(b)(2)(iv) and (b)(3)(iii).	CMS	Grounds to prohibit approval of Nurse Aide Training Program—if assessed a penalty in 1819(h)(2)(B)(i) or 1919(h)(2)(A)(ii) of "not less than \$5,000" (Not CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval).	2023	1,158	1,196
				2023	579	598
				2023	12,924	13,343

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1396f(h)(3)(C)(ii)(I)	42 CFR 483.151(c)(2) ...	CMS	Grounds to waive disapproval of nurse aide training program—reference to disapproval based on imposition of CMP “not less than \$5,000” [Not CMP authority but CMP imposition at this level determines eligibility to seek waiver of disapproval of nurse aide training program].	2023	12,924	13,343
1396f(i)(2)(C)		CMS	Penalty for each day of noncompliance for a home or community care provider that no longer meets the minimum requirements for home and community care.	2023		
			Minimum	2023	2	2
			Maximum	2023	22,324	23,048
1396u-2(e)(2)(A)(i)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services.	2023	46,102	47,596
		CMS	Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.	2023	46,102	47,596
		CMS	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	2023	46,102	47,596
		CMS	Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	2023	184,412	190,389
1396u-2(e)(2)(A)(ii)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary.	2023	184,412	190,389
		CMS	Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	2023		

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
1396u–2(e)(2)(A)(iv)	42 CFR 438.704	CMS	Penalty for each individual that does not enroll as a result of a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	2023	27,661	28,557
1396u(h)(2)	42 CFR part 441, sub-part I.	CMS	Penalty for a provider not meeting one of the requirements relating to the protection of the health, safety, and welfare of individuals receiving community supported living arrangements services.	2023	25,847	26,685
1396w–2(c)(1)	42 U.S.C. 300gg–22(b)(2)(C)(i), 45 CFR 150.315.	CMS	Penalty for each day, for each individual affected by the failure of a health insurance issuer or non-Federal governmental group health plan to comply with federal market reform provisions in part A or D of title XXVII of the PHS Act ¹ 2022[174] 177.	2023	13,785	14,232
18041(c)(2)	45 CFR 156.805(c)	CMS	Failure to comply with ACA requirements related to risk adjustment, reinsurance, risk corridors. Exchanges (including QHP standards) and other ACA Subtitle D standards; Penalty for violations of rules or standards of behavior associated with issuer compliance with risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards.	2023	187	193

42 U.S.C. 300gg-22(b)(2)(C)(i).	45 CFR 150.315	CMS	Penalty for each day, for each individual affected by the failure of a health insurance issuer or non-Federal governmental group health plan to comply with federal market reform provisions in part A or D of title XXVII of the PHS Act.	2023	177	183
18081(h)(1)(A)(i)(II)	45 CFR 155.285	CMS	Penalty for providing false information on Exchange application.	2023	34,065	35,169
18081(h)(1)(B)	45 CFR 155.285	CMS	Penalty for knowingly or willfully providing false information on Exchange application.	2023	340,641	351,681
18081(h)(2)	45 CFR 155.260	CMS	Penalty for knowingly or willfully disclosing protected information from Exchange.	2023		
		CMS	Maximum	2023	34,065	35,169
		CMS	Minimum	2023	348	359
18041(c)(2)	45 CFR 155.206(i)	CMS	Penalties for violation of applicable Exchange standards by consumer assistance entities in Federally-facilitated Exchanges.	2023	41,774	43,128
			Maximum (Per Day)	2023	115	119
31 U.S.C.			Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances.	2023	348	359
1352	45 CFR 93.400(e)	HHS	Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure.	2023	23,727	24,496
			Minimum	2023	23,727	24,496
			Maximum	2023	237,268	244,958
		HHS	Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances.	2023	23,727	24,496

TABLE 1 TO § 102.3—CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS—Continued

U.S.C. section(s)	CFR ¹	HHS agency	Description ²	Date of last penalty figure or adjustment ³	2023 Maximum adjusted penalty (\$)	2024 Maximum adjusted penalty (\$) ⁴
3801–3812	45 CFR part 93, Appendix A.	HHS	Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances.	2023		
			Minimum	2023	23,727	24,496
			Maximum	2023	237,268	244,958
			Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers.	2023		
3801–3812	45 CFR 79.3(a)(1)(iv)	HHS	Minimum	2023	23,727	24,496
			Maximum	2023	237,268	244,958
			Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions.	2023		
			Minimum	2023	23,727	24,496
3801–3812	45 CFR 79.3(a)(1)(iv)	HHS	Maximum	2023	237,268	244,958
			Penalty against any individual who— with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	2023	12,398	12,800
			Minimum	2023	23,727	24,496
			Maximum	2023	237,268	244,958
3801–3812	45 CFR 79.3(b)(1)(ii)	HHS	Penalty against any individual who— with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	2023	12,398	12,800
			Minimum	2023	23,727	24,496
			Maximum	2023	237,268	244,958
			Penalty against any individual who— with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department.	2023	12,398	12,800

¹ Some HHS components have not promulgated regulations regarding their civil monetary penalty-specific statutory authorities.

² The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding regulation, if applicable, should be consulted.

³ Statutory or Inflation Act Adjustment.

⁴OMB Memorandum *M-16-06*, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, published February 24, 2016, guided agencies on initial “catch-up” adjustment requirements, and *M-17-11*, Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, published December 16, 2016; followed by *M-18-03*, *M-19-04*, *M-20-05*, *M-21-10*, *M-22-07*, *M-23-05*, and *M-24-07* guided agencies on annual adjustment requirements.

⁵OMB Circular *A-136*, Financial Reporting Requirements, Section II.4.9, directs that agencies must make annual inflation adjustments to civil monetary penalties and report on the adjustments in the Agency Financial Report (AFR) or Performance and Accountability Report (PAR).

⁶Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, §701(b)(1)(A) (codified as amended at 28 U.S.C. 2461 note).

⁷Annual inflation adjustments are based on the percent change between each published October’s CPI-U. In this case, October 2023 CPI-U (307.671)/October 2022 CPI-U (298.012) = 1.03241.

[81 FR 61565, Sept. 6, 2016, as amended at 87 FR 15101, Mar. 17, 2022; 88 FR 69532, Oct. 6, 2023; 88 FR 70373, Oct. 11, 2023; 88 FR 82787, Nov. 27, 2023; 89 FR 64816, Aug. 8, 2024]

FINDING AIDS

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For changes to this volume of the CFR prior to this listing, consult the annual edition of the monthly List of CFR Sections Affected (LSA). The LSA is available at www.govinfo.gov. For changes to this volume of the CFR prior to 2001, see the “List of CFR Sections Affected, 1949–1963, 1964–1972, 1973–1985, and 1986–2000” published in 11 separate volumes. The “List of CFR Sections Affected 1986–2000” is available at www.govinfo.gov.

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