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Title 45—Public Welfare

(This book contains parts 1 to 199)

Part

SUBTITLE A—DEPARTMENT OF HEALTH AND HUMAN SERVICES 1

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—HHS'S REGULATIONS

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1.2 Subject matter of Office of the Secretary regulations in parts 1–99.

§ 1.1 Location of HHS regulations.

Regulations for HHS's programs and activities are located in several different titles of the Code of Federal Regulations:

• Regulations having HHS-wide application or which the Office of the Secretary administers are located in Parts 1–99 of Title 45.
• Health regulations are located at Parts 1–399 of Title 42.
• Health care financing regulations are located at Parts 400–499 of Title 42. These include regulations for Medicare and Medicaid.
• Human development services regulations are located at Parts 200–299 and 1300–1399 of Title 45. These include regulations for Head Start, social services, social and nutrition services for older persons, rehabilitative services, developmental disabilities services, Native American programs, and various programs relating to families and children.
• Social Security regulations are located at Parts 400–499 of Title 20.
• Food and Drug regulations are located at Parts 1–1299 of Title 21.
• Procurement (contract) regulations are located at Chapter 3 of Title 41.

Each volume of the Code contains an index of its parts.

(5 U.S.C. 301)

[44 FR 61598, Oct. 26, 1979, as amended at 48 FR 35099, Aug. 3, 1983]

§ 1.2 Subject matter of Office of the Secretary regulations in parts 1–99.

This subject matter of the regulations in Parts 1–99 of this title includes:

• *Civil rights/nondiscrimination:* Parts 80, 81, 83, 84, 86, 90.
• *Protection of human subjects:* part 46.
• *Day care requirements:* part 71.
• *Information, privacy, advisory committees:* Parts 5, 5a, 5b, 11, 17, 99.
• *Personnel:* Parts 50, 57, 73, 73a.
• *Grants and letter of credit administration, property, hearing rights:* Parts 10, 12, 15, 16, 74, 75, 77, 95.
• *Claims:* Parts 30, 35.
• *Inventions and patents:* Parts 6, 7, 8.
• *Miscellaneous:* Parts 3, 4, 9, 67.

(5 U.S.C. 301)

[50 FR 781, Jan. 7, 1985, as amended at 52 FR 28658, July 31, 1987]

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

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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.

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 person'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 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 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]

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

Subpart A—General

Sec.
3.1 Definitions.
3.2 Applicability.
3.3 Compliance.
3.4 False reports and reports of injury or damage.
3.5 Lost and found, and abandoned property.
3.6 Nondiscrimination.

Subpart B—Traffic Regulations

3.21 Emergency vehicles.
3.22 Request for identification.
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Subpart C—Facilities and Grounds

3.41 Admission to facilities or grounds.
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3.44 Solicitation.

Subpart D—Penalties

3.61 Penalties.

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).

Police officer means a uniformed or non-uniformed police officer appointed under a delegation of authority to the Director under Title 40 United States Code section 318 or 318d; 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.

§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.
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 occured 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.	Article 27, Sec. 36.	Prohibits, except for law enforcement personnel or as a reasonable precaution against apprehended danger.	Imprisonment 3 years or $1,000 fine.
6. Unlawful wearing, carrying, or transporting a handgun, whether concealed or openly.	Article 27, Sec. 36B.	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.	Article 27, Sec. 36B.	Prohibits	Imprisonment 20 years.
8. Disturbance of the peace	Article 27, Sec. 122.	Prohibits acting in a disorderly manner in public places.	Imprisonment 30 days and/or $500 fine.
9. Gambling	Article 27, Secs. 240, 245.	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.

§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. The Police Office's main location and telephone number is: Building 31, Room B3BN10; (301) 496–5685.

§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 part 101–48). 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 101–45.304 and 101–48.305.

[57 FR 1874, Jan. 16, 1992]

§ 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.

§ 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 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 nonemergency 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 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 dog by a handicapped person 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 prohibited: 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 in any building 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]

§ 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 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 of not more than $50 or imprisonment of not more than thirty days or both, for each violation (40 U.S.C. 318c).

(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.

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.
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, SW., 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 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.

SOURCE: 53 FR 47700, Nov. 25, 1988, unless otherwise noted.

Subpart A—Basic Policy

§ 5.1 Purpose.

This part contains the rules that the Department of Health and Human Services (HHS) follows in handling requests for records under the Freedom of Information Act (FOIA). It describes how to make a FOIA request; who can release records and who can decide not to release; how much time it should take to make a determination regarding release; what fees may be charged; what records are available for public inspection; why some records are not released; and your right to appeal and then go to court if we refuse to release records.

§ 5.2 Policy.

As a general policy, HHS follows a balanced approach in administering FOIA. We not only recognize the right of public access to information in the possession of the Department, but also protect the integrity of internal processes. In addition, we recognize the legitimate interests of organizations or persons who have submitted records to the Department or who would otherwise be affected by release of records. For example, we have no discretion to release certain records, such as trade secrets and confidential commercial information, prohibited from release by law. This policy calls for the fullest responsible disclosure consistent with those requirements of administrative necessity and confidentiality which are recognized in the Freedom of Information Act.

§ 5.3 Scope.

These rules apply to all components of the Department. Some units may establish additional rules because of unique program requirements, but such rules must be consistent with these rules and must have the concurrence of the Assistant Secretary for Public Affairs. Existing implementing rules remain in effect to the extent that they are consistent with the new Departmental regulation. If additional rules are issued, they will be published in the FEDERAL REGISTER, and you may get copies from our Freedom of information Officers.

§ 5.4 Relationship between the FOIA and the Privacy Act of 1974.

(a) *Coverage.* The FOIA and this rule apply to all HHS records. The Privacy Act, 5 U.S.C. 552a, applies to records that are about individuals, but only if the records are in a system of records. ''Individuals'' and ''system of records'' are defined in the Privacy Act and in

our Privacy Act regulation, part 5b of this title.

(b) *Requesting your own records.* If you are an individual and request records, then to the extent you are requesting your own records in a system of records, we will handle your request under the Privacy Act and part 5b. If there is any record that we need not release to you under those provisions, we will also consider your request under the FOIA and this rule, and we will release the record to you if the FOIA requires it.

(c) *Requesting another individual's record.* Whether or not you are an individual, if you request records that are about an individual (other than yourself) and that are in a system of records, we will handle your request under the FOIA and this rule. (However, if our disclosure in response to your request would be permitted by the Privacy Act's disclosure provision, 5 U.S.C. 552a(b), for reasons other than the requirements of the FOIA, and if we decide to make the disclosure, then we will not handle your request under the FOIA and this rule. For example, when we make routine use disclosures pursuant to requests, we do not handle them under the FOIA and this rule. ''Routine use'' is defined in the Privacy Act and in part 5b). If we handle your request under the FOIA and this rule and the FOIA does not require releasing the record to you, then the Privacy Act may prohibit the release and remove our discretion to release.

§5.5 Definitions.

As used in this part,

Agency means any executive department, military department, government corporation, government controlled corporation, or other establishment in the executive branch of the Federal Government, or any independent regulatory agency. Thus, HHS is an agency. A private organization is not an agency even if it is performing work under contract with the Government or is receiving Federal financial assistance. Grantee and contractor records are not subject to the FOIA unless they are in the possession or under the control of HHS or its agents, such as Medicare health insurance carriers and intermediaries.

Commercial use means, when referring to a request, that the request is from or on behalf of one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or of a person on whose behalf the request is made. Whether a request is for a commercial use depends on the purpose of the request and the use to which the records will be put; the identity of the requester (individual, non-profit corporation, for-profit corporation), on the nature of the records, while in some cases indicative of that purpose or use, is not necessarily determinative. When a request is from a representative of the news media, a purpose or use supporting the requester's news dissemination function is not a commercial use.

Department or *HHS* means the Department of Health and Human Services. It includes Medicare health insurance carriers and intermediaries to the extent they are performing functions under agreements entered into under sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h, 1395u.

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 paper copy, microform, audio-visual materials, and magnetic tapes, cards, and discs.

Educational institution means a preschool, elementary or secondary school, institution of undergraduate or graduate higher education, or institution of professional or vocational education, which operates a program of scholarly research.

Freedom of Information Act or *FOIA* means section 552 of Title 5, United States Code, as amended.

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

Non-commercial scientific institution means an institution that is not operated substantially for purposes of furthering its own or someone else's business, trade, or profit interests, and that is operated for purposes of conducting scientific research whose results are not intended to promote any particular product or industry.

Records means any handwritten, typed, or printed documents (such as memoranda, books, brochures, studies, writings, drafts, letters, transcripts, and minutes) and documentary material in other forms (such as punchcards; magnetic tapes, cards, or discs; paper tapes; audio or video recordings; maps; photographs; slides; microfilm; and motion pictures). It does not include objects or articles such as exhibits, models, equipment, and duplication machines or audiovisual processing materials. Nor does it include books, magazines, pamphlets, or other reference material in formally organized and officially designated HHS libraries, where such materials are available under the rules of the particular library.

Representative of the news media means a person actively gathering information for an entity organized and operated to publish or broadcast news to the public. News media entities include television and radio broadcasters, publishers of periodicals who distribute their products to the general public or who make their products available for purchase or subscription by the general public, and entities that may disseminate news through other media (e.g., electronic dissemination of text). We will treat freelance journalists as representatives of a new media entity if they can show a likelihood of publication through such an entity. A publication contract is such a basis, and the requester's past publication record may show such a basis.

Request means asking for records, whether or not you refer specifically to the Freedom of Information Act. Requests from Federal agencies and court orders for documents are not included within this definition. Subpoenas are requests only to the extent provided by part 2 of this title.

Review means, when used in connection with processing records for a commercial use request, examining the records to determine what portions, if any, may be withheld, and any other processing that is necessary to prepare the records for release. It includes only the examining and processing that are done the first time we analyze whether a specific exemption applies to a particular record or portion of a record. It does not include examination done in the appeal stage with respect to an exemption that was applied at the initial request stage. However, if we initially withhold a record under one exemption, and on appeal we determine that that exemption does not apply, then examining the record in the appeal stage for the purpose of determining whether a different exemption applies is included in *review*. It does not include the process of researching or resolving general legal or policy issues regarding exemptions.

Search means looking for records or portions of records responsive to a request. It includes reading and interpreting a request, and also page-by-page and line-by-line examination to identify responsive portions of a document. However, it does not include line-by-line examination where merely duplicating the entire page would be a less expensive and quicker way to comply with the request.

Subpart B—Obtaining a Record

§ 5.21 How to request records.

(a) *General.* Our policy is to answer all requests, both oral and written, for records. However, in order to have the rights given you by the FOIA and by this regulation (for example, the right to appeal if we deny your request and the right to have our decisions reviewed in court), you must either make your request in writing or make it orally to a Freedom of Information Officer. Freedom of Information Officers and their staffs may put in writing any oral requests they receive directly.

(b) *Addressing requests.* It will help us to handle your request sooner if you address it to the Freedom of Information Officer in the HHS unit that is most likely to have the records you want. (See § 5.31 of this part for a list of Freedom of Information Officers.) If you cannot determine this, send the request to: HHS Freedom of Information Officer, 645–F, Hubert H. Humphrey Building, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201. Write the words ''Freedom of Information Act Request'' on the envelope and letter.

(c) *Details in the letter*. You should provide details that will help us identify and find the records you are requesting. If there is insufficient information, we will ask you for more. Include your telephone number(s) to help us reach you if we have questions. If you are not sure how to write your request or what details to include, communicate with a Freedom of Information Officer.

§5.22 Requests not handled under the FOIA.

(a) We will not handle your request under the FOIA and this regulation to the extent it asks for records that are currently available, either from HHS or from another part of the Federal Government, under a statute that provides for charging fees for those records. For example, we will not handle your request under the FOIA and this regulation to the extent it asks for detailed earnings statements under the Social Security program, or records currently available from the Government Printing Office of the National Technical Information Service.

(b) We will not handle your request under the FOIA and this regulation to the extent it asks for records that are distributed by an HHS program office as part of its regular program activity, for example, health education brochures distributed by the Public Health Service or public information leaflets distributed by the Social Security Administration.

§5.23 Referral of requests outside the Department.

If you request records that were created by, or provided to us by, another Federal agency, and if that agency asserts control over the records, we may refer the records and your request to that agency. We may likewise refer requests for classified records to the agency that classified them. In these cases, the other agency will process and respond to your request, to the extent it concerns those records, under that agency's regulation, and you need not make a separate request to that agency. We will notify you when we refer your request to another agency.

§5.24 Responding to your request.

(a) *Retrieving records*. The Department is required to furnish copies of records only when they are in our possession or we can retrieve them from storage. If we have stored the records you want in the National Archives or another storage center, we will retrieve and review them for possible disclosure. However, the Federal Government destroys many old records, so sometimes it is impossible to fill requests. Various laws, regulations, and manuals give the time periods for keeping records before they may be destroyed. For example, there is information about retention of records in the Records Disposal Act of 1944, 44 U.S.C. 3301 through 3314; the Federal Property Management Regulations, 41 CFR 101–11.4; the General Records Schedules of the National Archives and Records Administration; and in the HHS Handbook: *Files Maintenance and Records Disposition*.

(b) *Furnishing records*. The requirement is that we furnish copies only of records that we have or can retrieve. We are not compelled to create new records. For example, we are not required to write a new program so that a computer will print information in the format you prefer. However, if the requested information is maintained in computerized form, but we can, with minimal computer instructions, produce the information on paper, we will do this if it is the only way to respond to a request. Nor are we required to perform research for you. On the other hand, we may decide to conserve government resources and at the same time supply the records you need by consolidating information from various records rather than copying them all. Moreover, we are required to furnish only one copy of a record and usually impose that limit. If information exists in different forms, we will provide the record in the form that best conserves government resources. For example, if it requires less time and expense to provide a computer record as a paper printout rather than in an electronic medium, we will provide the printout.

Subpart C—Release and Denial of Records

§ 5.31 Designation of authorized officials.

(a) *Freedom of Information Officers.* To provide coordination and consistency in responding to FOIA requests, only Freedom of Information Officers have the authority to release or deny records. These same officials determine fees.

(1) *HHS Freedom of Information Officer.* Only the HHS Freedom of Information Officer may determine whether to release or deny records in any of the following situations:

(i) The records you seek include records addressed to or sent from an official or office of the Office of the Secretary, including its staff offices, or of any Regional Director's Office;

(ii) The records you seek include any records of the Office of Human Development Services, the Family Support Administration, or any organizational unit of HHS not specifically indentified below; or

(iii) The records include records of more than one of the major units identified below (PHS, CMS, and SSA) either at headquarters or in a Regional Office.

(2) *PHS Freedom of Information Officer.* If the records you seek are exclusively records of the Public Health Service or if the records you seek involve more than one health agency of the Public Health Service, including its records in the regions, only the Deputy Assistant Secretary for Health (Communications), who also is the PHS Freedom of Information Officer, may determine whether to release or deny the records, except as follows:

(i) *CDC and ATSDR Freedom of Information Officer.* If the records you seek are exclusively records of the Centers for Disease Control and/or the Agency for Toxic Substances and Disease Registry, only the Director, Office of Public Affairs, CDC, who also is the CDC and ATSDR Freedom of Information Officer, may determine whether to release or deny the records.

(ii) *FDA Freedom of Information Officer.* If the records you seek are exclusively records of the Food and Drug Administration, only the Associate Commissioner for Public Affairs, FDA, who also is the FDA Freedom of Information Officer, may determine whether to release or deny the records.

(iii) *NIH Freedom of Information Officer.* If the records you seek are exclusively records of the National Institutes of Health, only the Associate Director of Communications, HIH, who also is the NIH Freedom of Information Officer, may determine whether to release or deny the records.

(iv) *HRSA Freedom of Information Officer.* If the records you seek are exclusively records of the Health Resources and Services Administration, only the Associate Administrator for Communications, HRSA, who also is the HRSA Freedom of Information Officer, may determine whether to release or deny the records.

(v) ADAMHA Freedom of Information Officer. If the records you seek are exclusively records of the Alcohol, Drug Abuse and Mental Health Administration, only the Associate Administrator for Communications and Public Affairs, ADAMHA, who is also the ADAMHA Freedom of Information Officer, may determine whether to release or deny the records.

(vi) *IHS Freedom of Information Officer.* If the records you seek are exclusively records of the Indian Health Service, only the Director of Communications, IHS, who also is the IHS Freedom of Information Officer, may determine whether to release or deny the records.

(3) *SSA Freedom of Information Officer.* If the records you seek are exclusively records of the Social Security Administration, including its records in the regions, only the Director, Office of Public Inquiries, SSA, who also is the SSA Freedom of Information Officer, may determine whether to release or deny the records.

(4) *CMS Freedom of Information Officer.* If the records you seek are exclusively records of theCenters for Medicare & Medicaid Services, including its records in the regions, only the Director, Office of Public Affairs, CMS, who also is the CMS Freedom of Information Officer, may determine whether to release or deny the records.

(b) *Delegations.* Any of the above Freedom of Information Officers may

delegate his or her authority to release or deny records and to determine fees. Any such delegation requires the concurrence of the Assistant Secretary for Public Affairs.

(c) *Addresses and telephone numbers.* The addresses and telephone numbers of the Freedom of Information Officers are listed below.

FREEDOM OF INFORMATION OFFICERS

HHS Freedom of Information Officer, Room 645–F, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, *Tel:* (202) 472–7453

SSA Freedom of Information Officer, Room 4–H–8, Annex Building, 6401 Security Boulevard, Baltimore, Maryland 21235, *Tel:* (301) 965–3962

CMS Freedom of Information Officer, Room 100, Professional Building, Office of Public Affairs, 6660 Security Boulevard, Baltimore, Maryland 21207, *Tel:* (301) 966–5352

PHS Freedom of Information Officer, Room 13–C–24, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, *Tel:* (301) 443–5252

FDA Freedom of Information Officer, HFW–35, Room 12A16, Parklawn Building, 5600 Fishers Land, Rockville, Maryland 20857, *Tel:* (301) 443–1813

NIH Freedom of Information Officer, National Institutes of Health, Building 31, Room 2B39, 9000 Rockville Pike, Bethesda, Maryland 20892, *Tel:* (301) 496–5633

CDC Freedom of Information Officer, Centers for Disease Control, 1600 Clifton Road, NE., Atlanta, Georgia 30333, *Tel:* (404) 329–3286

HRSA Freedom of Information Officer, Room 14–43, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, *Tel:* (301) 443–2086

ADAMHA Freedom of Information Officer, Room 12–C–15, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, *Tel:* (301) 443–3783

IHS Freedom of Information Officer, Room 5–A–39, Parklawn Building, 5600 Fishers Land, Rockville, Maryland 20857, *Tel:* (301) 443–1397.

§5.32 Release of records.

(a) *Records previously released.* If we have released a record, or a part of a record, to others in the past, we will ordinarily release it to you also. However, we will not release it to you if a statute forbids this disclosure, and we will not necessarily release it to you if an exemption applies in your situation and did not apply, or applied differently, in the previous situations.

(b) *Unauthorized disclosure.* The principle stated in paragraph (a) of this section, does not apply if the previous release was unauthorized.

(c) *Poor copy.* If we cannot make a legible copy of a record to be released, we do not attempt to reconstruct it. Instead, we furnish the best copy possible and note its poor quality in our reply.

§5.33 Denial of requests.

(a) *Information furnished.* All denials are in writing and describe in general terms the material withheld; state the reasons for the denial, including, as applicable, a reference to the specific exemption of the FOIA authorizing the withholding or deletion; explain your right to appeal the decision and identify the official to whom you should send the appeal; and are signed by the person who made the decision to deny all or part of the request.

(b) *Unproductive searches.* We make a diligent search for records to satisfy your request. Nevertheless, we may not be able always to find the records you want using the information you provided, or they may not exist. If we advise you that we have been unable to find the records despite a diligent search, this does not constitute a denial of your request.

§5.34 Appeal of denials.

(a) *Right of appeal.* You have the right to appeal a partial or full denial of your FOIA request. To do so, you must put your appeal in writing and send it to the review official identified in the denial letter. You must send your appeal within 30 days from the date you receive that letter or from the date you receive the records released as a partial grant of your request, whichever is later.

(b) *Letter of appeal.* The appeal letter should state reasons why you believe that the FOIA exemption(s) we cited do not apply to the records that you requested, or give reasons why they should be released regardless of whether the exemption(s) apply. Because we have some discretionary authority in deciding whether to release or withhold records, you may strengthen your request by explaining your reasons for

wanting the records. However, you are not required to give any explanation.

(c) *Review process.* Before making a decision on an appeal of a denial, the designated review official will consult with the General Counsel to ensure that the rights and interests of all parties affected by the request are protected. Also, the concurrence of the Assistant Secretary for Public Affairs is required in all appeal decisions, including those on fees. When the review official responds to an appeal, that constitutes the Department's final action on the request. If the review official grants your appeal, we will send the records to you promptly or let you inspect them, or else we will explain the reason for any delay and the approximate date you will receive copies or be allowed to inspect the records. If the decision is to deny your appeal, the official will state the reasons for the decision in writing and inform you of the FOIA provision for judicial review.

§ 5.35 Time limits.

(a) *General.* FOIA sets certain time limits for us to decide whether to disclose the records you requested, and to decide appeals. If we fail to meet the deadlines, you may proceed as if we had denied your request or your appeal. We will try diligently to comply with the time limits, but if it appears that processing your request may take longer than we would wish, we will acknowledge your request and tell you its status. Since requests may be misaddressed or misrouted, you should call or write to confirm that we have the request and to learn its status if you have not heard from us in a reasonable time.

(b) *Time allowed.* (1) We will decide whether to release records within 10 working days after your request reaches the appropriate FOI office, as identified in § 5.31 of this part. When we decide to release records, we will actually provide the records, or let you inspect them, as soon as possible after that decision.

(2) We will decide an appeal within 20 working days after the appeal reaches the appropriate review official

(c) *Extension of time limits.* FOI Officers of review officials may extend the time limits in unusual circumstances. Extension at the request stage and at the appeal stage may total up to 10 working days. We will notify you in writing of any extension. ''Unusual circumstances'' include situations when we:

(1) Search for and collect records from field facilites, archives, or locations other than the office processing the request.

(2) Search for, collect, or examine a great many records in response to a single request.

(3) Consult with another office or agency that has substantial interest in the determination of the request.

(4) Conduct negotiations with submitters and requesters of information to determine the nature and extent of non-disclosable proprietary materials.

Subpart D—Fees

§ 5.41 Fees to be charged—categories of requests.

The paragraphs below state, for each category of request, the type of fees that we will generally charge. However, for each of these categories, the fees may be limited, waived, or reduced for the reasons given in §§ 5.42 through 5.45 or for other reasons.

(a) *Commercial use request.* If your request is for a commercial use, HHS will charge you the costs of search, review, and duplication.

(b) *Educational and scientific institutions and news media.* If you are an educational institution or a non-commercial scientific institution, operated primarily for scholarly or scientific research, or a representative of the news media, and your request is not for a commercial use, HHS will charge you only for the duplication of documents. Also, HHS will not charge you the copying costs for the first 100 pages of duplication.

(c) *Other requesters.* If your request is not the kind described by paragraph (a) or (b) of this section, then HHS will charge you only for the search and the duplication. Also, we will not charge you for the first two hours of search time or for the copying costs of the first 100 pages of duplication.

§ 5.42 Fees to be charged—general provisions.

(a) We may charge search fees even if the records we find are exempt from disclosure, or even if we do not find any records at all.

(b) If we are not charging you for the first two hours of search time, under § 5.41(c), and those two hours are spent on a computer search, then the two free hours are the first two hours of the operator's own operation. If the operator spends less than two hours on the search, we well reduce the total search fees by the average hourly rate for the operator's time, multipled by two.

(c) If we are not charging you for the first 100 pages of duplication, under § 5.41 (b) or (c), then those 100 pages are the first 100 pages of photocopies of standard size pages, or the first 100 pages of computer printout. If we cannot use this method to calculate the fee reduction, then we will reduce your total duplication fee by the normal charge for photocopying a standard size page, multiplied by 100.

(d) We will not charge you any fee at all if the costs of routine collection and processing of the fee are likely to equal or exceed the amount of the fee. As of May 1987, such costs among the units HHS ranged between $6.00 and $12.50.

(e) If we determine that you (acting either alone or together with others) are breaking down a single request into a series of requests in order to avoid (or reduce) the fees charged, we may aggregate all these requests for purposes of calculating the fees charged.

(f) We will charge interest on unpaid bills beginning on the 31st day following the day the bill was sent. We will use the provisions of Part 30 of this Title in assessing interest, administrative costs, and penalties and in taking actions to encourage payment.

(g) This subpart does not apply to requests for Social Security program records on Social Security number holders, wage earners, employers, and claimants, where the requests are governed by section 1106 of the Social Security Act, 42 U.S.C. 1306(c), and by 20 CFR 442.441.

§ 5.43 Fee schedule.

HHS charges the following fees:

(a) Manual searching for or reviewing of records—when the search or review is performed by employees at grade GS–1 through GS–8, an hourly rate based on the salary of a GS–5, step 7, employee; when done by a GS–9 through GS–14, an hourly rate based on the salary of a GS–12, step 4, employee; and when done by a GS–15 or above, an hourly rate 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 for the specified grade and step, adding 16% of that rate to cover benefits, and rounding to the nearest whole dollar. As of November 25, 1988, these rates were $10, $20, and $37 respectively. When a search involves employees at more than one of these levels, we will charge the rate appropriate for each.

(b) Computer searching and printing—the actual cost of operating the computer plus charges for the time spent by the operator, at the rates given in paragraph (a) of this section.

(c) Photocopying standard size pages—$0.10 per page. FOI Officers may charge lower fees for particular documents where—

(1) The document has already been printed in large numbers,

(2) The program office determines that using existing stock to answer this request, and any other anticipated FOI requests, will not interfere with program requirements, and

(3) The FOI Officer determines that the lower fee is adequate to recover the prorated share of the original printing costs.

(d) Photocopying odd-size documents (such as punchcards or blueprints), or reproducing other records (such as tapes)—the actual costs of operating the machine, plus the actual cost of the materials used, plus charges for the time spent by the operator, at the rates given in paragraph (a) of this section.

(e) Certifying that records are true copies. This service is not required by the FOIA. If we agree to provide it, we will charge $10 per certification.

(f) Sending records by express mail, certified mail, or other special methods. This service is not required by the FOIA. If we agree to provide it, we will charge our actual costs.

(g) Performing any other special service that you request and we agree to—actual costs of operating any machinery, plus actual cost of any materials used, plus charges for the time of our employees, at the rates given in paragraph (a) of this section.

§ 5.44 Procedures for assessing and collecting fees.

(a) *Agreement to pay*. 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 the limit and ask whether you nevertheless want us to proceed with the search.

(b) *Advance payment*. If you have failed to pay previous bills in a timely fashion, or if our initial review of your request indicates that we will charge you fees exceeding $250, we will require you to pay your past due fees and/or the estimated fees, or a deposit, before we start searching for the records you want. If so, we will let you know promptly upon receiving your request. In such cases, the administrative time limits prescribed in § 5.35 of the part (i.e., ten working days from receipt of initial requests and 20 working days from receipt of appeals from initial denials, plus permissible extensions of these time limits) will begin only after we come to an agreement with you over payment of fees, or decide that fee waiver or reduction is appropriate.

(c) *Billing and payment*. We will normally require you to pay all fees before we furnish the records to you. We may, at our discretion, send you a bill along with or following the furnishing of the records. For example, we may do this if you have a history of prompt payment. We may also, at our discretion, aggregate the charges for certain time periods in order to avoid sending numerous small bills to frequent requesters, or to businesses or agents representing requesters. For example, we might send a bill to such a requester once a month. Fees should be paid in accordance with the instructions furnished by the person who responds to your requests.

§ 5.45 Waiver or reduction of fees.

(a) *Standard*. We will waive or reduce the fees we would otherwise charge if disclosure of the information meets both of the following tests:

(1) It is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and

(2) It is not primarily in the commercial interest of the requester.

These two tests are explained in paragraphs (b) and (c) of this section.

(b) *Public interest*. The disclosure passes the first test only if it furthers the specific public interest of being likely to contribute significantly to public understanding of government operations or activities, regardless of any other public interest it may further. In analyzing this question, we will consider the following factors.

(1) How, if at all, do the records to be disclosed pertain to the operations or activities of the Federal Government?

(2) Would disclosure of the records reveal any meaningful information about government operations or activities? Can one learn from these records anything about such operations that is not already public knowledge?

(3) Will the disclosure advance the understanding of the general public as distinguished from a narrow segment of interested persons? Under this factor we may consider whether the requester is in a position to contribute to public understanding. For example, we may consider whether the requester has such knowledge or expertise as may be necessary to understand the information, and whether the requester's intended use of the information would be likely to disseminate the information among the public. An unsupported claim to be doing research for a book or article does not demonstrate that likelihood, while such a claim by a representative of the news media is better evidence.

(4) Will the contribution to public understanding be a significant one? Will the public's understanding of the government's operations be substantially greater as a result of the disclosure?

(c) *Not primarily in the requester's commercial interest*. If the disclosure passes

the test of furthering the specific public interest described in paragraph (b) of this section, we will determine whether it also furthers the requester's commercial interest and, if so, whether this effect outweighs the advancement of that public interest. In applying this second test, we will consider the following factors:

(1) Would the disclosure further a commercial interest of the requester, or of someone on whose behalf the requester is acting? ''Commercial interests'' include interests relating to business, trade, and profit. Not only profit-making corporations have commercial interests—so do nonprofit corporations, individuals, unions, and other associations. The interest of a representative of the news media in using the information for news dissemination purposes will not be considered a commercial interest.

(2) If disclosure would further a commercial interest of the requester, would that effect outweigh the advancement of the public interest defined in paragraph (b) of this section? Which effect is primary?

(d) *Deciding between waiver and reduction*. If the disclosure passes both tests, we will normally waive fees. However, in some cases we may decide only to reduce the fees. For example, we may do this when disclosure of some but not all of the requested records passes the tests.

(e) *Procedure for requesting a waiver or reduction*. You must make your request for a waiver or reduction at the same time you make your request for records. You should explain why you believe a waiver or reduction is proper under the analysis in paragraphs (a) through (d) of this section. Only FOI Officers may make the decision whether to waive, or reduce, the fees. If we do not completely grant your request for a waiver or reduction, the denial letter will designate a review official. You may appeal the denial to that official. In your appeal letter, you should discuss whatever reasons are given in our denial letter. The process prescribed in §5.34(c) of this part will also apply to these appeals.

Subpart E—Records Available for Public Inspection

§5.51 Records available.

(a) *Records of general interest*. We will make the following records of general interest available for your inspection and copying. Before releasing them, however, we may delete the names of people, or information that would identify them, if release would invade their personal privacy to a clearly unwarranted degree. (See §5.67 of this part.)

(1) Orders and final opinions, including concurring and dissenting opinions in adjudications, such as Letters of Finding issued by the Office for Civil Rights in civil rights complaints, and Social Security Rulings. (See §5.66 of this part for availability of internal memoranda, including attorney opinions and advice.)

(2) Statements of policy and interpretations that we have adopted but have not published in the FEDERAL REGISTER.

(3) Administrative staff manuals and instructions to staff that affect the public. (We will not make available, however, manuals or instructions that reveal investigative or audit procedures as described in §§5.63 and 5.68 of this part.)

(b) *Other records*. In addition to such records as those described in paragraph (a) of this section, we will make available to any person a copy of all other agency records, unless we determine that such records should be withheld from disclosure under subsection (b) of the Act and Subpart F of this regulation.

§5.52 Indexes of records.

(a) *Inspection and copying*. We will maintain and provide for your inspection and copying current indexes of the records described in §5.51(a). We will also publish and distribute copies of the indexes unless we announce in the FEDERAL REGISTER that it is unnecessary or impracticable to do so. For assistance in locating indexes maintained in the Department, you may contact the HHS Freedom of Information Officer at the address and telephone number in §5.31(c).

(b) *Record citation as precedent.* We will not use or cite any record described in § 5.51(a) as a precedent for an action against a person unless we have indexed the record and published it or made it available, or unless the person has timely notice of the record.

Subpart F—Reasons for Withholding Some Records

§ 5.61 General.

Section 552(b) of the Freedom of Information Act contains nine exemptions to the mandatory disclosure of records. We describe these exemptions below and explain how this Department applies them to disclosure determinations. (In some cases more than one exemption may apply to the same document.) Information obtained by the Department from any individual or organization, furnished in reliance on a provision for confidentiality authorized by applicable statute or regulation, will not be disclosed, to the extent it can be withheld under one of these exemptions. This section does not itself authorize the giving of any pledge of confidentiality by any officer or employee of the Department.

§ 5.62 Exemption one: National defense and foreign policy.

We are not required to release records that, as provided by FOIA, are ''(a) specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy and (b) are in fact properly classified pursuant to such Executive Order.'' Executive Order No. 12356 (1982) provides for such classification. When the release of certain records may adversely affect U.S. relations with foreign countries, we usually consult with officials of those countries or officials of the Department of State. Also, we may on occasion have in our possession records classified by some other agency. We may refer your request for such records to the agency that classified them and notify you that we have done so, as explained in § 5.23.

§ 5.63 Exemption two: Internal personnel rules and practices.

We are not required to release records that are ''related solely to the internal personnel rules and practices of an agency.'' Under this exemption, we may withhold routine internal agency practices and procedures. For example, we may withhold guard schedules and rules governing parking facilities or lunch periods. Also under this exemption, we may withhold internal records whose release would help some persons circumvent the law or agency regulations. For example, we ordinarily do not disclose manuals that instruct our investigators or auditors how to investigate possible violations of law, to the extent that this release would help some persons circumvent the law.

§ 5.64 Exemption three: Records exempted by other statutes.

We are not required to release records if another statute specifically allows us to withhold them. We may use another statute to justify withholding only if it absolutely prohibits disclosure or if it sets forth criteria to guide our decision on releasing or identifies particular types of material to be withheld.

§ 5.65 Exemption four: Trade secrets and confidential commercial or financial information.

We will withhold trade secrets and commercial or financial information that is obtained from a person and is privileged or confidential.

(a) *Trade secrets.* A trade secret is a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process.

(b) *Commercial or financial information.* We will not disclose records whose information is ''commercial or financial,'' is obtained from a person, and is ''privileged or confidential.''

(1) Information is ''commercial or financial'' if it relates to businesses, commerce, trade, employment, profits,

or finances (including personal finances). We interpret this category broadly.

(2) Information is ''obtained from a person'' if HHS or another agency has obtained it from someone outside the Federal Government or from someone within the Government who has a commercial or financial interest in the information. ''Person'' includes an individual, partnership, corporation, association, state or foreign government, or other organization. Information is not ''obtained from a person'' if it is generated by HHS or another federal agency. However, information is ''obtained from a person'' if it is provided by someone, including but not limited to an agency employee, who retains a commercial or financial interest in the information.

(3) Information is ''privileged'' if it would ordinarily be protected from disclosure in civil discovery by a recognized evidentiary privilege, such as the attorney-client privilege or the work product privilege. Information may be privileged for this purpose under a privilege belonging to a person outside the government, unless the providing of the information to the government rendered the information no longer protectable in civil discovery.

(4) Information is ''confidential'' if it meets one of the following tests:

(i) Disclosure may impair the government's ability to obtain necessary information in the future;

(ii) Disclosure would substantially harm the competitive position of the person who submitted the information;

(iii) Disclosure would impair other government interests, such as program effectiveness and compliance; or

(iv) Disclosure would impair other private interests, such as an interest in controlling availability of intrinsically valuable records, which are sold in the market by their owner.

The following questions may be relevant in analyzing whether a record meets one or more of the above tests: Is the information of a type customarily held in strict confidence and not disclosed to the public by the person to whom it belongs? What is the general custom or usage with respect to such information in the relevant occupation or business? How many, and what types of, individuals have access to the information? What kind and degree of financial injury can be expected if the information is disclosed?

(c) *Designation of certain confidential information.* A person who submits records to the government may designate part or all of the information in such records as 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. Where a legend is required by a request for proposals or request for quotations, pursuant to 48 CFR 352.215–12, then that legend is necessary for this purpose. Any such designation will expire ten years after the records were submitted to the government.

(d) *Predisclosure notification.* The procedures in this paragraph apply to records on which the submitter has designated information as provided in paragraph (c) of this section. 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 (e) 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 notice in a place where the submitters are reasonably likely to become aware of it.

(2) The submitter has five working days from receipt of the notice to object to disclosure of any part of the records and to state all bases for its objections.

(3) We will give consideration to all bases that have been timely stated by the submitter. If we decide to disclose

the records, we will notify the submitter in writing. This notice will briefly explain why we did not sustain its objections. We will include with the notice a copy of the records about which the submitter objected, as we propose to disclose them. The notice will state that we intend to disclose the records five working days after the submitter receives the notice unless we are ordered by a United States District Court not to release them.

(4) When a requester files suit under the FOIA to obtain records covered by this paragraph, we will promptly notify the submitter.

(5) Whenever we send a notice to a submitter under paragraph (d)(1) of this section, we will notify the requester that we are giving the submitter a notice and an opportunity to object. Whenever we send a notice to a submitter under paragraph (d)(3) of this section, we will notify the requester of this fact.

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

(1) We decided not to disclose the records;

(2) The information has previously been published or made generally available;

(3) Disclosure is required by a regulation, issued after notice and opportunity for public comment, that specifies narrow categories of records that are to be disclosed under the FOIA, but in this case a submitter may still designate records as described in paragraph (c) of this section, and in exceptional cases, we may, at our discretion, follow the notice procedures in paragraph (d) of this section; or

(4) The designation appears to be obviously frivolous, but in this case we will still give the submitter the written notice required by paragraph (d)(3) of this section (although this notice need not explain our decision or include a copy of the records), and we will notify the requester as described in paragraph (d)(5) of this section.

§ 5.66 Exemption five: Internal memoranda.

This exemption covers internal government communications and notes that fall within a generally recognized evidentiary privilege. Internal government communications include an agency's communications with an outside consultant or other outside person, with a court, or with Congress, when those communications are for a purpose similar to the purpose of privileged intra-agency communications. Some of the most-commonly applicable privileges are described in the following paragraphs.

(a) *Deliberative process privilege*. This privilege protects predecisional deliberative communications. A communication is protected under this privilege if it was made before a final decision was reached on some question of policy and if it expressed recommendations or opinions on that question. The purpose of the privilege is to prevent injury to the quality of the agency decisionmaking process by encouraging open and frank internal policy discussions, by avoiding premature disclosure of policies not yet adopted, and by avoiding the public confusion that might result from disclosing reasons that were not in fact the ultimate grounds for an agency's decision. Purely factual material in a deliberative document is within this privilege only if it is inextricably intertwined with the deliberative portions so that it cannot reasonably be segregated, if it would reveal the nature of the deliberative portions, or if its disclosure would in some other way make possible an intrusion into the decisionmaking process. We will release purely factual material in a deliberative document unless that material is otherwise exempt. The privilege continues to protect predecisional documents even after a decision is made.

(b) *Attorney work product privilege*. This privilege protects documents prepared by or for an agency, or by or for its representative (typically, HHS attorneys) in anticipation of litigation or for trial. It includes documents prepared for purposes of administrative adjudications as well as court litigation. It includes documents prepared by program offices as well as by attorneys. It includes factual material in such documents as well as material revealing opinions and tactics. Finally, the privilege continues to protect the

documents even after the litigation is closed.

(c) *Attorney-client communication privilege*. This privilege protects confidential communications between a lawyer and an employee or agent of the government where there is an attorney-client relationship between them (typically, where the lawyer is acting as attorney for the agency and the employee is communicating on behalf of the agency) and where the employee has communicated information to the attorney in confidence in order to obtain legal advice or assistance.

§5.67 Exemption six: Clearly unwarranted invasion of personal privacy.

(a) *Documents affected*. We may withhold records about individuals if disclosure would constitute a clearly unwarranted invasion of their personal privacy.

(b) *Balancing test*. In deciding whether to release records to you that contain personal or private information about someone else, we weigh the foreseeable harm of invading that person's privacy against the public benefit that would result from the release. If you were seeking information for a purely commercial venture, for example, we might not think that disclosure would primarily benefit the public and we would deny your request. On the other hand, we would be more inclined to release information if you were working on a research project that gave promise of providing valuable information to a wide audience. However, in our evaluation of requests for records we attempt to guard against the release of information that might involve a violation of personal privacy because of a requester being able to ''read between the lines'' or piece together items that would constitute information that normally would be exempt from mandatory disclosure under Exemption Six.

(c) *Examples*. Some of the information that we frequently withhold under Exemption Six is: Home addresses, ages, and minority group status of our employees or former employees; social security numbers; medical information about individuals participating in clinical research studies; names and addresses of individual beneficiaries of our programs, or benefits such individuals receive; earning records, claim files, and other personal information maintained by the Social Security Administration, the Public Health Service, and theCenters for Medicare & Medicaid Services.

§5.68 Exemption seven: Law enforcement.

We are not required to disclose information or records that the government has compiled for law enforcement purposes. The records may apply to actual or potential violations of either criminal or civil laws or regulations. We can withhold these records only to the extent that releasing them would cause harm in at least one of the following situations:

(a) *Enforcement proceedings*. We may withhold information whose release could reasonably be expected to interfere with prospective or ongoing law enforcement proceedings. Investigations of fraud and mismanagement, employee misconduct, and civil rights violations may fall into this category. In certain cases—such as when a fraud investigation is likely—we may refuse to confirm or deny the existence of records that relate to the violations in order not to disclose that an investigation is in progress, or may be conducted.

(b) *Fair trial or impartial adjudication*. We may withhold records whose release would deprive a person of a fair trial or an impartial adjudication because of prejudicial publicity.

(c) *Personal privacy*. We are careful not to disclose information that could reasonably be expected to constitute an unwarranted invasion of personal privacy. When a name surfaces in an investigation, that person is likely to be vulnerable to innuendo, rumor, harassment, and retaliation.

(d) *Confidential sources and information*. We may withhold records whose release could reasonably be expected to disclose the identity of a confidential source of information. A confidential source may be an individual; a state, local, or foreign government agency; or any private organization. The exemption applies whether the source provides information under an express

promise of confidentiality or under circumstances from which such an assurance could be reasonably inferred. Also, where the record, or information in it, has been compiled by a criminal law enforcement authority conducting a criminal investigation, or by an agency conducting a lawful national security investigation, the exemption also protects all information supplied by a confidential source. Also protected from mandatory disclosure is any information which, if disclosed, could reasonably be expected to jeopardize the system of confidentiality that assures a flow of information from sources to investigatory agencies.

(e) *Techniques and procedures.* We may withhold records reflecting special techniques or procedures of investigation or prosecution, not otherwise generally known to the public. In some cases, it is not possible to describe even in general terms those techniques without disclosing the very material to be withheld. We may also withhold records whose release would disclose guidelines for law enforcement investigations or prosecutions if this disclosure could reasonably be expected to create a risk that someone could circumvent requirements of law or of regulation.

(f) *Life and physical safety.* We may withhold records whose disclosure could reasonably be expected to endanger the life or physical safety of any individual. This protection extends to threats and harassment as well as to physical violence.

§ 5.69 Exemptions 8 and 9: Records on financial institutions; records on wells.

Exemption eight permits us to withhold records about regulation or supervision of financial institutions. Exemption nine permits the withholding of geological and geophysical information and data, including maps, concerning wells.

PART 5a [RESERVED]

PART 5b—PRIVACY ACT REGULATIONS

Sec.

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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 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 Service 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 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 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 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 request 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 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 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 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 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.

(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 in the National Practitioner Data Bank (NPDB). (See §60.16 of this subtitle 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.

(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; and,

(B) The Suitability for Employment Records, HHS.

(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.

(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) *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, as amended at 43 FR 40229, Sept. 11, 1978; 47 FR 57040, Dec. 22, 1982; 49 FR 14108, Apr. 10, 1984; 51 FR 41352, Nov. 14, 1986; 59 FR 36717, July 19, 1994; 65 FR 34988, June 1, 2000; 65 FR 37289, June 14, 2000; 68 FR 62751, Nov. 6, 2003; 73 FR 55775, Sept. 26, 2008; 76 FR 72327, Nov. 23, 2011]

EFFECTIVE DATE NOTES: 1. At 77 FR 51912, Aug. 28, 2012, § 5b.11 was amended by adding paragraph (b)(2)(vii)(C), effective Jan. 10, 2013. For the convenience of the user, the added and revised text is set forth as follows:

§ 5b.11 Exempt systems.

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(C) FDA Records Related to Research Misconduct Proceedings, HHS/FDA/OC.

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2. At 77 FR 51935, Aug. 28, 2012, § 5b.11 was amended by adding paragraph (b)(2)(vii)(D), effective Jan. 10, 2013. For the convenience of the user, the added and revised text is set forth as follows:

§ 5b.11 Exempt systems.

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(b) * * *

(2) * * *

(vii) * * *

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

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§ 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 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 f 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 hiem;

(c) Failing to maintain any record pertaining to any individual with such accuracy, 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 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.

(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 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 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]

§ 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 8 [RESERVED]

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.

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 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.

§ 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 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.

§ 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 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 remain 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 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 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 PURPOSES [1]

Classification	Percent allowed											
	Organization allowances							Utilization allowances				Maximum public benefit allowance
	Basic public benefit allowance	Tax support	Accreditation	Hardship	Unmet needs			Integrated research program	Outpatient services	Public services	Training program	
					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 Administration	[2] 100	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	[2] 100
Public Refuse Disposal 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
Assistance to the Homeless	[2] 100	.....	.....	.....	.....	.....	.....	.....	.....	.....	.....	[2] 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.
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12a.4 Suitability determination.
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12a.10 Action on approved applications.
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12a.12 No applications approved.

AUTHORITY: 42 U.S.C. 11411; 40 U.S.C. 484(k); 42 U.S.C. 3535(d).

SOURCE: 56 FR 23794, 23795, May 24, 1991, unless otherwise noted.

EFFECTIVE DATE NOTE: At 56 FR 23794, 23795, May 24, 1991, part 12a was added, effective May 24, 1991, except for §12a.3, which will not become effective until approved by the District Court for the District of Columbia, pending further proceedings.

§ 12a.1 Definitions.

Applicant means any representative of the homeless which has submitted an application to the Department of Health and Human Services to obtain use of a particular suitable property to assist the homeless.

Checklist or property checklist means the form developed by HUD for use by landholding agencies to report the information to be used by HUD in making determinations of suitability.

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, unit of local government or a private non-profit organization which provides assistance to the homeless, and which is authorized by its charter or by State law to enter into an agreement with the Federal government for use of real property for the purposes of this subpart. Representatives of the homeless interested in receiving a deed for a particular piece of surplus Federal property must be section 501(c)(3) tax exempt.

Excess property means any property under the control of any Federal executive agency that is not required for the agency's needs or the discharge of its responsibilities, as determined by the head of the agency pursuant to 40 U.S.C. 483.

GSA means the General Services Administration.

HHS means the Department of Health and Human Services.

Homeless means:

(1) An individual or family that lacks a fixed, regular, and adequate nighttime residence; and

(2) An individual or family that has a primary nighttime residence that is:

(i) A supervised publicly or privately operated shelter designed to provide temporary living accommodations (including welfare hotels, congregate shelters, and transitional housing for the mentally ill);

(ii) An institution that provides a temporary residence for individuals intended to be institutionalized; or

(iii) A public or private place not designed for, or ordinarily used as, a regular sleeping accommodation for human beings. This term does not include any individual imprisoned or otherwise detained under an Act of the Congress or a State law.

HUD means the Department of Housing and Urban Development.

ICH means the Interagency Council on the Homeless.

Landholding agency means a Federal department or agency with statutory authority to control real property.

Lease means an agreement between either the Department of Health and Human Services for surplus property, or landholding agencies in the case of non-excess properties or properties subject to the Base Closure and Realignment Act (Public Law 100–526; 10 U.S.C. 2687), and the applicant, giving rise to the relationship of lessor and lessee for the use of Federal real property for a term of at least one year under the conditions set forth in the lease document.

Non-profit organization means an organization 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 nondiscrimination 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 under terms and conditions determined by the landholding agency.

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 section 202(b)(2) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 483(b)(2).)

Regional Homeless Coordinator means a regional coordinator of the Interagency Council on the Homeless.

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

Screen means the process by which GSA surveys Federal agencies, or State, local and non-profit entities, to determine if any such entity has an interest in using excess Federal property to carry out a particular agency mission or a specific public use.

State Homeless Coordinator means a state contact person designated by a state to receive and disseminate information and communications received from the Interagency Council on the Homeless in accordance with section 210(a) of the Stewart B. McKinney Act of 1987, as amended.

Suitable property means that HUD has determined that a particular property satisfies the criteria listed in § 12a.6.

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

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.

Unsuitable property means that HUD has determined that a particular property does not satisfy the criteria in § 12a.6.

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 real property which has been designated by Federal landholding agencies as unutilized, underutilized, excess or surplus and is therefore subject to the provisions of title V of the McKinney Act (42 U.S.C. 11411).

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

(1) Machinery and equipment.

(2) 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.

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

(4) Properties subject to a Court Order.

(5) Property not subject to survey requirements of Executive Order 12512 (April 29, 1985).

(6) Mineral rights interests.

(7) Air Space interests.

(8) Indian Reservation land subject to section 202(a)(2) of the Federal Property and Administrative Service Act of 1949, as amended.

(9) Property interests subject to reversion.

(10) Easements.

(11) 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 Collecting the information.

(a) *Canvass of landholding agencies.* On a quarterly basis, HUD will canvass

landholding agencies to collect information about property described as unutilized, underutilized, excess, or surplus, in surveys conducted by the agencies under section 202 of the Federal Property and Administrative Services Act (40 U.S.C. 483), Executive Order 12512, and 41 CFR part 101–47.800. Each canvass will collect information on properties not previously reported and about property reported previously the status or classification of which has changed or for which any of the information reported on the property checklist has changed.

(1) HUD will request descriptive information on properties sufficient to make a reasonable determination, under the criteria described below, of the suitability of a property for use as a facility to assist the homeless.

(2) HUD will direct landholding agencies to respond to requests for information within 25 days of receipt of such requests.

(b) *Agency Annual Report*. By December 31 of each year, each landholding agency must notify HUD regarding the current availability status and classification of each property controlled by the agency that:

(1) Was included in a list of suitable properties published that year by HUD, and

(2) Remains available for application for use to assist the homeless, or has become available for application during that year.

(c) *GSA Inventory*. HUD will collect information, in the same manner as described in paragraph (a) of this section, from GSA regarding property that is in GSA's current inventory of excess or surplus property.

(d) *Change in Status*. If the information provided on the property checklist changes subsequent to HUD's determination of suitability, and the property remains unutilized, underutilized, excess or surplus, the landholding agency shall submit a revised property checklist in response to the next quarterly canvass. HUD will make a new determination of suitability and, if it differs from the previous determination, republish the property information in the FEDERAL REGISTER. For example, property determined unsuitable for national security concerns may no longer be subject to security restrictions, or property determined suitable may subsequently be found to be contaminated.

§ 12a.4 Suitability determination.

(a) *Suitability determination*. Within 30 days after the receipt of information from landholding agencies regarding properties which were reported pursuant to the canvass described in § 12a.3(a), HUD will determine, under criteria set forth in § 12a.6, which properties are suitable for use as facilities to assist the homeless and report its determination to the landholding agency. Properties that are under lease, contract, license, or agreement by which a Federal agency retains a real property interest or which are scheduled to become unutilized or underutilized will be reviewed for suitability no earlier than six months prior to the expected date when the property will become unutilized or underutilized, except that properties subject to the Base Closure and Realignment Act may be reviewed up to eighteen months prior to the expected date when the property will become unutilized or underutilized.

(b) *Scope of suitability*. HUD will determine the suitability of a property for use as a facility to assist the homeless without regard to any particular use.

(c) *Environmental information*. HUD will evaluate the environmental information contained in property checklists forwarded to HUD by the landholding agencies solely for the purpose of determining suitability of properties under the criteria in § 12a.6.

(d) *Written record of suitability determination*. HUD will assign an identification number to each property reviewed for suitability. HUD will maintain a written public record of the following:

(1) The suitability determination for a particular piece of property, and the reasons for that determination; and

(2) The landholding agency's response to the determination pursuant to the requirements of § 12a.7(a).

(e) *Property determined unsuitable*. Property that is reviewed by HUD under this section and that is determined unsuitable for use to assist the homeless may not be made available

for any other purpose for 20 days after publication in the FEDERAL REGISTER of a Notice of unsuitability to allow for review of the determination at the request of a representative of the homeless.

(f) *Procedures for appealing unsuitability determinations.* (1) To request review of a determination of unsuitability, a representative of the homeless must contact HUD within 20 days of publication of notice in the FEDERAL REGISTER that a property is unsuitable. Requests may be submitted to HUD in writing or by calling 1–800–927–7588 (Toll Free). Written requests must be received no later than 20 days after notice of unsuitability is published in the FEDERAL REGISTER.

(2) Requests for review of a determination of unsuitability may be made only by representatives of the homeless, as defined in § 12a.1.

(3) The request for review must specify the grounds on which it is based, i.e., that HUD has improperly applied the criteria or that HUD has relied on incorrect or incomplete information in making the determination (e.g., that property is in a floodplain but not in a floodway).

(4) Upon receipt of a request to review a determination of unsuitability, HUD will notify the landholding agency that such a request has been made, request that the agency respond with any information pertinent to the review, and advise the agency that it should refrain from initiating disposal procedures until HUD has completed its reconsideration regarding unsuitability.

(i) HUD will act on all requests for review within 30 days of receipt of the landholding agency's response and will notify the representative of the homeless and the landholding agency in writing of its decision.

(ii) If a property is determined suitable as a result of the review, HUD will request the landholding agency's determination of availability pursuant to § 12a.7(a), upon receipt of which HUD will promptly publish the determination in the FEDERAL REGISTER. If the determination of unsuitability stands, HUD will inform the representative of the homeless of its decision.

§ 12a.5 Real property reported excess to GSA.

(a) Each landholding agency must submit a report to GSA of properties it determines excess. Each landholding agency must also provide a copy of HUD's suitability determination, if any, including HUD's identification number for the property.

(b) If a landholding agency reports a property to GSA which has been reviewed by HUD for homeless assistance suitability and HUD determined the property suitable, GSA will screen the property pursuant to § 12a.5(g) and will advise HUD of the availability of the property for use by the homeless as provided in § 12a.5(e). In lieu of the above, GSA may submit a new checklist to HUD and follow the procedures in § 12a.5(c) through § 12a.5(g).

(c) If a landholding agency reports a property to GSA which has not been reviewed by HUD for homeless assistance suitability, GSA will complete a property checklist, based on information provided by the landholding agency, and will forward this checklist to HUD for a suitability determination. This checklist will reflect any change in classification, i.e., from unutilized or underutilized to excess.

(d) Within 30 days after GSA's submission, HUD will advise GSA of the suitability determination.

(e) When GSA receives a letter from HUD listing suitable excess properties in GSA's inventory, GSA will transmit to HUD within 45 days a response which includes the following for each identified property:

(1) A statement that there is no other compelling Federal need for the property, and therefore, the property will be determined surplus; or

(2) A statement that there is further and compelling Federal need for the property (including a full explanation of such need) and that, therefore, the property is not presently available for use to assist the homeless.

(f) When an excess property is determined suitable and available and notice is published in the FEDERAL REGISTER, GSA will concurrently notify HHS, HUD, State and local government units, known homeless assistance providers that have expressed interest in

the particular property, and other organizations, as appropriate, concerning suitable properties.

(g) Upon submission of a Report of Excess to GSA, GSA may screen the property for Federal use. In addition, GSA may screen State and local governmental units and eligible nonprofit organizations to determine interest in the property in accordance with current regulations. (See 41 CFR 101–47.203–5, 101–47.204–1 and 101–47.303–2.)

(h) The landholding agency will retain custody and accountability and will protect and maintain any property which is reported excess to GSA as provided in 41 CFR 101–47.402.

§ 12a.6 Suitability criteria.

(a) All properties, buildings and land will be determined suitable unless a property's characteristics include one or more of the following conditions:

(1) *National security concerns*. A property located in an area to which the general public is denied access in the interest of national security (e.g., where a special pass or security clearance is a condition of entry to the property) will be determined unsuitable. Where alternative access can be provided for the public without compromising national security, the property will not be determined unsuitable on this basis.

(2) *Property containing flammable or explosive materials*. A property located within 2000 feet of an industrial, commercial or Federal facility handling flammable or explosive material (excluding underground storage) will be determined unsuitable. Above ground containers with a capacity of 100 gallons or less, or larger containers which provide the heating or power source for the property, and which meet local safety, operation, and permitting standards, will not affect whether a particular property is determined suitable or unsuitable. Underground storage, gasoline stations and tank trucks are not included in this category and their presence will not be the basis of an unsuitability determination unless there is evidence of a threat to personal safety as provided in paragraph (a)(5) of this section.

(3) *Runway clear zone and military airfield clear zone*. A property located within an airport runway clear zone or military airfield clear zone will be determined unsuitable.

(4) *Floodway*. A property located in the floodway of a 100 year floodplain will be determined unsuitable. If the floodway has been contained or corrected, or if only an incidental portion of the property not affecting the use of the remainder of the property is in the floodway, the property will not be determined unsuitable.

(5) *Documented deficiencies*. A property with a documented and extensive condition(s) that represents a clear threat to personal physical safety will be determined unsuitable. Such conditions may include, but are not limited to, contamination, structural damage or extensive deterioration, friable asbestos, PCB's, or natural hazardous substances such as radon, periodic flooding, sinkholes or earth slides.

(6) *Inaccessible*. A property that is inaccessible will be determined unsuitable. An inaccessible property is one that is not accessible by road (including property on small off-shore islands) or is land locked (e.g., can be reached only by crossing private property and there is no established right or means of entry).

§ 12a.7 Determination of availability.

(a) Within 45 days after receipt of a letter from HUD pursuant to § 12a.4(a), each landholding agency must transmit to HUD a statement of one of the following:

(1) In the case of unutilized or underutilized property:

(i) An intention to declare the property excess,

(ii) An intention to make the property available for use to assist the homeless, or

(iii) The reasons why the property cannot be declared excess or made available for use to assist the homeless. The reasons given must be different than those listed as suitability criteria in § 12a.6.

(2) In the case of excess property which had previously been reported to GSA:

(i) A statement that there is no compelling Federal need for the property, and that, therefore, the property will be determined surplus; or

(ii) A statement that there is a further and compelling Federal need for the property (including a full explanation of such need) and that, therefore, the property is not presently available for use to assist the homeless.

§ 12a.8 Public notice of determination.

(a) No later than 15 days after the last 45 day period has elapsed for receiving responses from the landholding agencies regarding availability, HUD will publish in the FEDERAL REGISTER a list of all properties reviewed, including a description of the property, its address, and classification. The following designations will be made:

(1) Properties that are suitable and available.

(2) Properties that are suitable and unavailable.

(3) Properties that are suitable and to be declared excess.

(4) Properties that are unsuitable.

(b) Information about specific properties can be obtained by contacting HUD at the following toll free number, 1–800–927–7588.

(c) HUD will transmit to the ICH a copy of the list of all properties published in the FEDERAL REGISTER. The ICH will immediately distribute to all state and regional homeless coordinators area-relevant portions of the list. The ICH will encourage the state and regional homeless coordinators to disseminate this information widely.

(d) No later than February 15 of each year, HUD shall publish in the FEDERAL REGISTER a list of all properties reported pursuant to § 12a.3(b).

(e) HUD shall publish an annual list of properties determined suitable but which agencies reported unavailable including the reasons such properties are not available.

(f) Copies of the lists published in the FEDERAL REGISTER will be available for review by the public in the HUD headquarters building library (room 8141); area-relevant portions of the lists will be available in the HUD regional offices and in major field offices.

§ 12a.9 Application process.

(a) *Holding period.* (1) Properties published as available for application for use to assist the homeless shall not be available for any other purpose for a period of 60 days beginning on the date of publication. Any representative of the homeless interested in any underutilized, unutilized, excess or surplus Federal property for use as a facility to assist the homeless must send to HHS a written expression of interest in that property within 60 days after the property has been published in the FEDERAL REGISTER.

(2) If a written expression of interest to apply for suitable property for use to assist the homeless is received by HHS within the 60 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.

(3) 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 the Division of Health Facilities Planning (DHFP) of the Department of Health and Human Services at the following address:

Director, Division of Health Facilities Planning, Public Health Service, Room 17A–10, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

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 particular property.

(4) An expression of interest may be sent to HHS any time after the 60 day holding period has expired. In such a case, an application submitted pursuant to this expression of interest may be approved for use by the homeless if:

(i) No application or written expression of interest has been made under any law for use of the property for any purpose; and

(ii) 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.

(b) *Application Requirements*. Upon receipt of an expression of interest, DHFP will send an application packet to the interested entity. The application packet requires the applicant to provide certain information, including the following—

(1) *Description of the applicant organization*. The applicant must document that it satisfies the definition of a ''representative of the homeless,'' as specified in § 12a.1 of this subpart. The applicant must document its authority to hold real property. Private non-profit organizations applying for deeds must document that they are section 501(c)(3) tax-exempt.

(2) *Description of the property desired*. The applicant must describe the property desired and indicate that any modifications made to the property will conform to local use restrictions except for local zoning regulations.

(3) *Description of the proposed program*. The applicant must fully describe the proposed program and demonstrate how the program will address the needs of the homeless population to be assisted. The applicant must fully describe what modifications will be made to the property before the program becomes operational.

(4) *Ability to finance and operate the proposed program*. The applicant must specifically describe all anticipated costs and sources of funding for the proposed program. The applicant must indicate that it can assume care, custody, and maintenance of the property and that it has the necessary funds or the ability to obtain such funds to carry out the approved program of use for the property.

(5) *Compliance with non-discrimination requirements*. Each applicant and lessee under this part must certify in writing that it will comply with the requirements of the Fair Housing Act (42 U.S.C. 3601–3619) and implementing regulations; and as applicable, Executive Order 11063 (Equal Opportunity in Housing) and implementing regulations; 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; 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; and the prohibitions against otherwise qualified individuals with handicaps under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and implementing regulations. The applicant must state that it will not discriminate on the basis of race, color, national origin, religion, sex, age, familial status, or handicap in the use of the property, and will maintain the required records to demonstrate compliance with Federal laws.

(6) *Insurance*. The applicant must certify that it will insure the property against loss, damage, or destruction in accordance with the requirements of 45 CFR 12.9.

(7) *Historic preservation*. Where applicable, the applicant must provide information that will enable HHS to comply with Federal historic preservation requirements.

(8) *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.

(9) *Local government notification*. The applicant must indicate that it has informed the applicable unit of general local government responsible for providing sewer, water, police, and fire services, in writing of its proposed program.

(10) *Zoning and Local Use Restrictions*. The applicant must indicate that it will comply with all local use restrictions, including local building code requirements. Any applicant which applies for a lease or permit for a particular property is not required to comply with local zoning requirements. Any applicant applying for a deed of a particular property, pursuant to § 12a.9(b)(3), must comply with local zoning requirements, as specified in 45 CFR part 12.

(c) *Scope of evaluations*. Due to the short time frame imposed for evaluating applications, HHS' evaluation will, generally, be limited to the information contained in the application.

(d) *Deadline*. Completed applications must be received by DHFP, at the above address, within 90 days after an expression of interest is received from a particular applicant for that property. Upon written request from the applicant, HHS may grant extensions, provided that the appropriate landholding agency concurs with the extension. Because each applicant will have a different deadline based on the date the applicant submitted an expression of interest, applicants should contact the individual landholding agency to confirm that a particular property remains available prior to submitting an application.

(e) *Evaluations*. (1) Upon receipt of an application, HHS will review it for completeness, and, if incomplete, may return it or ask the applicant to furnish any missing or additional required information prior to final evaluation of the application.

(2) HHS will evaluate each completed application within 25 days of receipt and will promptly advise the applicant of its decision. Applications are evaluated on a first-come, first-serve basis. HHS will notify all organizations which have submitted expressions of interest for a particular property regarding whether the first application received for that property has been approved or disapproved. All applications will be reviewed on the basis of the following elements, which are listed in descending order of priority, except that paragraphs (e)(2)(iv) and (e)(2)(v) of this section are of equal importance.

(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 and the degree to which the available property will be fully utilized.

(iii) *Implementation Time*. The amount of time necessary for the proposed program to become operational.

(iv) *Experience*. Demonstrated prior success in operating similar programs and recommendations attesting to that fact by Federal, State, and local authorities.

(v) *Financial Ability*. The adequacy of funding that will likely be available to run the program fully and properly and to operate the facility.

(3) Additional evaluation factors may be added as deemed necessary by HHS. If additional factors are added, the application packet will be revised to include a description of these additional factors.

(4) If HHS receives one or more competing applications for a property within 5 days of the first application HHS will evaluate all completed applications simultaneously. HHS will rank approved applications based on the elements listed in § 12a.8(e)(2), and notify the landholding agency, or GSA, as appropriate, of the relative ranks.

(Approved by the Office of Management and Budget under control number 0937–0191)

§ 12a.10 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. (Leases and permits will be for a period of at least one year unless the applicant requests a shorter term.)

(ii) Whether to grant use of the property via a lease or permit;

(iii) The terms and conditions of the lease or permit document.

(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 leasing. Upon receipt of the assignment, HHS will execute a lease in accordance with the procedures and requirements set out in 45 CFR part 12. In accordance with 41 CFR 101–47.402, custody and accountability of the property will remain throughout the lease term with the agency which initially reported the property as excess.

(2) Prior to assignment to HHS, GSA may consider other Federal uses and other important national needs; however, in deciding the disposition of surplus real property, GSA will generally

give priority of consideration to uses to assist the homeless. GSA may consider any competing request for the property made under section 203(k) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 484(k)) that is so meritorious and compelling that it outweighs the needs of the homeless, and HHS may likewise consider any competing request made under subsection 203(k)(1) of that law.

(3) Whenever GSA or HHS decides in favor of a competing request over a request for property for homeless assistance use as provided in paragraph (b)(2) of this section, the agency making the decision will transmit to the appropriate committees of the 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.

(4) *Deeds*. Surplus property may be conveyed to representatives of the homeless pursuant to section 203(k) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 484(k)(1), and section 501(f) of the McKinney Act as amended, 42 U.S.C. 11411. Representatives of the homeless must complete the application packet pursuant to the requirements of §12a.9 of this part and in accordance with the requirements of 45 CFR part 12.

(c) *Completion of Lease Term and Reversion of Title*. Lessees and grantees 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 Federal government, the lessee or grantee will be responsible for removing any improvements made to the property and will be responsible for restoration of the property. If such improvements are not removed, they will become the property of the Federal government. GSA or the landholding agency, as appropriate, will assume responsibility for protection and maintenance of a property when the lease terminates or title reverts.

§12a.11 Unsuitable properties.

The landholding agency will defer, for 20 days after the date that notice of a property is published in the FEDERAL REGISTER, action to dispose of properties determined unsuitable for homeless assistance. HUD will inform landholding agencies or GSA if appeal of an unsuitability determination is filed by a representative of the homeless pursuant to §12a.4(f)(4). HUD will advise the agency that it should refrain from initiating disposal procedures until HUD has completed its reconsideration process regarding unsuitability. Thereafter, or if no appeal has been filed after 20 days, GSA or the appropriate landholding agency may proceed with disposal action in accordance with applicable law.

§12a.12 No applications approved.

(a) At the end of the 60 day holding period described in §12a.9(a), HHS will notify GSA, or the landholding agency, as appropriate, if an expression of interest has been received for a particular 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 advice from HHS that all applications have been disapproved, or if no completed applications or requests for extensions have been received by HHS within 90 days from the date of the last expression of interest, disposal may proceed in accordance with applicable law.

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 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'' 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.

(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 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 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 reimbursement 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 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 (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 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 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); 1395*l*(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); 1395*l*(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.

Proceedings covered	Statutory authority	Applicable regulations
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); 1395l(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); 1396r–8(b)(3)(B), (C)(ii); 1396t(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. 1395l(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.
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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APPENDIX A TO PART 16—WHAT DISPUTES THE BOARD REVIEWS

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 part 74 of this title.

§ 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 part 74 of this title, unless the context below otherwise requires.

§ 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 45 CFR 74.304.

(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]

§ 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 45 CFR 74.304, 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.

§ 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 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 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)).

(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 necessary 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 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) All submissions should be addressed as follows: Departmental Grant Appeals Board, Room 2004, Switzer Building, 330 C Street SW., Washington, DC 20201.

(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 postmarked or hand delivered to the Board.

§ 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 § 74.114 of this title);

(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), 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; or

(4) Take other action to recover, withhold, or offset funds if specifically authorized by statute or regulation.

§ 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.

(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 nondiscrimination 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]

PART 17—RELEASE OF ADVERSE INFORMATION TO NEWS MEDIA

Sec.
17.1 Definition.
17.2 Basic policy.
17.3 Precautions to be taken.

17.4 Regulatory investigations and trial-type proceedings.
17.5 Context to be reflected.
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 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 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 30—CLAIMS COLLECTION

Subpart A—General Provisions

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30.36 Minimum amount of referrals.

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.

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.

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 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 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.

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 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 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 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 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.

(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 redelegated 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 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, 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 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 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 Department'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 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 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;

(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.

(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 meet.

(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 terminated, 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.

(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 exclusive 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.
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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 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 nontax 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 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:

(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;

(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 received 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 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 I-Iealth and 1—luman 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 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 following 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.

(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 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.

§ 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.

(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 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, 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 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;

(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;

(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 determines 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 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 Boards'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:

(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.

(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 employee 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 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 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

(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.
34.2 Definitions.
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34.4 Allowable claims.
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34.8 Computation of award and settlement.
34.9 Claims involving carriers or insurers.

AUTHORITY: 31 U.S.C. 3721.

SOURCE: 69 FR 13257, Mar. 22, 2004, unless otherwise noted.

§ 34.1 Purpose and scope.

(a) *Purpose.* This part prescribes polices 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 posses 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:

(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

(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 under orders or in connection with travel orders.

§ 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.

§ 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.

§ 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

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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 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.

(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.

(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

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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289(a).

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

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 289, 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28022, June 18, 1991, unless otherwise noted.

§46.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which 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.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § 46.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § 46.102(e) must be reviewed and approved, in compliance with § 46.101, § 46.102, and § 46.107 through § 46.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(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.

(c) Department or agency heads retain final judgment as to whether a particular activity is covered by this policy.

(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 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 which provide additional protections for human subjects.

(f) This policy does not affect any state or local laws or regulations which may otherwise be applicable and which provide additional protections for human subjects.

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which 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. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] 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. 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, and shall also publish them in the FEDERAL REGISTER or in such other manner as provided in department or agency procedures.[1]

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.102 Definitions.

(a) *Department or agency head* means the head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including federal, state, and other agencies).

(c) *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.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(e) *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements

[1] Institutions with HHS-approved assurances on file will abide by provisions of title 45 CFR part 46 subparts A–D. Some of the other Departments and Agencies have incorporated all provisions of title 45 CFR part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(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) *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.

(j) *Certification* means the official notification by the institution to the supporting department or agency, 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.

§ 46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

(a) Each institution engaged in research which is covered by this policy and which 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 set forth in 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 federalwide 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.

(b) Departments and agencies will conduct or support research covered by this policy only if the institution has an assurance approved 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 provided for in the assurance, and will be subject to continuing review by the IRB. Assurances applicable to federally supported or conducted research shall at a minimum include:

(1) A statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether

the research is subject to federal regulation. This may include an appropriate existing code, declaration, or statement of ethical principles, or a statement formulated by the institution itself. This requirement does not preempt provisions of this policy applicable to department- or agency-supported or regulated research and need not be applicable to any research exempted or waived under §46.101 (b) or (i).

(2) Designation of one or more IRBs established in accordance with the requirements of this policy, and for which provisions are made for meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

(3) A list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., 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. Changes in IRB membership shall be reported to the department or agency head, unless in accord with §46.103(a) of this policy, the existence of an HHS-approved assurance is accepted. In this case, change in IRB membership shall be reported to the Office for Human Research Protections, HHS, or any successor office.

(4) Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for 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 (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

(5) Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head 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.

(c) 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.

(d) The department or agency head will evaluate all assurances submitted in accordance with this policy through such officers and employees of the department or agency and such experts or consultants engaged for this purpose as the department or agency head determines to be appropriate. The department or agency head's evaluation will take into consideration the adequacy of the proposed IRB in light of the anticipated scope of the institution's research activities and the types of subject populations likely to be involved, the appropriateness of the proposed initial and continuing review procedures in light of the probable risks, and the size and complexity of the institution.

(e) On the basis of this evaluation, the department or agency head may approve or disapprove the assurance, or enter into negotiations to develop an approvable one. The department or agency head may limit the period during which any particular approved assurance or class of approved assurances shall remain effective or otherwise condition or restrict approval.

(f) Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101 (b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be

submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by § 46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.

(Approved by the Office of Management and Budget under Control Number 0990–0260)

[56 FR 28012, 28022, June 18, 1991; 56 FR 29756, June 28, 1991, as amended at 70 FR 36328, June 23, 2005]

§§ 46.104–46.106 [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, and the diversity of the members, including consideration of 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. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments 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 vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

(b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.

(c) 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.

(d) 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.

(e) 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.

(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which 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.

In order to fulfill the requirements of this policy each IRB shall:

(a) Follow written procedures in the same detail as described in § 46.103(b)(4) and, to the extent required by, § 46.103(b)(5).

(b) Except when an expedited review procedure is used (see § 46.110), 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.

§ 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.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with § 46.116. The IRB may require that information, in addition to that specifically mentioned in § 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 covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

(Approved by the Office of Management and Budget under Control Number 0990–0260)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 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, 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 list will be amended, as appropriate after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the FEDERAL REGISTER. A copy of the list is available from the Office for Human Research Protections, HHS, or any successor office.

(b) An IRB may use the expedited review procedure to review either or both of the following:

(1) Some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk,

(2) Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

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 non-expedited procedure set forth in § 46.108(b).

(c) Each IRB which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which 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.

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 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 which are consistent with sound research design and which 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 (for example, 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 and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, 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, in accordance with, and to the extent required by § 46.117.

(6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, 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, pregnant women, mentally disabled persons, 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.

§ 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.

(Approved by the Office of Management and Budget under Control Number 0990–0260)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 46.114 Cooperative research.

Cooperative research projects are those projects covered by this policy which 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. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified 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 documents, 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.

(4) Copies of all correspondence between the IRB and the investigators.

(5) A list of IRB members in the same detail as described is §46.103(b)(3).

(6) Written procedures for the IRB in the same detail as described in §46.103(b)(4) and §46.103(b)(5).

(7) Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

(b) The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§46.116 General requirements for informed consent.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the 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.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(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 which 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 which 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; and

(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.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(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) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject'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 which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(1) 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: (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

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[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 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 consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document 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. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the

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 representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) 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.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990–0260)

[56 FR 28012, 28022, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 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 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 which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 46.101 (b) or (i), 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 department or agency.

§ 46.119 Research undertaken without the intention of involving human subjects.

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 department or agency, and final approval given to the proposed change by the department or agency.

§ 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 department or agency through such officers and employees of the 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.

§ 46.121 [Reserved]

§ 46.122 Use of Federal funds.

Federal funds administered by a 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 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 paragarph (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 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 exemptions at § 46.101(b)(1) through (6) are applicable to this subpart.

(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.

§ 46.202 Definitions.

The definitions in § 46.102 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 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 heartbeat 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 subparts A and D of this part.

§ 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.

§ 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 subpart A of this part;

(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 subpart A of this part, 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.

§ 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 subpart A of this part, 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 subpart A of this part, except that the waiver and alteration provisions of § 46.116(c) and (d) 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 research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

§ 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

(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 of this part.

§ 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 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 this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by 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]

§ 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.

(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) 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 appropriate experts, including experts in penology medicine and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

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 do these regulations apply?

(a) 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 nonsubstantive, 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 paragraph (e) of § 46.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at § 46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at § 46.101(b)(2) regarding educational tests is also 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.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of § 46.101 of Subpart A are applicable to this subpart.

[48 FR 9818, Mar. 8, 1983; 56 FR 28032, June 18, 1991; 56 FR 29757, June 28, 1991]

§ 46.402 Definitions.

The definitions in § 46.102 of Subpart A 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.

§ 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 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:

(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 Subpart A.

(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 Subpart A, 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 Subpart A, 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 Subpart A of this part 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 Subpart A.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

§ 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 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.

§ 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

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 establish 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

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 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 than12 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]

§ 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.

§ 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 FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS

Subpart A—General Provisions

Sec.
60.1 The National Practitioner Data Bank.
60.2 Applicability of these regulations.
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, and revisions.
60.7 Reporting medical malpractice payments.
60.8 Reporting licensure actions taken by Boards of Medical Examiners.

60.9 Reporting licensure actions taken by States.
60.10 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.
60.11 Reporting adverse actions on clinical privileges.

Subpart C—Disclosure of Information by the National Practitioner Data Bank

60.12 Information which hospitals must request from the National Practitioner Data Bank.
60.13 Requesting information from the National Practitioner Data Bank.
60.14 Fees applicable to requests for information.
60.15 Confidentiality of National Practitioner Data Bank information.
60.16 How to dispute the accuracy of National Practitioner Data Bank information.

AUTHORITY: 42 U.S.C. 11101–11152; 42 U.S.C. 1396r–2.

SOURCE: : 54 FR 42730, Oct. 17, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 60.1 The National Practitioner Data Bank.

The Health Care Quality Improvement Act of 1986, as amended (HCQIA), title IV of Public Law 99–660 (42 U.S.C. 11101 *et seq.*), 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 (42 U.S.C. 1396r–2) (section 1921) requires each State to adopt a system of reporting to the Secretary adverse licensure actions taken against health care practitioners and entities. Section 1921 also requires States to report any negative action or finding which a State licensing authority, peer review organization, or private accreditation entity has concluded against a health care practitioner or entity. This information will be collected and released to authorized parties by the NPDB. The regulations in this part set forth the reporting and disclosure requirements for the NPDB.

[75 FR 4676, Jan. 28, 2010]

§ 60.2 Applicability of these regulations.

The regulations in this part establish reporting requirements applicable to hospitals; health care entities; Boards of Medical Examiners State licensing authorities; professional societies of physicians, dentists or other health care practitioners which take adverse licensure of professional review actions, State licensing or certification authorities, peer review organizations, and private accreditation entities that take negative actions or findings against health care practitioners, physicians, dentists, or entities; and entities (including insurance companies) making payments as a result of medical malpractice actions or claims. They also establish procedures to enable individuals or entities to obtain information from the NPDB or to dispute the accuracy of NPDB information.

[59 FR 61555, Dec. 1, 1994, as amended at 75 FR 4676, Jan. 28, 2010]

§ 60.3 Definitions.

Act means the Health Care Quality Improvement Act of 1986, title IV of Pub. L. 99–660, as amended.

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 Act, has designated an alternate entity to carry out the reporting activities of § 60.11

due to a Board's failure to comply with § 60.8, the term *Board of Medical Examiners* or *Board* refers to this alternate entity.

Clinical privileges means the authorization by a health care entity to a physician, dentist or other health care practitioner for the provision of health care services, including privileges and membership on the medical staff.

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).

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:

(a) A hospital;

(b) 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

(c) A professional society or a committee or agent thereof, including those at the national, State, or local level, of physicians, dentists, or other health care practitioners that engages in professional review activity through a formal peer review process, for the purpose of furthering quality health care.

For purposes of paragraph (b) 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 (b).

Health care practitioner means an individual other than a physician or dentist, who is licensed or otherwise authorized by a State to provide health care services.

Hospital means 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 physician's, dentists or other health care practitioner's provision of or failure to provide health care services, and includes the filing of a cause of action based on the law of tort, brought in any State or Federal Court or other adjudicative body.

Negative action or *finding* by a State licensing authority, peer review organization, or private accreditation entity means:

(a) 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;

(b) Any recommendation by a peer review organization to sanction a health care practitioner, physician, or dentist; or

(c) 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 excludes administrative fines or citations, and corrective action plans, unless they are:

(1) Connected to the delivery of health care services, or

(2) Taken in conjunction with other 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.

Peer review organization means an organization with the primary purpose of evaluating the quality of patient care

practices or services ordered or performed by health care practitioners, physicians, or dentists measured against objective criteria which define acceptable and adequate practice through an evaluation by a sufficient number of health practitioners in such an area to ensure adequate peer review. The organization has due process mechanisms available to health care practitioners, physicians, and dentists. This definition excludes utilization and quality control peer review organizations described in Part B of Title XI of the *Social Security Act* (referred to as QIOs) and other organizations funded by the Centers for Medicare and Medicaid Services (CMS) to support the QIO program.

Physician means 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:

(a) Evaluates and seeks to improve the quality of health care provided by a health care entity;

(b) Measures a health care entity's performance based on a set of standards and assigns a level of accreditation;

(c) Conducts ongoing assessments and periodic reviews of the quality of health care provided by a health care entity; and

(d) Has due process mechanisms available to health care entities.

Professional review action means an action or recommendation of a health care entity:

(a) Taken in the course of professional review activity;

(b) Based on the professional competence or professional conduct of an individual physician, dentist or other health care practitioner which affects or could affect adversely the health or welfare of a patient or patients; and

(c) Which adversely affects or may adversely affect the clinical privileges or membership in a professional society of the physician, dentist or other health care practitioner.

(d) This term excludes actions which are primarily based on:

(1) The physician's, dentist's or other health care practitioner's association, or lack of association, with a professional society or association;

(2) The physician's, dentist's or other health care practitioner's fees or the physician's, dentist's or other health care practitioner's advertising or engaging in other competitive acts intended to solicit or retain business;

(3) The physician's, dentist's or other 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;

(4) A physician's, dentist's or other 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

(5) Any other matter that does not relate to the competence or professional conduct of a physician, dentist or other health care practitioner.

Professional review activity means an activity of a health care entity with respect to an individual physician, dentist or other health care practitioner:

(a) To determine whether the physician, dentist or other health care practitioner may have clinical privileges with respect to, or membership in, the entity;

(b) To determine the scope or conditions of such privileges or membership; or

(c) 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:

(a)(1) 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

(2) 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;

(b) 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

(c) 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.

Voluntary surrender of license means a surrender made after a notification of investigation or a formal official request by a State licensing authority for a health care practitioner, physician, dentist, or entity to surrender a license. The definition also includes those instances where a health care practitioner, physician, dentist, or entity voluntarily surrenders a license in exchange for a decision by the licensing 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.

[54 FR 42730, Oct. 17, 1989; 54 FR 43890, Oct. 27, 1989, as amended at 75 FR 4676, Jan. 28, 2010]

Subpart B—Reporting of Information

SOURCE: : 75 FR 4677, Jan. 28, 2010, unless otherwise noted.

§ 60.4 How information must be reported.

Information must be reported to the NPDB or to a Board of Medical Examiners as required under §§ 60.7, 60.8, and 60.11 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 60.11 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, and information required under §§ 60.9 and 60.10 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, as follows:

(a) *Malpractice Payments (§ 60.7).* Persons or entities must submit information to the NPDB within 30 days from the date that a payment, as described in § 60.7, is made. If required under § 60.7, this information must be submitted simultaneously to the appropriate State licensing board.

(b) *Licensure Actions (§ 60.8 and § 60.9).* The Board of Medical Examiners or other licensing or certifying authority of a State must submit information within 30 days from the date the licensure action was taken.

(c) *Negative Action or Finding (§ 60.10).* Peer review organizations, or private accreditation entities must report any negative actions or findings to the State within 15 days from the date the action was taken or the finding was made. Each State, through the adopted system of reporting, must submit to the NPDB the information received from the peer review organization or private accreditation entity within 15 days from the date on which it received this information.

(d) *Adverse Actions (§ 60.11).* A health care entity must report an adverse action to the Board within 15 days from the date the adverse action was taken. The Board must submit the information received from a health care entity within 15 days from the date on which it received this information. If required under § 60.11, this information must be submitted by the Board simultaneously to the appropriate State licensing

board in the State in which the health care entity is located, if the Board is not such licensing Board.

§ 60.6 Reporting errors, omissions, and revisions.

(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 or, in the case of reports made under § 60.11, to the Board of Medical Examiners, as soon as possible.

(b) An individual or entity which reports information on licensure, negative actions or findings or clinical privileges under §§ 60.8, 60.9, 60.10, or 60.11 must also report any revision of the action originally reported. Revisions include reversal of a professional review action or reinstatement of a license. Revisions are subject to the same time constraints and procedures of §§ 60.5, 60.8, 60.9, 60.10, and 60.11, as applicable to the original action which was reported.

(Approved by the Office of Management and Budget under control number 0915–0126)

§ 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 physician, dentist or other health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such physician, dentist, or other 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 physician, dentist or other 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,

(ix) Name of each hospital with which he or she is affiliated, if known;

(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 physician, dentist, or other 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.

(Approved by the Office of Management and Budget under control number 0915–0126)

§ 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 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, if known, and if obtained in accordance with section 7 of the Privacy Act of 1974 (5 U.S.C. 552a note),

(5) The physician's or dentist's date of birth,

(6) Name of each professional school attended by the physician or dentist and year of graduation,

(7) 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,

(8) The physician's or dentist's Drug Enforcement Administration registration number, if known,

(9) A description of the acts or omissions or other reasons for the action taken,

(10) A description of the Board action, the date the action was taken, its effective date and duration,

(11) Classification of the action in accordance with a reporting code adopted by the Secretary, and

(12) 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 noncompliance and providing opportunity to correct noncompliance, the Secretary determines that a Board has failed to submit a report as required by this section, the Secretary will designate another qualified entity for the reporting of information under § 60.11.

§ 60.9 Reporting licensure 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, physician, dentist, or entity (as defined in § 60.3). 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 authority of the State as a result of a formal proceeding, including revocation or suspension of a license (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, physician, dentist, or entity surrendering the license, or the practitioner leaving the State or jurisdiction;

(3) Any other loss of the license of the health care practitioner, physician, dentist, or entity, whether by operation of law, voluntary surrender (excluding those due to non-payment of licensure renewal fees, retirement, or change to inactive status), or otherwise; and

(4) Any negative action or finding by such authority, organization, or entity regarding the health care practitioner, physician, dentist, or entity.

(b) *What information must be reported.* Each State must report the following information (not otherwise reported under §60.8):

(1) If the subject is a *health care practitioner, physician, or dentist,* personal identifiers, including:

(i) Name;

(ii) 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);

(iii) Home address or address of record;

(iv) Sex; and

(v) Date of birth.

(2) If the subject is a *health care practitioner, physician, or dentist,* employment or professional identifiers, including:

(i) Organization name and type;

(ii) Occupation and specialty, if applicable;

(iii) National Provider Identifier (NPI), when issued by the Centers for Medicare & Medicaid Services (CMS);

(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 a *health care entity,* 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, when issued by CMS;

(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;

(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:* Entities described in paragraph (a) of this section may voluntarily report, if known, the following information:

(1) If the subject is a *health care practitioner, physician, or dentist,* 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 a *health care practitioner, physician, or dentist,* 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 Drug Enforcement Administration (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 a *health care entity,* 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 Drug Enforcement Administration (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) [Reserved]

(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 of the Social Security Act.

§ 60.10 Reporting negative actions or findings taken by peer review organizations or private accreditation entities.

(a) *What actions must be reported.* Each State is required to adopt a system of reporting to the NPDB any negative actions or findings (as defined in § 60.3) which are taken against a health care practitioner, physician, dentist, or entity by a peer review organization or private accreditation entity. The health care practitioner, physician, dentist, or entity 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 State *must report* the information as required in § 60.9(b).

(c) *What information should be reported, if known:* Each State *should report, if known,* the information as described in § 60.9(c).

(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 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 of the Social Security Act.

§ 60.11 Reporting adverse actions on clinical privileges.

(a) *Reporting to the Board of Medical Examiners*—(1) *Actions that must be reported and to whom the report must be made.* Each health care entity must 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 Board of Medical Examiners 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,

(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,

(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 National Practitioner Data Bank.* Each Board must report, in accordance with §§60.4 and 60.5, the information reported to it by a health care entity and 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 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 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 the Act 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 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.

(Approved by the Office of Management and Budget under control number 0915–0126)

Subpart C—Disclosure of Information by the National Practitioner Data Bank

SOURCE: : 75 FR 4680, Jan. 28, 2010, unless otherwise noted.

§60.12 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 physician, dentist or

other health care practitioner as follows:

(1) At the time a physician, dentist or other 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 concerning any physician, dentist, or other 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 physician, dentist or other 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.

(Approved by the Office of Management and Budget under control number 0915–0126)

§ 60.13 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:

(1) Information reported under §§ 60.7, 60.8, and 60.11 is available to:

(i) A hospital that requests information concerning a physician, dentist or other health care practitioner who is on its medical staff (courtesy or otherwise) or has clinical privileges at the hospital;

(ii) A physician, dentist, or other health care practitioner who requests information concerning himself or herself;

(iii) A State Medical Board of Examiners or other State authority that licenses physicians, dentists, or other health care practitioners;

(iv) A health care entity which has entered or may be entering into an employment or affiliation relationship with a physician, dentist, or other health care practitioner, or to which the physician, dentist, or other 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 physician, dentist, or other 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 § 60.12(a), 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 and 60.10 is available to the agencies, authorities, and officials listed below that request information on licensure disciplinary actions and any other negative actions or findings concerning an individual health care practitioner, physician, dentist, or entity. 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 the requesting agency, and protecting the fiscal integrity of these programs.

(i) Agencies administering Federal health care programs, including private entities administering such programs under contract;

(ii) Authorities of States (or political subdivisions thereof) which are responsible for licensing health care practitioners, physicians, dentists, and entities;

(iii) State agencies administering or supervising the administration of State health care programs (as defined in 42 U.S.C. 1128(h));

(iv) State Medicaid Fraud Control Units (as defined in 42 U.S.C. 1903(q));

(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;

(H) Federal Bureau of Investigation; and

(I) State law enforcement agencies, which include, but are not limited to, State Attorneys General.

(vi) Utilization and quality control peer review organizations described in part B of title XI and appropriate entities with contracts under section 1154(a)(4)(C) of the Social Security Act with respect to eligible organizations reviewed under the contracts;

(vii) Hospitals and other health care entities (as defined in section 431 of the HCQIA), with respect to physicians or other licensed 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;

(viii) A physician, dentist, or other health care practitioner who, and an entity which, requests information concerning himself, herself, or itself; and

(ix) 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 National Practitioner Data Bank 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 §60.14.

§60.14 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 cover 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 or entity 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, insurance, 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.

§ 60.15 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 §§ 60.12, 60.13, and 60.16. Persons who, and entities which, receive information from the NPDB either directly or from another party must use it solely with respect to the purpose for which it was provided. Nothing in this paragraph shall prevent the disclosure of information by a party which is authorized under applicable State law to make such disclosure.

(b) *Penalty for violations.* Any person who violates paragraph (a) 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.

§ 60.16 How to dispute the accuracy of National Practitioner Data Bank information.

(a) *Who may dispute National Practitioner Data Bank information.* Any physician, dentist, or other health care practitioner or health care entity may dispute the accuracy of information in the NPDB concerning himself, herself or itself. The Secretary will routinely mail a copy of any report filed in the NPDB to the subject individual or entity.

(b) *Procedures for filing a dispute.* The subject of the report may dispute the accuracy of the report within 60 days from the date on which the Secretary mails the report to the subject individual or entity. The procedures for disputing a report are:

(1) Informing the Secretary and the reporting entity, in writing, of the disagreement, and the basis for it,

(2) Requesting simultaneously that the disputed information be entered into a ''disputed'' status and be reported to inquirers as being in a ''disputed'' status, and

(3) Attempting to enter into discussion with the reporting entity to resolve the dispute.

(c) *Procedures for revising disputed information.*

(1) If the reporting entity revises the information originally submitted to the NPDB, the Secretary will notify all entities to whom reports have been sent that the original information has been revised.

(2) If the reporting entity does not revise the reported information, the Secretary will, upon request, review the written information submitted by both parties (the subject individual or entity and the reporting entity). After review, the Secretary will either—

(i) If the Secretary concludes that the information is accurate, include a brief statement by the physician, dentist or other health care practitioner or health care entity describing the disagreement concerning the information, and an explanation of the basis for the decision that it is accurate, or

(ii) If the Secretary concludes that the information is incorrect, send corrected information to previous inquirers.

PART 61—HEALTHCARE INTEGRITY AND PROTECTION DATA BANK FOR FINAL ADVERSE INFORMATION ON HEALTH CARE PROVIDERS, SUPPLIERS AND PRACTITIONERS

Subpart A—General Provisions

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61.7 Reporting licensure actions taken by Federal or State licensing and certification agencies.
61.8 Reporting Federal or State criminal convictions related to the delivery of a health care item or service.
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61.10 Reporting exclusions from participation in Federal or State health care programs.

61.11 Reporting other adjudicated actions or decisions.

Subpart C—Disclosure of Information by the Healthcare Integrity and Protection Data Bank

61.12 Requesting information from the Healthcare Integrity and Protection Data Bank.
61.13 Fees applicable to requests for information.
61.14 Confidentiality of Healthcare Integrity and Protection Data Bank information.
61.15 How to dispute the accuracy of Healthcare Integrity and Protection Data Bank information.
61.16 Immunity.

AUTHORITY: 42 U.S.C. 1320a-7e.

SOURCE: 64 FR 57758, Oct. 26, 1999, unless otherwise noted.

Subpart A—General Provisions

§61.1 The Healthcare Integrity and Protection Data Bank.

(a) Section 1128E of the Social Security Act (the Act) authorizes the Secretary of Health and Human Services (the Secretary) to implement a national health care fraud and abuse data collection program for the reporting and disclosing of certain final adverse actions taken against health care providers, suppliers, or practitioners. Section 1128E of the Act also directs the Secretary to maintain a database of final adverse actions taken against health care providers, suppliers or practitioners. This data bank will be known as the Healthcare Integrity and Protection Data Bank (HIPDB). Settlements in which no findings or admissions of liability have been made will be excluded from being reported. However, if another action is taken against the provider, supplier or practitioner of a health care item or service as a result of or in conjunction with the settlement, that action is reportable to the HIPDB.

(b) Section 1128E of the Act also requires the Secretary to implement the HIPDB in such a manner as to avoid duplication with the reporting requirements established for the National Practitioner Data Bank (NPDB) (See 45 CFR part 60). In accordance with the statute, the reporter responsible for reporting the final adverse actions to both the HIPDB and the NPDB will be required to submit only one report, provided that reporting is made through the Department's consolidated reporting mechanism that will sort the appropriate actions into the HIPDB, NPDB, or both.

(c) The regulations in this part set forth the reporting and disclosure requirements for the HIPDB.

§61.2 Applicability of these regulations.

The regulations in this part establish reporting requirements applicable to Federal and State Government agencies and to health plans, as the terms are defined under §61.3.

§61.3 Definitions.

The following definitions apply to this part:

Act means the Social Security Act.

Affiliated or associated means health care entities with which a subject of a final adverse action has a commercial relationship, including but not limited to, organizations, associations, corporations, or partnerships. It also includes a professional corporation or other business entity composed of a single individual.

Any other negative action or finding by a Federal or State licensing agency means any action or finding that under the State's law is publicly available information, and 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 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:

(1) Connected to the delivery of health care services, and

(2) Taken in conjunction with other licensure or certification actions such

as revocation, suspension, censure, reprimand, probation or surrender.

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.

Criminal conviction means a conviction as described in section 1128(i) of the Act.

Exclusion means a temporary or permanent debarment of an individual or entity from participation in any Federal 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.

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) 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;

(4) Federal and State law enforcement agencies, including States Attorneys General and law enforcement investigators;

(5) State Medicaid Fraud Control Units; and

(6) Federal or State agencies responsible for the licensing and certification of health care providers, suppliers or licensed health care practitioners. 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.

Health care provider means a provider of services as defined in section 1861(u) of the Act; any health care entity (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 health care entity that, directly or through contracts, provides health care services.

Health care supplier means a provider of medical and other health care services as described in section 1861(s) of the 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 reinsurance intermediaries).

Health plan means 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 practitioner, provider or supplier group, third party administrator, integrated health care delivery system, employee welfare association, public service group or organization or professional association; and

(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.

Licensed health care practitioner, licensed practitioner, or practitioner

means, with respect to a State, an individual who is licensed or otherwise authorized by the State to provide health care services (or any individual who, without authority, holds himself or herself out to be so licensed or authorized).

Organization name means the subject's business or employer at the time the underlying acts occurred. If more than one business or employer is involved, the one most closely related to the underlying acts should be reported in the ''organization name,'' field with the others being reported in the ''affiliated or associated health care entities'' field.

Organization type means a brief 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 provider, supplier or practitioner by a Federal or State governmental 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 or State governmental 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 or State Government 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 Government agencies or health plans. 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.

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 any of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and Guam.

Voluntary surrender 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 provider, supplier or practitioner 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 provider, supplier or practitioner voluntarily surrenders a license or certification (including program participation agreements or contracts) 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.

[64 FR 57758, Oct. 26, 1999, as amended at 65 FR 70507, Nov. 24, 2000; 70 FR 53954, Sept. 13, 2005]

Subpart B—Reporting of Information

§61.4 How information must be reported.

Information must be reported to the HIPDB as required under §§61.6, 61.7, 61.8, 61.9, 61.10, 61.11 and 61.15 in such

form and manner as the Secretary may prescribe.

§ 61.5 When information must be reported.

(a) Information required under §§ 61.7, 61.8, 61.9, 61.10 and 61.11 must be submitted to the HIPDB—

(1) Within 30 calendar days from the date the final adverse action was taken or the date when the reporting entity became aware of the final adverse action; or

(2) By the close of the entity's next monthly reporting cycle, whichever is later.

(b) The date the final adverse action was taken, its effective date and duration of the action would be contained in the information reported to the HIPDB under §§ 61.7, 61.8, 61.9, 61.10 and 61.11.

§ 61.6 Reporting errors, omissions, revisions or whether an action is on appeal.

(a) If errors or omissions are found after information has been reported, the reporter must send an addition or correction to the HIPDB. The HIPDB will not accept requests for readjudication of the case.

(b) A reporter that reports information on licensure, criminal convictions, civil or administrative judgments, exclusions, or adjudicated actions or decisions under §§ 61.7, 61.8, 61.9, 61.10 or 61.11 also must report any revision of the action originally reported. Revisions include, but are not limited to, reversal of a criminal conviction, reversal of a judgment or other adjudicated decisions or whether the action is on appeal, and reinstatement of a license.

(c) The subject will receive 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 HIPDB that will be permanently appended to the report, either directly or through a designated representative (The HIPDB will distribute the statement to queriers, where identifiable, and to the reporting entity and the subject of the report. The HIPDB will not edit the statement; only the subject can, upon request, make changes to the statement); or

(3) May follow the dispute process in accordance with § 61.15.

§ 61.7 Reporting licensure actions taken by Federal or State licensing and certification agencies.

(a) *What actions must be reported.* Federal and State licensing and certification agencies must report to the HIPDB the following final adverse actions that are taken against a health care provider, supplier, or practitioner (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 Federal or State health care programs (and the length of any such suspension), reprimand, censure or probation;

(2) Any other loss of the license or loss of the certification agreement or contract for participation in Federal or State health care programs, or the right to apply for, or renew, a license or certification agreement or contract of the provider, supplier, or practitioner, whether by operation of law, voluntary surrender, non-renewal (excluding nonrenewals due to nonpayment of fees, retirement, or change to inactive status), or otherwise; and

(3) Any other negative action or finding by such Federal or State agency that is publicly available information.

(b) 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 Individual Taxpayer Identification Number (ITIN));

(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;

(iii) National Provider Identifier (NPI), when issued by theCenters for Medicare & Medicaid Services (CMS);

(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, when issued by CMS;

(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) 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) 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;

(iii) FEIN, when used by the individual as a TIN; and

(iv) If deceased, date of death.

(2) If the subject is an individual, that individual's 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, to include, but not limited to Drug Enforcement Administration (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 (or ITIN) 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, to include, but not limited to Drug Enforcement Administration (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) *Sanctions for failure to report.* The Secretary will provide for a publication of a public report that identifies those Government agencies that have failed

to report information on adverse actions as required to be reported under this section.

[64 FR 57758, Oct. 26, 1999, as amended at 69 FR 33868, June 17, 2004]

§ 61.8 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 providers, suppliers, and practitioners related to the delivery of a health care item or service (regardless of whether the conviction is the subject of a pending appeal).

(b) 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);

(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), when issued by theCenters for Medicare & Medicaid Services (CMS).

(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, when issued by CMS; 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 submitting the report on behalf of the reporting entity.

(c) 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; 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, to include, but not limited to Drug Enforcement Administration (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, to include, but not limited to Drug Enforcement Administration (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 of file number(s); and

(iv) The date of appeal, if any.

(d) *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 criminal convictions as required to be reported under this section.

[64 FR 57758, Oct. 26, 1999, as amended at 69 FR 33868, June 17, 2004]

§61.9 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 providers, suppliers, or practitioners 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) Entities described in paragraph (a) of this section must report the information as required in §61.8(b).

(c) Entities described in paragraph (a) of this section should report, if known the information as described in §61.8(c).

(d) *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 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.

§61.10 Reporting exclusions from participation in Federal or State health care programs.

(a) *Who must report*. Federal and State Government agencies must report health care providers, suppliers, or practitioners 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) 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);

(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), when issued by theCenters for Medicare & Medicaid Services (CMS).

(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, when issued by CMS; 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) 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;

(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, to include, but not limited to Drug Enforcement Administration (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, to include, but not limited to Drug Enforcement Administration (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) *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.

[64 FR 57758, Oct. 26, 1999, as amended at 69 FR 33869, June 17, 2004]

§61.11 Reporting other adjudicated actions or decisions.

(a) *Who must report.* Federal and State governmental agencies and health plans must report other adjudicated actions or decisions as defined in §61.3 related to the delivery, payment or provision of a health care item or service against health care providers, suppliers, and practitioners (regardless of whether the other adjudicated action or decision is subject to a pending appeal).

(b) Entities described in paragraph (a) of this section must report the information as required in §61.10(b).

(c) Entities described in paragraph (a) of this section should report, if known the information as described in §61.10(c).

(d) *Sanctions for failure to report.* Any health plan that fails to report information on an other 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 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 Healthcare Integrity and Protection Data Bank

§61.12 Requesting information from the Healthcare Integrity and Protection Data Bank.

(a) *Who may request information and what information may be available.* Information in the HIPDB will be available, upon request, to the following persons or entities, or their authorized agents—

(1) Federal and State Government agencies;

(2) Health plans;

(3) A health care practitioner, provider, or supplier requesting information concerning himself, herself or itself; and

(4) A person or entity requesting statistical information, which does not permit identification of any individual or entity. (For example, researchers can use statistical information to identify the total number of practitioners excluded from the Medicare and Medicaid programs. Similarly, health plans can use statistical information to develop outcome measures in their efforts to monitor and improve quality care.)

(b) *Procedures for obtaining HIPDB information.* Eligible individuals and entities may obtain information from the HIPDB by submitting a request in such form and manner as the Secretary may prescribe. These requests are subject to fees set forth in §61.13. The HIPDB will comply with the Department's principles of fair information practice by providing each subject of a report with a copy when the report is entered into the HIPDB.

(c) *Information provided in response to self-queries.* (1) At the time subjects request information as part of a ''self-query,'' the subject will receive—

(i) Any report(s) in the HIPDB specific to them; and

(ii) A disclosure history from the HIPDB of the name(s) of any entity (or entities) that have previously received the report(s).

(2) The disclosure history will be restricted in accordance with the Privacy Act regulations set forth in 45 CFR part 5b.

§61.13 Fees applicable to requests for information.

(a) *Policy on fees.* The fees described in this section apply to all requests for information from the HIPDB, except requests from Federal agencies. However, for purposes of verification and dispute resolution at the time the report is accepted, the HIPDB will provide a copy—at the time a report has been submitted automatically, without a request and free of charge—of every report to the health care provider, supplier or practitioner who is the subject of the report. For the same purpose, the Department will provide a copy of the report—at the time a report has been submitted automatically, without

a request and free of charge—to the reporter that submitted it. The fees are authorized by section 1128E(d)(2) of the Act, and they reflect the full costs of operating the database. The actual fees will be announced by the Secretary in periodic notices in the FEDERAL REGISTER.

(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;

(2) Physical overhead, consulting, and other indirect costs including 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 periodic notice in the FEDERAL REGISTER the method of payment of fees. In determining these methods, the Secretary will consider efficiency, effectiveness and convenience for users and for the Department. Methods may include credit card, electronic funds transfer and other methods of electronic payment.

§ 61.14 Confidentiality of Healthcare Integrity and Protection Data Bank information.

Information reported to the HIPDB is considered confidential and will not be disclosed outside the Department, except as specified in §§ 61.12 and 61.15. Persons and entities receiving information from the HIPDB, either directly or from another party, must use it solely with respect to the purpose for which it was provided. 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.

§ 61.15 How to dispute the accuracy of Healthcare Integrity and Protection Data Bank information.

(a) *Who may dispute the HIPDB information.* The HIPDB will routinely mail or transmit electronically to the subject a copy of the report filed in the HIPDB. In addition, as indicated in § 61.12(a)(3), 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.* If the subject disagrees with the reported information, the subject must request in writing that the HIPDB enter the report into ''disputed status.''

(2) The HIPDB 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 HIPDB, the HIPDB 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 HIPDB, either directly or through a designated representative, that will permanently append the report.

(c) *Procedures for requesting a Secretarial review.* The subject must request, in writing, that the Secretary of the Department review the report for accuracy. The subject must return this request to the HIPDB 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 HIPDB, the Secretary will inform the subject and the HIPDB 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 HIPDB 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 HIPDB or the reporting entity to revise the report. The Secretary will include a brief statement (Secretarial Statement) in the report describing the findings. The HIPDB 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 HIPDB 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 HIPDB 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 HIPDB, the Secretary will inform the subject and direct the HIPDB to void the report. The HIPDB will distribute a notice to previous queriers (where identifiable), the reporting entity and the subject of the report that the report has been voided.

[64 FR 57758, Oct. 26, 1999, as amended at 64 FR 71041, Dec. 20, 1999]

§ 61.16 Immunity.

Individuals, entities or their authorized agents and the HIPDB shall not be 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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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 41 CFR Chapters 1 and 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 41 CFR 3–1.53 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 health, education, and social service information.

[40 FR 23295, May 29, 1975, as amended at 42 FR 36149, July 13, 1977]

§ 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;

(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 (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;

(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

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.

(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) Part 74 of this title, establishing uniform administrative requirements and cost principles for grants by the Department of Health and Human Services.

(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.

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 Secretary, 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.

§ 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 facilitiate additional long range planning.

(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 individual 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 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 § 74.114 of this subtitle or such other regulations

as may be indicated in the grant terms and conditions.

§ 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 used or to be used for sectarian instruction or as a place for religious instruction.

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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.

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. 3371–3376). 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 oligations 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 Counselor 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].

(9) Designating and training an appropriate number of reviewing officials to assist him or her in carrying out the duties of the Designated Agency Offical 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 employee 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.

§ 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 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 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 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

(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 offical 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

(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, including 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.

(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 publicly 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.

§ 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 paty 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.

(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 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.

§ 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).

§ 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.

(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 her) private capacity. No official suport 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 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.

(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 $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 companies 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 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

(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 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 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, however, 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 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 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 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 interpretative 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.

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.

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.

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 Department). 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, misuse 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. 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.)

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 considertion 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 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]

PART 73a—STANDARDS OF CONDUCT: FOOD AND DRUG ADMINISTRATION SUPPLEMENT

Subpart A—General Provisions

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Subpart B—Miscellaneous Provisions

73a.735–201 Control activity employees formerly associated with organizations subject to FDA regulation.

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Subpart D—Outside Employment

73a.735–401 General provisions.

Subpart E—Financial Interests

73a.735–501 General provisions.
73a.735–502 Employees in regulatory activities.
73a.735–504 Exceptions.

Subparts F–I [Reserved]

Subpart J—Statements of Employment and Financial Interests

73a.735–1004 Submission and review of statements.

AUTHORITY: 45 CFR 73.735–105.

SOURCE: 43 FR 7619, Feb. 24, 1978, unless otherwise noted.

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 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 nonbusiness 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 conflict of interest. Permissible employment includes but is not limited to:

(1) Employment where the sale of FDA-regulated products is incidential 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 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 ''excepted'' 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 public 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 ''excepted'' ABC Foods interests.

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 reporting 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

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 otherwised noted.

§ 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 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 US.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 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.

PART 74—UNIFORM ADMINISTRATIVE REQUIREMENTS FOR AWARDS AND SUBAWARDS TO INSTITUTIONS OF HIGHER EDUCATION, HOSPITALS, OTHER NONPROFIT ORGANIZATIONS, AND COMMERCIAL ORGANIZATIONS

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APPENDIXES F–H TO PART 74 [RESERVED]

AUTHORITY: 5 U.S.C. 301.

Subpart A—General

SOURCE: 59 FR 43760, Aug. 25, 1994, unless otherwise noted.

§ 74.1 Purpose and applicability.

(a) Unless inconsistent with statutory requirements, this part establishes uniform administrative requirements governing:

(1) Department of Health and Human Services' (HHS) grants and agreements awarded to institutions of higher education, hospitals, other nonprofit organizations and only to commercial organizations in instances other than those involving procedures to make data available under the Freedom of Information Act provision set forth in § 74.36(d)(1).

(2) Subgrants or other subawards awarded by recipients of HHS grants and agreements to institutions of higher education, hospitals, other nonprofit organizations and commercial organizations, including subgrants or other subawards awarded under HHS grants and agreements administered by State, local and Indian Tribal governments; and

(b) Nonprofit organizations that implement HHS programs for the States are also subject to state requirements.

(c) HHS shall not impose additional or inconsistent requirements except as provided in §§ 74.4 and 74.14, or unless specifically required by Federal statute or executive order.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, 11747, Mar. 22, 1996; 65 FR 14418, Mar. 16, 2000; 68 FR 52844, Sept. 8, 2003]

§ 74.2 Definitions.

Accrued expenditures mean the charges incurred by the recipient during a given period requiring the provision of funds for: (1) Goods and other tangible property received; (2) services performed by employees, contractors, subrecipients, and other payees; and, (3) other amounts becoming owed under programs for which no current services or performance is required.

Accrued income means the sum of: (1) Earnings during a given period from (i) services performed by the recipient, and (ii) goods and other tangible property delivered to purchasers; and (2) amounts becoming owed to the recipient for which no current services or performance is required by the recipient.

Acquisition cost of equipment means the net invoice price of the equipment, including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired. Other charges, such as the cost of installation, transportation, taxes, duty or protective in-transit insurance, shall be included or excluded from the unit acquisition cost in accordance with the recipient's regular accounting practices.

Advance means a payment made by Treasury check or other appropriate payment mechanism to a recipient upon its request either before outlaysare made by the recipient or through the use of predetermined payment schedules.

Award means financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements in the form of money or property in lieu of money, by the Federal Government to an eligible recipient. The term does not include: technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; direct payments of any kind to individuals; and, contracts which are required to be entered into and administered under Federal procurement laws and regulations.

Cash contributions mean the recipient's cash outlay, including the outlay

of money contributed to the recipient by third parties.

Closeout means the process by which the HHS awarding agency determines that all applicable administrative actions and all required work of the award have been completed by the recipient and HHS.

Contract means a procurement contract under an award or subaward, and a procurement subcontract under a recipient's or subrecipient's contract.

Cost sharing or matching means that portion of project or program costs not borne by the Federal Government.

Current accounting period means, with respect to §74.27(b), the period of time the recipient chooses for purposes of financial statements and audits.

Date of completion means the date on which all work under an award is completed or the date on the award document, or any supplement or amendment thereto, on which HHS awarding agency sponsorship ends.

Departmental Appeals Board means the independent office established in the Office of the Secretary with delegated authority from the Secretary to review and decide certain disputes between recipients of HHS funds and HHS awarding agencies under 45 CFR part 16 and to perform other review, adjudication and mediation services as assigned.

Disallowed costs mean those charges to an award that the HHS awarding agency determines to be unallowable, in accordance with the applicable Federal cost principles or other terms and conditions contained in the award.

Discretionary award means an award made by an HHS awarding agency in keeping with specific statutory authority which enables the agency to exercise judgment (''discretion'') in selecting the applicant/recipient organization through a competitive award process.

Equipment means tangible nonexpendable personal property, including exempt property, charged directly to the award having a useful life of more than one year and an acquisition cost of $5000 or more per unit. However, consistent with recipient policy, lower limits may be established.

Excess property means property under the control of any HHS awarding agency that, as determined by the head of the awarding agency or his/her delegate, is no longer required for the agency's needs or the discharge of its responsibilities.

Exempt property means tangible personal property acquired in whole or in part with Federal funds, where the HHS awarding agency has statutory authority to vest title in the recipient without further obligation to the Federal Government. An example of exempt property authority is contained in the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6306, for property acquired under an award to conduct basic or applied research by a nonprofit institution of higher education or nonprofit organization whose principal purpose is conducting scientific research.

Federal funds authorized mean the total amount of Federal funds obligated by the HHS awarding agency for use by the recipient. This amount may include any authorized carryover of unobligated funds from prior funding periods when permitted by the HHS awarding agency's implementing instructions or authorized by the terms and conditions of the award.

Federal share of real property, equipment, or supplies means that percentage of the property's or supplies' acquisition costs and any improvement expenditures paid with Federal funds. This will be the same percentage as the Federal share of the total costs under the award for the funding period in which the property was acquired (excluding the value of third party in-kind contributions).

Federally recognized Indian Tribal government means the governing body of any Indian tribe, band, nation, or other organized group or community (including any Native village as defined in section 3 of the Alaska Native Claims Settlement Act certified by the Secretary of the Interior as eligible for the special programs and services provided by him through the Bureau of Indian Affairs.

Funding period means the period of time when Federal funding is available for obligation by the recipient.

Government means a State or local government or a federally recognized Indian tribal government.

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

HHS awarding agency means any organization component of HHS that is authorized to make and administer awards.

Intangible property and debt instruments mean, but are not limited to, trademarks, copyrights, patents and patent applications and such property as loans, notes and other debt instruments, lease agreements, stock and other instruments of property ownership, whether considered tangible or intangible.

Local government means a local unit of government, including specifically a county, municipality, city, town, township, local public authority, school district, special district, intra-state district, council of governments (whether or not incorporated as a nonprofit corporation under State law), any other regional or interstate entity, or any agency or instrumentality of local government.

Obligations mean the amounts of orders placed, contracts and grants awarded, services received and similar transactions during a given period that require payment by the recipient during the same or a future period.

OGAM means the Office of Grants and Acquisition Management, which is an organizational component within the Office of the Secretary, HHS, and reports to the Assistant Secretary for Management and Budget.

OMB means the U.S. Office of Management and Budget.

Outlays or expenditures mean charges made to the project or program. They may be reported on a cash or accrual basis. For reports prepared on a cash basis, outlays are the sum of cash disbursements for direct charges for goods and services, the amount of indirect expense charged, the value of third party in-kind contributions applied and the amount of cash advances and payments made to subrecipients. For reports prepared on an accrual basis, outlays are the sum of cash disbursements for direct charges for goods and services, the amount of indirect expense incurred, the value of in-kind contributions applied, and the net increase (or decrease) in the amounts owed by the recipient for goods and other property received, for services performed by employees, contractors, subrecipients and other payees and other amounts becoming owed under programs for which no current services or performance are required.

Personal property means property of any kind except real property. It may be tangible, having physical existence, or intangible, having no physical existence, such as copyrights, patents, or securities.

Prior approval means written approval by an authorized HHS official evidencing prior consent.

Program income means gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award (see exclusions in §74.24 (e) and (h)). Program income includes, but is not limited to, income from fees for services performed, the use or rental of real or personal property acquired under federally-funded projects, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and interest on loans made with award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in the terms and conditions of the award, program income does not include the receipt of principal on loans, rebates, credits, discounts, etc., or interest earned on any of them. Furthermore, program income does not include taxes, special assessments, levies, and fines raised by governmental recipients.

Project costs means all allowable costs, as set forth in the applicable Federal cost principles (see §74.27), incurred by a recipient and the value of the contributions made by third parties in accomplishing the objectives of the award during the project period.

Project period means the period established in the award document during which HHS awarding agency sponsorship begins and ends.

Property means, unless otherwise stated, real property, equipment, intangible property and debt instruments.

Real property means land, including land improvements, structures and appurtenances thereto, but excludes movable machinery and equipment.

Recipient means an organization receiving financial assistance directly from an HHS awarding agency to carry out a project or program. The term includes public and private institutions of higher education, public and private hospitals, commercial organizations, and other quasi-public and private nonprofit organizations such as, but not limited to, community action agencies, research institutes, educational associations, and health centers. The term may include foreign or international organizations (such as agencies of the United Nations) which are recipients, subrecipients, or contractors or subcontractors of recipients or subrecipients at the discretion of the HHS awarding agency. The term does not include government-owned contractor-operated facilities or research centers providing continued support for mission-oriented, large-scale programs that are government-owned or controlled, or are designated as federally-funded research and development centers. For entitlement programs listed at 45 CFR 92.4(a)(3), (a)(7), and (a)(8) ''recipient'' means the government to which an HHS awarding agency awards funds and which is accountable for the use of the funds provided. The recipient in this case is the entire legal entity even if only a particular component of the entity is designated in the award document.

Research and development means all research activities, both basic and applied, and all development activities that are supported at universities, colleges, hospitals, other nonprofit institutions, and commercial organizations. ''Research'' is defined as a systematic study directed toward fuller scientific knowledge or understanding of the subject studied. ''Development'' is the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function.

Small awards means a grant or cooperative agreement not exceeding the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently $100,000).

State means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments.

Subaward means an award of financial assistance in the form of money, or property in lieu of money, made under an award by a recipient to an eligible subrecipient or by a subrecipient to a lower tier subrecipient. The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract, but does not include procurement of goods and services nor does it include any form of assistance which is excluded from the definition of ''award'' in this section.

Subrecipient means the legal entity to which a subaward is made and which is accountable to the recipient for the use of the funds provided. The term may include foreign or international organizations (such as agencies of the United Nations) at the discretion of the HHS awarding agency.

Supplies means all personal property excluding equipment, intangible property, and debt instruments as defined in this section, and inventions of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement (''subject inventions''), as defined in 37 CFR part 401, ''Rights to Inventions Made by Nonprofit Organizations and Business Firms Under Government Grants, Contracts, and Cooperative Agreements.''

Suspension means an action by the HHS awarding agency that temporarily withdraws the agency's financial assistance sponsorship under an award, pending corrective action by the recipient or pending a decision to terminate the award.

Suspension of an award is a separate action from suspension under HHS regulations (45 CFR part 76) implementing E.O.s 12549 and 12689, ''Debarment and Suspension.''

Termination means the cancellation of HHS awarding agency sponsorship, in whole or in part, under an agreement at any time prior to the date of completion. For the entitlement programs listed at 45 CFR 92.4 (a)(3), (a)(7), and (a)(8), ''termination'' shall have that meaning assigned at 45 CFR 92.3.

Third party in-kind contributions means the value of non-cash contributions provided by non-Federal third parties. Third party in-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and the value of goods and services directly benefiting and specifically identifiable to the project or program.

Unliquidated obligations, for financial reports prepared on a cash basis, mean the amount of obligations incurred by the recipient that has not been paid. For reports prepared on an accrued expenditure basis, they represent the amount of obligations incurred by the recipient for which an outlay has not been recorded.

Unobligated balance means the portion of the funds authorized by the HHS awarding agency that has not been obligated by the recipient and is determined by deducting the cumulative obligations from the cumulative funds authorized.

Unrecovered indirect cost means the difference between the amount awarded and the amount which could have been awarded under the recipient's approved negotiated indirect cost rate.

Working capital advance means a procedure whereby funds are advanced to the recipient to cover its estimated disbursement needs for a given initial period.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996; 62 FR 41878, Aug. 4, 1997]

§ 74.3 Effect on other issuances.

This part supersedes all administrative requirements of codified program regulations, program manuals, handbooks and other nonregulatory materials which are inconsistent with the requirements of this part, except to the extent they are required by Federal statute, or authorized in accordance with the deviations provision in § 74.4.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996]

§ 74.4 Deviations.

(a) After consultation with OMB, the HHS OGAM may grant exceptions to HHS awarding agencies for classes of awards or recipients subject to the requirements of this part when exceptions are not prohibited by statute. However, in the interest of maximum uniformity, exceptions from the requirements of this part shall be permitted only in unusual circumstances. HHS awarding agencies may apply more restrictive requirements to a class of awards or recipients when approved by the OGAM, after consultation with the OMB. HHS awarding agencies may apply less restrictive requirements without approval by the OGAM when making small awards except for those requirements which are statutory. Exceptions on a case-by-case basis may also be made by HHS awarding agencies without seeking prior approval from the OGAM. OGAM will maintain a record of all requests for exceptions from the provisions of this part that have been approved for classes of awards or recipients.

(b) As a matter of Departmental policy, requests for individual case deviations will be considered favorably by HHS and its awarding agencies whenever the deviation will facilitate comprehensive or integrated service delivery, or multiple-source consolidated awards, unless the deviation would impair the integrity of the program.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996]

§ 74.5 Subawards.

(a) Unless inconsistent with statutory requirements, this part (except for § 74.12 and the forms prescribed in § 74.22) shall apply to—

(1) Except for subawards under block grants (45 CFR part 96), all subawards received by institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations from any recipient of an HHS award, including any subawards received from States, local governments,

and Indian tribal governments covered by 45 CFR part 92; and

(2) All subawards received from States by any entity, including a government entity, under the entitlement programs identified at 45 CFR part 92, § 92.4 (a), (a)(7), and (a)(8), except that §§ 74.12 and 74.25 of this part shall not apply.

(b) Except as provided in paragraph (a)(2) of this section, when State, local, and Indian Tribal government recipients of HHS awards make subawards to a government entity, they shall apply the regulations at 45 CFR part 92, ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments,'' or State rules, whichever apply, to such awards.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996]

Subpart B—Pre-Award Requirements

SOURCE: 59 FR 43760, Aug. 25, 1994, unless otherwise noted.

§ 74.10 Purpose.

Sections 74.11 through 74.17 prescribe forms and instructions and other pre-award matters to be used in applying for HHS awards.

§ 74.11 Pre-award policies.

(a) Use of Grants and Cooperative Agreements, and Contracts. The Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6301–08, governs the use of grants, cooperative agreements and contracts. A grant or cooperative agreement shall be used only when the principal purpose of a transaction is to accomplish a public purpose of support or stimulation authorized by Federal statute. The statutory criterion for choosing between grants and cooperative agreements is that for the latter, ''substantial involvement is expected between the executive agency and the State, local government, or other recipient when carrying out the activity contemplated in the agreement.'' Contracts shall be used when the principal purpose is acquisition of property or services for the direct benefit or use of the HHS awarding agency.

(b) HHS awarding agencies shall notify the public of funding priorities for discretionary grant programs, unless funding priorities are established by Federal statute.

§ 74.12 Forms for applying for HHS financial assistance.

(a) HHS awarding agencies shall comply with the applicable report clearance requirements of 5 CFR part 1320, ''Controlling Paperwork Burdens on the Public,'' with regard to all forms used in place of or as a supplement to the Standard Form 424 (SF–424) series. However, HHS awarding agencies should use the SF–424 series and its program narrative whenever possible.

(b) Applicants shall use the SF–424 series or those forms and instructions prescribed by the HHS awarding agency. Applicants shall submit the original and two copies of any applications unless additional copies are required pursuant to 5 CFR part 1320.

(c) For Federal programs covered by E.O. 12372, as amended by E.O. 12416, ''Intergovernmental Review of Federal Programs,'' the applicant shall complete the appropriate sections of the SF–424 (Application for Federal Assistance) indicating whether the application was subject to review by the State Single Point of Contact (SPOC). The name and address of the SPOC for a particular State can be obtained from the HHS awarding agency or the Catalog of Federal Domestic Assistance. The SPOC shall advise the applicant whether the program for which application is made has been selected by that State for review. (See also 45 CFR part 100.)

(d) HHS awarding agencies that do not use the SF–424 form will indicate on the application form they prescribe whether the application is subject to review by the State under E.O. 12372.

(e) This section does not apply to applications for subawards.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996]

§ 74.13 Debarment and suspension.

Recipients are subject to the nonprocurement debarment and suspension common rule implementing E.O.s 12549 and 12689, ''Debarment and Suspension,''2 CFR part 376. This common

rule restricts subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal assistance programs or activities.

[59 FR 43760, Aug. 25, 1994, as amended at 72 FR 9235, Mar. 1, 2007]

§ 74.14 Special award conditions.

(a) The HHS awarding agency may impose additional requirements as needed, without regard to § 74.4, above, if an applicant or recipient:

(1) Has a history of poor performance;

(2) Is not financially stable;

(3) Has a management system that does not meet the standards prescribed in this part;

(4) Has not conformed to the terms and conditions of a previous award; or

(5) Is not otherwise responsible.

(b) When it imposes any additional requirements, the HHS awarding agency must notify the recipient in writing as to the following:

(1) The nature of the additional requirements;

(2) The reason why the additional requirements are being imposed;

(3) The nature of the corrective actions needed;

(4) The time allowed for completing the corrective actions; and

(5) The method for requesting reconsideration of the additional requirements imposed.

(c) The HHS awarding agency will promptly remove any additional requirements once the conditions that prompted them have been corrected.

§ 74.15 Metric system of measurement.

The Metric Conversion Act, as amended by the Omnibus Trade and Competitiveness Act, 15 U.S.C. 205, declares that the metric system is the preferred measurement system for U.S. trade and commerce. The Act requires each Federal agency to establish a date or dates in consultation with the Secretary of Commerce, when the metric system of measurement will be used in the agency's procurements, grants, and other business-related activities. Metric implementation may take longer where the use of the system is initially impractical or likely to cause significant inefficiencies in the accomplishment of federally-funded activities. HHS awarding agencies will follow the provisions of E.O. 12770, ''Metric Usage in Federal Government Programs.''

§ 74.16 Resource Conservation and Recovery Act (RCRA, Section 6002 of Pub. L. No. 94–580 (Codified at 42 U.S.C. 6962)).

Under the Act, any State agency or agency of a political subdivision of a State which is using appropriated Federal funds must comply with section 6002 of the RCRA. This section requires that preference be given in procurement programs to the purchase of specific products containing recycled materials identified in guidelines developed by the Environmental Protection Agency (EPA) (40 CFR parts 247–254). Accordingly, State and local institutions of higher education, hospitals, and other nonprofit organizations that receive direct HHS awards or other Federal funds shall give preference in their procurement programs funded with Federal funds to the purchase of recycled products pursuant to the EPA guidelines.

§ 74.17 Certifications and representations.

Unless prohibited by statute or codified regulation, each HHS awarding agency is authorized and encouraged to allow recipients to submit certifications and representations required by statute, executive order, or regulation on an annual basis, if the recipients have ongoing and continuing relationships with the HHS awarding agency. Annual certifications and representations shall be signed by the responsible official(s) with the authority to ensure recipients' compliance with the pertinent requirements.

(a) 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.

(b) [Reserved]

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996; 69 FR 42592, July 16, 2004]

§ 74.18 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—Post-Award Requirements

SOURCE: 59 FR 43760, Aug. 25, 1994, unless otherwise noted.

FINANCIAL AND PROGRAM MANAGEMENT

§ 74.20 Purpose of financial and program management.

Sections 74.21 through 74.28 prescribe standards for financial management systems, methods for making payments, and rules for satisfying cost sharing and matching requirements, accounting for program income, budget revision approvals, making audits, determining allowability of cost, and establishing fund availability.

§ 74.21 Standards for financial management systems.

(a) Recipients shall relate financial data to performance data and develop unit cost information whenever practical. For awards that support research, unit cost information is usually not appropriate.

(b) Recipients' financial management systems shall provide for the following:

(1) Accurate, current and complete disclosure of the financial results of each HHS-sponsored project or program in accordance with the reporting requirements set forth in § 74.52. If the HHS awarding agency requires reporting on an accrual basis from a recipient that maintains its records on other than an accrual basis, the recipient shall not be required to establish an accrual accounting system. These recipients may develop such accrual data for their reports on the basis of an analysis of the documentation on hand.

(2) Records that identify adequately the source and application of funds for HHS-sponsored activities. These records shall contain information pertaining to Federal awards, authorizations, obligations, unobligated balances, assets, outlays, income and interest.

(3) Effective control over and accountability for all funds, property and other assets. Recipients shall adequately safeguard all such assets and assure they are used solely for authorized purposes.

(4) Comparison of outlays with budget amounts for each award. Whenever appropriate, financial information should be related to performance and unit cost data. (Unit cost data are usually not appropriate for awards that support research.)

(5) Written procedures to minimize the time elapsing between the transfer of funds to the recipient from the U.S. Treasury and the issuance or redemption of checks, warrants or payments by other means for program purposes by the recipient. To the extent that the provisions of the Cash Management Improvement Act (CMIA) (Pub. L. 101–453) and its implementing regulations, ''Rules and Procedures for Funds Transfers,'' (31 CFR part 205) apply, payment methods of State agencies, instrumentalities, and fiscal agents shall be consistent with CMIA Treasury-State Agreements, or the CMIA default procedures codified at 31 CFR 205.9(f).

(6) Written procedures for determining the reasonableness, allocability and allowability of costs in accordance with the provisions of the applicable Federal cost principles and the terms and conditions of the award.

(7) Accounting records, including cost accounting records, that are supported by source documentation.

(c) Where the Federal Government guarantees or insures the repayment of money borrowed by the recipient, the HHS awarding agency, at its discretion, may require adequate bonding and insurance if the bonding and insurance requirements of the recipient are not deemed adequate to protect the interest of the Federal Government.

(d) The HHS awarding agency may require adequate fidelity bond coverage where the recipient lacks sufficient coverage to protect the Federal Government's interest.

(e) Where bonds are required in the situations described in § 74.21 (c) and (d), the bonds shall be obtained from companies holding certificates of authority as acceptable sureties, as prescribed in 31 CFR part 223, ''Surety Companies Doing Business with the United States.''

§ 74.22 Payment.

(a) Unless inconsistent with statutory program purposes, payment methods shall minimize the time elapsing between the transfer of funds from the U.S. Treasury and the issuance or redemption of checks, warrants, or payment by other means by the recipients. Payment methods of State agencies or instrumentalities shall be consistent with Treasury-State CMIA agreements, or the CMIA default procedures codified at 31 CFR 205.9, to the extent that either applies.

(b)(1) Recipients will be paid in advance, provided they maintain or demonstrate the willingness to maintain:

(i) Written procedures that minimize the time elapsing between the transfer of funds and disbursement by the recipient; and

(ii) Financial management systems that meet the standards for fund control and accountability as established in § 74.21.

(2) Unless inconsistent with statutory program purposes, cash advances to a recipient organization shall be limited to the minimum amounts needed and be timed to be in accordance with the actual, immediate cash requirements of the recipient organization in carrying out the purpose of the approved program or project. The timing and amount of cash advances shall be as close as is administratively feasible to the actual disbursements by the recipient organization for direct program or project costs and the proportionate share of any allowable indirect costs.

(c) Whenever possible, advances will be consolidated to cover anticipated cash needs for all awards made by all HHS awarding agencies to the recipient.

(1) Advance payment mechanisms include electronic funds transfer, with Treasury checks available on an exception basis.

(2) Advance payment mechanisms are subject to 31 CFR part 205.

(3) Recipients may submit requests for advances and reimbursements at least monthly when electronic fund transfers are not used.

(d) Requests for Treasury check advance payment shall be submitted on PMS–270, ''Request for Advance or Reimbursement,'' or other forms as may be authorized by HHS. This form is not to be used when Treasury check advance payments are made to the recipient automatically through the use of a predetermined payment schedule or if precluded by special HHS-wide instructions for electronic funds transfer.

(e) Reimbursement is the preferred method when the requirements in paragraph (b) of this section cannot be met. The HHS awarding agency may also use this method on any construction agreement, or if the major portion of the construction project is accomplished through private market financing or Federal loans, and the HHS assistance constitutes a minor portion of the project.

(1) When the reimbursement method is used, HHS will make payment within 30 days after receipt of the billing, unless the billing is improper.

(2) Recipients may submit a request for reimbursement at least monthly when electronic funds transfers are not used.

(f) If a recipient cannot meet the criteria for advance payments and the HHS awarding agency has determined that reimbursement is not feasible because the recipient lacks sufficient working capital, HHS may provide cash on a working capital advance basis. Under this procedure, HHS advances cash to the recipient to cover its estimated disbursement needs for an initial period generally geared to the recipient's disbursing cycle. Thereafter, HHS reimburses the recipient for its actual cash disbursements. The working capital advance method of payment will not be used for recipients unwilling or unable to provide timely advances to their subrecipient to meet the subrecipient's actual cash disbursements.

(g) Unless inconsistent with statutory program purposes, to the extent available, recipients shall disburse funds available from repayments to and interest earned on a revolving fund, program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds before requesting additional cash payments.

(h) Unless otherwise required by statute, the HHS awarding agency will not

withhold payments for proper charges made by recipients at any time during the project period unless paragraph (h)(1) or (2) of this section applies:

(1) A recipient has failed to comply with the project objectives, the terms and conditions of the award, or HHS awarding agency reporting requirements.

(2) The recipient or subrecipient is delinquent in a debt to the United States. Under such conditions, the HHS awarding agency may, upon reasonable notice, inform the recipient that payments shall not be made for obligations incurred after a specified date until the conditions are corrected or the indebtedness to the Federal Government is liquidated. (See 45 CFR part 30).

(i) Standards governing the use of banks and other institutions as depositories of funds advanced under awards are as follows.

(1) Except for situations described in paragraph (i)(2) of this section, HHS will not require separate depository accounts for funds provided to a recipient or establish any eligibility requirements for depositories for funds provided to a recipient. However, recipients must be able to account for the receipt, obligation and expenditure of funds.

(2) Advances of Federal funds shall be deposited and maintained in insured accounts whenever possible.

(j) Consistent with the national goal of expanding the opportunities for women-owned and minority-owned business enterprises, recipients are encouraged to use women-owned and minority-owned banks (a bank which is owned at least 50 percent by women or minority group members).

(k) Recipients shall maintain advances of Federal funds in interest bearing accounts, unless one of the following conditions apply:

(1) The recipient receives less than $120,000 in Federal awards per year.

(2) The best reasonably available interest bearing account would not be expected to earn interest in excess of $250 per year on Federal cash balances.

(3) The depository would require an average or minimum balance so high that it would not be feasible within the expected Federal and non-Federal cash resources.

(l) For those entities where CMIA and its implementing regulations do not apply (*see* 31 CFR part 205), interest earned on Federal advances deposited in interest bearing accounts shall be remitted annually to the Department of Health and Human Services, Payment Management System, P.O. Box 6021, Rockville, MD 20852. Recipients with Electronic Funds Transfer capability should use an electronic medium such as the FEDWIRE Deposit System. Interest amounts up to $250 per year may be retained by the recipient for administrative expense. State universities and hospitals shall comply with CMIA, as it pertains to interest. If an entity subject to CMIA uses its own funds to pay pre-award costs for discretionary awards without prior written approval from the HHS awarding agency, it waives its right to recover the interest under CMIA. (See § 74.25(d)).

(m) *PMS–270, Request for Advance or Reimbursement*. Recipients shall use the PMS–270 to request advances or reimbursement for all programs when electronic funds transfer or predetermined advance methods are not used. HHS shall not require recipients to submit more than an original and two copies.

(n) Recipients and subrecipients are not required to use forms PMS–270 and 272 in connection with subaward payments.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996]

§ 74.23 Cost sharing or matching.

(a) To be accepted, all cost sharing or matching contributions, including cash and third party in-kind, shall meet all of the following criteria:

(1) Are verifiable from the recipient's records;

(2) Are not included as contributions for any other federally-assisted project or program;

(3) Are necessary and reasonable for proper and efficient accomplishment of project or program objectives;

(4) Are allowable under the applicable cost principles;

(5) Are not paid by the Federal Government under another award, except where authorized by Federal statute to be used for cost sharing or matching;

(6) Are provided for in the approved budget; and

(7) Conform to other provisions of this part, as applicable.

(b) Unrecovered indirect costs may be included as part of cost sharing or matching.

(c) Values for recipient contributions of services and property shall be established in accordance with the applicable cost principles. If the HHS awarding agency authorizes recipients to donate buildings or land for construction/facilities acquisition projects or long-term use, the value of the donated property for cost sharing or matching shall be the lesser of:

(1) The certified value of the remaining life of the property recorded in the recipient's accounting records at the time of donation; or

(2) The current fair market value. However, when there is sufficient justification, the HHS awarding agency may approve the use of the current fair market value of the donated property, even if it exceeds the certified value at the time of donation to the project.

(d) Volunteer services furnished by professional and technical personnel, consultants, and other skilled and unskilled labor may be counted as cost sharing or matching if the service is an integral and necessary part of an approved project or program. Rates for volunteer services shall be consistent with those paid for similar work in the recipient's organization. In those instances in which the required skills are not found in the recipient's organization, rates shall be consistent with those paid for similar work in the labor market in which the recipient competes for the kind of services involved. In either case, fringe benefits consistent with those paid that are reasonable, allowable, and allocable may be included in the valuation.

(e) When an employer other than the recipient furnishes the services of an employee, these services shall be valued at the employee's regular rate of pay (plus an amount of fringe benefits that are reasonable, allowable, and allocable, but exclusive of overhead costs), provided these services are in the same skill for which the employee is normally paid.

(f) Donated supplies may include such items as expendable property, office supplies, laboratory supplies or workshop and classroom supplies. Value assessed to donated supplies included in the cost sharing or matching share shall be reasonable and shall not exceed the fair market value of the property at the time of the donation.

(g) The method used for determining cost sharing or matching for donated equipment, buildings and land for which title passes to the recipient may differ according to the purpose of the award, if paragraph (g)(1) or (2) of this section applies:

(1) If the purpose of the award is to assist the recipient in the acquisition of equipment, buildings or land, the total value of the donated property may be claimed as cost sharing or matching.

(2) If the purpose of the award is to support activities that require the use of equipment, buildings or land, normally only depreciation or use charges for equipment and buildings may be made. However, the full value of equipment or other capital assets and fair rental charges for land may be allowed, provided that the HHS awarding agency has approved the charges.

(h) The value of donated property shall be determined in accordance with the usual accounting policies of the recipient, with the following qualifications.

(1) The value of donated land and buildings shall not exceed its fair market value at the time of donation to the recipient as established by an independent appraiser (e.g., certified real property appraiser or General Services Administration representative) and certified by a responsible official of the recipient.

(2) The value of donated equipment shall not exceed the fair market value of equipment of the same age and condition at the time of donation.

(3) The value of donated space shall not exceed the fair rental value of comparable space as established by an independent appraisal of comparable space and facilities in a privately-owned building in the same locality.

(4) The value of loaned equipment shall not exceed its fair rental value.

(i) The following requirements pertain to the recipient's supporting records for in-kind contributions from third parties.

(1) Volunteer services shall be documented and, to the extent feasible, supported by the same methods used by the recipient for its own employees, including time records.

(2) The basis for determining the valuation for personal service, material, equipment, buildings and land shall be documented.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996]

§ 74.24 Program income.

(a) The standards set forth in this section shall be used to account for program income related to projects financed in whole or in part with Federal funds.

(b) Except as provided below in paragraph (h) of this section, program income earned during the project period shall be retained by the recipient and, in accordance with the terms and conditions of the award, shall be used in one or more of the following ways:

(1) Added to funds committed to the project or program, and used to further eligible project or program objectives;

(2) Used to finance the non-Federal share of the project or program; or

(3) Deducted from the total project or program allowable cost in determining the net allowable costs on which the Federal share of costs is based.

(c) When the HHS awarding agency authorizes the disposition of program income as described in paragraph (b)(1) or (b)(2) of this section, program income in excess of any limits stipulated shall be used in accordance with paragraph (b)(3) of this section.

(d) In the event that the HHS awarding agency does not specify in the terms and conditions of the award how program income is to be used, paragraph (b)(3) of this section shall apply automatically to all projects or programs except research. For awards that support performance of research work, paragraph (b)(1) of this section shall apply automatically unless:

(1) The HHS awarding agency indicates in the terms and conditions of the award another alternative; or

(2) The recipient is subject to special award conditions under § 74.14; or

(3) The recipient is a commercial organization (*see* § 74.82).

(e) Unless the terms and conditions of the award provide otherwise, recipients shall have no obligation to the Federal Government regarding program income earned after the end of the project period.

(f) Costs incident to the generation of program income may be deducted from gross income to determine program income, provided these costs have not been charged to the award.

(g) Proceeds from the sale of property shall be handled in accordance with the requirements of the Property Standards. (See §§ 74.30 through 74.37, below).

(h) The Patent and Trademark Laws Amendments, 35 U.S.C. section 200–212, apply to inventions made under an award for performance of experimental, developmental, or research work. Unless the terms and conditions for the award provide otherwise, recipients shall have no obligation to HHS with respect to program income earned from license fees and royalties for copyrighted material, patents, patent applications, trademarks, and inventions made under an award. However, no scholarship, fellowship, training grant, or other funding agreement made primarily to a recipient for educational purposes will contain any provision giving the Federal agency rights to inventions made by the recipient.

§ 74.25 Revision of budget and program plans.

(a) The budget plan is the financial expression of the project or program as approved during the award process. It may include either the sum of the Federal and non-Federal shares, or only the Federal share, depending upon HHS awarding agency requirements. It shall be related to performance for program evaluation purposes whenever appropriate.

(b) Recipients are required to report deviations from budget and program plans, and request prior approvals for budget and program plan revisions, in accordance with this section. Except as provided at §§ 74.4, 74.14, and this section, HHS awarding agencies may not impose other prior approval requirements for specific items.

(c) For nonconstruction awards, recipients shall obtain prior approvals from the HHS awarding agency for one

or more of the following program or budget related reasons.

(1) Change in the scope or the objective of the project or program (even if there is no associated budget revision requiring prior written approval).

(2) Change in the project director or principal investigator or other key persons specified in the application or award document.

(3) The absence for more than three months, or a 25 percent reduction in time devoted to the project, by the approved project director or principal investigator.

(4) The need for additional Federal funding.

(5) The inclusion, unless waived by the HHS awarding agency, of costs that require prior approval in accordance with OMB Circular A–21, ''Cost Principles for Educational Institutions;'' OMB Circular A–122, ''Cost Principles for Nonprofit Organizations;'' or appendix E of this part, ''Principles for Determining Costs Applicable to Research and Development under Grants and Contracts with Hospitals,'' or 48 CFR part 31, ''Contract Cost Principles and Procedures,'' as applicable.

(6) The transfer of funds allotted for training allowances (direct payment to trainees) to other categories of expense.

(7) Unless described in the application and funded in the approved award, the subaward, transfer or contracting out of any work under an award. This provision does not apply to the purchase of supplies, material, equipment or general support services.

(8) The inclusion of research patient care costs in research awards made for the performance of research work.

(d) Except for requirements listed in paragraphs (c)(1) and (c)(4) of this section, the HHS awarding agency is authorized, at its option, to waive cost-related and administrative prior written approvals required by this part and its appendixes. Additional waivers may be granted authorizing recipients to do any one or more of the following:

(1) Incur pre-award costs up to 90 calendar days prior to award, or more than 90 calendar days with the prior approval of the HHS awarding agency. However, all pre-award costs are incurred at the recipient's risk: the HHS awarding agency is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award to the recipient is less than anticipated and inadequate to cover such costs.

(2) Initiate a one-time extension of the expiration date of the award of up to 12 months unless one or more of the conditions identified at paragraphs (d)(2)(i), (ii), and (iii) of this section apply. For one-time extensions, the recipient must notify the HHS awarding agency in writing, with the supporting reasons and revised expiration date, at least 10 days before the date specified in the award. This one-time extension may not be exercised either by recipients or HHS awarding agencies merely for the purpose of using unobligated balances. Such extensions are not permitted where:

(i) The terms and conditions of award prohibit the extension; or

(ii) The extension requires additional Federal funds; or

(iii) The extension involves any change in the approved objectives or scope of the project.

(3) Carry forward unobligated balances to subsequent funding periods.

(4) For awards that support performance of research work, unless the HHS awarding agency provides otherwise in the award, or the award is subject to § 74.14 or subpart E of this Part, the prior approval requirements described in paragraphs (d) (1)–(3) of this section are automatically waived (i.e., recipients need not obtain such prior approvals). However, extension of award expiration dates must be approved by the HHS awarding agency if one of the conditions in paragraph (d)(2) of this section applies.

(e) The HHS awarding agencies may not permit any budget changes in a recipient's award that would cause any Federal appropriation to be used for purposes other then those consistent with the original purpose of the authorization and appropriation under which the award was funded.

(f) For construction awards, recipients shall obtain prior written approval promptly from the HHS awarding agency for budget revisions whenever:

(1) The revision results from changes in the scope or the objective of the project or program;

(2) The need arises for additional Federal funds to complete the project; or

(3) A revision is desired which involves specific costs for which prior written approval requirements apply in keeping with the applicable cost principles listed in § 74.27.

(g) When an HHS awarding agency makes an award that provides support for both construction and nonconstruction work, it may require the recipient to obtain prior approval before making any fund or budget transfers between the two types of work supported.

(h) For both construction and nonconstruction awards, recipients shall notify the HHS awarding agency in writing promptly whenever the amount of Federal authorized funds is expected to exceed the needs of the recipient for the project period by more than $5000 or five percent of the Federal award, whichever is greater. This notification shall not be required if an application for additional funding is submitted for a continuation award.

(i) Within 30 calendar days from the date of receipt of the request for budget revisions, HHS awarding agencies shall notify the recipient whether its requested budget revisions have been approved. If the requested revision is still under consideration at the end of 30 calendar days, the HHS awarding agency must inform the recipient in writing of the date when the recipient may expect a decision.

(j) When requesting approval for budget changes, recipients shall make their requests in writing.

(k) All approvals granted in keeping with the provisions of this section shall not be valid unless they are in writing, and signed by at least one of the following HHS officials:

(1) The Head of the HHS Operating or Staff Division that made the award or subordinate official with proper delegated authority from the Head, including the Head of the Regional Office of the HHS Operating or Staff Division that made the award; or

(2) The responsible Grants Officer of the HHS Operating or Staff Division that made the award or an individual duly authorized by the Grants Officer.

(l) No other prior approval requirements for specific items may be imposed unless a class deviation has been approved by OMB.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996]

§ 74.26 Non-Federal audits.

(a) Recipients and subrecipients that are institutions of higher education or other non-profit organizations (including hospitals) shall be subject to the audit requirements contained in the Single Audit Act Amendments of 1996 (31 U.S.C. 7501–7507) and revised OMB Circular A–133, ''Audits of States, Local Governments, and Non-Profit Organizations.''

(b) State and local governments shall be subject to the audit requirements contained in the Single Audit Act Amendments of 1996 (31 U.S.C. 7501–7507) and revised OMB Circular A–133, ''Audits of States, Local Governments, and Non-Profit Organizations.''

(c) For-profit hospitals not covered by the audit provisions of revised OMB Circular A–133 shall be subject to the audit requirements of the Federal awarding agencies.

(d)(1) Recipients and subrecipients that are commercial organizations (including for-profit hospitals) have two options regarding audits:

(i) A financial related audit (as defined in the Government Auditing Standards, GPO Stock #020–000–00–265–4) of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all HHS awards in accordance with Government Auditing Standards; or

(ii) An audit that meets the requirements contained in OMB Circular A–133.

(2) Commercial organizations that receive annual HHS awards totaling less than OMB Circular A–133's audit requirement threshold are exempt from requirements for a non-Federal audit for that year, but records must be

available for review by appropriate officials of Federal agencies.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11746, Mar. 22, 1996; 61 FR 15564, Apr. 8, 1996; 62 FR 41878, Aug. 4, 1997; 62 FR 45939, 45945, Aug. 29, 1997]

§ 74.27 Allowable costs.

(a) For each kind of recipient, there is a particular set of Federal principles that applies in determining allowable costs. Allowability of costs shall be determined in accordance with the cost principles applicable to the entity incurring the costs. Thus, allowability of costs incurred by State, local or federally-recognized Indian tribal governments is determined in accordance with the provisions of OMB Circular A–87, ''Cost Principles for State and Local Governments.'' The allowability of costs incurred by nonprofit organizations (except for those listed in Attachment C of Circular A–122) is determined in accordance with the provisions of OMB Circular A–122, ''Cost Principles for Nonprofit Organizations'' and paragraph (b) of this section. The allowability of costs incurred by institutions of higher education is determined in accordance with the provisions of OMB Circular A–21, ''Cost Principles for Educational Institutions.'' The allowability of costs incurred by hospitals is determined in accordance with the provisions of appendix E of this part, ''Principles for Determining Costs Applicable to Research and Development Under Grants and Contracts with Hospitals.'' The allowability of costs incurred by commercial organizations and those nonprofit organizations listed in Attachment C to Circular A–122 is determined in accordance with the provisions of the Federal Acquisition Regulation (FAR) at 48 CFR part 31, except that independent research and development costs are unallowable.

(b) OMB Circular A–122 does not cover the treatment of bid and proposal costs or independent research and development costs. The following rules apply to these costs for nonprofit organizations subject to that Circular.

(1) *Bid and proposal costs.* Bid and proposal costs are the immediate costs of preparing bids, proposals, and applications for Federal and non-Federal awards, contracts, and other agreements, including the development of scientific, cost, and other data needed to support the bids, proposals, and applications. Bid and proposal costs of the current accounting period are allowable as indirect costs. Bid and proposal costs of past accounting periods are unallowable in the current period. However, if the recipient's established practice is to treat these costs by some other method, they may be accepted if they are found to be reasonable and equitable. Bid and proposal costs do not include independent research and development costs covered by paragraph (b)(2) of this section, or pre-award costs covered by OMB Circular A–122, Attachment B, paragraph 33 and § 74.25(d)(1).

(2) *Independent Research and Development costs.* Independent research and development is research and development which is conducted by an organization, and which is not sponsored by Federal or non-Federal awards, contracts, or other agreements. Independent research and development shall be allocated its proportionate share of indirect costs on the same basis as the allocation of indirect costs to sponsored research and development. The cost of independent research and development, including their proportionate share of indirect costs, are unallowable.

§ 74.28 Period of availability of funds.

Where a funding period is specified, a recipient may charge to the award only allowable costs resulting from obligations incurred during the funding period and any pre-award costs authorized by the HHS awarding agency pursuant to § 74.25(d)(1).

PROPERTY STANDARDS

§ 74.30 Purpose of property standards.

Sections 74.31 through 74.37 set forth uniform standards governing management and disposition of property furnished by HHS or whose cost was charged directly to a project supported by an HHS award. The HHS awarding agency may not impose additional requirements, unless specifically required to do so by Federal statute. The recipient may use its own property management standards and procedures

provided they meet the provisions of §§ 74.31 through 74.37.

§ 74.31 Insurance coverage.

Recipients shall, at a minimum, provide the equivalent insurance coverage for real property and equipment acquired with HHS funds as provided to other property owned by the recipient.

§ 74.32 Real property.

(a) Title to real property shall vest in the recipient subject to the condition that the recipient shall use the real property for the authorized purpose of the project as long as it is needed and shall not encumber the property without approval of the HHS awarding agency.

(b) The recipient shall obtain written approval from the HHS awarding agency for the use of real property in other federally-sponsored projects when the recipient determines that the property is no longer needed for the purpose of the original project. Use in other projects shall be limited to those under federally-sponsored projects (i.e., awards) or programs that have purposes consistent with those authorized for support by the HHS awarding agency.

(c) When the real property is no longer needed as provided in paragraphs (a) and (b) of this section, the recipient shall request disposition instructions from the HHS awarding agency or its successor. The HHS awarding agency must provide one or more of the following disposition instructions:

(1) The recipient may be permitted to retain title without further obligation to the Federal Government after it compensates the Federal Government for that percentage of the current fair market value of the property attributable to the Federal share in the project.

(2) The recipient may be directed to sell the property under guidelines provided by the HHS awarding agency and pay the Federal Government for that percentage of the current fair market value of the property attributable to the Federal share in the project (after deducting actual and reasonable selling and fix-up expenses, if any, from the sales proceeds). When the recipient is authorized or required to sell the property, proper sales procedures shall be established that provide for competition to the extent practicable and result in the highest possible return.

(3) The recipient may be directed to transfer title to the property to the Federal Government or to an eligible third party provided that, in such cases, the recipient shall be entitled to compensation for its attributable percentage of the current fair market value of the property.

§ 74.33 Federally-owned and exempt property.

(a)(1) Title of federally-owned property remains vested in the Federal Government. Recipients shall submit annually an inventory listing of federally-owned property in their custody to the HHS awarding agency. Upon completion of the award or when the property is no longer needed, the recipient shall report the property to the HHS awarding agency for further agency utilization.

(2) If the HHS awarding agency has no further need for the property, it shall be declared excess and reported to the General Services Administration, unless the HHS awarding agency has statutory authority to dispose of the property by alternative methods (e.g., the authority provided by the Federal Technology Transfer Act, 15 U.S.C. 3710(I), to donate research equipment to educational and nonprofit organizations in accordance with E.O. 12821, ''Improving Mathematics and Science Education in Support of the National Education Goals''). Appropriate instructions shall be issued to the recipient by the HHS awarding agency.

(b) For research awards to certain types of recipients, 31 U.S.C. 6306 authorizes HHS to vest title to property acquired with Federal funds in the recipient without further obligation to the Federal government and under conditions that HHS considers appropriate. Such property is ''exempt property''. Exempt property shall not be subject to the requirements of § 74.34, except that it shall be subject to paragraphs (h)(1), (2), and (4) of that section

concerning the HHS awarding agency's right to require transfer.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996]

§ 74.34 Equipment.

(a) Title to equipment acquired by a recipient with HHS funds shall vest in the recipient, subject to the conditions of this section.

(b)(1) The recipient shall not use equipment acquired with HHS funds to provide services to non-Federal organizations for a fee that is less than private companies charge for equivalent services, unless specifically authorized by Federal statute, for so long as the Federal Government retains an interest in the equipment.

(2) If the equipment is owned by the Federal Government, use on other activities not sponsored by the Federal Government shall be permissible if authorized by the HHS awarding agency.

(3) User charges shall be treated as program income, in keeping with the provisions of § 74.24.

(c) The recipient shall use the equipment in the project or program for which it was acquired as long as needed, whether or not the project or program continues to be supported by Federal funds and shall not encumber the property without approval of the HHS awarding agency. When no longer needed for the original project or program, the recipient shall use the equipment in connection with its other federally-sponsored activities, if any, in the following order of priority:

(1) Programs, projects, or activities sponsored by the HHS awarding agency;

(2) Programs, projects, or activities sponsored by other HHS awarding agencies; then

(3) Programs, project, or activities sponsored by other Federal agencies.

(d) During the time that equipment is used on the program, project, or activity for which it was acquired, the recipient shall make it available for use on other projects or programs if such other use will not interfere with the work on the program, project, or activity for which the equipment was originally acquired. First preference for such other use shall be given to other programs, projects, or activities sponsored by the HHS awarding agency. Second preference shall be given to programs, projects, or activities sponsored by other HHS awarding agencies. Third preference shall be given to programs, projects, or activities sponsored by other Federal agencies.

(e) When acquiring replacement equipment, the recipient may use the equipment to be replaced as trade-in or sell the equipment and use the proceeds to offset the costs of the replacement equipment subject to the approval of the HHS awarding agency.

(f) The recipient's property management standards for equipment acquired with Federal funds and federally-owned equipment shall include all of the following:

(1) Equipment records shall be maintained accurately and shall include the following information:

(i) A description of the equipment;

(ii) Manufacturer's serial number, model number, Federal stock number, national stock number, or other identification number;

(iii) Source of the equipment, including the award number;

(iv) Whether title vests in the recipient or the Federal Government;

(v) Acquisition date (or date received, if the equipment was furnished by the Federal Government) and cost;

(vi) Information from which one can calculate the percentage of HHS's share in the cost of the equipment (not applicable to equipment furnished by the Federal Government);

(vii) Location and condition of the equipment and the date the information was reported;

(viii) Unit acquisition cost; and

(ix) Ultimate disposition data, including date of disposal and sales price or the method used to determine current fair market value where a recipient compensates the HHS awarding agency for its share.

(2) Equipment owned by the Federal Government shall be identified to indicate Federal ownership.

(3) The recipient shall take a physical inventory of equipment and the results reconciled with the equipment records at least once every two years. Any differences between quantities determined by the physical inspection and those shown in the accounting

records shall be investigated to determine the causes of the difference. The recipient shall, in connection with the inventory, verify the existence, current utilization, and continued need for the equipment.

(4) recipient shall maintain a control system to insure adequate safeguards to prevent loss, damage, or theft of the equipment. Any loss, damage, or theft of equipment shall be investigated and fully documented; if the equipment was owned by the Federal Government, the recipient shall promptly notify the HHS awarding agency.

(5) The recipient shall implement adequate maintenance procedures to keep the equipment in good condition.

(6) Where the recipient is authorized or required to sell the equipment, proper sales procedures shall be established which provide for competition to the extent practicable and result in the highest possible return.

(g) When the recipient no longer needs the equipment, it may use the equipment for other activities in accordance with the following standards. For equipment with a current per unit fair market value of $5000 or more, the recipient may retain the equipment for other uses provided that compensation is made to the original HHS awarding agency or its successor. The amount of compensation shall be computed by applying the percentage of HHS's share in the cost of the original project or program to the current fair market value of the equipment. If the recipient has no need for the equipment, the recipient shall request disposition instructions from the HHS awarding agency; such instructions must be issued to the recipient no later than 120 calendar days after the recipient's request and the following procedures shall govern:

(1) If so instructed or if disposition instructions are not issued within 120 calendar days after the recipient's request, the recipient shall sell the equipment and reimburse the HHS awarding agency an amount computed by applying to the sales proceeds the percentage of HHS share in the cost of the original project or program. However, the recipient shall be permitted to deduct and retain from the HHS share $500 or ten percent of the proceeds, whichever is less, for the recipient's selling and handling expenses.

(2) If the recipient is instructed to ship the equipment elsewhere, the recipient shall be reimbursed by the HHS awarding agency by an amount which is computed by applying the percentage of the recipient's share in the cost of the original project or program to the current fair market value of the equipment, plus any reasonable shipping or interim storage costs incurred.

(3) If the recipient is instructed to otherwise dispose of the equipment, the recipient will be reimbursed by the HHS awarding agency for such costs incurred in its disposition.

(4) If the recipient's project or program for which or under which the equipment was acquired is still receiving support from the same HHS program, and if the HHS awarding agency approves, the net amount due may be used for allowable costs of that project or program. Otherwise the net amount must be remitted to the HHS awarding agency by check.

(h) The HHS awarding agency reserves the right to order the transfer of title to the Federal Government or to a third party named by the awarding agency when such third party is otherwise eligible under existing statutes. Such transfer shall be subject to the following standards:

(1) The equipment shall be appropriately identified in the award or otherwise made known to the recipient in writing.

(2) The HHS awarding agency may require submission of a final inventory that lists all equipment acquired with HHS funds and federally-owned equipment.

(3) If the HHS awarding agency fails to issue disposition instructions within 120 calendar days after receipt of the inventory, the recipient shall apply the standards of paragraph (g)(1) of this section as appropriate.

(4) When the HHS awarding agency exercises its right to order the transfer of title to the Federal Government, the equipment shall be subject to the rules for federally-owned equipment. (See § 74.34(g)).

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996]

§ 74.35 Supplies.

(a) Title to supplies shall vest in the recipient upon acquisition. If there is a residual inventory of unused supplies exceeding $5000 in total aggregate value upon termination or completion of the project or program and the supplies are not needed for any other federally-sponsored project or program, the recipient shall retain the supplies for use on non-federally sponsored activities or sell them, but shall, in either case, compensate the Federal Government for its share. The amount of compensation shall be computed in the same manner as for equipment. (See § 74.34(g)).

(b)(1) The recipient shall not use supplies acquired with Federal funds to provide services to non-Federal organizations for a fee that is less than private companies charge for equivalent services, unless specifically authorized by Federal statute as long as the Federal Government retains an interest in the supplies.

(2) If the supplies are owned by the Federal Government, use on other activities not sponsored by the Federal Government shall be permissible if authorized by the HHS awarding agency.

(3) User charges shall be treated as program income, in keeping with the provisions of § 74.24.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996]

§ 74.36 Intangible property.

(a) The recipient may copyright any work that is subject to copyright and was developed, or for which ownership was purchased, under an award. The HHS awarding agency reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so.

(b) Recipients are subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401, ''Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements.''

(c) The Federal Government has the right to:

(1) Obtain, reproduce, publish or otherwise use the data first produced under an award; and

(2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

(d)(1) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the HHS Awarding Agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA. If the HHS Awarding Agency obtains the research data solely in response to a FOIA request, the agency may charge the requester a reasonable fee equaling the full incremental cost of obtaining the research data. This fee should reflect costs incurred by the agency, the recipient, and applicable subrecipients. This fee is in addition to any fees the agency may assess under the FOIA (5 U.S.C. 552(a)(4)(A)).

(2) The following definitions apply for purposes of this paragraph (d):

(i) *Research data* is defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This ''recorded'' material excludes physical objects (e.g., laboratory samples). *Research data* also do not include:

(A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study.

(ii) *Published* is defined as either when:

(A) Research findings are published in a peer-reviewed scientific or technical journal; or

(B) A Federal agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(iii) *Used by the Federal Government in developing an agency action that has the force and effect of law* is defined as when an agency publicly and officially cites the research findings in support of an agency action that has the force and effect of law.

(3) The requirements set forth in paragraph (d)(1) of this section do not apply to commercial organizations.

(e) Title to intangible property and debt instruments purchased or otherwise acquired under an award or subaward vests upon acquisition in the recipient. The recipient shall use that property for the originally—authorized purpose, and the recipient shall not encumber the property without approval of the HHS awarding agency. When no longer needed for the originally authorized purpose, disposition of the intangible property shall occur in accordance with the provisions of § 74.34 (g) and (h).

[59 FR 43760, Aug. 25, 1994, as amended at 65 FR 14407, 14418, Mar. 16, 2000]

§ 74.37 Property trust relationship.

Real property, equipment, intangible property and debt instruments that are acquired or improved with Federal funds shall be held in trust by the recipients as trustee for the beneficiaries of the project or program under which the property was acquired or improved, and shall not be encumbered without the approval of the HHS awarding agency. Recipients shall record liens or other appropriate notices of record to indicate that real property has been acquired or constructed or, where applicable, improved with Federal funds, and that use and disposition conditions apply to the property.

PROCUREMENT STANDARDS

§ 74.40 Purpose of procurement standards.

Sections 74.41 through 74.48 set forth standards for use by recipients in establishing procedures for the procurement of supplies and other expendable property, equipment, real property and other services with Federal funds. These standards are established to ensure that such materials and services are obtained in an effective manner and in compliance with the provisions of applicable Federal statutes and executive orders. The standards apply where the cost of the procurement is treated as a direct cost of an award.

§ 74.41 Recipient responsibilities.

The standards contained in this section do not relieve the recipients of the contractual responsibilities arising under its contract(s). The recipient is the responsible authority, without recourse to the HHS awarding agency, regarding the settlement and satisfaction of all contractual and administrative issues arising out of procurements entered into in support of an award or other agreement. This includes disputes, claims, protests of award, source evaluation or other matters of a contractual nature. Matters concerning violation of statute are to be referred to such Federal, State or local authority as may have proper jurisdiction.

§ 74.42 Codes of conduct.

The recipient shall maintain written standards of conduct governing the performance of its employees engaged in the award and administration of contracts. No employee, officer, or agent shall participate in the selection, award, or administration of a contract supported by Federal funds if a real or apparent conflict of interest would be involved. Such a conflict would arise when the employee, officer, or agent, or any member of his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for an award. The officers, employees, and agents of the recipient shall neither solicit nor accept gratuities, favors, or anything of

monetary value from contractors, or parties to subagreements. However, recipients may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The standards of conduct shall provide for disciplinary actions to be applied for violations of such standards by officers, employers, or agents of the recipients.

§ 74.43 Competition.

All procurement transactions shall be conducted in a manner to provide, to the maximum extent practical, open and free competition. The recipient shall be alert to organizational conflicts of interest as well as noncompetitive practices among contractors that may restrict or eliminate competition or otherwise restrain trade. In order to ensure objective contractor performance and eliminate unfair competitive advantage, contractors that develop or draft grant applications, or contract specifications, requirements, statements of work, invitations for bids and/or requests for proposals shall be excluded from competing for such procurements. Awards shall be made to the bidder or offeror whose bid or offer is responsive to the solicitation and is most advantageous to the recipient, price, quality and other factors considered. Solicitations shall clearly set forth all requirements that the bidder or offeror shall fulfill in order for the bid or offer to be evaluated by the recipient. Any and all bids or offers may be rejected when it is in the recipient's interest to do so.

§ 74.44 Procurement procedures.

(a) All recipients shall establish written procurement procedures. These procedures shall provide for, at a minimum, that:

(1) Recipients avoid purchasing unnecessary items;

(2) Where appropriate, an analysis is made of lease and purchase alternatives to determine which would be the most economical and practical procurement for the recipient and the Federal Government; and

(3) Solicitations for goods and services provide for all of the following:

(i) A clear and accurate description of the technical requirements for the material, product or service to be procured. In competitive procurements, such a description shall not contain features which unduly restrict competition.

(ii) Requirements which the bidder/offeror must fulfill and all other factors to be used in evaluating bids or proposals.

(iii) A description, whenever practicable, of technical requirements in terms of functions to be performed or performance required, including the range of acceptable characteristics or minimum acceptable standards.

(iv) The specific features of ''brand name or equal'' descriptions that bidders are required to meet when such items are included in the solicitation.

(v) The acceptance, to the extent practicable and economically feasible, of products and services dimensioned in the metric system of measurement.

(vi) Preference, to the extent practicable and economically feasible, for products and services that conserve natural resources and protect the environment and are energy efficient.

(b) Positive efforts shall be made by recipients to utilize small businesses, minority-owned firms, and women's business enterprises, whenever possible. Recipients of HHS awards shall take all of the following steps to further this goal.

(1) Ensure that small businesses, minority-owned firms, and women's business enterprises are used to the fullest extent practicable.

(2) Make information on forthcoming opportunities available and arrange time frames for purchases and contracts to encourage and facilitate participation by small businesses, minority-owned firms, and women's business enterprises.

(3) Consider in the contract process whether firms competing for larger contracts intend to subcontract with small businesses, minority-owned firms, and women's business enterprises.

(4) Encourage contracting with consortiums of small businesses, minority-owned firms and women's business enterprises when a contract is too large

for one of these firms to handle individually.

(5) Use the services and assistance, as appropriate, of such organizations as the Small Business Administration and the Department of Commerce's Minority Business Development Agency in the solicitation and utilization of small businesses, minority-owned firms and women's business enterprises.

(c) The type of procuring instruments used (e.g., fixed price contracts, cost reimbursable contracts, purchase orders, and incentive contracts) shall be determined by the recipient but shall be appropriate for the particular procurement and for promoting the best interest of the program or project involved. The ''cost-plus-a-percentage-of-cost'' or ''percentage of construction cost'' methods of contracting shall not be used.

(d) Contracts shall be made only with responsible contractors who possess the potential ability to perform successfully under the terms and conditions of the proposed procurement. Consideration shall be given to such matters as contractor integrity, record of past performance, financial and technical resources or accessibility to other necessary resources. In certain circumstances, contracts with certain parties are restricted by agencies' implementation of E.O.s 12549 and 12689, ''Debarment and Suspension.'' (See 45 CFR part 76.)

(e) Recipients shall, on request, make available for the HHS awarding agency, pre-award review, procurement documents such as requests for proposals or invitations for bids, independent cost estimates, etc., when any of the following conditions apply:

(1) A recipient's procurement procedures or operation fails to comply with the procurement standards in this Part.

(2) The procurement is expected to exceed the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently $100,000) and is to be awarded without competition or only one bid or offer is received in response to a solicitation.

(3) The procurement, which is expected to exceed the simplified acquisition threshold specifies a ''brand name'' product.

(4) The proposed award over the simplified acquisition threshold is to be awarded to other than the apparent low bidder under a sealed bid procurement.

(5) A proposed contract modification changes the scope of a contract or increases the contract amount by more than the amount of the simplified acquisition threshold.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996; 62 FR 41878, Aug. 4, 1997; 62 FR 51377, Oct. 1, 1997]

§ 74.45 Cost and price analysis.

Some form of cost or price analysis shall be made and documented in the procurement files in connection with every procurement action. Price analysis may be accomplished in various ways, including the comparison of price quotations submitted, market prices and similar indicia, together with discounts. Cost analysis is the review and evaluation of each element of cost to determine reasonableness, allocability and allowability.

§ 74.46 Procurement records.

Procurement records and files for purchases in excess of the simplified acquisition threshold shall include the following at a minimum: (a) Basis for contractor selection, (b) justification for lack of competition when competitive bids or offers are not obtained, and (c) basis for award cost or price.

[59 FR 43760, Aug. 25, 1994, as amended at 62 FR 41878, Aug. 4, 1997]

§ 74.47 Contract administration.

A system for contract administration shall be maintained to ensure contractor conformance with the terms, conditions and specifications of the contract and to ensure adequate and timely follow up of all purchases. Recipients shall evaluate contractor performance and document, as appropriate, whether contractors have met the terms, conditions and specifications of the contract.

§ 74.48 Contract provisions.

The recipient shall include, in addition to provisions to define a sound and complete agreement, the following provisions in all contracts. The following

provisions shall also be applied to subcontracts:

(a) Contracts in excess of the simplified acquisition threshold shall contain contractual provisions or conditions that allow for administrative, contractual, or legal remedies in instances in which a contractor violates or breaches the contract terms, and provide for such remedial actions as may be appropriate.

(b) All contracts in excess of the simplified acquisition threshold (currently $100,000) shall contain suitable provisions for termination by the recipient, including the manner by which termination shall be effected and the basis for settlement. In addition, such contracts shall describe conditions under which the contract may be terminated for default as well as conditions where the contract may be terminated because of circumstances beyond the control of the contractor.

(c) Except as otherwise required by statute, an award that requires the contracting (or subcontracting) for construction or facility improvements shall provide for the recipient to follow its own requirements relating to bid guarantees, performance bonds, and payment bonds unless the construction contract or subcontract exceeds $100,000. For those contracts or subcontracts exceeding $100,000, the HHS awarding agency may accept the bonding policy and requirements of the recipient, provided the HHS awarding agency has made a determination that the Federal Government's interest is adequately protected. If such a determination has not been made, the minimum requirements shall be as follows:

(1) A bid guarantee from each bidder equivalent to five percent of the bid price. The ''bid guarantee'' shall consist of a firm commitment such as a bid bond, certified check, or other negotiable instrument accompanying a bid as assurance that the bidder shall, upon acceptance of his bid, execute such contractual documents as may be required within the time specified.

(2) A performance bond on the part of the contractor for 100 percent of the contract price. A ''performance bond'' is one executed in connection with a contract to secure fulfillment of all the contractor's obligations under such contract.

(3) A payment bond on the part of the contractor for 100 percent of the contract price. A ''payment bond'' is one executed in connection with a contract to assure payment as required by statute of all persons supplying labor and material in the execution of the work provided for in the contract.

(4) Where bonds are required in the situations described herein, the bonds shall be obtained from companies holding certificates of authority as acceptable sureties pursuant to 31 CFR part 223, ''Surety Companies Doing Business with the United States.''

(d) All negotiated contracts (except those for less than the simplified acquisition threshold) awarded by recipients shall include a provision to the effect that the recipient, the HHS awarding agency, the U.S. Comptroller General, or any of their duly authorized representatives, shall have access to any books, documents, papers and records of the contractor which are directly pertinent to a specific program for the purpose of making audits, examinations, excerpts and transcriptions.

(e) All contracts, including small purchases, awarded by recipients and their contractors shall contain the procurement provisions of appendix A to this part, as applicable.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996; 62 FR 41878, Aug. 4, 1997]

REPORTS AND RECORDS

§ 74.50 Purpose of reports and records.

Sections 74.51 through 74.53 set forth the procedures for monitoring and reporting on the recipient's financial and program performance and the necessary standard reporting forms. They also set forth record retention requirements.

§ 74.51 Monitoring and reporting program performance.

(a) Recipients are responsible for managing and monitoring each project, program, subaward, function or activity supported by the award. Recipients shall monitor subawards to ensure that

subrecipients have met the audit requirements as set forth in § 74.26.

(b) The HHS awarding agency will prescribe the frequency with which the performance reports shall be submitted. Except as provided in paragraph (f) of this section, performance reports will not be required more frequently than quarterly or, less frequently than annually. Annual reports shall be due 90 calendar days after the award year; quarterly or semi-annual reports shall be due 30 days after the reporting period. The HHS awarding agency may require annual reports before the anniversary dates of multiple year awards in lieu of these requirements. The final performance reports are due 90 calendar days after the expiration or termination of the award.

(c) If inappropriate, a final technical or performance report will not be required after completion of the project.

(d) Performance reports shall generally contain, for each award, brief information on each of the following:

(1) A comparison of actual accomplishments with the goals and objectives established for the period, the findings of the investigator, or both. Whenever appropriate and the output of programs or projects can be readily quantified, such quantitative data should be related to cost data for computation of unit costs.

(2) Reasons why established goals were not met, if appropriate.

(3) Other pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs.

(e) Recipients shall submit the original and two copies of performance reports.

(f) Recipients shall immediately notify the HHS awarding agency of developments that have a significant impact on the award-supported activities. Also, notification shall be given in the case of problems, delays, or adverse conditions which materially impair the ability to meet the objectives of the award. This notification shall include a statement of the action taken or contemplated, and any assistance needed to resolve the situation.

(g) HHS may make site visits, as needed.

(h) The HHS awarding agency complies with the applicable report clearance requirements of 5 CFR part 1320, ''Controlling Paperwork Burdens on the Public,'' when requesting performance data from recipients.

§ 74.52 Financial reporting.

(a) The following forms are used for obtaining financial information from recipients:

(1) SF–269 or SF–269A, Financial Status Report.

(i) The HHS awarding agency will require recipients to use either the SF–269 (long form) or SF–269A to report the status of funds for all nonconstruction projects or programs. The SF–269 shall always be used if income has been earned. The awarding agency may, however, waive the SF–269 or SF–269A requirement when the PMS–270, Request for Advance or Reimbursement, or PMS–272, Report of Federal Cash Transactions, will provide adequate information to meet its needs, except that a final SF–269 or SF–269A shall be required at the completion of the project when the PMS–270 is used only for advances.

(ii) If the HHS awarding agency requires accrual information and the recipient's accounting records are not normally kept on the accrual basis, the recipient shall not be required to convert its accounting system, but shall develop such accrual information through best estimates based on an analysis of the documentation on hand.

(iii) The HHS awarding agency will determine the frequency of the Financial Status Report for each project or program, considering the size and complexity of the particular project or program. However, the report will not be required more frequently than quarterly or less frequently than annually except under § 74.14. A final report shall be required at the completion of the agreement.

(iv) Recipients shall submit the SF–269 and SF–269A (an original and two copies) no later than 30 days after the end of each specified reporting period for quarterly and semi-annual reports, and 90 calendar days for annual and final reports. Extensions of reporting due dates may be approved by the HHS

awarding agency upon request of the recipient.

(2) PMS–272, Report of Federal Cash Transactions.

(i) When funds are advanced to recipients, the HHS awarding agency requires each recipient to submit the PMS–272 and, when necessary, its continuation sheet, PMS–272A through G. The HHS awarding agency uses this report to monitor cash advanced to recipients and to obtain disbursement information for each agreement with the recipients.

(ii) The HHS awarding agency may require forecasts of Federal cash requirements in the ''Remarks'' section of the report.

(iii) Recipients shall submit the original and two copies of the PMS–272 15 calendar days following the end of each quarter. The HHS awarding agency may require a monthly report from those recipients receiving advances totaling $1 million or more per year.

(iv) The HHS awarding agency may waive the requirement for submission of the PMS–272 for any one of the following reasons: (A) When monthly advances do not exceed $25,000 per recipient, provided that such advances are monitored through other forms contained in this section; (B) If, in HHS' opinion, the recipient's accounting controls are adequate to minimize excessive Federal advances; or, (C) When the electronic payment mechanisms provide adequate data.

(b) When the HHS awarding agency needs additional information or more frequent reports, the following shall be observed.

(1) When additional information is needed to comply with legislative requirements, the HHS awarding agency will issue instructions to require recipients to submit that information under the ''Remarks'' section of the reports.

(2) When HHS determines that a recipient's accounting system does not meet the standards in § 74.21, additional pertinent information to further monitor awards may be obtained, without regard to § 74.4, upon written notice to the recipient until such time as the system is brought up to standard. In obtaining this information, the HHS awarding agencies comply with report clearance requirements of 5 CFR part 1320, ''Controlling Paperwork Burdens on the Public.''

(3) The HHS awarding agency may accept the identical information from a recipient in machine readable format or computer printouts or electronic outputs in lieu of prescribed formats.

(4) The HHS awarding agency may provide computer or electronic outputs to recipients when such action expedites or contributes to the accuracy of reporting.

§ 74.53 Retention and access requirements for records.

(a) This section sets forth requirements for record retention and access to records for awards to recipients.

(b) Financial records, supporting documents, statistical records, and all other records pertinent to an award shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report. The only exceptions are the following:

(1) If any litigation, claim, financial management review, or audit is started before the expiration of the 3-year period, the records shall be retained until all litigation, claims or audit findings involving the records have been resolved and final action taken.

(2) Records for real property and equipment acquired with Federal funds shall be retained for 3 years after final disposition.

(3) When records are transferred to or maintained by the HHS awarding agency, the 3-year retention requirement is not applicable to the recipient.

(4) Indirect cost rate proposals, cost allocations plans, etc., as specified in § 74.53(g).

(c) Copies of original records may be substituted for the original records if authorized by the HHS awarding agency.

(d) The HHS awarding agency will request transfer of certain records to its custody from recipients when it determines that the records possess long term retention value. However, in order to avoid duplicate recordkeeping, the HHS awarding agency may make

arrangements for recipients to retain any records that are continuously needed for joint use.

(e) HHS awarding agencies, the HHS Inspector General, the U.S. Comptroller General, or any of their duly authorized representatives, have the right of timely and unrestricted access to any books, documents, papers, or other records of recipients that are pertinent to the awards, in order to make audits, examinations, excerpts, transcripts and copies of such documents. This right also includes timely and reasonable access to a recipient's personnel for the purpose of interview and discussion related to such documents. The rights of access in this paragraph are not limited to the required retention period, but shall last as long as records are retained.

(f) Unless required by statute, the HHS awarding agency will not place restrictions on recipients that limit public access to the records of recipients that are pertinent to an award, except when the HHS awarding agency can demonstrate that such records shall be kept confidential and would have been exempted from disclosure pursuant to the Freedom of Information Act, 5 U.S.C. 552, if the records had belonged to the HHS awarding agency.

(g) Paragraphs (g)(1) and (g)(2) of this section apply to the following types of documents, and their supporting records: Indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates).

(1) If the recipient submits to the Federal Government or the subrecipient submits to the recipient the proposal, plan, or other computation to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts on the date of such submission.

(2) If the recipient is not required to submit to the Federal Government or the subrecipient is not required to submit to the recipient the proposal, plan, or other computation for negotiation purposes, then the 3-year retention period for the proposal, plan, or other computation and its supporting records starts at the end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

TERMINATION AND ENFORCEMENT

§ 74.60 Purpose of termination and enforcement.

Sections 74.61 and 74.62 set forth uniform suspension, termination and enforcement procedures.

§ 74.61 Termination.

(a) Awards may be terminated in whole or in part only if paragraph (a)(1), (2), or (3) of this section applies.

(1) By the HHS awarding agency, if a recipient materially fails to comply with the terms and conditions of an award.

(2) By the HHS awarding agency with the consent of the recipient, in which case the two parties shall agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated.

(3) By the recipient upon sending to the HHS awarding agency written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency determines in the case of partial termination that the reduced or modified portion of the award will not accomplish the purposes for which the award was made, it may terminate the award in its entirety.

(b) If costs are allowed under an award, the responsibilities of the recipient referred to in § 74.71(a), including those for property management as applicable, shall be considered in the termination of the award, and provision shall be made for continuing responsibilities of the recipient after termination, as appropriate.

§ 74.62 Enforcement.

(a) If a recipient materially fails to comply with the terms and conditions of an award, whether stated in a Federal statute or regulation, an assurance, an application, or a notice of award, the HHS awarding agency may,

in addition to imposing any of the special conditions outlined in § 74.14, take one or more of the following actions, as appropriate in the circumstances:

(1) Temporarily withhold cash payments pending correction of the deficiency by the recipient or more severe enforcement action by the HHS awarding agency.

(2) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.

(3) Wholly or partly suspend or terminate the current award.

(4) Withhold further awards for the project or program.

(5) Take any other remedies that may be legally available.

(b) In taking an enforcement action, the HHS awarding agency will provide the recipient or subrecipient an opportunity for such hearing, appeal, or other administrative proceeding to which the recipient or subrecipient is entitled under any statute or regulation applicable to the action. (See also 45 CFR parts 16 and 95.)

(c) Costs to a recipient resulting from obligations incurred by the recipient during a suspension or after termination of an award are not allowable unless the HHS awarding agency expressly authorizes them in the notice of suspension or termination or subsequently. Other recipient costs during suspension or after termination which are necessary and not reasonably avoidable are allowable if:

(1) The costs result from obligations which were properly incurred by the recipient before the effective date of suspension or termination, are not in anticipation of it, and in the case of a termination, are noncancellable; and

(2) The costs would be allowable if the award were not suspended or expired normally at the end of the funding period in which the termination takes effect.

(d) The enforcement remedies identified in this section, including suspension and termination, do not preclude a recipient from being subject to debarment and suspension under E.O.s 12549 and 12689 and the HHS implementing regulations at § 74.13 of this part and 45 CFR part 76.

[59 FR 43760, Aug. 25, 1994, as amended at 62FR 38218, July 17, 1997]

Subpart D—After-the-Award Requirements

SOURCE: 59 FR 43760, Aug. 25, 1994, unless otherwise noted.

§ 74.70 Purpose.

Sections 74.71 through 74.73 contain closeout procedures and other procedures for subsequent disallowances and adjustments.

§ 74.71 Closeout procedures.

(a) Recipients shall submit, within 90 calendar days after the date of completion of the award, all financial, performance, and other reports as required by the terms and conditions of the award. The HHS awarding agency may approve extensions when requested by the recipient.

(b) Unless the HHS awarding agency authorizes an extension, a recipient shall liquidate all obligations incurred under the award not later than 90 calendar days after the funding period or the date of completion as specified in the terms and conditions of the award or in agency implementing instructions.

(c) HHS will make prompt payments to a recipient for allowable reimbursable costs under the award being closed out.

(d) The recipient shall promptly refund any balances of unobligated cash that HHS has advanced or paid and that is not authorized to be retained by the recipient for use in other projects. 45 CFR part 30 governs unreturned amounts that become delinquent debts.

(e) When authorized by the terms and conditions of the award, HHS will make a settlement for any upward or downward adjustments to the Federal share of costs after closeout reports are received.

(f) The recipient shall account for any real and personal property acquired with HHS funds or received from the Federal Government in accordance with §§ 74.31 through 74.37.

(g) In the event a final audit has not been performed prior to the closeout of an award, HHS retains the right to recover an appropriate amount after fully considering the recommendations on disallowed costs resulting from the final audit.

§ 74.72 Subsequent adjustments and continuing responsibilities.

(a) The closeout of an award does not affect any of the following:

(1) The right of the HHS awarding agency to disallow costs and recover funds on the basis of a later audit or other review.

(2) The obligation of the recipient to return any funds due as a result of later refunds, corrections, or other transactions.

(3) Audit requirements in § 74.26.

(4) Property management requirements in §§ 74.31 through 74.37.

(5) Records retention requirements in § 74.53.

(b) After closeout of an award, a relationship created under an award may be modified or ended in whole or in part with the consent of the HHS awarding agency and the recipient, provided the responsibilities of the recipient referred to in § 74.72(a), including those for property management as applicable, are considered and provisions made for continuing responsibilities of the recipient, as appropriate.

§ 74.73 Collection of amounts due.

(a) Any funds paid to a recipient in excess of the amount to which the recipient is finally determined to be entitled under the terms and conditions of the award constitute a debt to the Federal Government. If not paid within a reasonable period after the demand for payment, the HHS awarding agency may reduce the debt by paragraph (a)(1), (2), or (3) of this section:

(1) Making an administrative offset against other requests for reimbursements.

(2) Withholding advance payments otherwise due the recipient.

(3) Taking other action permitted by statute.

(b) Except as otherwise provided by law, HHS awarding agencies will charge interest on an overdue debt in accordance with 4 CFR ch. II, ''Federal Claims Collection Standards.'' (See 45 CFR part 30.)

Subpart E—Special Provisions for Awards to Commercial Organizations

SOURCE: 59 FR 43760, Aug. 25, 1994, unless otherwise noted.

§ 74.80 Scope of subpart.

This subpart contains provisions that apply to awards to commercial organizations. These provisions are in addition to other applicable provisions of this part, or they make exceptions from other provisions of this part for awards to commercial organizations.

§ 74.81 Prohibition against profit.

Except for awards under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs (15 U.S.C. 638), no HHS funds may be paid as profit to any recipient even if the recipient is a commercial organization. Profit is any amount in excess of allowable direct and indirect costs.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996]

§ 74.82 Program income.

The additional costs alternative described in § 74.24(b)(1) may not be applied to program income earned by a commercial organization except in the SBIR and STTR programs.

§ 74.83 Effect on intangible property.

Data sharing (FOIA) requirements as set forth in § 74.36(d)(1) do not apply to commercial organizations.

[65 FR 14418, Mar. 16, 2000]

Subpart F—Disputes

SOURCE: 59 FR 43760, Aug. 25, 1994, unless otherwise noted.

§ 74.90 Final decisions in disputes.

(a) HHS attempts to promptly issue final decisions in disputes and in other matters affecting the interests of recipients. However, final decisions adverse to the recipient are not issued until it is clear that the matter cannot

be resolved through further exchange of information and views.

(b) Under various HHS statutes or regulations, recipients have the right to appeal from, or to have a hearing on, certain final decisions by HHS awarding agencies. (See, for example, subpart D of 42 CFR part 50, and 45 CFR part 16). Paragraphs (c) and (d) of this section set forth the standards HHS expects its member agencies to meet in issuing a final decision covered by any of the statutes or regulations.

(c) The decision may be brief but must contain:

(1) A complete statement of the background and basis of the awarding agency's decision, including reference to the pertinent statutes, regulations, or other governing documents; and

(2) Enough information to enable the recipient to understand the issues and the position of the HHS awarding agency.

(d) The following or similar language (consistent with the terminology of the applicable statutes or regulations) should appear at the end of the decision: ''This is the final decision of the (title of grants officer or other official responsible for the decision). It shall be the final decision of the Department unless, within 30 days after receiving this decision, you deliver or mail (you should use registered or certified mail to establish the date) a written notice of appeal to (name and address of appropriate contact, e.g., the office responsible for awarding agency preliminary appeal process or, where none, the Departmental Appeals Board, Department of Health and Human Services, Washington, DC 20201). You shall attach to the notice a copy of this decision, note that you intend an appeal, state the amount in dispute, and briefly state why you think that this decision is wrong. You will be notified of further procedures.''

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996; 62 FR 38218, July 17, 1997]

§ 74.91 Alternative dispute resolution.

HHS encourages its awarding agencies and recipients to try to resolve disputes by using alternative dispute resolution (ADR) techniques. ADR often is effective in reducing the cost, delay and contentiousness involved in appeals and other traditional ways of handling disputes. ADR techniques include mediation, neutral evaluation and other consensual methods. Information about ADR is available from the HHS Dispute Resolution Specialist at the Departmental Appeals Board, U.S. Department of Health and Human Services, Washington, DC 20201.

APPENDIX A TO PART 74—CONTRACT PROVISIONS

All contracts awarded by a recipient, including small purchases, shall contain the following provisions as applicable where the cost of the contract is treated as a direct cost of an award:

1. *Equal Employment Opportunity*— All contracts shall contain a provision requiring compliance with E.O. 11246, ''Equal Employment Opportunity,'' as amended by E.O. 11375, ''Amending Executive Order 11246 Relating to Equal Employment Opportunity,'' and as supplemented by regulations at 41 CFR part 60, ''Office of Federal Contract Compliance Programs, Equal Employment Opportunity, Department of Labor.''

2. *Copeland ''Anti-Kickback'' Act (18 U.S.C. 874 and 40 U.S.C. 276c)*— All contracts and subgrants in excess of $2,000 for construction or repair awarded by recipients and subrecipients shall include a provision for compliance with the Copeland ''Anti-Kickback'' Act, 18 U.S.C. 874, as supplemented by Department of Labor regulations, 29 CFR part 3, ''Contractors and Subcontractors on Public Building or Public Work Financed in Whole or in Part by Loans or Grants from the United States.'' The Act provides that each contractor or subrecipient shall be prohibited from inducing, by any means, any person employed in the construction, completion, or repair of public work, to give up any part of the compensation to which he is otherwise entitled. The recipient shall report all suspected or reported violations to the Federal awarding agency.

3. *Davis-Bacon Act, as amended (40 U.S.C. 276a to a–7)*— When required by Federal program legislation, all construction contracts awarded by the recipients and subrecipients of more than $2000 shall include a provision for compliance with the Davis-Bacon Act, 40 U.S.C. 276a to a–7, and as supplemented by Department of Labor regulations, 29 CFR part 5, ''Labor Standards Provisions Applicable to Contracts Governing Federally Financed and Assisted Construction.'' Under this Act, contractors shall be required to pay wages to laborers and mechanics at a rate not less than the minimum wages specified in a wage determination made by the Secretary of Labor. In addition, contractors shall be required to pay wages not less than

once a week. The recipient shall place a copy of the current prevailing wage determination issued by the Department of Labor in each solicitation and the award of a contract shall be conditioned upon the acceptance of the wage determination. The recipient shall report all suspected or reported violations to the HHS awarding agency.

4. *Contract Work Hours and Safety Standards Act (40 U.S.C. 327–333)*— Where applicable, all contracts awarded by recipients in excess of $100,000 for construction contracts and for other contracts that involve the employment of mechanics or laborers shall include a provision for compliance with sections 102 and 107 of the Contract Work Hours and Safety Standards Act, 40 U.S.C. 327–333, as supplemented by Department of Labor regulations, 29 CFR part 5. Under section 102 of the Act, each contractor shall be required to compute the wages of every mechanic and laborer on the basis of a standard work week of 40 hours. Work in excess of the standard work week is permissible provided that the worker is compensated at a rate of not less than 1½ times the basic rate of pay for all hours worked in excess of 40 hours in the work week. Section 107 of the Act is applicable to construction work and provides that no laborer or mechanic shall be required to work in surroundings or under working conditions which are unsanitary, hazardous or dangerous. These requirements do not apply to the purchases of supplies or materials or articles ordinarily available on the open market, or contracts for transportation or transmission of intelligence.

5. *Rights to Inventions Made Under a Contract or Agreement*— Contracts or agreements for the performance of experimental, developmental, or research work shall provide for the rights of the Federal Government and the recipient in any resulting invention in accordance with 37 CFR part 401, ''Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts and Cooperative Agreements,'' and any further implementing regulations issued by HHS.

6. *Clean Air Act (42 U.S.C. 7401 et seq.) and the Federal Water Pollution Control Act as amended (33 U.S.C. 1251 et seq.)*— Contracts and subgrants of amounts in excess of $100,000 shall contain a provision that requires the recipient to agree to comply with all applicable standards, orders or regulations issued pursuant to the Clean Air Act, 42 U.S.C. 7401 et seq., and the Federal Water Pollution Control Act, as amended 33 U.S.C. 1251 et seq. Violations shall be reported to the HHS and the appropriate Regional Office of the Environmental Protection Agency.

7. *Byrd Anti-Lobbying Amendment (31 U.S.C. 1352)*— Contractors who apply or bid for an award of more than $100,000 shall file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any Federal agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant or any other award covered by 31 U.S.C. 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient. (See also 45 CFR part 93).

8. *Debarment and Suspension (E.O.s 12549 and 12689)*— Certain contracts shall not be made to parties listed on the nonprocurement portion of the General Services Administration's ''Lists of Parties Excluded from Federal Procurement or Nonprocurement Programs'' in accordance with E.O.s 12549 and 12689, ''Debarment and Suspension.'' (See 45 CFR part 76.) This list contains the names of parties debarred, suspended, or otherwise excluded by agencies, and contractors declared ineligible under statutory authority other than E.O. 12549. Contractors with awards that exceed the simplified acquisition threshold shall provide the required certification regarding their exclusion status and that of their principals prior to award.

[59 FR 43760, Aug. 25, 1994, as amended at 61 FR 11747, Mar. 22, 1996; 62 FR 41878, Aug. 4, 1997]

APPENDIXES B–D TO PART 74 [RESERVED]

APPENDIX E TO PART 74—PRINCIPLES FOR DETERMINING COSTS APPLICABLE TO RESEARCH AND DEVELOPMENT UNDER GRANTS AND CONTRACTS WITH HOSPITALS

I. PURPOSE AND SCOPE

A. *Objectives.* This appendix provides principles for determining the costs applicable to research and development work performed by hospitals under grants and contracts with the Department of Health and Human Services. These principles are confined to the subject of cost determination and make no attempt to identify the circumstances or dictate the extent of hospital participation in the financing of a particular research or development project. The principles are designed to provide recognition of the full allocated costs of such research work under generally accepted accounting principles. These principles will be applicable to both proprietary and non-profit hospitals. No provision for profit or other increment above cost is provided for in these principles. However, this is not to be interpreted as precluding a

negotiated fee between contracting parties when a fee is appropriate.

B. *Policy guides*. The successful application of these principles requires development of mutual understanding between representatives of hospitals and of the Department of Health and Human Services as to their scope, applicability and interpretation. It is recognized that:

1. The arrangements for hospital participation in the financing of a research and development project are properly subject to negotiation between the agency and the hospital concerned in accordance with such Government-wide criteria as may be applicable.

2. Each hospital, possessing its own unique combination of staff, facilities and experience, should be encouraged to conduct research in a manner consonant with its own institutional philosophies and objectives.

3. Each hospital in the fulfillment of its contractual obligations should be expected to employ sound management practices.

4. The application of the principles established herein shall be in conformance with the generally accepted accounting practices of hospitals.

5. Hospitals receive reimbursements from the Federal Government for differing types of services under various programs such as support of Research and Development (including discrete clinical centers) Health Services Projects, Medicare, etc. It is essential that consistent procedures for determining reimbursable costs for similar services be employed without regard to program differences. Therefore, both the direct and indirect costs of research programs must be identified as a cost center(s) for the cost finding and step-down requirements of the Medicare program, or in its absence the Medicaid program.

C. *Application*. All operating agencies within the Department of Health and Human Services that sponsor research and development work in hospitals will apply these principles and related policy guides in determining the costs incurred for such work under grants and cost-reimbursement type contracts and subcontracts. These principles will also be used as a guide in the pricing of fixed-price contracts and subcontracts.

II. DEFINITIONS OF TERMS

A. *Organized research* means all research activities of a hospital that may be identified whether the support for such research is from a federal, non-federal or internal source.

B. *Departmental research* means research activities that are not separately budgeted and accounted for. Such work, which includes all research activities not encompassed under the term organized research, is regarded for purposes of this document as a part of the patient care activities of the hospital.

C. *Research agreement* means any valid arrangement to perform federally-sponsored research or development including grants, cost-reimbursement type contracts, cost-reimbursement type subcontracts, and fixed-price contracts and subcontracts.

D. *Instruction and training* means the formal or informal programs of educating and training technical and professional health services personnel, primarily medical and nursing training. This activity, if separately budgeted or identifiable with specific costs, should be considered as a cost objective for purposes of indirect cost allocations and the development of patient care costs.

E. *Other hospital activities* means all organized activities of a hospital not immediately related to the patient care, research, and instructional and training functions which produce identifiable revenue from the performance of these activities. If a non-related activity does not produce identifiable revenue, it may be necessary to allocate this expense using an appropriate basis. In such a case, the activity may be included as an allocable cost (See paragraph III D below.) Also included under this definition is any category of cost treated as ''Unallowable,'' provided such category of cost identifies a function or activity to which a portion of the institution's indirect cost (as defined in paragraph V. A.) are properly allocable.

F. *Patient care* means those departments or cost centers which render routine or ancillary services to in-patients and/or out-patients. As used in paragraph IX B.23, it means the cost of these services applicable to patients involved in research programs.

G. *Allocation* means the process by which the indirect costs are assigned as between:

1. Organized research,

2. Patient care including departmental research.

3. Instruction and training, and

4. Other hospital activities.

H. *Cost center* means an identifiable department or area (including research) within the hospital which has been assigned an account number in the hospital accounting system for the purpose of accumulating expense by department or area.

I. *Cost finding* is the process of recasting the data derived from the accounts ordinarily kept by a hospital to ascertain costs of the various types of services rendered. It is the determination of direct costs by specific identification and the proration of indirect costs by allocation.

J. *Step down* is a cost finding method that recognizes that services rendered by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue producing centers as well as by the revenue-producing centers. All costs of nonrevenue-producing centers are allocated to all centers which they serve, regardless of whether

or not these centers produce revenue. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered closed and no further costs are apportioned to that center.

K. *Scatter bed* is a bed assigned to a research patient based on availability. Research patients occupying these beds are not physically segregated from nonresearch patients occupying beds. Scatter beds are geographically dispersed among all the beds available for use in the hospital. There are no special features attendant to a scatter bed that distinguishes it from others that could just as well have been occupied.

L. *Discrete bed* is a bed or beds that have been set aside for occupancy by research patients and are physically segregated from other hospital beds in an environment that permits an easily ascertainable allocation of costs associated with the space they occupy and the services they generate.

III. BASIC CONSIDERATIONS

A. *Composition of total costs.* The cost of a research agreement is comprised of the allowable direct costs incident to its performance plus the allocable portion of the allowable indirect costs of the hospital less applicable credits. (See paragraph III-E.)

B. *Factors affecting allowability of costs.* The tests of allowability of costs under these principles are:

1. They must be reasonable.

2. They must be assigned to research agreements under the standards and methods provided herein.

3. They must be accorded consistent treatment through application of those generally accepted accounting principles appropriate to the circumstances (See paragraph I-E.5.) and

4. They must conform to any limitations or exclusions set forth in these principles or in the research agreement as to types or amounts of cost items.

C. *Reasonable costs.* A cost may be considered reasonable if the nature of the goods or services acquired or applied, and the amount involved therefor reflect the action that a prudent person would have taken under the circumstances prevailing at the time the decision to incur the cost was made. Major considerations involved in the determination of the reasonableness of a cost are:

1. Whether or not the cost is of a type generally recognized as necessary for the operation of the hospital or the performance of the research agreement,

2. The restraints or requirements imposed by such factors as arm's length bargaining, federal and state laws and regulations, and research agreement terms and conditions,

3. Whether or not the individuals concerned acted with due prudence in the circumstances, considering their responsibilities to the hospital, its patients, its employees, its students, the Government, and the public at large, and

4. The extent to which the actions taken with respect to the incurrence of the cost are consistent with established hospital policies and practices applicable to the work of the hospital generally, including Government research.

D. *Allocable costs.* 1. A cost is allocable to a particular cost center (i.e., a specific function, project, research agreement, department, or the like) if the goods or services involved are chargeable or assignable to such cost center in accordance with relative benefits received or other equitable relationship. Subject to the foregoing, a cost is allocable to a research agreement if it is incurred solely to advance the work under the research agreement; or it benefits both the research agreement and other work of the hospital in proportions that can be approximated through use of reasonable methods; or it is necessary to the overall operation of the hospital and, in light of the standards provided in this chapter, is deemed to be assignable in part to organized research. Where the purchase of equipment or other capital items are specifically authorized under a research agreement, the amounts thus authorized for such purchases are allocable to the research agreement regardless of the use that may subsequently be made of the equipment or other capital items involved.

2. Any costs allocable to a particular research agreement under the standards provided in these principles may not be shifted to other research agreements in order to meet deficiencies caused by overruns or other fund considerations, to avoid restrictions imposed by law or by terms of the research agreement, or for other reasons of convenience.

E. *Applicable credits.* 1. The term applicable credits refers to those receipts or negative expenditure types of transactions which operate to offset or reduce expense items that are allocable to research agreements as direct or indirect costs as outlined in paragraph V-A. Typical examples of such transactions are: purchase discounts, rebates, or allowances; recoveries or indemnities on losses; sales of scrap or incidental services; tuition; adjustments of overpayments or erroneous charges; and services rendered to patients admitted to federally funded clinical research centers, primarily for care though also participating in research protocols.

2. In some instances, the amounts received from the Federal Government to finance hospital activities or service operations should be treated as applicable credits. Specifically, the concept of netting such credit items against related expenditures should be applied by the hospital in determining the rates or amounts to be charged to government research for services rendered whenever the facilities or other resources used in

providing such services have been financed directly, in whole or in part, by federal funds. Thus, where such items are provided for or benefit a particular hospital activity, i.e., patient care, research, instruction and training, or other, they should be treated as an offset to the indirect costs apportioned to that activity. Where the benefits are common to all hospital activities they should be treated as a credit to the total indirect cost pool before allocation to the various cost objectives.

IV. DIRECT COSTS

A. *General*. Direct costs are those that can be identified specifically with a particular cost center. For this purpose, the term cost center refers not only to the ultimate centers against which costs are finally lodged such as research agreements, but also to other established cost centers such as the individual accounts for recording particular objects or items of expense, and the separate account groupings designed to record the expenses incurred by individual organizational units, functions, projects and the like. In general, the administrative functions and service activities described in paragraph VI are identifiable as separate cost centers, and the expenses associated with such centers become eligible in due course for distribution as indirect costs of research agreements and other ultimate cost centers.

B. *Application to research agreements*. Identifiable benefit to the research work rather than the nature of the goods and services involved is the determining factor in distinguishing direct from indirect costs of research agreements. Typical of transactions chargeable to a research agreement as direct costs are the compensation of employees for the time or effort devoted to the performance of work under the research agreement, including related staff benefit and pension plan costs to the extent that such items are consistently accorded to all employees and treated by the hospital as direct rather than indirect costs (see paragraph V. B4b); the costs of materials consumed or expended in the performance of such work; and other items of expense incurred for the research agreement, such as extraordinary utility consumption. The cost of materials supplied from stock or services rendered by specialized facilities or other institutional service operations may be included as direct costs of research agreements provided such items are consistently treated by the institution as direct rather than indirect costs and are charged under a recognized method of costing or pricing designed to recover only the actual direct and indirect costs of such material or service and conforming to generally accepted cost accounting practices consistently followed by the institution.

V. INDIRECT COSTS

A. *General*. Indirect costs are those that have been incurred for common or joint objectives, and thus are not readily subject to treatment as direct costs of research agreements or other ultimate or revenue producing cost centers. In hospitals such costs normally are classified but not necessarily restricted to the following functional categories: Depreciation; Administrative and General (including fringe benefits if not charged directly); Operation of Plant; Maintenance of Plant; Laundry and Linen Service; Housekeeping; Dietary; Maintenance of Personnel; and Medical Records and Library.

B. *Criteria for distribution*—1. *Base period*. A base period for distribution of indirect costs is the period during which such costs are incurred and accumulated for distribution to work performed within that period. The base period normally should coincide with the fiscal year established by the hospital, but in any event the base period should be so selected as to avoid inequities in the distribution of costs.

2. *Need for cost groupings*. The overall objective of the allocation process is to distribute the indirect costs described in paragraph VI to organized research, patient care, instruction and training, and other hospital activities in reasonable proportions consistent with the nature and extent of the use of the hospital's resources by research personnel, medical staff, patients, students, and other personnel or organizations. In order to achieve this objective with reasonable precision, it may be necessary to provide for selective distribution by establishing separate groupings of cost within one or more of the functional categories of indirect costs referred to in paragraph V-A. In general, the cost groupings established within a functional category should constitute, in each case, a pool of those items of expense that are considered to be of like character in terms of their relative contribution to (or degree of remoteness from) the particular cost centers to which distribution is appropriate. Each such pool or cost grouping should then be distributed individually to the related cost centers, using the distribution base or method most appropriate in the light of the guides set out in B3 below. While this paragraph places primary emphasis on a step-down method of indirect cost computation, paragraph VIII provides an alternate method which may be used under certain conditions.

3. *Selection of distribution method*. Actual conditions must be taken into account in selecting the method or base to be used in distributing to related cost centers the expenses assembled under each of the individual cost groups established as indicated under B2 above. Where a distribution can be

made by assignment of a cost grouping directly to the area benefited, the distribution should be made in that manner. Care should be given, however, to eliminate similar or duplicative costs from any other distribution made to this area. Where the expenses under a cost grouping are more general in nature, the distribution to related cost centers should be made through use of a selected base which will produce results which are equitable to both the Government and the hospital. In general, any cost element or cost-related factor associated with the hospital's work is potentially adaptable for use as a distribution base provided:

a. It can readily be expressed in terms of dollars or other quantitative measure (total direct expenditures, direct salaries, manhours applied, square feet utilized, hours of usage, number of documents processed, population served, and the like); and

b. It is common to the related cost centers during the base period. The essential consideration in selection of the distribution base in each instance is that it be the one best suited for assigning the pool of costs to related cost centers in accord with the relative benefits derived; the traceable cause and effect relationship; or logic and reason, where neither benefit nor cause and effect relationship is determinable.

4. *General consideration on cost groupings.* The extent to which separate cost groupings and selective distribution would be appropriate at a hospital is a matter of judgment to be determined on a case-by-case basis. Typical situations which may warrant the establishment of two or more separate cost groups (based on account classification or analysis) within a functional category include but are not limited to the following:

a. Where certain items or categories of expense relate solely to one of the major divisions of the hospital (patient care, sponsored research, instruction and training, or other hospital activities) or to any two but not all, such expenses should be set aside as a separate cost grouping for direct assignment or selective distribution in accordance with the guides provided in B2 and B3 above.

b. Where any types of expense ordinary treated as indirect cost as outlined in paragraph V-A are charged to research agreements as direct costs, the similar type expenses applicable to other activities of the institution must through separate cost grouping be excluded from the indirect costs allocable to research agreements.

c. Where it is determined that certain expenses are for the support of a service unit or facility whose output is susceptible of measurement on a workload or other quantitative basis, such expenses should be set aside as a separate cost grouping for distribution on such basis to organized research and other hospital activities.

d. Where organized activities (including identifiable segments of organized research as well as the activities cited in paragraph II-E) provide their own purchasing, personnel administration, building maintenance, or housekeeping or similar service, the distribution of such elements of indirect cost to such activities should be accomplished through cost grouping which includes only that portion of central indirect costs (such as for overall management) which are properly allocable to such activities.

e. Where the hospital elects to treat as indirect charges the costs of pension plans and other staff benefits, such costs should be set aside as a separate cost grouping for selective distribution to related cost centers, including organized research.

f. Where the hospital is affiliated with a medical school or some other institution which performs organized research on the hospital's premises, every effort should be made to establish separate cost groupings in the Administrative and General or other applicable category which will reasonably reflect the use of services and facilities by such research. (See also paragraph VII-A.3)

5. *Materiality.* Where it is determined that the use of separate cost groupings and selective distribution are necessary to produce equitable results, the number of such separate cost groupings within a functional category should be held within practical limits, after taking into consideration the materiality of the amounts involved and the degree of precision attainable through less selective methods of distribution.

C. *Administration of limitations on allowances for indirect costs.* 1. Research grants may be subject to laws and/or administrative regulations that limit the allowance for indirect costs under each such grant to a stated percentage of the direct costs allowed. Agencies that sponsor such grants will establish procedures which will assure that:

a. The terms and amount authorized in each case conform with the provisions of paragraphs III, V and IX of these principles as they apply to matters involving the consistent treatment and allowability of individual items of cost; and

b. The amount actually allowed for indirect costs under each such research grant does not exceed the maximum allowable under the limitation or the amount otherwise allowable under these principles, whichever is the smaller.

2. Where the actual allowance for indirect costs on any research grant must be restricted to the smaller of the two alternative amounts referred to in C1 above, such alternative amounts should be determined in accordance with the following guides:

a. The maximum allowable under the limitation should be established by applying the stated percentage to a direct cost base which

shall include all items of expenditure authorized by the sponsoring agency for inclusion as part of the total cost for the direct benefit of the work under the grant; and

b. The amount otherwise allowable under these principles should be established by applying the current institutional indirect cost rate to those elements of direct cost which were included in the base on which the rate was computed.

3. When the maximum amount allowable under a statutory limitation or the terms of a research agreement is less than the amount otherwise allocable as indirect costs under these principles, the amount not recoverable as indirect costs under the research agreement involved may not be shifted to other research agreements.

VI. IDENTIFICATION AND ASSIGNMENT OF INDIRECT COSTS

A. *Depreciation or use charge*. 1. The expenses under this heading should include depreciation (as defined in paragraph IX-B.9a) on buildings, fixed equipment, and movable equipment, except to the extent purchased through federal funds. Where adequate records for the recording of depreciation are not available, a use charge may be substituted for depreciation (See paragraph IX-B.)

2. The expenses included in this category should be allocated to applicable cost centers in a manner consistent with the guides set forth in paragraph V-B, on a basis that gives primary emphasis to (a) space utilization with respect to depreciation on buildings and fixed equipment; and (b) specific identification of assets and their use with respect to movable equipment as it relates to patient care, organized research, instruction and training, and other hospital activities. Where such records are not sufficient for the purpose of the foregoing, reasonable estimates will suffice as a means for effecting distribution of the amounts involved.

B. *Administration and general expenses*. 1. The expenses under this heading are those that have been incurred for the administrative offices of the hospital including accounting, personnel, purchasing, information centers, telephone expense, and the like which do not relate solely to any major division of the institution, i.e., solely to patient care, organized research, instruction and training, or other hospital activities.

2. The expenses included in this category may be allocated on the basis of total expenditures exclusive of capital expenditures, or salaries and wages in situations where the results of the distribution made on this basis are deemed to be equitable both to the Government and the hospital; otherwise the distribution of Administration and General expenses should be made through use of selected bases, applied to separate cost groupings established within this category of expenses in accordance with the guides set out in paragraph V-B.

C. *Operation of plant*. 1. The expenses under this heading are those that have been incurred by a central service organization or at the departmental level for the administration, supervision, and provision of utilities (exclusive of telephone expense) and protective services to the physical plant. They include expenses incurred for such items as power plant operations, general utility costs, elevator operations, protection services, and general parking lots.

2. The expenses included in this category should be allocated to applicable cost centers in a manner consistent with the guides provided in paragraph V-B, on a basis that gives primary emphasis to space utilization. The allocations should be developed as follows:

a. Where actual space and related cost records are available or can readily be developed and maintained without significant change in the accounting practices, the amount distributed should be based on such records;

b. Where the space and related cost records maintained are not sufficient for purposes of the foregoing, a reasonable estimate of the proportion of total space assigned to the various costs centers normally will suffice as a means for effecting distribution of the amounts involved; or

c. Where it can be demonstrated that an area or volume or space basis of allocation is impractical or inequitable, other bases may be used provided consideration is given to the use of facilities by research personnel and others, including patients.

D. *Maintenance of plant*. 1. The expenses under this heading should include:

a. All salaries and wages pertaining to ordinary repair and maintenance work performed by employees on the payroll of the hospital;

b. All supplies and parts used in the ordinary repairing and maintaining of buildings and general equipment; and

c. Amounts paid to outside concerns for the ordinary repairing and maintaining of buildings and general equipment.

2. The expenses included in this category should be allocated to applicable cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to space utilization. The allocations and apportionments should be developed as follows:

a. Where actual space and related cost records are available and can readily be developed and maintained without significant change in the accounting practices, the amount distributed should be based on such records;

b. Where the space and related cost records maintained are not sufficient for purposes of the foregoing, a reasonable estimate of the

proportion of total space assigned to the various cost centers normally will suffice as a means for effecting distribution of the amounts involved; or

c. Where it can be demonstrated that an area or volume of space basis of allocation is impractical or inequitable, other basis may be used provided consideration is given to the use of facilities by research personnel and others, including patients.

E. *Laundry and linen*. 1. The expenses under this heading should include:

a. Salaries and wages of laundry department employees, seamstresses, clean linen handlers, linen delivery men, etc.;

b. Supplies used in connection with the laundry operation and all linens purchased; and

c. Amounts paid to outside concerns for purchased laundry and/or linen service.

2. The expense included in this category should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to actual pounds of linen used. The allocations should be developed as follows:

a. Where actual poundage and related cost records are available or can readily be developed and maintained without significant change in the accounting practices, the amount distributed should be based on such records;

b. Where it can be demonstrated that a poundage basis of allocation is impractical or inequitable other bases may be used provided consideration is given to the use of linen by research personnel and others, including patients.

F. *Housekeeping*. 1. The expenses under this heading should include:

a. All salaries and wages of the department head, foreman, maids, porters, janitors, wall washers, and other housekeeping employees;

b. All supplies used in carrying out the housekeeping functions; and

c. Amounts paid to outside concerns for purchased services such as window washing, insect extermination, etc.

2. The expenses included in this category should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to space actually serviced by the housekeeping department. The allocations and apportionments should be developed as follows:

a. Where actual space serviced and related cost records are available or can readily be developed and maintained without significant change in the accounting practices, the amount distributed should be based on such records;

b. Where the space serviced and related cost records maintained are not sufficient for purposes of the foregoing, a reasonable estimate of the proportion of total space assigned to the various cost centers normally will suffice as a means for effecting distribution of the amounts of housekeeping expenses involved; or

c. Where it can be demonstrated that the space serviced basis of allocation is impractical or inequitable, other bases may be used provided consideration is given to the use of housekeeping services by research personnel and others, including patients.

G. *Dietary*. 1. These expenses, as used herein, shall mean only the subsidy provided by the hospital to its employees including research personnel through its cafeteria operation. The hospital must be able to demonstrate through the use of proper cost accounting techniques that the cafeteria operates at a loss to the benefit of employees.

2. The reasonable operating loss of a subsidized cafeteria operation should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to number of employees.

H. *Maintenance (housing) of personnel*. 1. The expenses under this heading should include:

a. The salaries and wages of matrons, clerks, and other employees engaged in work in nurses' residences and other employees' quarters;

b. All supplies used in connection with the operation of such dormitories; and

c. Payments to outside agencies for the rental of houses, apartments, or rooms used by hospital personnel.

2. The expenses included in this category should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to employee utilization of housing facilities. The allocation should be developed as follows:

a. Appropriate credit should be given for all payments received from employees or otherwise to reduce the expense to be allocated;

b. A net cost per housed employee may then be computed; and

c. Allocation should be made on a departmental basis based on the number of housed employees in each respective department.

I. *Medical records and library*. 1. The expenses under this heading should include:

a. The salaries and wages of the records librarian, medical librarian, clerks, stenographers, etc.; and

b. All supplies such as medical record forms, chart covers, filing supplies, stationery, medical library books, periodicals, etc.

2. The expenses included in this category should be allocated to related cost centers in a manner consistent with the guides provided in paragraph V-B. on a basis that gives primary emphasis to a special time survey of medical records personnel. If this appears to

be impractical or inequitable, other bases may be used provided consideration is given to the use of these facilities by research personnel and others, including patients.

VII. DETERMINATION AND APPLICATION OF INDIRECT COST RATE OR RATES

A. *Indirect cost pools.* 1. Subject to (2) below, indirect costs allocated to organized research should be treated as a common pool, and the costs in such common pool should be distributed to individual research agreements benefiting therefrom on a single rate basis.

2. In some instances a single rate basis for use on all government research at a hospital may not be appropriate since it would not take into account those different environmental factors which may affect substantially the indirect costs applicable to a particular segment of government research at the institution. For this purpose, a particular segment of government research may be that performed under a single research agreement or it may consist of research under a group of research agreements performed in a common environment. The environmental factors are not limited to the physical location of the work. Other important factors are the level of the administrative support required, the nature of the facilities or other resources employed, the scientific disciplines or technical skills involved, the organizational arrangements used, or any combination thereof. Where a particular segment of government research is performed within an environment which appears to generate a significantly different level of indirect costs, provision should be made for a separate indirect cost pool applicable to such work. An example of this differential may be in the development of a separate indirect cost pool for a clinical research center grant. The separate indirect cost pool should be developed during the course of the regular distribution process, and the separate indirect cost rate resulting therefrom should be utilized provided it is determined that:

a. Such indirect cost rate differs significantly from that which would have obtained under (1) above; and

b. The volume of research work to which such rate would apply is material in relation to other government research at the institution.

3. It is a common practice for grants or contracts awarded to other institutions, typically University Schools of Medicine, to be performed on hospital premises. In these cases the hospital should develop a separate indirect cost pool applicable to the work under such grants or contracts. This pool should be developed by a selective distribution of only those indirect cost categories which benefit the work performed by the other institution, within the practical limits dictated by available data and the materiality of the amounts involved. Hospital costs determined to be allocable to grants or contracts awarded to another institution may not be recovered as a cost of grants or contracts awarded directly to the hospital.

B. *The distribution base.* Preferably, indirect costs allocated to organized research should be distributed to applicable research agreements on the basis of direct salaries and wages. However, where the use of salaries and wages results in an inequitable allocation of costs to the research agreements, total direct costs or a variation thereof, may be used in lieu of salaries and wages. Regardless of the base used, an indirect cost rate should be determined for each of the separate indirect cost pools developed pursuant to paragraph VII-A. The rate in each case should be stated as the percentage which the amount of the particular indirect cost pool is of the total direct salaries and wages (or other base selected) for all research agreements identified with such a pool.

C. *Negotiated lump sum for overhead.* A negotiated fixed amount in lieu of indirect costs may be appropriate for self-contained or off-campus research activities where the benefits derived from a hospital's indirect services cannot be readily determined. Such amount negotiated in lieu of indirect costs will be treated as an offset to the appropriate indirect cost pool after allocation to patient care, organized research, instruction and training, and other hospital activities. The base on which such remaining expenses are allocated should be appropriately adjusted.

D. *Predetermined overhead rates.* The utilization of predetermined fixed overhead rates may offer potential advantages in the administration of research agreements by facilitating the preparation of research budgets and permitting more expeditious close out of the agreements when the work is completed. Therefore, to the extent allowed by law, consideration may be given to the negotiation of predetermined fixed rates in those situations where the cost experience and other pertinent factors available are deemed sufficient to enable the Government and the hospital to reach a reasonable conclusion as to the probable level of the indirect cost rate for the ensuing accounting period.

VIII. SIMPLIFIED METHOD FOR SMALL INSTITUTIONS

A. *General.* 1. Where the total direct cost of all government-sponsored research and development work at a hospital in a year is minimal, the use of the abbreviated procedure described in paragraph VIII-B below may be acceptable in the determination of allowable indirect costs. This method may also be used to initially determine a provisional indirect cost rate for hospitals that have not previously established a rate. Under

this abbreviated procedure, data taken directly from the institution's most recent annual financial report and immediately available supporting information will be utilized as a basis for determining the indirect cost rate applicable to research agreements at the institution.

2. The rigid formula approach provided under the abbreviated procedure has limitations which may preclude its use at some hospitals either because the minimum data required for this purpose are not readily available or because the application of the abbreviated procedure to the available data produces results which appear inequitable to the Government or the hospital. In any such case, indirect costs should be determined through use of the regular procedure rather than the abbreviated procedure.

3. In certain instances where the total direct cost of all government-sponsored research and development work at the hospital is more than minimal, the abbreviated procedure may be used if prior permission is obtained. This alternative will be granted only in those cases where it can be demonstrated that the step-down technique cannot be followed.

B. *Abbreviated procedure.* 1. Total expenditures as taken from the most recent annual financial report will be adjusted by eliminating from further consideration expenditures for capital items as defined in paragraph IX-B.4 and unallowable costs as defined under various headings in paragraph IX and paragraph III-E.

2. Total expenditures as adjusted under the foregoing will then be distributed among (a) expenditures applicable to administrative and general overhead functions, (b) expenditures applicable to all other overhead functions, and (c) expenditures for all other purposes. The first group shall include amounts associated with the functional categories, Administration and General, and Dietary, as defined in paragraph VI. The second group shall include Depreciation, Operation of Plant, Maintenance of Plant, and Housekeeping. The third group—expenditures for all other purposes—shall include the amounts applicable to all other activities, namely, patient care, organized research, instruction and training, and other hospital activities as defined under paragraph II-E. For the purposes of this section, the functional categories of Laundry and Linen, Maintenance of Personnel, and Medical Records and Library as defined in paragraph VI shall be considered as expenditures for all other purposes.

3. The expenditures distributed to the first two groups in paragraph VIII-B.2 should then be adjusted by those receipts or negative expenditure types of transactions which tend to reduce expense items allocable to research agreements as indirect costs. Examples of such receipts or negative expenditures are itemized in paragraph III-E.1.

4. In applying the procedures in paragraphs VIII-B.1 and B.2, the cost of unallowable activities such as Gift Shop, Investment Property Management, Fund Raising, and Public Relations, when they benefit from the hospital's indirect cost services, should be treated as expenditures for all other purposes. Such activities are presumed to benefit from the hospital's indirect cost services when they include salaries of personnel working in the hospital. When they do not include such salaries, they should be eliminated from the indirect cost rate computation.

5. The indirect cost rate will then be computed in two stages. The first stage requires the computation of an Administrative and General rate component. This is done by applying a ratio of research direct costs over total direct costs to the Administrative and General pool developed under paragraphs VIII-B.2 and B.3 above. The resultant amount—that which is allocable to research—is divided by the direct research cost base. The second stage requires the computation of an All Other Indirect Cost rate component. This is done by applying a ratio of research direct space over total direct space to All Other Indirect Cost pool developed under paragraphs VIII-B.2 and B.3 above. The resultant amount—that which is allocable to research—is divided by the direct research cost base.

The total of the two rate components will be the institution's indirect cost rate. For the purposes of this section, the research direct cost or space and total direct cost or space will be that cost or space identified with the functional categories classified under Expenditures for all other purposes under paragraph VIII-B.2.

IX. GENERAL STANDARDS FOR SELECTED ITEMS OF COST

A. *General.* This section provides standards to be applied in establishing the allowability of certain items involved in determining cost. These standards should apply irrespective of whether a particular item of cost is properly treated as direct cost or indirect cost. Failure to mention a particular item of cost in the standards is not intended to imply that it is either allowable or unallowable; rather, determination as to allowability in each case should be based on the treatment or standards provided for similar or related items of cost. In case of discrepancy between the provisions of a specific research agreement and the applicable standards provided, the provisions of the research agreement should govern. However, in some cases advance understandings should be reached on particular cost items in order that the full costs of research be supported. The extent of allowability of the selected items of cost covered in this section has been

stated to apply broadly to many accounting systems in varying environmental situations. Thus, as to any given research agreement, the reasonableness and allocability of certain items of costs may be difficult to determine, particularly in connection with hospitals which have medical school or other affiliations. In order to avoid possible subsequent disallowance or dispute based on unreasonableness or nonallocability, it is important that prospective recipients of federal funds particularly those whose work is predominantly or substantially with the Government, seek agreement with the Government in advance of the incurrence of special or unusual costs in categories where reasonableness or allocability are difficult to determine. Such agreement may also be initiated by the Government. Any such agreement should be incorporated in the research agreement itself. However, the absence of such an advance agreement on any element of cost will not in itself serve to make that element either allowable or unallowable. Examples of costs on which advance agreements may be particularly important are:

1. Facilities costs, such as;

a. Depreciation

b. Rental

c. Use charges for fully depreciated assets

d. Idle facilities and idle capacity

e. Plant reconversion

f. Extraordinary or deferred maintenance and repair

g. Acquisition of automatic data processing equipment.

2. Preaward costs

3. Non-hospital professional activities

4. Self-insurance

5. Support services charged directly (computer services, printing and duplicating services, etc.)

6. Employee compensation, travel, and other personnel costs, including;

a. Compensation for personal service, including wages and salaries, bonuses and incentives, premium payments, pay for time not worked, and supplementary compensation and benefits, such as pension and retirement, group insurance, severance pay plans, and other forms of compensation

b. Morale, health, welfare, and food service and dormitory costs

c. Training and education costs

d. Relocation costs, including special or mass personnel movement

B. *Selected items*—1. *Advertising costs*. The term advertising costs means the costs of advertising media and corollary administrative costs. Advertising media include magazines, newspapers, radio and television programs, direct mail, exhibits, and the like. The only advertising costs allowable are those which are solely for;

a. The recruitment of persons required for the performance by the institution of obligations arising under the research agreement, when considered in conjunction with all other recruitment costs as set forth in paragraph IX-B.34.

b. The procurement of scarce items for the performance of the research agreement; or

c. The disposal of scrap or surplus materials acquired in the performance of the research agreement.

Costs of this nature, if incurred for more than one research agreement or for both research agreement work and other work of the institution, are allowable to the extent that the principles in paragraphs IV and V are observed.

2. *Bad debts*. Losses arising from uncollectible accounts and other claims and related collection and legal costs are unallowable except that a bad debt may be included as a direct cost of the research agreement to the extent that it is caused by a research patient and approved by the awarding agency. This inclusion is only intended to cover the situation of the patient admitted for research purposes who subsequently or in conjunction with the research receives clinical care for which a charge is made to the patient. If, after exhausting all means of collecting these charges, a bad debt results, it may be considered an appropriate charge to the research agreement.

3. *Bonding costs*. a. Bonding costs arise when the Government requires assurance against financial loss to itself or others by reason of the act or default of the hospital. They arise also in instances where the hospital requires similar assurance.

Included are such types as bid, performance, payment, advance payment, infringement, and fidelity bonds.

b. Costs of bonding required pursuant to the terms of the research agreement are allowable.

c. Costs of bonding required by the hospital in the general conduct of its business are allowable to the extent that such bonding is in accordance with sound business practice and the rates and premiums are reasonable under the circumstances.

4. *Capital expenditures*. The costs of equipment, buildings, and repairs which materially increase the value or useful life of buildings or equipment should be capitalized and are unallowable except as provided for in the research agreement.

5. *Civil defense costs*. Civil defense costs are those incurred in planning for, and the protection of life and property against the possible effects of enemy attack. Reasonable costs of civil defense measures (including costs in excess of normal plant protection costs, first-aid training and supplies, firefighting training, posting of additional exit notices and directions, and other approved civil defense measures) undertaken on the institution's premises pursuant to suggestions or requirements of civil defense authorities are allowable when distributed to

all activities of the institution. Capital expenditures for civil defense purposes will not be allowed, but a use allowance or depreciation may be permitted in accordance with provisions set forth elsewhere. Costs of local civil defense projects not on the institution's premises are unallowable.

6. *Communication costs.* Costs incurred for telephone services, local and long distance telephone calls, telegrams, radiograms, postage, and the like are allowable.

7. *Compensation for personal services*— a. *General.* Compensation for personal services covers all remuneration paid currently or accrued to employees of the hospital for services rendered during the period of performance under government research agreements. Such remuneration includes salaries, wages, staff benefits (see paragraph IX-B.10), and pension plan costs (see paragraph IX-B.25). The costs of such remuneration are allowable to the extent that the total compensation to individual employees is reasonable for the services rendered and conforms to the established policy of the institution consistently applied, and provided that the charges for work performed directly on government research agreements and for other work allocable as indirect costs to sponsored research are determined and supported as hereinafter provided. For non-profit, non-proprietary institutions, where federally supported programs constitute less than a preponderance of the activity at the institution the primary test of reasonableness will be to require that the institution's compensation policies be applied consistently both to federally-sponsored and non-sponsored activities alike. However, where special circumstances so dictate a contractual clause may be utilized which calls for application of the test of comparability in determining the reasonableness of compensation.

b. *Payroll distribution.* Amounts charged to organized research for personal services, regardless of whether treated as direct costs or allocated as indirect costs, will be based on hospital payrolls which have been approved and documented in accordance with generally accepted hospital practices. In order to develop necessary direct and indirect allocations of cost, supplementary data on time or effort as provided in paragraph (c) below, normally need be required only for individuals whose compensation is properly chargeable to two or more research agreements or to two or more of the following broad functional categories: (1) Patient care; (2) organized research; (3) instruction and training; (4) indirect activities as defined in paragraph V-A; or (5) other hospital activities as defined in paragraph II-E.

c. *Reporting time or effort.* Charges for salaries and wages of individuals other than members of the professional staff will be supported by daily time and attendance and payroll distribution records. For members of the professional staff, current and reasonable estimates of the percentage distribution of their total effort may be used as support in the absence of actual time records. The term professional staff for purposes of this section includes physicians, research associates, and other personnel performing work at responsible levels of activities. These personnel normally fulfill duties, the competent performance of which usually requires persons possessing degrees from accredited institutions of higher learning and/or state licensure. In order to qualify as current and reasonable, estimates must be made no later than one month (though not necessarily a calendar month) after the month in which the services were performed.

d. *Preparation of estimates of effort.* Where required under paragraph (c) above, estimates of effort spent by a member of the professional staff on each research agreement should be prepared by the individual who performed the services or by a responsible individual such as a department head or supervisor having first-hand knowledge of the services performed on each research agreement. Estimates must show the allocation of effort between organized research and all other hospital activities in terms of the percentage of total effort devoted to each of the broad functional categories referred to in (b) above. The estimate of effort spent on a research agreement may include a reasonable amount of time spent in activities contributing and intimately related to work under the agreement, such as preparing and delivering special lectures about specific aspects of the ongoing research, writing research reports and articles, participating in appropriate research seminars, consulting with colleagues with respect to related research, and attending appropriate scientific meetings and conferences. The term ''all other hospital activities'' would include departmental research, administration, committee work, and public services undertaken on behalf of the hospital.

e. *Application of budget estimates.* Estimates determined before the performance of services, such as budget estimates on a monthly, quarterly, or yearly basis do not qualify as estimates of effort spent.

f. *Non-hospital professional activities.* A hospital must not alter or waive hospital-wide policies and practices dealing with the permissible extent of professional services over and above those traditionally performed without extra hospital compensation, unless such arrangements are specifically authorized by the sponsoring agency. Where hospital-wide policies do not adequately define the permissible extent of consultantships or other non-hospital activities undertaken for extra pay, the Government may require that the effort of professional staff working under research agreements be allocated as between (1) hospital activities, and (2) non-hospital

professional activities. If the sponsoring agency should consider the extent of non-hospital professional effort excessive, appropriate arrangements governing compensation will be negotiated on a case by case basis.

g. *Salary rates for part-time appointments.* Charges for work performed on government research by staff members having only part-time appointments will be determined at a rate not in excess of that for which he is regularly paid for his part-time staff assignment.

8. *Contingency provisions.* Contributions to a contingency reserve or any similar provisions made for events the occurrence of which cannot be foretold with certainty as to time, intensity, or with an assurance of their happening, are unallowable.

9. *Depreciation and use allowances.* a. Hospitals may be compensated for the use of buildings, capital improvements and usable equipment on hand through depreciation or use allowances. Depreciation is a charge to current operations which distributes the cost of a tangible capital asset, less estimated residual value, over the estimated useful life of the asset in a systematic and logical manner. It does not involve a process of valuation. Useful life has reference to the prospective period of economic usefulness in the particular hospital's operations as distinguished from physical life. Use allowances are the means of allowing compensation when depreciation or other equivalent costs are not considered.

b. Due consideration will be given to government-furnished research facilities utilized by the institution when computing use allowances and/or depreciation if the government-furnished research facilities are material in amount. Computation of the use allowance and/or depreciation will exclude both the cost or any portion of the cost of grounds, buildings and equipment borne by or donated by the Federal Government, irrespective of where title was originally vested or where it presently resides, and secondly, the cost of grounds. Capital expenditures for land improvements (paved areas, fences, streets, sidewalks, utility conduits, and similar improvements not already included in the cost of buildings) are allowable provided the systematic amortization of such capital expenditures has been provided in the institution's books of accounts, based on reasonable determinations of the probable useful lives of the individual items involved, and the share allocated to organized research is developed from the amount thus amortized for the base period involved.

c. Normal depreciation on a hospital's plant, equipment, and other capital facilities, except as excluded by (d) below, is an allowable element of research cost provided that the amount thereof is computed:

1. Upon the property cost basis used by the hospital for Federal Income Tax purposes (See section 167 of the Internal Revenue Code of 1954); or

2. In the case of non-profit or tax exempt organizations, upon a property cost basis which could have been used by the hospital for Federal Income Tax purposes, had such hospital been subject to the payment of income tax; and in either case

3. By the consistent application to the assets concerned of any generally accepted accounting method, and subject to the limitations of the Internal Revenue Code of 1954 as amended, including—

i. The straight line method;

ii. The declining balance method, using a rate not exceeding twice the rate which would have been used had the annual allowance been computed under the method described in (i) above;

iii. The sum of the years-digits method; and

iv. Any other consistent method productive of an annual allowance which, when added to all allowances for the period commencing with the use of the property and including the current year, does not during the first two-thirds of the useful life of the property exceed the total of such allowances which would have been used had such allowances been computed under the method described in (ii) above.

d. Where the depreciation method is followed, adequate property records must be maintained. The period of useful service (service life) established in each case for usable capital assets must be determined on a realistic basis which takes into consideration such factors as type of construction, nature of the equipment used, technological developments in the particular research area, and the renewal and replacement policies followed for the individual items or classes of assets involved. Where the depreciation method is introduced for application to assets acquired in prior years, the annual charges therefrom must not exceed the amounts that would have resulted had the depreciation method been in effect from the date of acquisition of such assets.

e. Depreciation on idle or excess facilities shall not be allowed except on such facilities as are reasonably necessary for standby purposes.

f. Where an institution elects to go on a depreciation basis for a particular class of assets, no depreciation, rental or use charge may be allowed on any such assets that would be viewed as fully depreciated; provided, however, that reasonable use charges may be negotiated for any such assets if warranted after taking into consideration the cost of the facility or item involved, the estimated useful life remaining at time of negotiation, the actual replacement policy followed in the light of service lives used for

calculating depreciation, the effect of any increased maintenance charges or decreased efficiency due to age, and any other factors pertinent to the utilization of the facility or item for the purpose contemplated.

g. Hospitals which choose a depreciation allowance for assets purchased prior to 1966 based on a percentage of operating costs in lieu of normal depreciation for purposes of reimbursement under Pub. L. 89–97 (Medicare) shall utilize that method for determining depreciation applicable to organized research.

The operating costs to be used are the lower of the hospital's 1965 operating costs or the hospital's current year's allowable costs. The percent to be applied is 5 percent starting with the year 1966–67, with such percentage being uniformity reduced by one-half percent each succeeding year. The allowance based on operating costs is in addition to regular depreciation on assets acquired after 1965. However, the combined amount of such allowance on pre-1966 assets and the allowance for actual depreciation on assets acquired after 1965 may not exceed 6 percent of the hospital's allowable cost for the current year. After total depreciation has been computed, allocation methods are used to determine the share attributable to organized research.

For purposes of this section, *Operating Costs* means the total costs incurred by the hospital in operating the institution, and includes patient care, research, and other activities. *Allowable Costs* means operating costs less unallowable costs as defined in these principles; by the application of allocation methods to the total amount of such allowable costs, the share attributable to Federally-sponsored research is determined.

A hospital which elects to use this procedure under Pub. L. 89–97 and subsequently changes to an actual depreciation basis on pre-1966 assets in accordance with the option afforded under the Medicare program shall simultaneously change to an actual depreciation basis for organized research.

Where the hospital desires to change to actual depreciation but either has no historical cost records or has incomplete records, the determination of historical cost could be made through appropriate means involving expert consultation with the determination being subject to review and approval by the Department of Health and Human Services.

h. Where the use allowance method is followed, the use allowance for buildings and improvements will be computed at an annual rate not exceeding two percent of acquisition cost. The use allowance for equipment will be computed at an annual rate not exceeding six and two-thirds percent of acquisition cost of usable equipment in those cases where the institution maintains current records with respect to such equipment on hand. Where the institution's records reflect only the cost (actual or estimated) of the original complement of equipment, the use allowance will be computed at an annual rate not exceeding ten percent of such cost. Original complement for this purpose means the complement of equipment initially placed in buildings to perform the functions currently being performed in such buildings; however, where a permanent change in the function of a building takes place, a redetermination of the original complement of equipment may be made at that time to establish a new original complement. In those cases where no equipment records are maintained, the institution will justify a reasonable estimate of the acquisition cost of usable equipment which may be used to compute the use allowance at an annual rate not exceeding six and two-thirds percent of such estimate.

i. Depreciation and/or use charges should usually be allocated to research and other activities as an indirect cost.

10. *Employee morale, health, and welfare costs and credits.* The costs of house publications, health or first-aid benefits, recreational activities, employees' counseling services, and other expenses incurred in accordance with the hospital's established practice or custom for the improvement of working conditions, employer-employee relations, employee morale, and employee performance, are allowable. Such costs will be equitably apportioned to all activities of the hospital. Income generated from any of these activities will be credited to the cost thereof unless such income has been irrevocably set over to employee welfare organizations.

11. *Entertainment costs.* Except as pertains to 10 above, costs incurred for amusement, social activities, entertainment, and any items relating thereto, such as meals, lodging, rentals, transportation, and gratuities are unallowable.

12. *Equipment and other facilities.* The cost of equipment or other facilities are allowable on a direct charge basis where such purchases are approved by the sponsoring agency concerned or provided for by the terms of the research agreement.

13. *Fines and penalties.* Costs resulting from violations of, or failure of the institution to comply with federal, state and local laws and regulations are unallowable except when incurred as a result of compliance with specific provisions of the research agreement, or instructions in writing from the awarding agency.

14. *Insurance and indemnification.* a. Costs of insurance required or approved and maintained pursuant to the research agreement are allowable.

b. Costs of other insurance maintained by the hospital in connection with the general conduct of its activities are allowable subject to the following limitations: (1) Types and extent and cost of coverage must be in

accordance with sound institutional practice; (2) costs of insurance or of any contributions to any reserve covering the risk of loss of or damage to government owned property are unallowable except to the extent that the Government has specifically required or approved such costs; and (3) costs of insurance on the lives of officers or trustees are unallowable except where such insurance is part of an employee plan which is not unduly restricted.

c. Contributions to a reserve for an approved self-insurance program are allowable to the extent that the types of coverage, extent of coverage, and the rates and premiums would have been allowed had insurance been purchased to cover the risks. Such contributions are subject to prior approval of the Government.

d. Actual losses which could have been covered by permissible insurance (through an approved self-insurance program or otherwise) are unallowable unless expressly provided for in the research agreement, except that costs incurred because of losses not covered under nominal deductible insurance coverage provided in keeping with sound management practice as well as minor losses not covered by insurance such as spoilage, breakage and disappearance of small hand tools which occur in the ordinary course of operations are allowable.

15. *Interest, fund raising and investment management costs.* a. Costs incurred for interest on borrowed capital or temporary use of endowment funds, however represented, are unallowable.

b. Costs of organized fund raising, including financial campaigns, endowment drives, solicitation of gifts and bequests, and similar expenses incurred solely to raise capital or obtain contributions are not allowable.

c. Costs of investment counsel and staff and similar expenses incurred solely to enhance income from investments are not allowable.

d. Costs related to the physical custody and control of monies and securities are allowable.

16. *Labor relations costs.* Costs incurred in maintaining satisfactory relations between the hospital and its employees, including costs of labor management committees, employees' publications, and other related activities are allowable.

17. *Losses on research agreements or contracts.* Any excess of costs over income under any agreement or contract of any nature is unallowable. This includes, but is not limited to, the hospital's contributed portion by reason of cost-sharing agreements, under-recoveries through negotiation of flat amounts for overhead, or legal or administrative limitations.

18. *Maintenance and repair costs.* a. Costs necessary for the upkeep of property (including government property unless otherwise provided for), which neither add to the permanent value of the property nor appreciably prolong its intended life, but keep it in an efficient operating condition, are to be treated as follows:

1. Normal maintenance and repair costs are allowable;

2. Extraordinary maintenance and repair costs are allowable, provided they are allocated to the periods to which applicable for purposes of determining research costs.

b. Expenditures for plant and equipment, including rehabilitation thereof, which according to generally accepted accounting principles as applied under the hospital's established policy, should be capitalized and subjected to depreciation, are allowable only on a depreciation basis.

19. *Material costs.* Costs incurred for purchased materials, supplies and fabricated parts directly or indirectly related to the research agreement, are allowable. Purchases made specifically for the research agreement should be charged thereto at their actual prices after deducting all cash discounts, trade discounts, rebates, and allowances received by the institution. Withdrawals from general stores or stockrooms should be charged at their cost under any recognized method of pricing stores withdrawals conforming to sound accounting practices consistently followed by the hospital. Incoming transportation charges are a proper part of material cost. Direct material cost should include only the materials and supplies actually used for the performance of the research agreement, and due credit should be given for any excess materials retained or returned to vendors. Due credit should be given for all proceeds or value received for any scrap resulting from work under the research agreement. Where government donated or furnished material is used in performing the research agreement, such material will be used without charge.

20. *Memberships, subscriptions and professional activity costs.* a. Costs of the hospital's membership in civic, business, technical and professional organizations are allowable.

b. Costs of the hospital's subscriptions to civic, business, professional and technical periodicals are allowable.

c. Costs of meetings and conferences, when the primary purpose is the dissemination of technical information, are allowable. This includes costs of meals, transportation, rental of facilities, and other items incidental to such meetings or conferences.

21. *Organization costs.* Expenditures such as incorporation fees, attorneys' fees, accountants' fees, brokers' fees, fees to promoters and organizers in connection with (a) organization or reorganization of a hospital, or (b) raising capital, are unallowable.

22. *Other business expenses.* Included in this item are such recurring expenses as registry and transfer charges resulting from changes

in ownership of securities issued by the hospital, cost of shareholders meetings preparation and publication of reports to shareholders, preparation and submission of required reports and forms to taxing and other regulatory bodies, and incidental costs of directors and committee meetings. The above and similar costs are allowable when allocated on an equitable basis.

23. *Patient care.* The cost of routine and ancillary or special services to research patients is an allowable direct cost of research agreements.

a. Routine services shall include the costs of the regular room, dietary and nursing services, minor medical and surgical supplies and the use of equipment and facilities for which a separate charge is not customarily made.

b. Ancillary or special services are the services for which charges are customarily made in addition to routine services, such as operating rooms, anesthesia, laboratory, BMR-EKG, etc.

c. Patient care, whether expressed as a rate or an amount, shall be computed in a manner consistent with the procedures used to determine reimbursable costs under Pub. L. 89–97 (Medicare Program) as defined under the ''Principles Of Reimbursement For Provider Costs'' published by the Social Security Administration of the Department of Health and Human Services. The allowability of specific categories of cost shall be in accordance with those principles rather than the principles for research contained herein. In the absence of participation in the Medicare program by a hospital, all references to the Medicare program in these principles shall be construed as meaning the Medicaid program.

i. Once costs have been recognized as allowable, the indirect costs or general service center's cost shall be allocated (stepped-down) to special service centers, and all patient and nonpatient costs centers based upon actual services received or benefiting these centers.

ii. After allocation, routine and ancillary costs shall be apportioned to scatter-bed research patients on the same basis as is used to apportion costs to Medicare patients, i.e. using either the departmental method or the combination method, as those methods are defined by the Social Security Administration; except that final settlement shall be on a grant-by-grant basis. However, to the extent that the Social Security Administration has recognized any other method of cost apportionment, that method generally shall also be recognized as applicable to the determination of research patient care costs.

iii. A cost center must be established on Medicare reimbursement forms for each discrete-bed unit grant award received by a hospital. Routine costs should be stepped-down to this line item(s) in the normal course of stepping-down costs under Medicare/Medicaid requirements. However, in stepping-down routine costs, consideration must be given to preventing a step-down of those costs to discrete-bed unit line items that have already been paid for directly by the grant, such as bedside nursing costs. Ancillary costs allocable to research discrete-bed units shall be determined and proposed in accordance with Section 23.c.ii.

d. Where federally sponsored research programs provide specifically for the direct reimbursement of nursing, dietary, and other services, appropriate adjustment must be made to patient care costs to preclude duplication and/or misallocation of costs.

24. *Patent costs.* Costs of preparing disclosures, reports and other documents required by the research agreement and of searching the art to the extent necessary to make such invention disclosures are allowable. In accordance with the clauses of the research agreement relating to patents, costs of preparing documents and any other patent costs, in connection with the filing of a patent application where title is conveyed to the Government, are allowable. (See also paragraph IX-B.36.)

25. *Pension plan costs.* Costs of the hospital's pension plan which are incurred in accordance with the established policies of the institution are allowable, provided such policies meet the test of reasonableness and the methods of cost allocation are not discriminatory, and provided appropriate adjustments are made for credits or gains arising out of normal and abnormal employee turnover or any other contingencies that can result in forfeitures by employees which inure to the benefit of the hospital.

26. *Plan security costs.* Necessary expenses incurred to comply with government security requirements including wages, uniforms and equipment of personnel engaged in plant protection are allowable.

27. *Preresearch agreement costs.* Costs incurred prior to the effective date of the research agreement, whether or not they would have been allowable thereunder if incurred after such date, are unallowable unless specifically set forth and identified in the research agreement.

28. *Professional services costs.* a. Costs of professional services rendered by the members of a particular profession who are not employees of the hospital are allowable subject to (b) and (c) below when reasonable in relation to the services rendered and when not contingent upon recovery of the costs from the Government. Retainer fees to be allowable must be reasonably supported by evidence of services rendered.

b. Factors to be considered in determining the allowability of costs in a particular case include (1) the past pattern of such costs, particularly in the years prior to the award of government research agreements on the

institution's total activity; (2) the nature and scope of managerial services expected of the institution's own organizations; and (3) whether the proportion of government work to the hospital's total activity is such as to influence the institution in favor of incurring the cost, particularly where the services rendered are not of a continuing nature and have little relationship to work under government research agreements.

c. Costs of legal, accounting and consulting services, and related costs incurred in connection with organization and reorganization or the prosecution of claims against the Government are unallowable. Costs of legal, accounting and consulting services, and related costs incurred in connection with patent infringement litigation are unallowable unless otherwise provided for in the research agreement.

29. *Profits and losses on disposition of plant equipment, or other assets.* Profits or losses of any nature arising from the sale or exchange of plant, equipment, or other capital assets, including sales or exchange of either short- or long-term investments, shall be excluded in computing research agreement costs.

30. *Proposal costs.* Proposal costs are the costs of preparing bids or proposals on potential government and non-government research agreements or projects, including the development of technical data and cost data necessary to support the institution's bids or proposals. Proposal costs of the current accounting period of both successful and unsuccessful bids and proposals normally should be treated as indirect costs and allocated currently to all activities of the institution, and no proposal costs of past accounting periods will be allocable in the current period to the government research agreement. However, the institution's established practices may be to treat proposal costs by some other recognized method. Regardless of the methods used, the results obtained may be accepted only if found to be reasonable and equitable.

31. *Public information services costs.* Costs of news releases pertaining to specific research or scientific accomplishment are unallowable unless specifically authorized by the sponsoring agency.

32. *Rearrangement and alteration costs.* Costs incurred for ordinary or normal rearrangement and alteration of facilities are allowable. Special rearrangement and alteration costs incurred specifically for a project are allowable only as a direct charge when such work has been approved in advance by the sponsoring agency concerned.

33. *Reconversion costs.* Costs incurred in the restoration or rehabilitation of the institution's facilities to approximately the same condition existing immediately prior to commencement of government research agreement work, fair wear and tear excepted, are allowable.

34. *Recruiting costs.* a. Subject to (b), (c), and (d) below, and provided that the size of the staff recruited and maintained is in keeping with workload requirements, costs of ''help wanted'' advertising, operating costs of an employment office necessary to secure and maintain an adequate staff, costs of operating an aptitude and educational testing program, travel costs of employees while engaged in recruiting personnel, travel costs of applicants for interviews for prospective employment, and relocation costs incurred incident to recruitment of new employees are allowable to the extent that such costs are incurred pursuant to a well managed recruitment program. Where an institution uses employment agencies, costs not in excess of standard commercial rates for such services are allowable.

b. In publications, costs of help wanted advertising that includes color, includes advertising material for other than recruitment purposes, or is excessive in size (taking into consideration recruitment purposes for which intended and normal institutional practices in this respect) are unallowable.

c. Costs of help wanted advertising, special emoluments; fringe benefits, and salary allowances incurred to attract professional personnel from other institutions that do not meet the test of reasonableness or do not conform with the established practices of the institution are unallowable.

d. Where relocation costs incurred incident to recruitment of a new employee have been allowed either as an allocable direct or indirect cost, and the newly hired employee resigns for reasons within his control within twelve months after hire, the institution will be required to refund or credit such relocations costs as were charged to the Government.

35. *Rental costs (including sale and lease-back of facilities).* a. Rental costs of land, building, and equipment and other personal property are allowable if the rates are reasonable in light of such factors as rental costs of comparable facilities and market conditions in the area, the type, life expectancy, condition, and value of the facilities leased, options available, and other provisions of the rental agreement. Application of these factors, in situations where rentals are extensively used, may involve among other considerations comparison of rental costs with the amount which the hospital would have received had it owned the facilities.

b. Charges in the nature of rent between organizations having a legal or other affiliation or arrangement such as hospitals, medical schools, foundations, etc., are allowable to the extent such charges do not exceed the normal costs of ownership such as depreciation, taxes, insurance, and maintenance, provided that no part of such costs shall duplicate any other allowed costs.

c. Unless otherwise specifically provided in the agreement, rental costs specified in sale and lease-back agreements incurred by hospitals through selling plant facilities to investment organizations such as insurance companies or to private investors, and concurrently leasing back the same facilities are allowable only to the extent that such rentals do not exceed the amount which the hospital would have received had it retained legal title to the facilities.

36. *Royalties and other costs for use of patents.* Royalties on a patent or amortization of the cost of acquiring a patent or invention or rights thereto necessary for the proper performance of the research agreement and applicable to tasks or processes thereunder are allowable unless the Government has a license or the right to free use of the patent, the patent has been adjudicated to be invalid, or has been administratively determined to be invalid, the patent is considered to be unenforceable, or the patent has expired.

37. *Severance pay.* a. Severance pay is compensation in addition to regular salaries and wages which is paid by a hospital to employees whose services are being terminated. Costs of severance pay are allowable only to the extent that such payments are required by law, by employer-employee agreement, by established policy that constitutes in effect an implied agreement on the institution's part, or by circumstances of the particular employment.

b. Severance payments that are due to normal, recurring turnover, and which otherwise meet the conditions of (a) above may be allowed provided the actual costs of such severance payments are regarded as expenses applicable to the current fiscal year and are equitably distributed among the institution's activities during that period.

c. Severance payments that are due to abnormal or mass terminations are of such conjectural nature that allowability must be determined on a case-by-case basis. However, the Government recognizes its obligation to participate to the extent of its fair share in any specific payment.

38. *Specialized service facilities operated by a hospital.* a. The costs of institutional services involving the use of highly complex and specialized facilities such as electronic computers and reactors are allowable provided the charges therefor meet the conditions of (b) or (c) below, and otherwise take into account any items of income or federal financing that qualify as applicable credits under paragraph III-E.

b. The costs of such hospital services normally will be charged directly to applicable research agreements based on actual usage or occupancy of the facilities at rates that (1) are designed to recover only actual costs of providing such services, and (2) are applied on a nondiscriminatory basis as between organized research and other work of the hospital including commercial or accommodation sales and usage by the hospital for internal purposes. This would include use of such facilities as radiology, laboratories, maintenance men used for a special purpose, medical art, photography, etc.

c. In the absence of an acceptable arrangement for direct costing as provided in (b) above, the costs incurred for such institutional services may be assigned to research agreements as indirect costs, provided the methods used achieve substantially the same results. Such arrangements should be worked out in coordination with all government users of the facilities in order to assure equitable distribution of the indirect costs.

39. *Special administrative costs.* Costs incurred for general public relations activities, catalogs, alumni activities, and similar services are unallowable.

40. *Staff and/or employee benefits.* a. Staff and/or employee benefits in the form of regular compensation paid to employees during periods of authorized absences from the job such as for annual leave, sick leave, military leave and the like are allowable provided such costs are absorbed by all hospital activities including organized research in proportion to the relative amount of time or effort actually devoted to each.

b. Staff benefits in the form of employer contributions or expenses for Social Security taxes, employee insurance, Workmen's Compensation insurance, the Pension Plan (see paragraph IX-B.25), hospital costs or remission of hospital charges to the extent of costs for individual employees or their families, and the like are allowable provided such benefits are granted in accordance with established hospital policies, and provided such contributions and other expenses whether treated as indirect costs or an increment of direct labor costs are distributed to particular research agreements and other activities in a manner consistent with the pattern of benefits accruing to the individuals or groups of employees whose salaries and wages are chargeable to such research agreements and other activities.

41. *Taxes.* a. In general, taxes which the hospital is required to pay and which are paid or accrued in accordance with generally accepted accounting principles, and payments made to local governments in lieu of taxes which are commensurate with the local government services received are allowable except for (1) taxes from which exemptions are available to the hospital directly or which are available to the hospital based on an exemption afforded the Government and in the latter case when the sponsoring agency makes available the necessary exemption certificates, (2) special assessments on land which represent capital improvements, and (3) Federal Income Taxes.

b. Any refund of taxes, interest, or penalties, and any payment to the hospital of interest thereon attributable to taxes, interest or penalties, which were allowed as research agreement costs will be credited or paid to the Government in the manner directed by the Government provided any interest actually paid or credited to a hospital incident to a refund of tax, interest, and penalty will be paid or credited to the Government only to the extent that such interest accrued over the period during which the hospital had been reimbursed by the Government for the taxes, interest, and penalties.

42. *Transportation costs.* Costs incurred for inbound freight, express, cartage, postage and other transportation services relating either to goods purchased, in process, or delivered are allowable. When such costs can readily be identified with the items involved, they may be charged directly as transportation costs or added to the cost of such items. Where identification with the material received cannot readily be made, inbound transportation costs may be charged to the appropriate indirect cost accounts if the institution follows a consistent equitable procedure in this respect. Outbound freight, if reimbursable under the terms of the research agreement, should be treated as a direct cost.

43. *Travel costs.* a. Travel costs are the expenses for transportation, lodging, subsistence, and related items incurred by employees who are in travel status on official business of the hospital. Such costs may be charged on an actual basis, on a per diem or mileage basis in lieu of actual costs incurred, or on a combination of the two provided the method used is applied to an entire trip and not to selected days of the trip, and results in charges consistent with those normally allowed by the institution in its regular operations.

b. Travel costs are allowable subject to (c) and (d) below when they are directly attributable to specific work under a research agreement or when they are incurred in the normal course of administration of the hospital or a department or research program thereof.

c. The difference in cost between first class air accommodations and less than first class air accommodations is unallowable except when less than first class air accommodations are not reasonably available to meet necessary mission requirements such as where less than first class accommodations would (1) require circuitous routing, (2) require travel during unreasonable hours, (3) greatly increase the duration of the flight, (4) result in additional costs which would offset the transportation savings, or (5) offer accommodations which are not reasonably adequate for the medical needs of the traveler.

d. Costs of personnel movements of a special or mass nature are allowable only when authorized or approved in writing by the sponsoring agency or its authorized representative.

44. *Termination costs applicable to contracts.* a. Contract terminations generally give rise to the incurrence of costs or to the need for special treatment of costs which would not have arisen had the contract not been terminated. Items peculiar to termination are set forth below. They are to be used in conjunction with all other provisions of these principles in the case of contract termination.

b. The cost of common items of material reasonably usable on the hospital's other work will not be allowable unless the hospital submits evidence that it could not retain such items at cost without sustaining a loss. In deciding whether such items are reasonably usable on other work of the institution, consideration should be given to the hospital's plans for current scheduled work or activities including other research agreements. Contemporaneous purchases of common items by the hospital will be regarded as evidence that such items are reasonably usable on the hospital's other work. Any acceptance of common items as allowable to the terminated portion of the contract should be limited to the extent that the quantities of such items on hand, in transit, and on order are in excess of the reasonable quantitative requirement of other work.

c. If in a particular case, despite all reasonable efforts by the hospital, certain costs cannot be discontinued immediately after the effective date of termination, such costs are generally allowable within the limitations set forth in these principles, except that any such costs continuing after termination due to the negligent or willful failure of the hospital to discontinue such costs will be considered unacceptable.

d. Loss of useful value of special tooling and special machinery and equipment is generally allowable, provided (1) such special tooling, machinery or equipment is not reasonably capable of use in the other work of the hospital; (2) the interest of the Government is protected by transfer of title or by other means deemed appropriate by the contracting officer; and (3) the loss of useful value as to any one terminated contract is limited to that portion of the acquisition cost which bears the same ratio to the total acquisition cost as the terminated portion of the contract bears to the entire terminated contract and other government contracts for which the special tooling, special machinery or equipment was acquired.

e. Rental costs under unexpired leases are generally allowable where clearly shown to have been reasonably necessary for the performance of the terminated contract, less the residual value of such leases, if (1) the

amount of such rental claimed does not exceed the reasonable use value of the property leased for the period of the contract and such further period as may be reasonable; and (2) the hospital makes all reasonable efforts to terminate, assign, settle, or otherwise reduce the cost of such lease. There also may be included the cost of alterations of such leased property, provided such alterations were necessary for the performance of the contract and of reasonable restoration required by the provisions of the lease.

f. Settlement expenses including the following are generally allowable: (1) Accounting, legal, clerical, and similar costs reasonably necessary for the preparation and presentation to contracting officers of settlement claims and supporting data with respect to the terminated portion of the contract and the termination and settlement of subcontracts; and (2) reasonable costs for the storage, transportation, protection, and disposition of property provided by the Government or acquired or produced by the institution for the contract.

g. Subcontractor claims including the allocable portion of claims which are common to the contract and to other work of the contractor are generally allowable.

45. *Voluntary services.* The value of voluntary services provided by sisters or other members of religious orders is allowable provided that amounts do not exceed that paid other employees for similar work. Such amounts must be identifiable in the records of the hospital as a legal obligation of the hospital. This may be reflected by an agreement between the religious order and the hospital supported by evidence of payments to the order.

APPENDIXES F–H TO PART 74
[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.

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 programs 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.
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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 pursuant 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.

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.

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 $5,500[1] for each such claim.

(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 $5,500[2] for each such statement.

(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;

[1] As adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–143).

[2] As adjusted in accordance with the Federal Civil Monetary Penalty Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L 104–143).

(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 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]

§ 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.

(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.

(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 § 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.

(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 parities 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 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 communciate 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;

(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) Simplication of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact____, or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery;

(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 revelant 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 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;

(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 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 following 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.

§ 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;

(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—

(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 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 paragraph, 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 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 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.
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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.

§ 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 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.

(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 competive 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, 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 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 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 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]

§ 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 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, 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 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, 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 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 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 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 noncompliance 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 discrimination 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 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 casual 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).

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 disabilities 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 primate 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 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)).

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 C.F.R. 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).

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).

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).

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]

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 recipient, 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 *subrecipient*, 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.

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 origin, 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 nondiscrimination, 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 predominantely 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 nondiscrimination, 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, 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 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 nonhandicapped 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 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]

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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 contumacious 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.

§ 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 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 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:

(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 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.

§ 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 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 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 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 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

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83.3 Remedial and affirmative actions.
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83.10 General obligations.
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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 overcome 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 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 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 of 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 (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:

(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 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 nondiscrimination 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.

PART 84—NONDISCRIMINATION ON THE BASIS OF HANDICAP IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

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APPENDIX C TO PART 84—GUIDELINES RELATING TO HEALTH CARE FOR HANDICAPPED INFANTS

AUTHORITY: 20 U.S.C. 1405; 29 U.S.C. 794; 42 U.S.C. 290dd–2; 21 U.S.C. 1174.

SOURCE: 42 FR 22677, May 4, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 84.1 Purpose.

The purpose of this part is to effectuate section 504 of the Rehabilitation

Act of 1973, which is designed to eliminate discrimination on the basis of handicap in any program or activity receiving Federal financial assistance.

§ 84.2 Application.

This part applies to each recipient of Federal financial assistance from the Department of Health and Human Services and to the program or activity that receives such assistance.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.3 Definitions.

As used in this part, the term:

(a) *The Act* means the Rehabilitation Act of 1973, Pub. L. 93–112, as amended by the Rehabilitation Act Amendments of 1974, Pub. L. 93–516, 29 U.S.C. 794.

(b) *Section 504* means section 504 of the Act.

(c) *Education of the Handicapped Act* means that statute as amended by the Education for all Handicapped Children Act of 1975, Pub. L. 94–142, 20 U.S.C. 1401 et seq.

(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) *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.

(g) *Applicant for assistance* 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.

(h) *Federal financial assistance* means any grant, loan, contract (other than a procurement contract or a contract of insurance or guaranty), 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; or

(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.

(i) *Facility* means all or any portion of buildings, structures, equipment, roads, walks, parking lots, or other real or personal property or interest in such property.

(j) *Handicapped person.* (1) *Handicapped persons* means any person who (i) has a physical or mental impairment which substantially limits one or more major life activities, (ii) has a record of such an impairment, or (iii) is regarded as having such an impairment.

(2) As used in paragraph (j)(1) of this section, the phrase:

(i) *Physical or mental impairment* means (A) 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 (B) any mental or psychological disorder, such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

(ii) *Major life activities* means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(iii) *Has a record of such an impairment* means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(iv) *Is regarded as having an impairment* means (A) has a physical or mental impairment that does not substantially limit major life activities but that is treated by a recipient as constituting such a limitation; (B) 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 (C) has none of the impairments defined in paragraph (j)(2)(i) of this section but is treated by a recipient as having such an impairment.

(k) *Program or activity* 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 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 (k)(1), (2), or (3) of this section; any part of which is extended Federal financial assistance.

(l) *Qualified handicapped person* means:

(1) With respect to employment, a handicapped person who, with reasonable accommodation, can perform the essential functions of the job in question;

(2) With respect to public preschool elementary, secondary, or adult educational services, a handicappped person (i) of an age during which nonhandicapped persons are provided such services, (ii) of any age during which it is mandatory under state law to provide such services to handicapped persons, or (iii) to whom a state is required to provide a free appropriate public education under section 612 of the Education of the Handicapped Act; and

(3) With respect to postsecondary and vocational education services, a handicapped person who meets the academic and technical standards requisite to admission or participation in the recipient's education program or activity;

(4) With respect to other services, a handicapped person who meets the essential eligibility requirements for the receipt of such services.

(m) *Handicap* means any condition or characteristic that renders a person a handicapped person as defined in paragraph (j) of this section.

(29 U.S.C. 794(b))

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.4 Discrimination prohibited.

(a) *General.* No qualified handicapped person 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 which receives Federal financial assistance.

(b) *Discriminatory actions prohibited.* (1) A recipient, 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 handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

(ii) Afford a qualified handicapped person 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 handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

(iv) Provide different or separate aid, benefits, or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

(v) Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to an agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or service to beneficiaries of the recipients program or activity;

(vi) Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

(vii) Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving an aid, benefit, or service.

(2) For purposes of this part, aids, benefits, and services, to be equally effective, are not required to produce the identical result or level of achievement for handicapped and nonhandicapped persons, but must afford handicapped persons equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement, in the most integrated setting appropriate to the person's needs.

(3) Despite the existence of separate or different aids, benefits, or services provided in accordance with this part, a recipient may not deny a qualified handicapped person the opportunity to participate in such aids, benefits, or services that are not separate or different.

(4) 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 handicapped persons to discrimination on the basis of handicap, (ii) that have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the recipient's program or activity with respect to handicapped persons, 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.

(5) In determining the site or location of a facility, an applicant for assistance or a recipient may not make selections (i) that have the effect of excluding handicapped persons from, denying them the benefits of, or otherwise subjecting them to discrimination under any program or activity that receives Federal financial assistance 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 handicapped persons.

(6) As used in this section, the aid, benefit, or service provided under a program or activity receiving Federal financial assistance includes any aid, benefit, or service provided in or through a facility that has been constructed, expanded, altered, leased or rented, or otherwise acquired, in whole or in part, with Federal financial assistance.

(c) *Aids, benefits, or services limited by Federal law.* The exclusion of nonhandicapped persons from aids, benefits, or services limited by Federal statute or executive order to handicapped persons or the exclusion of a specific class of handicapped persons from aids, benefits, or services limited by Federal statute or executive order to a different class of handicapped persons is not prohibited by this part.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 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 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.

(2) Where no transfer of property is involved but property is purchased or 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 handicap 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 handicap 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 handicapped persons 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 handicapped persons 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 handicapped persons.

(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 handicapped persons or organizations representing handicapped persons, 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 handicapped persons or organizations representing handicapped persons, any

policies and practices that do not meet the requirements of this part; and

(iii) Take, after consultation with interested persons, including handicapped persons or organizations representing handicapped persons, 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]

§ 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) A recipient that employs fifteen or more persons shall take appropriate initial and continuing steps to notify participants, beneficiaries, applications, and employees, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient that it does not discriminate on the basis of handicap in violation of section 504 and this part. The notification shall state, where appropriate, that the recipient does not discriminate in admission or access to, or treatment or employment in, its programs or activities. The notification shall also include an identification of the responsible employee designated pursuant to § 84.7(a). A recipient shall make the initial notification required by this paragraph within 90 days of the effective date of this part. Methods of initial and continuing notification may include the posting of notices, publication in newspapers and magazines, placement of notices in recipients' publication, and distribution of memoranda or other written communications.

(b) If a recipient publishes or uses recruitment materials or publications containing general information that it makes available to participants, beneficiaries, applicants, or employees, it shall include in those materials or publications a statement of the policy described in paragraph (a) of this section. A recipient may meet the requirement of this paragraph either by including appropriate inserts in existing materials and publications or by revising and reprinting the materials and publications.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 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 Effect of State or local law or other requirements and effect of employment opportunities.

(a) The obligation to comply with this part is not obviated or alleviated by the existence of any state or local law or other requirement that, on the basis of handicap, imposes prohibitions or limits upon the eligibility of qualified handicapped persons to receive

services or to practice any occupation or profession.

(b) 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 handicapped persons than for nonhandicapped persons.

Subpart B—Employment Practices

§ 84.11 Discrimination prohibited.

(a) *General.* (1) No qualified handicapped person shall, on the basis of handicap, be subjected to discrimination in employment under any program or activity to which this part applies.

(2) A recipient that receives assistance under the Education of the Handicapped Act shall take positive steps to employ and advance in employment qualified handicapped persons in programs or activities assisted under that Act.

(3) A recipient shall make all decisions concerning employment under any program or activity to which this part applies in a manner which ensures that discrimination on the basis of handicap does not occur and may not limit, segregate, or classify applicants or employees in any way that adversely affects their opportunities or status because of handicap.

(4) A recipient may not participate in a contractual or other relationship that has the effect of subjecting qualified handicapped applicants or employees to discrimination prohibited by this subpart. The relationships referred to in this paragraph include relationships with employment and referral agencies, with labor unions, with organizations providing or administering fringe benefits to employees of the recipient, and with organizations providing training and apprenticeships.

(b) *Specific activities.* The provisions of this subpart apply to:

(1) Recruitment, advertising, and the processing of applications for employment;

(2) Hiring, upgrading, promotion, 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, job classifications, organizational structures, position descriptions, lines of progression, and seniority lists;

(5) Leaves of absense, sick leave, or any other leave;

(6) Fringe benefits available by virtue of employment, whether or not administered by the recipient;

(7) Selection and financial support for training, including apprenticeship, professional meetings, conferences, and other related activities, and selection for leaves of absence to pursue training;

(8) Employer sponsored activities, including those that are social or recreational; and

(9) Any other term, condition, or privilege of employment.

(c) A recipient's obligation to comply with this subpart is not affected by any inconsistent term of any collective bargaining agreement to which it is a party.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.12 Reasonable accommodation.

(a) A recipient shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program or activity.

(b) Reasonable accommodation may include: (1) Making facilities used by employees readily accessible to and usable by handicapped persons, and (2) job restructuring, part-time or modified work schedules, acquisition or modification of equipment or devices, the provision of readers or interpreters, and other similar actions.

(c) In determining pursuant to paragraph (a) of this section whether an accommodation would impose an undue hardship on the operation of a recipient's program or activity, factors to be considered include:

(1) The overall size of the recipient's program or activity with respect to number of employees, number and type of facilities, and size of budget;

(2) The type of the recipient's operation, including the composition and structure of the recipient's workforce; and

(3) The nature and cost of the accommodation needed.

(d) A recipient may not deny any employment opportunity to a qualified handicapped employee or applicant if the basis for the denial is the need to make reasonable accommodation to the physical or mental limitations of the employee or applicant.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.13 Employment criteria.

(a) A recipient may not make use of any employment test or other selection criterion that screens out or tends to screen out handicapped persons or any class of handicapped persons unless: (1) The test score or other selection criterion, as used by the recipient, is shown to be job-related for the position in question, and (2) alternative job-related 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.

(b) A recipient shall select and administer tests concerning employment so as best to ensure that, when administered to an applicant or employee who has a handicap that impairs sensory, manual, or speaking skills, the test results accurately reflect the applicant's or employee's job skills, aptitude, or whatever other factor the test purports to measure, rather than reflecting the applicant's or employee's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

§ 84.14 Preemployment inquiries.

(a) Except as provided in paragraphs (b) and (c) of this section, a recipient may not conduct a preemployment medical examination or may not make preemployment inquiry of an applicant as to whether the applicant is a handicapped person or as to the nature or severity of a handicap. A recipient may, however, make preemployment inquiry into an applicant's ability to perform job-related functions.

(b) When a recipient is taking remedial action to correct the effects of past discrimination pursuant to § 84.6 (a), 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), or when a recipient is taking affirmative action pursuant to section 503 of the Act, the recipient may invite applicants for employment to indicate whether and to what extent they are handicapped, *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 or affirmative action efforts; and

(2) The recipient states clearly that the information is being requested on a voluntary basis, that it will be kept confidential as provided in paragraph (d) of this section, that refusal to provide it will not subject the applicant or employee to any adverse treatment, and that it will be used only in accordance with this part.

(c) Nothing in this section shall prohibit a recipient from conditioning an offer of employment on the results of a medical examination conducted prior to the employee's entrance on duty, *Provided*, That: (1) All entering employees are subjected to such an examination regardless of handicap, and (2) the results of such an examination are used only in accordance with the requirements of this part.

(d) Information obtained in accordance with this section as to the medical condition or history of the applicant shall be collected and maintained on separate forms that shall be accorded confidentiality as medical records, except that:

(1) Supervisors and managers may be informed regarding restrictions on the work or duties of handicapped persons and regarding necessary accommodations;

(2) First aid and safety personnel may be informed, where appropriate, if the condition might require emergency treatment; and

(3) Government officials investigating compliance with the Act shall be provided relevant information upon request.

§§ 84.15–84.20 [Reserved]

Subpart C—Accessibility

§ 84.21 Discrimination prohibited.

No qualified handicapped person shall, because a recipient's facilities are inaccessible to or unusable by handicapped persons, be denied the benefits of, be excluded from participation in, or otherwise be subjected to discrimination under any program or activity to which this part applies.

§ 84.22 Existing facilities.

(a) *Accessibility*. A recipient shall operate its program or activity so that when each part is viewed in its entirety, it is readily accessible to handicapped persons. This paragraph does not require a recipient to make each of its existing facilities or every part of a facility accessible to and usable by handicapped persons.

(b) *Methods*. A recipient may comply with the requirements of paragraph (a) of this section through such means as redesign of equipment, reassignment of classes or other services to accessible buildings, assignment of aides to beneficiaries, home visits, delivery of health, welfare, or other social services at alternate accessible sites, alteration of existing facilities and construction of new facilities in conformance with the requirements of § 84.23, or any other methods that result in making its program or activity accessible to handicapped persons. A recipient is not required to make structural changes in existing facilities where other methods are effective in achieving compliance with paragraph (a) of this section. In choosing among available methods for meeting the requirement of paragraph (a) of this section, a recipient shall give priority to those methods that serve handicapped persons 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 handicapped person 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 handicapped person 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 handicapped persons or organizations representing handicapped persons. 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 handicapped persons;

(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 handicapped persons.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.23 New construction.

(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 handicapped persons, if the construction was commenced after the effective date of this part.

(b) *Alteration.* Each facility or part of a facility which is altered by, on behalf of, or for the use of a recipient after the effective date of this part 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 handicapped persons.

(c) *Conformance with Uniform Federal Accessibility Standards.* (1) Effective as of January 18, 1991, design, construction, or alteration of buildings in conformance with sections 3–8 of the Uniform Federal Accessibility Standards (UFSA) (appendix A to 41 CFR subpart 101–19.6) shall be deemed to comply with the requirements of this section with respect to those buildings. Departures from particular technical and scoping requirements of UFAS by the use of other methods are permitted where substantial equivalent or greater access to and usability of the building is provided.

(2) For purposes of this section, section 4.1.6(1)(g) of UFAS shall 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 persons with physical handicaps.

(3) This section does not require recipients to make building alterations that have little likelihood of being accomplished without removing or altering a load-bearing structural member.

[42 FR 22677, May 4, 1977, as amended at 55 FR 52138, 52142, Dec. 19, 1990]

§§ 84.24–84.30 [Reserved]

Subpart D—Preschool, Elementary, and Secondary Education

§ 84.31 Application of this subpart.

Subpart D applies to preschool, elementary, 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.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005]

§ 84.32 Location and notification.

A recipient that operates a public elementary or secondary education program or activity shall annually:

(a) Undertake to identify and locate every qualified handicapped person residing in the recipient's jurisdiction who is not receiving a public education; and

(b) Take appropriate steps to notify handicapped persons and their parents or guardians of the recipient's duty under this subpart.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.33 Free appropriate public education.

(a) *General.* A recipient that operates a public elementary or secondary education program or activity shall provide a free appropriate public education to each qualified handicapped person who is in the recipient's jurisdiction, regardless of the nature or severity of the person's handicap.

(b) *Appropriate education.* (1) For the purpose of this subpart, the provision of an appropriate education is the provision of regular or special education and related aids and services that (i) are designed to meet individual educational needs of handicapped persons as adequately as the needs of nonhandicapped persons are met and (ii) are based upon adherence to procedures that satisfy the requirements of §§ 84.34, 84.35, and 84.36.

(2) Implementation of an Individualized Education Program developed in accordance with the Education of the

Handicapped Act is one means of meeting the standard established in paragraph (b)(1)(i) of this section.

(3) A recipient may place a handicapped person or refer such a person for aids, benefits, or services other than those that it operates or provides as its means of carrying out the requirements of this subpart. If so, the recipient remains responsible for ensuring that the requirements of this subpart are met with respect to any handicapped person so placed or referred.

(c) *Free education*—(1) *General.* For the purpose of this section, the provision of a free education is the provision of educational and related services without cost to the handicapped person or to his or her parents or guardian, except for those fees that are imposed on non-handicapped persons or their parents or guardian. It may consist either of the provision of free services or, if a recipient places a handicapped person or refers such person for aids, benefits, or services not operated or provided by the recipient as its means of carrying out the requirements of this subpart, of payment for the costs of the aids, benefits, or services. Funds available from any public or private agency may be used to meet the requirements of this subpart. Nothing in this section shall be construed to relieve an insurer or similar third party from an otherwise valid obligation to provide or pay for services provided to a handicapped person.

(2) *Transportation.* If a recipient places a handicapped person or refers such person for aids, benefits, or services not operated or provided by the recipient as its means of carrying out the requirements of this subpart, the recipient shall ensure that adequate transportation to and from the aids, benefits, or services is provided at no greater cost than would be incurred by the person or his or her parents or guardian if the person were placed in the aids, benefits, or services operated by the recipient.

(3) *Residential placement.* If a public or private residential placement is necessary to provide a free appropriate public education to a handicapped person because of his or her handicap, the placement, including non-medical care and room and board, shall be provided at no cost to the person or his or her parents or guardian.

(4) *Placement of handicapped persons by parents.* If a recipient has made available, in conformance with the requirements of this section and § 84.34, a free appropriate public education to a handicapped person and the person's parents or guardian choose to place the person in a private school, the recipient is not required to pay for the person's education in the private school. Disagreements between a parent or guardian and a recipient regarding whether the recipient has made a free appropriate public education available or otherwise regarding the question of financial responsibility are subject to the due process procedures of § 84.36.

(d) *Compliance.* A recipient may not exclude any qualified handicapped person from a public elementary or secondary education after the effective date of this part. A recipient that is not, on the effective date of this regulation, in full compliance with the other requirements of the preceding paragraphs of this section shall meet such requirements at the earliest practicable time and in no event later than September 1, 1978.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, 24320, May 9, 2005]

§ 84.34 Educational setting.

(a) *Academic setting.* A recipient to which this subpart applies shall educate, or shall provide for the education of, each qualified handicapped person in its jurisdiction with persons who are not handicapped to the maximum extent appropriate to the needs of the handicapped person. A recipient shall place a handicapped person in the regular educational environment operated by the recipient unless it is demonstrated by the recipient that the education of the person in the regular environment with the use of supplementary aids and services cannot be achieved satisfactorily. Whenever a recipient places a person in a setting other than the regular educational environment pursuant to this paragraph, it shall take into account the proximity of the alternate setting to the person's home.

(b) *Nonacademic settings.* In providing or arranging for the provision of nonacademic and extracurricular services and activities, including meals, recess periods, and the services and activities set forth in § 84.37(a)(2), a recipient shall ensure that handicapped persons participate with nonhandicapped persons in such activities and services to the maximum extent appropriate to the needs of the handicapped person in question.

(c) *Comparable facilities.* If a recipient, in compliance with paragraph (a) of this section, operates a facility that is identifiable as being for handicapped persons, the recipient shall ensure that the facility and the services and activities provided therein are comparable to the other facilities, services, and activities of the recipient.

§ 84.35 Evaluation and placement.

(a) *Preplacement evaluation.* A recipient that operates a public elementary or secondary education program or activity shall conduct an evaluation in accordance with the requirements of paragraph (b) of this section of any person who, because of handicap, needs or is believed to need special education or related services before taking any action with respect to the initial placement of the person in regular or special education and any subsequent significant change in placement.

(b) *Evaluation procedures.* A recipient to which this subpart applies shall establish standards and procedures for the evaluation and placement of persons who, because of handicap, need or are believed to need special education or related services which ensure that:

(1) Tests and other evaluation materials have been validated for the specific purpose for which they are used and are administered by trained personnel in conformance with the instructions provided by their producer;

(2) Tests and other evaluation materials include those tailored to assess specific areas of educational need and not merely those which are designed to provide a single general intelligence quotient; and

(3) Tests are selected and administered so as best to ensure that, when a test is administered to a student with impaired sensory, manual, or speaking skills, the test results accurately reflect the student's aptitude or achievement level or whatever other factor the test purports to measure, rather than reflecting the student's impaired sensory, manual, or speaking skills (except where those skills are the factors that the test purports to measure).

(c) *Placement procedures.* In interpreting evaluation data and in making placement decisions, a recipient shall (1) draw upon information from a variety of sources, including aptitude and achievement tests, teacher recommendations, physical condition, social or cultural background, and adaptive behavior, (2) establish procedures to ensure that information obtained from all such sources is documented and carefully considered, (3) ensure that the placement decision is made by a group of persons, including persons knowledgeable about the child, the meaning of the evaluation data, and the placement options, and (4) ensure that the placement decision is made in conformity with § 84.34.

(d) *Reevaluation.* A recipient to which this section applies shall establish procedures, in accordance with paragraph (b) of this section, for periodic reevaluation of students who have been provided special education and related services. A reevaluation procedure consistent with the Education for the Handicapped Act is one means of meeting this requirement.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005]

§ 84.36 Procedural safeguards.

A recipient that operates a public elementary or secondary education program or activity shall establish and implement, with respect to actions regarding the identification, evaluation, or educational placement of persons who, because of handicap, need or are believed to need special instruction or related services, a system of procedural safeguards that includes notice, an opportunity for the parents or guardian of the person to examine relevant records, an impartial hearing with opportunity for participation by the person's parents or guardian and representation by counsel, and a review procedure. Compliance with the procedural

safeguards of section 615 of the Education of the Handicapped Act is one means of meeting this requirement.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24319, May 9, 2005]

§ 84.37 Nonacademic services.

(a) *General.* (1) A recipient to which this subpart applies shall provide nonacademic and extracurricular services and activities in such manner as is necessary to afford handicapped students an equal opportunity for participation in such services and activities.

(2) Nonacademic and extracurricular services and activities may include counseling services, physical recreational athletics, transportation, health services, recreational activities, special interest groups or clubs sponsored by the recipients, referrals to agencies which provide assistance to handicapped persons, and employment of students, including both employment by the recipient and assistance in making available outside employment.

(b) *Counseling 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 handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students with similar interests and abilities.

(c) *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 handicap. A recipient that offers physical education courses or that operates or sponsors interscholastic, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation.

(2) A recipient may offer to handicapped students physical education and athletic activities that are separate or different from those offered to nonhandicapped students only if separation or differentiation is consistent with the requirements of § 84.34 and only if no qualified handicapped student is denied the opportunity to compete for teams or to participate in courses that are not separate or different.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005]

§ 84.38 Preschool and adult education.

A recipient to which this subpart applies that provides preschool education or day care or adult education may not, on the basis of handicap, exclude qualified handicapped persons and shall take into account the needs of such persons in determining the aids, benefits, or services to be provided.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005]

§ 84.39 Private education.

(a) A recipient that provides private elementary or secondary education may not, on the basis of handicap, exclude a qualified handicapped person if the person can, with minor adjustments, be provided an appropriate education, as defined in § 84.33(b)(1), within that recipient's program or activity.

(b) A recipient to which this section applies may not charge more for the provision of an appropriate education to handicapped persons than to nonhandicapped persons except to the extent that any additional charge is justified by a substantial increase in cost to the recipient.

(c) A recipient to which this section applies that provides special education shall do so in accordance with the provisions of §§ 84.35 and 84.36. Each recipient to which this section applies is subject to the provisions of §§ 84.34, 84.37, and 84.38.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005]

§ 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 handicapped persons may not, on the basis of handicap, 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 handicapped persons who may be admitted;

(2) May not make use of any test or criterion for admission that has a disproportionate, adverse effect on handicapped persons or any class of handicapped persons 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 handicap 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, 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 handicapped persons; 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 handicapped person but, after admission, may make inquiries on a confidential basis as to handicaps 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 conditons 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 handicapped, *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.

§ 84.43 Treatment of students; general.

(a) No qualified handicapped student shall, on the basis of handicap, 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 handicapped persons.

(c) A recipient to which this subpart applies may not, on the basis of handicap, exclude any qualified handicapped student 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]

§ 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 handicap, against a qualified handicapped applicant or student. 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 requirements, 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 handicapped students 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 handicapped students 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 handicap 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 handicapped student 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]

§ 84.45 Housing.

(a) *Housing provided by the recipient.* A recipient that provides housing to its nonhandicapped students shall provide comparable, convenient, and accessible housing to handicapped students at the same cost as to others. At the end of the transition period provided for in Subpart C, such housing shall be available in sufficient quantity and variety so that the scope of handicapped students' choice of living accommodations is, as a whole, comparable to that of nonhandicapped students.

(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 handicap.

§ 84.46 Financial and employment assistance to students.

(a) *Provision of financial assistance.* (1) In providing financial assistance to qualified handicapped persons, a recipient to which this subpart applies may not (i), on the basis of handicap, provide less assistance than is provided to nonhandicapped persons, 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 handicapped persons on the basis of handicap.

(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 handicap only if the overall effect of the award of scholarships, fellowships, and other forms of financial assistance is not discriminatory on the basis of handicap.

(b) *Assistance in making available outside employment.* A recipient that assists 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.

§ 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 handicap. A recipient that offers physical education courses or that operates or sponsors intercollegiate, club, or intramural athletics shall provide to qualified handicapped students an equal opportunity for participation in these activities.

(2) A recipient may offer to handicapped students 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 handicapped student 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 handicap. The recipient shall ensure that qualified handicapped students are not counseled toward more restrictive career objectives than are nonhandicapped students 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 handicapped persons in their pursuit of particular careers.

(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]

§§ 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 handicapped person these benefits or services;

(2) Afford a qualified handicapped person an opportunity to receive benefits or services that is not equal to that offered nonhandicapped persons;

(3) Provide a qualified handicapped person 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 handicapped persons; or

(5) Provide different or separate benefits or services to handicapped persons except where necessary to provide qualified handicapped persons 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 handicapped persons, including those with impaired sensory or speaking skills, are not denied effective notice because of their handicap.

(c) *Emergency treatment for the hearing impaired.* A recipient hospital that provides health services or benefits shall establish a procedure for effective communication with persons with impaired hearing for the purpose of providing emergency health care.

(d) *Auxiliary aids.* (1) A recipient to which this subpart applies that employs fifteen or more persons shall provide appropriate auxiliary aids to persons with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(2) The Director may require recipients with fewer than fifteen employees to provide auxiliary aids where the provision of aids would not significantly impair the ability of the recipient to provide its benefits or services.

(3) For the purpose of this paragraph, auxiliary aids may include brailled and taped material, interpreters, and other aids for persons with impaired hearing or vision.

§ 84.53 Drug and alcohol addicts.

A recipient to which this subpart applies that operates a general hospital or outpatient facility may not discriminate in admission or treatment against a drug or alcohol abuser or alcoholic who is suffering from a medical condition, because of the person's drug or alcohol abuse or alcoholism.

§ 84.54 Education of institutionalized persons.

A recipient to which this subpart applies and that provides aids, benefits, or services for persons who are institutionalized because of handicap shall ensure that each qualified handicapped person, as defined in § 84.3(l)(2), in its program or activity is provided an appropriate education, as defined in § 84.33(b). Nothing in this section shall be interpreted as altering in any way the obligations of recipients under Subpart D.

[42 FR 22677, May 4, 1977, as amended at 70 FR 24320, May 9, 2005]

§ 84.55 Procedures relating to health care for handicapped infants.

(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 handicapped infants and in making 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) *Posting of informational notice.* (1) Each recipient health care provider that provides health care services to infants in programs or activities receiving Federal financial assistance shall post and keep posted in appropriate places an informational notice.

(2) The notice must be posted at location(s) where nurses and other medical professionals who are engaged in providing health care and related services to infants will see it. To the extent it does not impair accomplishment of the requirement that copies of the notice be posted where such personnel will see it, the notice need not be posted in area(s) where parents of infant patients will see it.

(3) Each health care provider for which the content of the following notice (identified as Notice A) is truthful may use Notice A. For the content of the notice to be truthful: (i) The provider must have a policy consistent with that stated in the notice; (ii) the provider must have a procedure for review of treatment deliberations and decisions to which the notice applies, such as (but not limited to) an Infant Care Review Committee; and (iii) the statements concerning the identity of callers and retaliation are truthful.

Notice A:

PRINCIPLES OF TREATMENT OF DISABLED INFANTS

It is the policy of this hospital, consistent with Federal law, that, nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.

This Federal law, section 504 of the Rehabilitation Act of 1973, prohibits discrimination on the basis of handicap in programs or activities receiving Federal financial assistance. For further information, or to report suspected noncompliance, call:

[Identify designated hospital contact point and telephone number] or

[Identify appropriate child protective services agency and telephone number] or

U.S. Department of Health and Human Services (HHS): 800–368–1019 (Toll-free; available 24 hours a day; TDD capability).

The identity of callers will be held confidential. Retaliation by this hospital against any person for providing information about possible noncompliance is prohibited by this hospital and Federal regulations.

(4) Health care providers other than those described in paragraph (b)(3) of this section must post the following notice (identified as Notice B):

Notice B:

PRINCIPLES OF TREATMENT OF DISABLED INFANTS

Federal law prohibits discrimination on the basis of handicap. Under this law, nourishment and medically beneficial treatment (as determined with respect for reasonable medical judgments) should not be withheld from handicapped infants solely on the basis of their present or anticipated mental or physical impairments.

This Federal law, section 504 of the Rehabilitation Act of 1973, applies to programs or activities receiving Federal financial assistance. For further information, or to report suspected noncompliance, call:

[Identify appropriate child protective services agency and telephone number] or

U.S. Department of Health and Human Services (HHS): 800–368–1019 (Toll-free; available 24 hours a day: TDD capability)

The identity of callers will be held confidential. Federal regulations prohibit retaliation by this hospital against any person who provides information about possible violations.

(5) The notice may be no smaller than 5 by 7 inches, and the type size no smaller than that generally used for similar internal communications to staff. The recipient must insert the specified information on the notice it selects. Recipient hospitals in Washington, DC, must list 863–0100 as the telephone number for HHS. No other alterations may be made to the notice. Copies of the notices may be obtained from the Department of Health and Human Services upon request, or the recipient may produce its own notices in conformance with the specified wording.

(c) *Responsibilities of recipient state child protective services agencies.* (1) Within 60 days of the effective date of this section, each recipient state child protective services agency shall establish and maintain in written form

methods of administration and procedures to assure that the agency utilizes its full authority pursuant to state law to prevent instances of unlawful medical neglect of handicapped infants. These methods of administration and procedures shall include:

(i) A requirement that health care providers report on a timely basis to the state agency circumstances which they determine to constitute known or suspected instances of unlawful medical neglect of handicapped infants;

(ii) A method by which the state agency can receive reports of suspected unlawful medical neglect of handicapped infants from health care providers, other individuals, and the Department on a timely basis;

(iii) Immediate review of reports of suspected unlawful medical neglect of handicapped infants and, where appropriate, on-site investigation of such reports;

(iv) Provision of child protective services to such medically neglected handicapped infants, including, where appropriate, seeking a timely court order to compel the provision of necessary nourishment and medical treatment; and

(v) Timely notification to the responsible Department official of each report of suspected unlawful medical neglect involving the withholding, solely on the basis of present or anticipated physical or mental impairments, of treatment or nourishment from a handicapped infant who, in spite of such impairments, will medically benefit from the treatment or nourishment, the steps taken by the state agency to investigate such report, and the state agency's final disposition of such report.

(2) Whenever a hospital at which an infant who is the subject of a report of suspected unlawful medical neglect is being treated has an Infant Care Review Committee (ICRC) the Department encourages the state child protective services agency to consult with the ICRC in carrying out the state agency's authorities under its state law and methods of administration. In developing its methods of administration and procedures, the Department encourages child protective services agencies to adopt guidelines for investigations similar to those of the Department regarding the involvement of ICRC's.

(d) *Expedited access to records.* Access to pertinent records and facilities of a recipient pursuant to 45 CFR 80.6(c) (made applicable to this part by 45 CFR 84.61) shall not be limited to normal business hours when, in the judgment of the responsible Department official, immediate access is necessary to protect the life or health of a handicapped individual.

(e) *Expedited action to effect compliance.* The requirement of 45 CFR 80.8(d)(3) pertaining to notice to recipients prior to the initiation of action to effect compliance (made applicable to this part by 45 CFR 84.61) shall not apply when, in the judgment of the responsible Department official, immediate action to effect compliance is necessary to protect the life or health of a handicapped individual. In such cases the recipient will, as soon as practicable, be given oral or written notice of its failure to comply, of the action to be taken to effect compliance, and its continuing opportunity to comply voluntarily.

(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 handicapped infants, 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 handicapped infants 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 handicapped infants.

(B) As stated in the ''Principles of Treatment of Disabled Infants'' of the coalition of major medical and disability organizations, including the 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 handicapped infants; the Commission finds it imperative to counteract this by treating them no less vigorously than their healthy peers or than older children with similar handicaps 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 diagnoses, 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 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 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]

§§ 84.56–84.60 [Reserved]

Subpart G—Procedures

§ 84.61 Procedures.

The procedural provisions applicable to title VI of the Civil Rights Act of 1964 apply to this part. These procedures are found in §§ 80.6 through 80.10 and Part 81 of this Title.

[42 FR 22677, May 4, 1977; 42 FR 22888, May 5, 1977]

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 beneficiairies 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.

In its May 1976 Notice of Intent, the Department suggested that the arrangement under which individual practitioners, hospitals, and other facilities receive reimbursement for providing services to beneficiaries under Part B of title XVIII of the Social Security Act (Medicare) constitutes a contract of insurance or guaranty and thus falls within the exemption from the regulation. This explanation oversimplified the Department's view of whether Medicare Part B constitutes Federal financial assistance. The Department's position has consistently been that, whether or not Medicare Part B arrangements involve a contract of insurance or guaranty, no Federal financial assistance flows from the Department to the doctor or other practitioner under the program, since Medicare Part B—like other social security programs—is basically a program of payments to direct beneficiaries.

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, emotional 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 possesion 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 marginal 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 nonacademic 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 appropriated 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 nondicrimination 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 nondiscrimination 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 laywers may find it more difficult to find jobs that do nonhandicapped lawyers.

SUBPART B—EMPLOYMENT PRACTICES

Subpart B prescribes requirements for nondiscrimination 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 requries 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 noncompliance.

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 nonessential 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 unless 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 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 nonhandicapped 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 proivde 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 facilties 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 takenplace.'' 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 regerence 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 nondiscrimination 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 designed 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 nonacademic 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 appropriate, 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 accessibile 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 nondiscriminatory. 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 nonhandicapped 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 shoud 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 braillers 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 recipients 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 tacticle 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 providing 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.

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 neglect 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 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 NONDISCRIMINATION 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 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.

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.

(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 Commission 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.

(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.

§§ 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;

(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 Peronnel 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

Public Health Service
- 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 Disability 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.

[1] Financial 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.

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 activities 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 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 nondiscrimination 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 nondiscrimination 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 (1) 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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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.

(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:

(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 United States Commissioner 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.

(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]

§ 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 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.

(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, subcontractors, 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 student, 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)

§ 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 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 nondiscrimination 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)

§ 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 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 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]

§§ 86.18–86.20 [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 admision, 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 subpart, 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) Discriminate against any person in the application of any rules of appearance;

(6) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for instate fees and tuition;

(7) 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;

(8) 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]

§ 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)

§ 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 result 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 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 recipent 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 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 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 noncompliance 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]

§ 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 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 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.

(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 compensation, 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 [Reserved]

Subpart F—Procedures [Interim]

§ 86.71 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 title

IX 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.

(Secs. 901, 902, Education Amendments of 1972, 86 Stat. 373, 374; 20 U.S.C. 1681, 1682)

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APPENDIX A TO PART 86—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]

PART 87—EQUAL TREATMENT FOR FAITH-BASED ORGANIZATIONS

Sec.
87.1 Discretionary grants
87.2 Formula and block grants

AUTHORITY: 5 U.S.C. 301.

SOURCE: 69 FR 42593, July 16, 2004, unless otherwise noted.

§ 87.1 Discretionary grants.

(a) This section is not applicable to the programs governed by the Charitable Choice regulations found at 42 CFR Part 54a.

(b) Religious organizations are eligible, on the same basis as any other organization, to participate in any Department program for which they are otherwise eligible. Neither the Department nor any State or local government and other intermediate organizations receiving funds under any Department program shall, in the selection of service providers, discriminate for or against an organization on the basis of the organization's religious character or affiliation. As used in this section, ''program'' refers to activities supported by discretionary grants under which recipients are selected through a competitive process. As used in this section, the term ''recipient'' means an organization receiving financial assistance from an HHS awarding agency to carry out a project or program and includes the term ''grantee'' as used in 45 CFR Parts 74, 92, and 96.

(c) Organizations that receive direct financial assistance from the Department under any Department program may not engage in inherently religious activities, such as worship, religious instruction, or proselytization, as part of the programs or services funded with direct financial assistance from the Department. 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 Department, and participation must be voluntary for beneficiaries of the programs or services funded with such assistance.

(d) A religious organization that participates in the Department-funded programs or services will retain its independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from the Department to support any inherently religious activities, such as worship, religious instruction, or proselytization. Among other things, a faith-based organization may use space in its facilities to provide programs or services funded with financial assistance from the Department without removing religious art, icons, scriptures, or other religious symbols. In addition, a religious organization that receives financial assistance from the Department retains its authority over its internal governance, and it may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents in accordance with all program requirements, statutes, and other applicable requirements governing the conduct of Department-funded activities.

(e) An organization that participates in programs funded by direct financial assistance from the Department shall not, in providing services, discriminate against a program beneficiary or prospective program beneficiary on the basis of religion or religious belief.

(f) No grant document, agreement, covenant, memorandum of understanding, policy, or regulation that is used by the Department or a State or local government in administering financial assistance from the Department shall require only religious organizations to provide assurances that they will not use monies or property for inherently religious activities. Any restrictions on the use of grant funds

shall apply equally to religious and non-religious organizations. All organizations that participate in Department programs, including organizations with religious character or affiliations, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing the conduct of Department-funded activities, including those prohibiting the use of direct financial assistance from the Department to engage in inherently religious activities. No grant document, agreement, covenant, memorandum of understanding, policy, or regulation that is used by the Department or a State or local government in administering financial assistance from the Department shall disqualify religious organizations from participating in the Department's programs because such organizations are motivated or influenced by religious faith to provide social services, or because of their religious character or affiliation.

(g) A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in section 702(a) of the Civil Rights Act of 1964, 42 U.S.C. 2000e–1, is not forfeited when the organization receives direct or indirect financial assistance from the Department. Some Department programs, however, contain independent statutory provisions requiring that all recipients agree not to discriminate in employment on the basis of religion. Accordingly, recipients should consult with the appropriate Department program office if they have questions about the scope of any applicable requirement.

(h) In general, the Department does not require that a recipient, including a religious organization, obtain tax-exempt status under section 501(c)(3) of the Internal Revenue Code to be eligible for funding under Department 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 Department program office to determine the scope of any applicable requirements. In Department 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 (h)(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.

(i) If a grantee contributes its own funds in excess of those funds required by a matching or grant agreement to supplement Department-supported activities, the grantee 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 section 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 section apply irrespective of whether such funds are commingled with Federal funds or segregated.

(j) To the extent otherwise permitted by Federal law, the restrictions on inherently religious activities set forth

in this section do not apply where Department funds are provided to religious organizations as a result of a genuine and independent private choice of a beneficiary or through other indirect funding mechanisms, provided the religious organizations otherwise satisfy the requirements of the program. A religious organization may receive such funds as the result of a beneficiary's genuine and independent choice if, for example, a beneficiary redeems a voucher, coupon, or certificate, allowing the beneficiary to direct where funds are to be paid, or through a similar funding mechanism provided to that beneficiary and designed to give that beneficiary a genuine and independent choice among providers.

§ 87.2 Formula and block grants.

(a) This section is not applicable to the programs governed by the Charitable Choice regulations found at 42 CFR Part 54 and 45 CFR Parts 96, 260, and 1050.

(b) Religious organizations are eligible, on the same basis as any other organization, to participate in any Department program for which they are otherwise eligible. Neither the Department nor any State or local government receiving funds under any Department program nor any intermediate organization with the same duties as a governmental entity under this part shall, in the selection of service providers, discriminate for or against an organization on the basis of the organization's religious character or affiliation. As used in this section, ''program'' refers to activities supported by formula or block grants. As used in this section, the term ''recipient'' means an organization receiving financial assistance from an HHS awarding agency to carry out a project or program and includes the term ''grantee'' as used in 45 CFR Parts 74, 92, and 96.

(c) Organizations that receive direct financial assistance from the Department may not engage in inherently religious activities, such as worship, religious instruction, or proselytization, as part of the programs or services funded with direct financial assistance from the Department. 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 Department, and participation must be voluntary for beneficiaries of the programs or services funded with such assistance.

(d) A religious organization that participates in the Department-funded programs or services will retain its independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from the Department to support any inherently religious activities, such as worship, religious instruction, or proselytization. Among other things, a faith-based organization that receives financial assistance from the Department may use space in its facilities, without removing religious art, icons, scriptures, or other religious symbols. In addition, a religious organization that receives financial assistance from the Department retains its authority over its internal governance and it may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents in accordance with all program requirements, statutes, and other applicable requirements governing the conduct of Department-funded activities.

(e) An organization that participates in programs funded by direct financial assistance from the Department shall not, in providing services, discriminate against a program beneficiary or prospective program beneficiary on the basis of religion or religious belief.

(f) No grant document, agreement, covenant, memorandum of understanding, policy, or regulation that is used by the Department or a State or local government in administering financial assistance from the Department shall require only religious organizations to provide assurances that they will not use monies or property for inherently religious activities. Any restrictions on the use of grant funds shall apply equally to religious and

non-religious organizations. All organizations that participate in Department programs, including organizations with religious character or affiliations, must carry out eligible activities in accordance with all program requirements and other applicable requirements governing the conduct of Department-funded activities, including those prohibiting the use of direct financial assistance to engage in inherently religious activities. No grant document, agreement, covenant, memorandum of understanding, policy, or regulation that is used by the Department or a State or local government in administering financial assistance from the Department shall disqualify religious organizations from participating in the Department's programs because such organizations are motivated or influenced by religious faith to provide social services, or because of their religious character or affiliation.

(g) A religious organization's exemption from the Federal prohibition on employment discrimination on the basis of religion, set forth in section 702(a) of the Civil Rights Act of 1964, 42 U.S.C. 2000e–1, is not forfeited when the religious organization receives direct or indirect financial assistance from the Department. Some Department programs, however, contain independent statutory provisions requiring that all recipients agree not to discriminate in employment on the basis of religion. Accordingly, grantees should consult with the appropriate Department program office if they have questions about the scope of any applicable requirement.

(h) In general, the Department does not require that a recipient, including a religious organization, obtain tax-exempt status under section 501(c)(3) of the Internal Revenue Code to be eligible for funding under Department programs. Many grant programs, however, do require an organization to be a ''nonprofit organization'' in order to be eligible for funding. Individual solicitations that require organizations to have nonprofit status will specifically so indicate in the eligibility section of a solicitation. In addition, any solicitation that requires an organization to maintain tax-exempt status will expressly state the statutory authority for requiring such status. Grantees should consult with the appropriate Department program office to determine the scope of any applicable requirements. In Department 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 (h)(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.

(i) If a State or local government contributes its own funds in excess of those funds required by a matching or grant agreement to supplement Department-supported activities, the State or local government 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 section 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 matching funds, the provisions of this section apply irrespective of whether such funds are commingled with Federal funds or segregated.

(j) To the extent otherwise permitted by Federal law, the restrictions on inherently religious activities set forth in this section do not apply where Department funds are provided to religious organizations as a result of a

genuine and independent private choice of a beneficiary or through other indirect funding mechanisms, provided the religious organizations otherwise satisfy the requirements of the program. A religious organization may receive such funds as the result of a beneficiary's genuine and independent choice if, for example, a beneficiary redeems a voucher, coupon, or certificate, allowing the beneficiary to direct where funds are to be paid, or through a similar funding mechanism provided to that beneficiary and designed to give that beneficiary a choice among providers.

PART 88—ENSURING THAT DEPARTMENT OF HEALTH AND HUMAN SERVICES FUNDS DO NOT SUPPORT COERCIVE OR DISCIMINATORY POLICIES OR PRACTICES IN VIOLATION OF FEDERAL LAW

Sec.
88.1 Purpose.
88.2 Complaint handling and investigating.

AUTHORITY: 5 U.S.C. 301.

SOURCE: 73 FR 78096, Dec. 19, 2008, 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, section 245 of the Public Health Service Act, 42 U.S.C. 238n, and the Weldon Amendment, Consolidated Appropriations Act, 2010, Public Law 111–117, Div. D, Sec. 508(d), 123 Stat. 3034, 3279–80, referred to collectively as the ''federal health care provider conscience protection statutes.''

[76 FR 9976, Feb. 23, 2011]

§ 88.2 Complaint handling and investigating.

The Office for Civil Rights (OCR) of the Department of Health and Human Services is designated to receive complaints based on the Federal health care provider conscience protection statutes. OCR will coordinate the handling of complaints with the Departmental funding component(s) from which the entity, to which a complaint has been filed, receives funding.

[76 FR 9976, Feb. 23, 2011]

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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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 disbursal 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, 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 form 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;

(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 sub-division, 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 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

(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 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 disbursal 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 obligations 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 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:

(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 activities, 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 nonprofit 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 adminstrative 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.
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.
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91.31 General responsibilities.
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91.49 Alternate funds disbursal 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 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 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.

[1] Published at 44 FR 33768, June 12, 1979.

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.

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 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 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 sufficent 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*

(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).

(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 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 disbursal 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

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—UNIFORM ADMINISTRATIVE REQUIREMENTS FOR GRANTS AND COOPERATIVE AGREEMENTS TO STATE, LOCAL, AND TRIBAL GOVERNMENTS

Subpart A—General

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92.40 Monitoring and reporting program performance.
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92.52 Collection of amounts due.

AUTHORITY: 5 U.S.C. 301.

SOURCE: 53 FR 8079, 8087, Mar. 11, 1988, unless otherwise noted.

EDITORIAL NOTE: For additional information, see related documents published at 49 FR 24958, June 18, 1984, 52 FR 20178, May 29, 1987, and 53 FR 8028, Mar. 11, 1988.

Subpart A—General

§92.1 Purpose and scope of this part.

This part establishes uniform administrative rules for Federal grants and cooperative agreements and subawards to State, local and Indian tribal governments.

§92.2 Scope of subpart.

This subpart contains general rules pertaining to this part and procedures for control of exceptions from this part.

§92.3 Definitions.

As used in this part:

Accrued expenditures mean the charges incurred by the grantee during a given period requiring the provision of funds for: (1) Goods and other tangible property received; (2) services performed by employees, contractors, subgrantees, subcontractors, and other payees; and (3) other amounts becoming owed under programs for which no current services or performance is required, such as annuities, insurance claims, and other benefit payments.

Accrued income means the sum of: (1) Earnings during a given period from services performed by the grantee and goods and other tangible property delivered to purchasers, and (2) amounts becoming owed to the grantee for

which no current services or performance is required by the grantee.

Acquisition cost of an item of purchased equipment means the net invoice unit price of the property including the cost of modifications, attachments, accessories, or auxiliary apparatus necessary to make the property usable for the purpose for which it was acquired. Other charges such as the cost of installation, transportation, taxes, duty or protective in-transit insurance, shall be included or excluded from the unit acquisition cost in accordance with the grantee's regular accounting practices.

Administrative requirements mean those matters common to grants in general, such as financial management, kinds and frequency of reports, and retention of records. These are distinguished from *programmatic* requirements, which concern matters that can be treated only on a program-by-program or grant-by-grant basis, such as kinds of activities that can be supported by grants under a particular program.

Awarding agency means (1) with respect to a grant, the Federal agency, and (2) with respect to a subgrant, the party that awarded the subgrant.

Cash contributions means the grantee's cash outlay, including the outlay of money contributed to the grantee or subgrantee by other public agencies and institutions, and private organizations and individuals. When authorized by Federal legislation, Federal funds received from other assistance agreements may be considered as grantee or subgrantee cash contributions.

Contract means (except as used in the definitions for *grant* and *subgrant* in this section and except where qualified by *Federal*) a procurement contract under a grant or subgrant, and means a procurement subcontract under a contract.

Cost sharing or matching means the value of the third party in-kind contributions and the portion of the costs of a federally assisted project or program not borne by the Federal Government.

Cost-type contract means a contract or subcontract under a grant in which the contractor or subcontractor is paid on the basis of the costs it incurs, with or without a fee.

Equipment means tangible, nonexpendable, personal property having a useful life of more than one year and an acquisition cost of $5,000 or more per unit. A grantee may use its own definition of equipment provided that such definition would at least include all equipment defined above.

Expenditure report means: (1) For nonconstruction grants, the SF–269 ''Financial Status Report'' (or other equivalent report); (2) for construction grants, the SF–271 ''Outlay Report and Request for Reimbursement'' (or other equivalent report).

Federally recognized Indian tribal government means the governing body or a governmental agency of any Indian tribe, band, nation, or other organized group or community (including any Native village as defined in section 3 of the Alaska Native Claims Settlement Act, 85 Stat 688) certified by the Secretary of the Interior as eligible for the special programs and services provided by him through the Bureau of Indian Affairs.

Government means a State or local government or a federally recognized Indian tribal government.

Grant means an award of financial assistance, including cooperative agreements, in the form of money, or property in lieu of money, by the Federal Government to an eligible grantee. 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, interest subsidies, insurance, or direct appropriations. Also, the term does not include assistance, such as a fellowship or other lump sum award, which the grantee is not required to account for.

Grantee means the government to which a grant is awarded and which is accountable for the use of the funds provided. The grantee is the entire legal entity even if only a particular component of the entity is designated in the grant award document.

Local government means a county, municipality, city, town, township, local public authority (including any public and Indian housing agency under the United States Housing Act of

1937) school district, special district, intrastate district, council of governments (whether or not incorporated as a nonprofit corporation under state law), any other regional or interstate government entity, or any agency or instrumentality of a local government.

Obligations means the amounts of orders placed, contracts and subgrants awarded, goods and services received, and similar transactions during a given period that will require payment by the grantee during the same or a future period.

OMB means the United States Office of Management and Budget.

Outlays (expenditures) mean charges made to the project or program. They may be reported on a cash or accrual basis. For reports prepared on a cash basis, outlays are the sum of actual cash disbursement for direct charges for goods and services, the amount of indirect expense incurred, the value of in-kind contributions applied, and the amount of cash advances and payments made to contractors and subgrantees. For reports prepared on an accrued expenditure basis, outlays are the sum of actual cash disbursements, the amount of indirect expense incurred, the value of inkind contributions applied, and the new increase (or decrease) in the amounts owed by the grantee for goods and other property received, for services performed by employees, contractors, subgrantees, subcontractors, and other payees, and other amounts becoming owed under programs for which no current services or performance are required, such as annuities, insurance claims, and other benefit payments.

Percentage of completion method refers to a system under which payments are made for construction work according to the percentage of completion of the work, rather than to the grantee's cost incurred.

Prior approval means documentation evidencing consent prior to incurring specific cost.

Real property means land, including land improvements, structures and appurtenances thereto, excluding movable machinery and equipment.

Share, when referring to the awarding agency's portion of real property, equipment or supplies, means the same percentage as the awarding agency's portion of the acquiring party's total costs under the grant to which the acquisition costs under the grant to which the acquisition cost of the property was charged. Only costs are to be counted—not the value of third-party in-kind contributions.

State means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments. The term does not include any public and Indian housing agency under United States Housing Act of 1937.

Subgrant means an award of financial assistance in the form of money, or property in lieu of money, made under a grant by a grantee to an eligible subgrantee. The term includes financial assistance when provided by contractual legal agreement, but does not include procurement purchases, nor does it include any form of assistance which is excluded from the definition of *grant* in this part.

Subgrantee means the government or other legal entity to which a subgrant is awarded and which is accountable to the grantee for the use of the funds provided.

Supplies means all tangible personal property other than *equipment* as defined in this part.

Suspension means depending on the context, either (1) temporary withdrawal of the authority to obligate grant funds pending corrective action by the grantee or subgrantee or a decision to terminate the grant, or (2) an action taken by a suspending official in accordance with agency regulations implementing E.O. 12549 to immediately exclude a person from participating in grant transactions for a period, pending completion of an investigation and such legal or debarment proceedings as may ensue.

Termination means permanent withdrawal of the authority to obligate previously-awarded grant funds before that authority would otherwise expire. It also means the voluntary relinquishment of that authority by the grantee or subgrantee. ''Termination'' does not

include: (1) Withdrawal of funds awarded on the basis of the grantee's underestimate of the unobligated balance in a prior period; (2) Withdrawal of the unobligated balance as of the expiration of a grant; (3) Refusal to extend a grant r award additional funds, to make a competing or noncompeting continuation, renewal, extension, or supplemental award; or (4) voiding of a grant upon determination that the award was obtained fraudulently, or was otherwise illegal or invalid from inception.

Terms of a grant or subgrant mean all requirements of the grant or subgrant, whether in statute, regulations, or the award document.

Third party in-kind contributions mean property or services which benefit a federally assisted project or program and which are contributed by non-Federal third parties without charge to the grantee, or a cost-type contractor under the grant agreement.

Unliquidated obligations for reports prepared on a cash basis mean the amount of obligations incurred by the grantee that has not been paid. For reports prepared on an accrued expenditure basis, they represent the amount of obligations incurred by the grantee for which an outlay has not been recorded.

Unobligated balance means the portion of the funds authorized by the Federal agency that has not been obligated by the grantee and is determined by deducting the cumulative obligations from the cumulative funds authorized.

§ 92.4 Applicability.

(a) *General.* Subparts A through D of this part apply to all grants and subgrants to governments, except where inconsistent with Federal statutes or with regulations authorized in accordance with the exception provision of § 92.6, or:

(1) Grants and subgrants to State and local institutions of higher education or State and local hospitals.

(2) The block grants authorized by the Omnibus Budget Reconciliation Act of 1981 (Community Services; Preventive Health and Health Services; Alcohol, Drug Abuse, and Mental Health Services; Maternal and Child Health Services; Social Services; Low-Income Home Energy Assistance; States' Program of Community Development Block Grants for Small Cities; and Elementary and Secondary Education other than programs administered by the Secretary of Education under Title V, Subtitle D, Chapter 2, Section 583—the Secretary's discretionary grant program) and Titles I-III of the Job Training Partnership Act of 1982 and under the Public Health Services Act (Section 1921), Alcohol and Drug Abuse Treatment and Rehabilitation Block Grant and Part C of Title V, Mental Health Service for the Homeless Block Grant).

(3) Grants to local education agencies under 20 U.S.C. 236 through 241–1(a), and 242 through 244 (portions of the Impact Aid program), except for 20 U.S.C. 238(d)(2)(c) and 240(f) (Entitlement Increase for Handicapped Children); and

(4) Payments under the Veterans Administration's State Home Per Diem Program (38 U.S.C. 641(a)).

(b) [Reserved]

[53 FR 8079, 8087, Mar. 11, 1988, as amended at 65 FR 33632, May 24, 2000; 68 FR 52844, Sept. 8, 2003]

§ 92.5 Effect on other issuances.

All other grants administration provisions of codified program regulations, program manuals, handbooks and other nonregulatory materials which are inconsistent with this part are superseded, except to the extent they are required by statute, or authorized in accordance with the exception provision in § 92.6.

§ 92.6 Additions and exceptions.

(a) For classes of grants and grantees subject to this part, Federal agencies may not impose additional administrative requirements except in codified regulations published in the FEDERAL REGISTER.

(b) Exceptions for classes of grants or grantees may be authorized only by OMB.

(c) Exceptions on a case-by-case basis and for subgrantees may be authorized by the affected Federal agencies.

Subpart B—Pre-Award Requirements

§ 92.10 Forms for applying for grants.

(a) *Scope.* (1) This section prescribes forms and instructions to be used by governmental organizations (except hospitals and institutions of higher education operated by a government) in applying for grants. This section is not applicable, however, to formula grant programs which do not require applicants to apply for funds on a project basis.

(2) This section applies only to applications to Federal agencies for grants, and is not required to be applied by grantees in dealing with applicants for subgrants. However, grantees are encouraged to avoid more detailed or burdensome application requirements for subgrants.

(b) *Authorized forms and instructions for governmental organizations.* (1) In applying for grants, applicants shall only use standard application forms or those prescribed by the granting agency with the approval of OMB under the Paperwork Reduction Act of 1980.

(2) Applicants are not required to submit more than the original and two copies of preapplications or applications.

(3) Applicants must follow all applicable instructions that bear OMB clearance numbers. Federal agencies may specify and describe the programs, functions, or activities that will be used to plan, budget, and evaluate the work under a grant. Other supplementary instructions may be issued only with the approval of OMB to the extent required under the Paperwork Reduction Act of 1980. For any standard form, except the SF–424 facesheet, Federal agencies may shade out or instruct the applicant to disregard any line item that is not needed.

(4) When a grantee applies for additional funding (such as a continuation or supplemental award) or amends a previously submitted application, only the affected pages need be submitted. Previously submitted pages with information that is still current need not be resubmitted.

§ 92.11 State plans.

(a) *Scope.* The statutes for some programs require States to submit plans before receiving grants. Under regulations implementing Executive Order 12372, ''Intergovernmental Review of Federal Programs,'' States are allowed to simplify, consolidate and substitute plans. This section contains additional provisions for plans that are subject to regulations implementing the Executive order.

(b) *Requirements.* A State need meet only Federal administrative or programmatic requirements for a plan that are in statutes or codified regulations.

(c) *Assurances.* In each plan the State will include an assurance that the State shall comply with all applicable Federal statutes and regulations in effect with respect to the periods for which it receives grant funding. For this assurance and other assurances required in the plan, the State may:

(1) Cite by number the statutory or regulatory provisions requiring the assurances and affirm that it gives the assurances required by those provisions,

(2) Repeat the assurance language in the statutes or regulations, or

(3) Develop its own language to the extent permitted by law.

(d) *Amendments.* A State will amend a plan whenever necessary to reflect: (1) New or revised Federal statutes or regulations or (2) a material change in any State law, organization, policy, or State agency operation. The State will obtain approval for the amendment and its effective date but need submit for approval only the amended portions of the plan.

§ 92.12 Special grant or subgrant conditions for "high-risk" grantees.

(a) A grantee or subgrantee may be considered ''high risk'' if an awarding agency determines that a grantee or subgrantee:

(1) Has a history of unsatisfactory performance, or

(2) Is not financially stable, or

(3) Has a management system which does not meet the management standards set forth in this part, or

(4) Has not conformed to terms and conditions of previous awards, or

(5) Is otherwise not responsible; and if the awarding agency determines that an award will be made, special conditions and/or restrictions shall correspond to the high risk condition and shall be included in the award.

(b) Special conditions or restrictions may include:

(1) Payment on a reimbursement basis;

(2) Withholding authority to proceed to the next phase until receipt of evidence of acceptable performance within a given funding period;

(3) Requiring additional, more detailed financial reports;

(4) Additional project monitoring;

(5) Requiring the grantee or subgrantee to obtain technical or management assistance; or

(6) Establishing additional prior approvals.

(c) If an awarding agency decides to impose such conditions, the awarding official will notify the grantee or subgrantee as early as possible, in writing, of:

(1) The nature of the special conditions/restrictions;

(2) The reason(s) for imposing them;

(3) The corrective actions which must be taken before they will be removed and the time allowed for completing the corrective actions and

(4) The method of requesting reconsideration of the conditions/restrictions imposed.

§ 92.13 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]

§ 92.14 Compliance with Part 87.

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—Post-Award Requirements

FINANCIAL ADMINISTRATION

§ 92.20 Standards for financial management systems.

(a) A State must expand and account for grant funds in accordance with State laws and procedures for expending and accounting for its own funds. Fiscal control and accounting procedures of the State, as well as its subgrantees and cost-type contractors, must be sufficient to—

(1) Permit preparation of reports required by this part and the statutes authorizing the grant, and

(2) Permit the tracing of funds to a level of expenditures adequate to establish that such funds have not been used in violation of the restrictions and prohibitions of applicable statutes.

(b) The financial management systems of other grantees and subgrantees must meet the following standards:

(1) *Financial reporting.* Accurate, current, and complete disclosure of the financial results of financially assisted activities must be made in accordance with the financial reporting requirements of the grant or subgrant.

(2) *Accounting records.* Grantees and subgrantees must maintain records which adequately identify the source and application of funds provided for financially-assisted activities. These records must contain information pertaining to grant or subgrant awards and authorizations, obligations, unobligated balances, assets, liabilities, outlays or expenditures, and income.

(3) *Internal control.* Effective control and accountability must be maintained for all grant and subgrant cash, real and personal property, and other assets. Grantees and subgrantees must adequately safeguard all such property and must assure that it is used solely for authorized purposes.

(4) *Budget control.* Actual expenditures or outlays must be compared with budgeted amounts for each grant or subgrant. Financial information

must be related to performance or productivity data, including the development of unit cost information whenever appropriate or specifically required in the grant or subgrant agreement. If unit cost data are required, estimates based on available documentation will be accepted whenever possible.

(5) *Allowable cost*. Applicable OMB cost principles, agency program regulations, and the terms of grant and subgrant agreements will be followed in determining the reasonableness, allowability, and allocability of costs.

(6) *Source documentation*. Accounting records must be supported by such source documentation as cancelled checks, paid bills, payrolls, time and attendance records, contract and subgrant award documents, etc.

(7) *Cash management*. Procedures for minimizing the time elapsing between the transfer of funds from the U.S. Treasury and disbursement by grantees and subgrantees must be followed whenever advance payment procedures are used. Grantees must establish reasonable procedures to ensure the receipt of reports on subgrantees' cash balances and cash disbursements in sufficient time to enable them to prepare complete and accurate cash transactions reports to the awarding agency. When advances are made by letter-of-credit or electronic transfer of funds methods, the grantee must make drawdowns as close as possible to the time of making disbursements. Grantees must monitor cash drawdowns by their subgrantees to assure that they conform substantially to the same standards of timing and amount as apply to advances to the grantees.

(c) An awarding agency may review the adequacy of the financial management system of any applicant for financial assistance as part of a preaward review or at any time subsequent to award.

§92.21 Payment.

(a) *Scope*. This section prescribes the basic standard and the methods under which a Federal agency will make payments to grantees, and grantees will make payments to subgrantees and contractors.

(b) *Basic standard*. Methods and procedures for payment shall minimize the time elapsing between the transfer of funds and disbursement by the grantee or subgrantee, in accordance with Treasury regulations at 31 CFR Part 205.

(c) *Advances*. Grantees and subgrantees shall be paid in advance, provided they maintain or demonstrate the willingness and ability to maintain procedures to minimize the time elapsing between the transfer of the funds and their disbursement by the grantee or subgrantee.

(d) *Reimbursement*. Reimbursement shall be the preferred method when the requirements in paragraph (c) of this section are not met. Grantees and subgrantees may also be paid by reimbursement for any construction grant. Except as otherwise specified in regulation, Federal agencies shall not use the percentage of completion method to pay construction grants. The grantee or subgrantee may use that method to pay its construction contractor, and if it does, the awarding agency's payments to the grantee or subgrantee will be based on the grantee's or subgrantee's actual rate of disbursement.

(e) *Working capital advances*. If a grantee cannot meet the criteria for advance payments described in paragraph (c) of this section, and the Federal agency has determined that reimbursement is not feasible because the grantee lacks sufficient working capital, the awarding agency may provide cash or a working capital advance basis. Under this procedure the awarding agency shall advance cash to the grantee to cover its estimated disbursement needs for an initial period generally geared to the grantee's disbursing cycle. Thereafter, the awarding agency shall reimburse the grantee for its actual cash disbursements. The working capital advance method of payment shall not be used by grantees or subgrantees if the reason for using such method is the unwillingness or inability of the grantee to provide timely advances to the subgrantee to meet the subgrantee's actual cash disbursements.

(f) *Effect of program income, refunds, and audit recoveries on payment*. (1)

Grantees and subgrantees shall disburse repayments to and interest earned on a revolving fund before requesting additional cash payments for the same activity.

(2) Except as provided in paragraph (f)(1) of this section, grantees and subgrantees shall disburse program income, rebates, refunds, contract settlements, audit recoveries and interest earned on such funds before requesting additional cash payments.

(g) *Withholding payments.* (1) Unless otherwise required by Federal statute, awarding agencies shall not withhold payments for proper charges incurred by grantees or subgrantees unless—

(i) The grantee or subgrantee has failed to comply with grant award conditions or

(ii) The grantee or subgrantee is indebted to the United States.

(2) Cash withheld for failure to comply with grant award condition, but without suspension of the grant, shall be released to the grantee upon subsequent compliance. When a grant is suspended, payment adjustments will be made in accordance with § 92.43(c).

(3) A Federal agency shall not make payment to grantees for amounts that are withheld by grantees or subgrantees from payment to contractors to assure satisfactory completion of work. Payments shall be made by the Federal agency when the grantees or subgrantees actually disburse the withheld funds to the contractors or to escrow accounts established to assure satisfactory completion of work.

(h) *Cash depositories.* (1) Consistent with the national goal of expanding the opportunities for minority business enterprises, grantees and subgrantees are encouraged to use minority banks (a bank which is owned at least 50 percent by minority group members). A list of minority owned banks can be obtained from the Minority Business Development Agency, Department of Commerce, Washington, DC 20230.

(2) A grantee or subgrantee shall maintain a separate bank account only when required by Federal-State agreement.

(i) *Interest earned on advances.* Except for interest earned on advances of funds exempt under the Intergovernmental Cooperation Act (31 U.S.C. 6501 et seq.) and the Indian Self-Determination Act (23 U.S.C. 450), grantees and subgrantees shall promptly, but at least quarterly, remit interest earned on advances to the Federal agency. The grantee or subgrantee may keep interest amounts up to $100 per year for administrative expenses.

§ 92.22 Allowable costs.

(a) *Limitation on use of funds.* Grant funds may be used only for:

(1) The allowable costs of the grantees, subgrantees and cost-type contractors, including allowable costs in the form of payments to fixed-price contractors; and

(2) Reasonable fees or profit to cost-type contractors but not any fee or profit (or other increment above allowable costs) to the grantee or subgrantee.

(b) *Applicable cost principles.* For each kind of organization, there is a set of Federal principles for determining allowable costs. Allowable costs will be determined in accordance with the cost principles applicable to the organization incurring the costs. The following chart lists the kinds of organizations and the applicable cost principles.

For the costs of a—	Use the principles in—
State, local or Indian tribal government.	OMB Circular A–87.
Private nonprofit organization other than an (1) institution of higher education, (2) hospital, or (3) organization named in OMB Circular A–122 as not subject to that circular.	OMB Circular A–122.
Educational institutions.	OMB Circular A–21.
For-profit organization other than a hospital and an organization named in OBM Circular A–122 as not subject to that circular.	48 CFR Part 31. Contract Cost Principles and Procedures, or uniform cost accounting standards that comply with cost principles acceptable to the Federal agency.

§ 92.23 Period of availability of funds.

(a) *General.* Where a funding period is specified, a grantee may charge to the award only costs resulting from obligations of the funding period unless carryover of unobligated balances is permitted, in which case the carryover balances may be charged for costs resulting from obligations of the subsequent funding period.

(b) *Liquidation of obligations.* A grantee must liquidate all obligations incurred under the award not later than 90 days after the end of the funding period (or as specified in a program regulation) to coincide with the submission of the annual Financial Status Report (SF–269). The Federal agency may extend this deadline at the request of the grantee.

§ 92.24 Matching or cost sharing.

(a) *Basic rule: Costs and contributions acceptable.* With the qualifications and exceptions listed in paragraph (b) of this section, a matching or cost sharing requirement may be satisfied by either or both of the following:

(1) Allowable costs incurred by the grantee, subgrantee or a cost-type contractor under the assistance agreement. This includes allowable costs borne by non-Federal grants or by others cash donations from non-Federal third parties.

(2) The value of third party in-kind contributions applicable to the period to which the cost sharing or matching requirements applies.

(b) *Qualifications and exceptions*—(1) *Costs borne by other Federal grant agreements.* Except as provided by Federal statute, a cost sharing or matching requirement may not be met by costs borne by another Federal grant. This prohibition does not apply to income earned by a grantee or subgrantee from a contract awarded under another Federal grant.

(2) *General revenue sharing.* For the purpose of this section, general revenue sharing funds distributed under 31 U.S.C. 6702 are not considered Federal grant funds.

(3) *Cost or contributions counted towards other Federal costs-sharing requirements.* Neither costs nor the values of third party in-kind contributions may count towards satisfying a cost sharing or matching requirement of a grant agreement if they have been or will be counted towards satisfying a cost sharing or matching requirement of another Federal grant agreement, a Federal procurement contract, or any other award of Federal funds.

(4) *Costs financed by program income.* Costs financed by program income, as defined in § 92.25, shall not count towards satisfying a cost sharing or matching requirement unless they are expressly permitted in the terms of the assistance agreement. (This use of general program income is described in § 92.25(g).)

(5) *Services or property financed by income earned by contractors.* Contractors under a grant may earn income from the activities carried out under the contract in addition to the amounts earned from the party awarding the contract. No costs of services or property supported by this income may count toward satisfying a cost sharing or matching requirement unless other provisions of the grant agreement expressly permit this kind of income to be used to meet the requirement.

(6) *Records.* Costs and third party in-kind contributions counting towards satisfying a cost sharing or matching requirement must be verifiable from the records of grantees and subgrantee or cost-type contractors. These records must show how the value placed on third party in-kind contributions was derived. To the extent feasible, volunteer services will be supported by the same methods that the organization uses to support the allocability of regular personnel costs.

(7) *Special standards for third party in-kind contributions.* (i) Third party in-kind contributions count towards satisfying a cost sharing or matching requirement only where, if the party receiving the contributions were to pay for them, the payments would be allowable costs.

(ii) Some third party in-kind contributions are goods and services that, if the grantee, subgrantee, or contractor receiving the contribution had to pay for them, the payments would have been an indirect costs. Costs sharing or matching credit for such contributions shall be given only if the grantee, subgrantee, or contractor has established, along with its regular indirect cost rate, a special rate for allocating to individual projects or programs the value of the contributions.

(iii) A third party in-kind contribution to a fixed-price contract may count towards satisfying a cost sharing or matching requirement only if it results in:

(A) An increase in the services or property provided under the contract (without additional cost to the grantee or subgrantee) or

(B) A cost savings to the grantee or subgrantee.

(iv) The values placed on third party in-kind contributions for cost sharing or matching purposes will conform to the rules in the succeeding sections of this part. If a third party in-kind contribution is a type not treated in those sections, the value placed upon it shall be fair and reasonable.

(c) *Valuation of donated services*—(1) *Volunteer services.* Unpaid services provided to a grantee or subgrantee by individuals will be valued at rates consistent with those ordinarily paid for similar work in the grantee's or subgrantee's organization. If the grantee or subgrantee does not have employees performing similar work, the rates will be consistent with those ordinarily paid by other employers for similar work in the same labor market. In either case, a reasonable amount for fringe benefits may be included in the valuation.

(2) *Employees of other organizations.* When an employer other than a grantee, subgrantee, or cost-type contractor furnishes free of charge the services of an employee in the employee's normal line of work, the services will be valued at the employee's regular rate of pay exclusive of the employee's fringe benefits and overhead costs. If the services are in a different line of work, paragraph (c)(1) of this section applies.

(d) *Valuation of third party donated supplies and loaned equipment or space.* (1) If a third party donates supplies, the contribution will be valued at the market value of the supplies at the time of donation.

(2) If a third party donates the use of equipment or space in a building but retains title, the contribution will be valued at the fair rental rate of the equipment or space.

(e) *Valuation of third party donated equipment, buildings, and land.* If a third party donates equipment, buildings, or land, and title passes to a grantee or subgrantee, the treatment of the donated property will depend upon the purpose of the grant or subgrant, as follows:

(1) *Awards for capital expenditures.* If the purpose of the grant or subgrant is to assist the grantee or subgrantee in the acquisition of property, the market value of that property at the time of donation may be counted as cost sharing or matching,

(2) *Other awards.* If assisting in the acquisition of property is not the purpose of the grant or subgrant, paragraphs (e)(2) (i) and (ii) of this section apply:

(i) If approval is obtained from the awarding agency, the market value at the time of donation of the donated equipment or buildings and the fair rental rate of the donated land may be counted as cost sharing or matching. In the case of a subgrant, the terms of the grant agreement may require that the approval be obtained from the Federal agency as well as the grantee. In all cases, the approval may be given only if a purchase of the equipment or rental of the land would be approved as an allowable direct cost. If any part of the donated property was acquired with Federal funds, only the non-federal share of the property may be counted as cost-sharing or matching.

(ii) If approval is not obtained under paragraph (e)(2)(i) of this section, no amount may be counted for donated land, and only depreciation or use allowances may be counted for donated equipment and buildings. The depreciation or use allowances for this property are not treated as third party in-kind contributions. Instead, they are treated as costs incurred by the grantee or subgrantee. They are computed and allocated (usually as indirect costs) in accordance with the cost principles specified in § 92.22, in the same way as depreciation or use allowances for purchased equipment and buildings. The amount of depreciation or use allowances for donated equipment and buildings is based on the property's market value at the time it was donated.

(f) *Valuation of grantee or subgrantee donated real property for construction/acquisition.* If a grantee or subgrantee donates real property for a construction or facilities acquisition project, the current market value of that property may be counted as cost sharing or matching. If any part of the donated property was acquired with Federal

funds, only the non-federal share of the property may be counted as cost sharing or matching.

(g) *Appraisal of real property*. In some cases under paragraphs (d), (e) and (f) of this section, it will be necessary to establish the market value of land or a building or the fair rental rate of land or of space in a building. In these cases, the Federal agency may require the market value or fair rental value be set by an independent appraiser, and that the value or rate be certified by the grantee. This requirement will also be imposed by the grantee on subgrantees.

§92.25 Program income.

(a) *General*. Grantees are encouraged to earn income to defray program costs. Program income includes income from fees for services performed, from the use or rental of real or personal property acquired with grant funds, from the sale of commodities or items fabricated under a grant agreement, and from payments of principal and interest on loans made with grant funds. Except as otherwise provided in regulations of the Federal agency, program income does not include interest on grant funds, rebates, credits, discounts, refunds, etc. and interest earned on any of them.

(b) *Definition of program income*. Program income means gross income received by the grantee or subgrantee directly generated by a grant supported activity, or earned only as a result of the grant agreement during the grant period. ''During the grant period'' is the time between the effective date of the award and the ending date of the award reflected in the final financial report.

(c) *Cost of generating program income*. If authorized by Federal regulations or the grant agreement, costs incident to the generation of program income may be deducted from gross income to determine program income.

(d) *Governmental revenues*. Taxes, special assessments, levies, fines, and other such revenues raised by a grantee or subgrantee are not program income unless the revenues are specifically identified in the grant agreement or Federal agency regulations as program income.

(e) *Royalties*. Income from royalties and license fees for copyrighted material, patents, and inventions developed by a grantee or subgrantee is program income only if the revenues are specifically identified in the grant agreement or Federal agency regulations as program income. (See §92.34.)

(f) *Property*. Proceeds from the sale of real property or equipment will be handled in accordance with the requirements of §§92.31 and 92.32.

(g) *Use of program income*. Program income shall be deducted from outlays which may be both Federal and non-Federal as described below, unless the Federal agency regulations or the grant agreement specify another alternative (or a combination of the alternatives). In specifying alternatives, the Federal agency may distinguish between income earned by the grantee and income earned by subgrantees and between the sources, kinds, or amounts of income. When Federal agencies authorize the alternatives in paragraphs (g) (2) and (3) of this section, program income in excess of any limits stipulated shall also be deducted from outlays.

(1) *Deduction*. Ordinarily program income shall be deducted from total allowable costs to determine the net allowable costs. Program income shall be used for current costs unless the Federal agency authorizes otherwise. Program income which the grantee did not anticipate at the time of the award shall be used to reduce the Federal agency and grantee contributions rather than to increase the funds committed to the project.

(2) *Addition*. When authorized, program income may be added to the funds committed to the grant agreement by the Federal agency and the grantee. The program income shall be used for the purposes and under the conditions of the grant agreement.

(3) *Cost sharing or matching*. When authorized, program income may be used to meet the cost sharing or matching requirement of the grant agreement. The amount of the Federal grant award remains the same.

(h) *Income after the award period*. There are no Federal requirements governing the disposition of program income earned after the end of the award

period (i.e., until the ending date of the final financial report, see paragraph (a) of this section), unless the terms of the agreement or the Federal agency regulations provide otherwise.

§ 92.26 Non-Federal audit.

(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 States, Local Governments, and Non-Profit Organizations.'' The audits shall be made by 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, which expends $300,000 or more (or other amount as specified by OMB) in Federal awards in a fiscal year, shall:

(1) Determine whether State or local subgrantees have met the audit requirements of the Act and whether subgrantees covered by OMB Circular A–110, ''Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations,'' 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, Circular A–110, 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 instance 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.

(c) *Auditor selection.* In arranging for audit services, § 92.36 shall be followed.

[53 FR 8079, 8087, Mar. 11, 1988, as amended at 62 FR 45939, 45945, Aug. 29, 1997]

CHANGES, PROPERTY, AND SUBAWARDS

§ 92.30 Changes.

(a) *General.* Grantees and subgrantees are permitted to rebudget within the approved direct cost budget to meet unanticipated requirements and may make limited program changes to the approved project. However, unless waived by the awarding agency, certain types of post-award changes in budgets and projects shall require the prior written approval of the awarding agency.

(1) Approvals shall not be valid unless they are in writing, and signed by at least one of the following officials of the Department of Health and Human Services (HHS):

(i) The responsible Grants Officer or his or her designee;

(ii) The head of the HHS Operating or Staff Division that awarded the grant; or

(iii) The head of the Regional Office of the HHS Operating or Staff Division that awarded the grant.

(b) *Relation to cost principles.* The applicable cost principles (see § 92.22) contain requirements for prior approval of certain types of costs. Except where waived, those requirements apply to all grants and subgrants even if paragraphs (c) through (f) of this section do not.

(c) *Budget changes*—(1) *Nonconstruction projects.* Except as stated in other regulations or an award document, grantees or subgrantees shall obtain the prior approval of the awarding agency whenever any of the following changes is anticipated under a nonconstruction award:

(i) Any revision which would result in the need for additional funding.

(ii) Unless waived by the awarding agency, cumulative transfers among direct cost categories, or, if applicable, among separately budgeted programs, projects, functions, or activities which exceed or are expected to exceed ten percent of the current total approved budget, whenever the awarding agency's share exceeds $100,000.

(iii) Transfer of funds allotted for training allowances (i.e., from direct payments to trainees to other expense categories).

(2) *Construction projects.* Grantees and subgrantees shall obtain prior written approval for any budget revision which would result in the need for additional funds.

(3) *Combined construction and nonconstruction projects.* When a grant or subgrant provides funding for both construction and nonconstruction activities, the grantee or subgrantee must obtain prior written approval from the awarding agency before making any fund or budget transfer from nonconstruction to construction or vice versa.

(d) *Programmatic changes.* Grantees or subgrantees must obtain the prior approval of the awarding agency whenever any of the following actions is anticipated:

(1) Any revision of the scope or objectives of the project (regardless of whether there is an associated budget revision requiring prior approval).

(2) Need to extend the period of availability of funds.

(3) Changes in key persons in cases where specified in an application or a grant award. In research projects, a change in the project director or principal investigator shall always require approval unless waived by the awarding agency.

(4) Under nonconstruction projects, contracting out, subgranting (if authorized by law) or otherwise obtaining the services of a third party to perform activities which are central to the purposes of the award. This approval requirement is in addition to the approval requirements of §92.36 but does not apply to the procurement of equipment, supplies, and general support services.

(5) Providing medical care to individuals under research grants.

(e) *Additional prior approval requirements.* The awarding agency may not require prior approval for any budget revision which is not described in paragraph (c) of this section.

(f) *Requesting prior approval.* (1) A request for prior approval of any budget revision will be in the same budget formal the grantee used in its application and shall be accompanied by a narrative justification for the proposed revision.

(2) A request for a prior approval under the applicable Federal cost principles (see §92.22) may be made by letter.

(3) A request by a subgrantee for prior approval will be addressed in writing to the grantee. The grantee will promptly review such request and shall approve or disapprove the request in writing. A grantee will not approve any budget or project revision which is inconsistent with the purpose or terms and conditions of the Federal grant to the grantee. If the revision, requested by the subgrantee would result in a change to the grantee's approved project which requires Federal prior approval, the grantee will obtain the Federal agency's approval before approving the subgrantee's request.

[53 FR 8079, 8087, Mar. 11, 1988, as amended at 53 FR 8079, Mar. 11, 1988]

§92.31 Real property.

(a) *Title.* Subject to the obligations and conditions set forth in this section, title to real property acquired under a grant or subgrant will vest upon acquisition in the grantee or subgrantee respectively.

(b) *Use.* Except as otherwise provided by Federal statutes, real property will be used for the originally authorized purposes as long as needed for that purposes, and the grantee or subgrantee shall not dispose of or encumber its title or other interests.

(c) *Disposition.* When real property is no longer needed for the originally authorized purpose, the grantee or subgrantee will request disposition instructions from the awarding agency. The instructions will provide for one of the following alternatives:

(1) *Retention of title.* Retain title after compensating the awarding agency.

The amount paid to the awarding agency will be computed by applying the awarding agency's percentage of participation in the cost of the original purchase to the fair market value of the property. However, in those situations where a grantee or subgrantee is disposing of real property acquired with grant funds and acquiring replacement real property under the same program, the net proceeds from the disposition may be used as an offset to the cost of the replacement property.

(2) *Sale of property*. Sell the property and compensate the awarding agency. The amount due to the awarding agency will be calculated by applying the awarding agency's percentage of participation in the cost of the original purchase to the proceeds of the sale after deduction of any actual and reasonable selling and fixing-up expenses. If the grant is still active, the net proceeds from sale may be offset against the original cost of the property. When a grantee or subgrantee is directed to sell property, sales procedures shall be followed that provide for competition to the extent practicable and result in the highest possible return.

(3) *Transfer of title*. Transfer title to the awarding agency or to a third-party designated/approved by the awarding agency. The grantee or subgrantee shall be paid an amount calculated by applying the grantee or subgrantee's percentage of participation in the purchase of the real property to the current fair market value of the property.

§ 92.32 Equipment.

(a) *Title*. Subject to the obligations and conditions set forth in this section, title to equipment acquired under a grant or subgrant will vest upon acquisition in the grantee or subgrantee respectively.

(b) *States*. A State will use, manage, and dispose of equipment acquired under a grant by the State in accordance with State laws and procedures. Other grantees and subgrantees will follow paragraphs (c) through (e) of this section.

(c) *Use*. (1) Equipment shall be used by the grantee or subgrantee in the program or project for which it was acquired as long as needed, whether or not the project or program continues to be supported by Federal funds. When no longer needed for the original program or project, the equipment may be used in other activities currently or previously supported by a Federal agency.

(2) The grantee or subgrantee shall also make equipment available for use on other projects or programs currently or previously supported by the Federal Government, providing such use will not interfere with the work on the projects or program for which it was originally acquired. First preference for other use shall be given to other programs or projects supported by the awarding agency. User fees should be considered if appropriate.

(3) Notwithstanding the encouragement in § 92.25(a) to earn program income, the grantee or subgrantee must not use equipment acquired with grant funds to provide services for a fee to compete unfairly with private companies that provide equivalent services, unless specifically permitted or contemplated by Federal statute.

(4) When acquiring replacement equipment, the grantee or subgrantee may use the equipment to be replaced as a trade-in or sell the property and use the proceeds to offset the cost of the replacement property, subject to the approval of the awarding agency.

(d) *Management requirements*. Procedures for managing equipment (including replacement equipment), whether acquired in whole or in part with grant funds, until disposition takes place will, as a minimum, meet the following requirements:

(1) Property records must be maintained that include a description of the property, a serial number or other identification number, the source of property, who holds title, the acquisition date, and cost of the property, percentage of Federal participation in the cost of the property, the location, use and condition of the property, and any ultimate disposition data including the date of disposal and sale price of the property.

(2) A physical inventory of the property must be taken and the results reconciled with the property records at least once every two years.

(3) A control system must be developed to ensure adequate safeguards to prevent loss, damage, or theft of the property. Any loss, damage, or theft shall be investigated.

(4) Adequate maintenance procedures must be developed to keep the property in good condition.

(5) If the grantee or subgrantee is authorized or required to sell the property, proper sales procedures must be established to ensure the highest possible return.

(e) *Disposition*. When original or replacement equipment acquired under a grant or subgrant is no longer needed for the original project or program or for other activities currently or previously supported by a Federal agency, disposition of the equipment will be made as follows:

(1) Items of equipment with a current per-unit fair market value of less than $5,000 may be retained, sold or otherwise disposed of with no further obligation to the awarding agency.

(2) Items of equipment with a current per unit fair market value in excess of $5,000 may be retained or sold and the awarding agency shall have a right to an amount calculated by multiplying the current market value or proceeds from sale by the awarding agency's share of the equipment.

(3) In cases where a grantee or subgrantee fails to take appropriate disposition actions, the awarding agency may direct the grantee or subgrantee to take excess and disposition actions.

(f) *Federal equipment*. In the event a grantee or subgrantee is provided federally-owned equipment:

(1) Title will remain vested in the Federal Government.

(2) Grantees or subgrantees will manage the equipment in accordance with Federal agency rules and procedures, and submit an annual inventory listing.

(3) When the equipment is no longer needed, the grantee or subgrantee will request disposition instructions from the Federal agency.

(g) *Right to transfer title*. The Federal awarding agency may reserve the right to transfer title to the Federal Government or a third part named by the awarding agency when such a third party is otherwise eligible under existing statutes. Such transfers shall be subject to the following standards:

(1) The property shall be identified in the grant or otherwise made known to the grantee in writing.

(2) The Federal awarding agency shall issue disposition instruction within 120 calendar days after the end of the Federal support of the project for which it was acquired. If the Federal awarding agency fails to issue disposition instructions within the 120 calendar-day period the grantee shall follow §92.32(e).

(3) When title to equipment is transferred, the grantee shall be paid an amount calculated by applying the percentage of participation in the purchase to the current fair market value of the property.

§92.33 Supplies.

(a) *Title*. Title to supplies acquired under a grant or subgrant will vest, upon acquisition, in the grantee or subgrantee respectively.

(b) *Disposition*. If there is a residual inventory of unused supplies exceeding $5,000 in total aggregate fair market value upon termination or completion of the award, and if the supplies are not needed for any other federally sponsored programs or projects, the grantee or subgrantee shall compensate the awarding agency for its share.

§92.34 Copyrights.

The Federal awarding agency reserves a royalty-free, nonexclusive, and irrevocable license to reproduce, publish or otherwise use, and to authorize others to use, for Federal Government purposes:

(a) The copyright in any work developed under a grant, subgrant, or contract under a grant or subgrant; and

(b) Any rights of copyright to which a grantee, subgrantee or a contractor purchases ownership with grant support.

§92.35 Subawards to debarred and suspended parties.

Grantees and subgrantees must not make any award or permit any award (subgrant or contract) at any tier to any party which is debarred or suspended or is otherwise excluded from or

ineligible for participation in Federal assistance programs under Executive Order 12549, ''Debarment and Suspension.''

§ 92.36 Procurement.

(a) *States.* When procuring property and services under a grant, a State will follow the same policies and procedures it uses for procurements from its non-Federal funds. The State will ensure that every purchase order or other contract includes any clauses required by Federal statutes and executive orders and their implementing regulations. Other grantees and subgrantees will follow paragraphs (b) through (i) in this section.

(b) *Procurement standards.* (1) Grantees and subgrantees will use their own procurement procedures which reflect applicable State and local laws and regulations, provided that the procurements conform to applicable Federal law and the standards identified in this section.

(2) Grantees and subgrantees will maintain a contract administration system which ensures that contractors perform in accordance with the terms, conditions, and specifications of their contracts or purchase orders.

(3) Grantees and subgrantees will maintain a written code of standards of conduct governing the performance of their employees engaged in the award and administration of contracts. No employee, officer or agent of the grantee or subgrantee shall participate in selection, or in the award or administration of a contract supported by Federal funds if a conflict of interest, real or apparent, would be involved. Such a conflict would arise when:

(i) The employee, officer or agent,

(ii) Any member of his immediate family,

(iii) His or her partner, or

(iv) An organization which employs, or is about to employ, any of the above, has a financial or other interest in the firm selected for award. The grantee's or subgrantee's officers, employees or agents will neither solicit nor accept gratuities, favors or anything of monetary value from contractors, potential contractors, or parties to subagreements. Grantee and subgrantees may set minimum rules where the financial interest is not substantial or the gift is an unsolicited item of nominal intrinsic value. To the extent permitted by State or local law or regulations, such standards or conduct will provide for penalties, sanctions, or other disciplinary actions for violations of such standards by the grantee's and subgrantee's officers, employees, or agents, or by contractors or their agents. The awarding agency may in regulation provide additional prohibitions relative to real, apparent, or potential conflicts of interest.

(4) Grantee and subgrantee procedures will provide for a review of proposed procurements to avoid purchase of unnecessary or duplicative items. Consideration should be given to consolidating or breaking out procurements to obtain a more economical purchase. Where appropriate, an analysis will be made of lease versus purchase alternatives, and any other appropriate analysis to determine the most economical approach.

(5) To foster greater economy and efficiency, grantees and subgrantees are encouraged to enter into State and local intergovernmental agreements for procurement or use of common goods and services.

(6) Grantees and subgrantees are encouraged to use Federal excess and surplus property in lieu of purchasing new equipment and property whenever such use is feasible and reduces project costs.

(7) Grantees and subgrantees are encouraged to use value engineering clauses in contracts for construction projects of sufficient size to offer reasonable opportunities for cost reductions. Value engineering is a systematic and creative anaylsis of each contract item or task to ensure that its essential function is provided at the overall lower cost.

(8) Grantees and subgrantees will make awards only to responsible contractors possessing the ability to perform successfully under the terms and conditions of a proposed procurement. Consideration will be given to such matters as contractor integrity, compliance with public policy, record of past performance, and financial and technical resources.

(9) Grantees and subgrantees will maintain records sufficient to detail the significant history of a procurement. These records will include, but are not necessarily limited to the following: rationale for the method of procurement, selection of contract type, contractor selection or rejection, and the basis for the contract price.

(10) Grantees and subgrantees will use time and material type contracts only—

(i) After a determination that no other contract is suitable, and

(ii) If the contract includes a ceiling price that the contractor exceeds at its own risk.

(11) Grantees and subgrantees alone will be responsible, in accordance with good administrative practice and sound business judgment, for the settlement of all contractual and administrative issues arising out of procurements. These issues include, but are not limited to source evaluation, protests, disputes, and claims. These standards do not relieve the grantee or subgrantee of any contractual responsibilities under its contracts. Federal agencies will not substitute their judgment for that of the grantee or subgrantee unless the matter is primarily a Federal concern. Violations of law will be referred to the local, State, or Federal authority having proper jurisdiction.

(12) Grantees and subgrantees will have protest procedures to handle and resolve disputes relating to their procurements and shall in all instances disclose information regarding the protest to the awarding agency. A protestor must exhaust all administrative remedies with the grantee and subgrantee before pursuing a protest with the Federal agency. Reviews of protests by the Federal agency will be limited to:

(i) Violations of Federal law or regulations and the standards of this section (violations of State or local law will be under the jurisdiction of State or local authorities) and

(ii) Violations of the grantee's or subgrantee's protest procedures for failure to review a complaint or protest. Protests received by the Federal agency other than those specified above will be referred to the grantee or subgrantee.

(c) *Competition*. (1) All procurement transactions will be conducted in a manner providing full and open competition consistent with the standards of §92.36. Some of the situations considered to be restrictive of competition include but are not limited to:

(i) Placing unreasonable requirements on firms in order for them to qualify to do business,

(ii) Requiring unnecessary experience and excessive bonding,

(iii) Noncompetitive pricing practices between firms or between affiliated companies,

(iv) Noncompetitive awards to consultants that are on retainer contracts,

(v) Organizational conflicts of interest,

(vi) Specifying only a ''brand name'' product instead of allowing ''an equal'' product to be offered and describing the performance of other relevant requirements of the procurement, and

(vii) Any arbitrary action in the procurement process.

(2) Grantees and subgrantees will conduct procurements in a manner that prohibits the use of statutorily or administratively imposed in-State or local geographical preferences in the evaluation of bids or proposals, except in those cases where applicable Federal statutes expressly mandate or encourage geographic preference. Nothing in this section preempts State licensing laws. When contracting for architectural and engineering (A/E) services, geographic location may be a selection criteria provided its application leaves an appropriate number of qualified firms, given the nature and size of the project, to compete for the contract.

(3) Grantees will have written selection procedures for procurement transactions. These procedures will ensure that all solicitations:

(i) Incorporate a clear and accurate description of the technical requirements for the material, product, or service to be procured. Such description shall not, in competitive procurements, contain features which unduly restrict competition. The description may include a statement of the qualitative nature of the material, product or service to be procured, and when necessary, shall set forth those minimum essential characteristics and

standards to which it must conform if it is to satisfy its intended use. Detailed product specifications should be avoided if at all possible. When it is impractical or uneconomical to make a clear and accurate description of the technical requirements, a ''brand name or equal'' description may be used as a means to define the performance or other salient requirements of a procurement. The specific features of the named brand which must be met by offerors shall be clearly stated; and

(ii) Identify all requirements which the offerors must fulfill and all other factors to be used in evaluating bids or proposals.

(4) Grantees and subgrantees will ensure that all prequalified lists of persons, firms, or products which are used in acquiring goods and services are current and include enough qualified sources to ensure maximum open and free competition. Also, grantees and subgrantees will not preclude potential bidders from qualifying during the solicitation period.

(d) *Methods of procurement to be followed*—(1) *Procurement by small purchase procedures*. Small purchase procedures are those relatively simple and informal procurement methods for securing services, supplies, or other property that do not cost more than the simplified acquisition threshold fixed at 41 U.S.C. 403(11) (currently set at $100,000). If small purchase procedures are used, price or rate quotations shall be obtained from an adequate number of qualified sources.

(2) Procurement by *sealed bids* (formal advertising). Bids are publicly solicited and a firm-fixed-price contract (lump sum or unit price) is awarded to the responsible bidder whose bid, conforming with all the material terms and conditions of the invitation for bids, is the lowest in price. The sealed bid method is the preferred method for procuring construction, if the conditions in § 92.36(d)(2)(i) apply.

(i) In order for sealed bidding to be feasible, the following conditions should be present:

(A) A complete, adequate, and realistic specification or purchase description is available;

(B) Two or more responsible bidders are willing and able to compete effectively and for the business; and

(C) The procurement lends itself to a firm fixed price contract and the selection of the successful bidder can be made principally on the basis of price.

(ii) If sealed bids are used, the following requirements apply:

(A) The invitation for bids will be publicly advertised and bids shall be solicited from an adequate number of known suppliers, providing them sufficient time prior to the date set for opening the bids;

(B) The invitation for bids, which will include any specifications and pertinent attachments, shall define the items or services in order for the bidder to properly respond;

(C) All bids will be publicly opened at the time and place prescribed in the invitation for bids;

(D) A firm fixed-price contract award will be made in writing to the lowest responsive and responsible bidder. Where specified in bidding documents, factors such as discounts, transportation cost, and life cycle costs shall be considered in determining which bid is lowest. Payment discounts will only be used to determine the low bid when prior experience indicates that such discounts are usually taken advantage of; and

(E) Any or all bids may be rejected if there is a sound documented reason.

(3) Procurement by *competitive proposals*. The technique of competitive proposals is normally conducted with more than one source submitting an offer, and either a fixed-price or cost-reimbursement type contract is awarded. It is generally used when conditions are not appropriate for the use of sealed bids. If this method is used, the following requirements apply:

(i) Requests for proposals will be publicized and identify all evaluation factors and their relative importance. Any response to publicized requests for proposals shall be honored to the maximum extent practical;

(ii) Proposals will be solicited from an adequate number of qualified sources;

(iii) Grantees and subgrantees will have a method for conducting technical evaluations of the proposals received and for selecting awardees;

(iv) Awards will be made to the responsible firm whose proposal is most advantageous to the program, with price and other factors considered; and

(v) Grantees and subgrantees may use competitive proposal procedures for qualifications-based procurement of architectural/engineering (A/E) professional services whereby competitors' qualifications are evaluated and the most qualified competitor is selected, subject to negotiation of fair and reasonable compensation. The method, where price is not used as a selection factor, can only be used in procurement of A/E professional services. It cannot be used to purchase other types of services though A/E firms are a potential source to perform the proposed effort.

(4) Procurement by *noncompetitive proposals* is procurement through solicitation of a proposal from only one source, or after solicitation of a number of sources, competition is determined inadequate.

(i) Procurement by noncompetitive proposals may be used only when the award of a contract is infeasible under small purchase procedures, sealed bids or competitive proposals and one of the following circumstances applies:

(A) The item is available only from a single source;

(B) The public exigency or emergency for the requirement will not permit a delay resulting from competitive solicitation;

(C) The awarding agency authorizes noncompetitive proposals; or

(D) After solicitation of a number of sources, competition is determined inadequate.

(ii) Cost analysis, i.e., verifying the proposed cost data, the projections of the data, and the evaluation of the specific elements of costs and profits, is required.

(iii) Grantees and subgrantees may be required to submit the proposed procurement to the awarding agency for pre-award review in accordance with paragraph (g) of this section.

(e) *Contracting with small and minority firms, women's business enterprise and labor surplus area firms.* (1) The grantee and subgrantee will take all necessary affirmative steps to assure that minority firms, women's business enterprises, and labor surplus area firms are used when possible.

(2) Affirmative steps shall include:

(i) Placing qualified small and minority businesses and women's business enterprises on solicitation lists;

(ii) Assuring that small and minority businesses, and women's business enterprises are solicited whenever they are potential sources;

(iii) Dividing total requirements, when economically feasible, into smaller tasks or quantities to permit maximum participation by small and minority business, and women's business enterprises;

(iv) Establishing delivery schedules, where the requirement permits, which encourage participation by small and minority business, and women's business enterprises;

(v) Using the services and assistance of the Small Business Administration, and the Minority Business Development Agency of the Department of Commerce; and

(vi) Requiring the prime contractor, if subcontracts are to be let, to take the affirmative steps listed in paragraphs (e)(2) (i) through (v) of this section.

(f) *Contract cost and price.* (1) Grantees and subgrantees must perform a cost or price analysis in connection with every procurement action including contract modifications. The method and degree of analysis is dependent on the facts surrounding the particular procurement situation, but as a starting point, grantees must make independent estimates before receiving bids or proposals. A cost analysis must be performed when the offeror is required to submit the elements of his estimated cost, e.g., under professional, consulting, and architectural engineering services contracts. A cost analysis will be necessary when adequate price competition is lacking, and for sole source procurements, including contract modifications or change orders, unless price resonableness can be established on the basis of a catalog or market price of a commercial product sold in substantial quantities to the

general public or based on prices set by law or regulation. A price analysis will be used in all other instances to determine the reasonableness of the proposed contract price.

(2) Grantees and subgrantees will negotiate profit as a separate element of the price for each contract in which there is no price competition and in all cases where cost analysis is performed. To establish a fair and reasonable profit, consideration will be given to the complexity of the work to be performed, the risk borne by the contractor, the contractor's investment, the amount of subcontracting, the quality of its record of past performance, and industry profit rates in the surrounding geographical area for similar work.

(3) Costs or prices based on estimated costs for contracts under grants will be allowable only to the extent that costs incurred or cost estimates included in negotiated prices are consistent with Federal cost principles (see § 92.22). Grantees may reference their own cost principles that comply with the applicable Federal cost principles.

(4) The cost plus a percentage of cost and percentage of construction cost methods of contracting shall not be used.

(g) *Awarding agency review.* (1) Grantees and subgrantees must make available, upon request of the awarding agency, technical specifications on proposed procurements where the awarding agency believes such review is needed to ensure that the item and/or service specified is the one being proposed for purchase. This review generally will take place prior to the time the specification is incorporated into a solicitation document. However, if the grantee or subgrantee desires to have the review accomplished after a solicitation has been developed, the awarding agency may still review the specifications, with such review usually limited to the technical aspects of the proposed purchase.

(2) Grantees and subgrantees must on request make available for awarding agency pre-award review procurement documents, such as requests for proposals or invitations for bids, independent cost estimates, etc. when:

(i) A grantee's or subgrantee's procurement procedures or operation fails to comply with the procurement standards in this section; or

(ii) The procurement is expected to exceed the simplified acquisition threshold and is to be awarded without competition or only one bid or offer is received in response to a solicitation; or

(iii) The procurement, which is expected to exceed the simplified acquisition threshold, specifies a ''brand name'' product; or

(iv) The proposed award is more than the simplified acquisition threshold and is to be awarded to other than the apparent low bidder under a sealed bid procurement; or

(v) A proposed contract modification changes the scope of a contract or increases the contract amount by more than the simplified acquisition threshold.

(3) A grantee or subgrantee will be exempt from the pre-award review in paragraph (g)(2) of this section if the awarding agency determines that its procurement systems comply with the standards of this section.

(i) A grantee or subgrantee may request that its procurement system be reviewed by the awarding agency to determine whether its system meets these standards in order for its system to be certified. Generally, these reviews shall occur where there is a continuous high-dollar funding, and third-party contracts are awarded on a regular basis.

(ii) A grantee or subgrantee may self-certify its procurement system. Such self-certification shall not limit the awarding agency's right to survey the system. Under a self-certification procedure, awarding agencies may wish to rely on written assurances from the grantee or subgrantee that it is complying with these standards. A grantee or subgrantee will cite specific procedures, regulations, standards, etc., as being in compliance with these requirements and have its system available for review.

(h) *Bonding requirements.* For construction or facility improvement contracts or subcontracts exceeding the simplified acquisition threshold, the

awarding agency may accept the bonding policy and requirements of the grantee or subgrantee provided the awarding agency has made a determination that the awarding agency's interest is adequately protected. If such a determination has not been made, the minimum requirements shall be as follows:

(1) *A bid guarantee from each bidder equivalent to five percent of the bid price.* The ''bid guarantee'' shall consist of a firm commitment such as a bid bond, certified check, or other negotiable instrument accompanying a bid as assurance that the bidder will, upon acceptance of his bid, execute such contractual documents as may be required within the time specified.

(2) *A performance bond on the part of the contractor for 100 percent of the contract price.* A ''performance bond'' is one executed in connection with a contract to secure fulfillment of all the contractor's obligations under such contract.

(3) *A payment bond on the part of the contractor for 100 percent of the contract price.* A ''payment bond'' is one executed in connection with a contract to assure payment as required by law of all persons supplying labor and material in the execution of the work provided for in the contract.

(i) *Contract provisions.* A grantee's and subgrantee's contracts must contain provisions in paragraph (i) of this section. Federal agencies are permitted to require changes, remedies, changed conditions, access and records retention, suspension of work, and other clauses approved by the Office of Federal Procurement Policy.

(1) Administrative, contractual, or legal remedies in instances where contractors violate or breach contract terms, and provide for such sanctions and penalties as may be appropriate. (Contracts more than the simplified acquisition threshold)

(2) Termination for cause and for convenience by the grantee or subgrantee including the manner by which it will be effected and the basis for settlement. (All contracts in excess of $10,000)

(3) Compliance with Executive Order 11246 of September 24, 1965, entitled ''Equal Employment Opportunity,'' as amended by Executive Order 11375 of October 13, 1967, and as supplemented in Department of Labor regulations (41 CFR chapter 60). (All construction contracts awarded in excess of $10,000 by grantees and their contractors or subgrantees)

(4) Compliance with the Copeland ''Anti-Kickback'' Act (18 U.S.C. 874) as supplemented in Department of Labor regulations (29 CFR Part 3). (All contracts and subgrants for construction or repair)

(5) Compliance with the Davis-Bacon Act (40 U.S.C. 276a to 276a–7) as supplemented by Department of Labor regulations (29 CFR Part 5). (Construction contracts in excess of $2000 awarded by grantees and subgrantees when required by Federal grant program legislation)

(6) Compliance with Sections 103 and 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 327–330) as supplemented by Department of Labor regulations (29 CFR Part 5). (Construction contracts awarded by grantees and subgrantees in excess of $2000, and in excess of $2500 for other contracts which involve the employment of mechanics or laborers)

(7) Notice of awarding agency requirements and regulations pertaining to reporting.

(8) Notice of awarding agency requirements and regulations pertaining to patent rights with respect to any discovery or invention which arises or is developed in the course of or under such contract.

(9) Awarding agency requirements and regulations pertaining to copyrights and rights in data.

(10) Access by the grantee, the subgrantee, the Federal grantor agency, the Comptroller General of the United States, or any of their duly authorized representatives to any books, documents, papers, and records of the contractor which are directly pertinent to that specific contract for the purpose of making audit, examination, excerpts, and transcriptions.

(11) Retention of all required records for three years after grantees or subgrantees make final payments and all other pending matters are closed.

(12) Compliance with all applicable standards, orders, or requirements

issued under section 306 of the Clean Air Act (42 U.S.C. 1857(h)), section 508 of the Clean Water Act (33 U.S.C. 1368), Executive Order 11738, and Environmental Protection Agency regulations (40 CFR part 15). (Contracts, subcontracts, and subgrants of amounts in excess of $100,000)

(13) Mandatory standards and policies relating to energy efficiency which are contained in the state energy conservation plan issued in compliance with the Energy Policy and Conservation Act (Pub. L. 94–163, 89 Stat. 871).

[53 FR 8079, 8087, Mar. 11, 1988, as amended at 60 FR 19639, 19645, Apr. 19, 1995]

§ 92.37 Subgrants.

(a) *States.* States shall follow state law and procedures when awarding and administering subgrants (whether on a cost reimbursement or fixed amount basis) of financial assistance to local and Indian tribal governments. States shall:

(1) Ensure that every subgrant includes any clauses required by Federal statute and executive orders and their implementing regulations;

(2) Ensure that subgrantees are aware of requirements imposed upon them by Federal statute and regulation;

(3) Ensure that a provision for compliance with § 92.42 is placed in every cost reimbursement subgrant; and

(4) Conform any advances of grant funds to subgrantees substantially to the same standards of timing and amount that apply to cash advances by Federal agencies.

(b) *All other grantees.* All other grantees shall follow the provisions of this part which are applicable to awarding agencies when awarding and administering subgrants (whether on a cost reimbursement or fixed amount basis) of financial assistance to local and Indian tribal governments. Grantees shall:

(1) Ensure that every subgrant includes a provision for compliance with this part;

(2) Ensure that every subgrant includes any clauses required by Federal statute and executive orders and their implementing regulations; and

(3) Ensure that subgrantees are aware of requirements imposed upon them by Federal statutes and regulations.

(c) *Exceptions.* By their own terms, certain provisions of this part do not apply to the award and administration of subgrants:

(1) Section 92.10;

(2) Section 92.11;

(3) The letter-of-credit procedures specified in Treasury Regulations at 31 CFR Part 205, cited in § 92.21; and

(4) Section 92.50.

REPORTS, RECORDS RETENTION, AND ENFORCEMENT

§ 92.40 Monitoring and reporting program performance.

(a) *Monitoring by grantees.* Grantees are responsible for managing the day-to-day operations of grant and subgrant supported activities. Grantees must monitor grant and subgrant supported activities to assure compliance with applicable Federal requirements and that performance goals are being achieved. Grantee monitoring must cover each program, function or activity.

(b) *Nonconstruction performance reports.* The Federal agency may, if it decides that performance information available from subsequent applications contains sufficient information to meet its programmatic needs, require the grantee to submit a performance report only upon expiration or termination of grant support. Unless waived by the Federal agency this report will be due on the same date as the final Financial Status Report.

(1) Grantees shall submit annual performance reports unless the awarding agency requires quarterly or semi-annual reports. However, performance reports will not be required more frequently than quarterly. Annual reports shall be due 90 days after the grant year, quarterly or semi-annual reports shall be due 30 days after the reporting period. The final performance report will be due 90 days after the expiration or termination of grant support. If a justified request is submitted by a grantee, the Federal agency may extend the due date for any performance report. Additionally, requirements for unnecessary performance reports may be waived by the Federal agency.

(2) Performance reports will contain, for each grant, brief information on the following:

(i) A comparison of actual accomplishments to the objectives established for the period. Where the output of the project can be quantified, a computation of the cost per unit of output may be required if that information will be useful.

(ii) The reasons for slippage if established objectives were not met.

(iii) Additional pertinent information including, when appropriate, analysis and explanation of cost overruns or high unit costs.

(3) Grantees will not be required to submit more than the original and two copies of performance reports.

(4) Grantees will adhere to the standards in this section in prescribing performance reporting requirements for subgrantees.

(c) *Construction performance reports.* For the most part, on-site technical inspections and certified percentage-of-completion data are relied on heavily by Federal agencies to monitor progress under construction grants and subgrants. The Federal agency will require additional formal performance reports only when considered necessary, and never more frequently than quarterly.

(d) *Significant developments.* Events may occur between the scheduled performance reporting dates which have significant impact upon the grant or subgrant supported activity. In such cases, the grantee must inform the Federal agency as soon as the following types of conditions become known:

(1) Problems, delays, or adverse conditions which will materially impair the ability to meet the objective of the award. This disclosure must include a statement of the action taken, or contemplated, and any assistance needed to resolve the situation.

(2) Favorable developments which enable meeting time schedules and objectives sooner or at less cost than anticipated or producing more beneficial results than originally planned.

(e) Federal agencies may make site visits as warranted by program needs.

(f) *Waivers, extensions.* (1) Federal agencies may waive any performance report required by this part if not needed.

(2) The grantee may waive any performance report from a subgrantee when not needed. The grantee may extend the due date for any performance report from a subgrantee if the grantee will still be able to meet its performance reporting obligations to the Federal agency.

§92.41 Financial reporting.

(a) *General.* (1) Except as provided in paragraphs (a) (2) and (5) of this section, grantees will use only the forms specified in paragraphs (a) through (e) of this section, and such supplementary or other forms as may from time to time be authorized by OMB, for:

(i) Submitting financial reports to Federal agencies, or

(ii) Requesting advances or reimbursements when letters of credit are not used.

(2) Grantees need not apply the forms prescribed in this section in dealing with their subgrantees. However, grantees shall not impose more burdensome requirements on subgrantees.

(3) Grantees shall follow all applicable standard and supplemental Federal agency instructions approved by OMB to the extend required under the Paperwork Reduction Act of 1980 for use in connection with forms specified in paragraphs (b) through (e) of this section. Federal agencies may issue substantive supplementary instructions only with the approval of OMB. Federal agencies may shade out or instruct the grantee to disregard any line item that the Federal agency finds unnecessary for its decisionmaking purposes.

(4) Grantees will not be required to submit more than the original and two copies of forms required under this part.

(5) Federal agencies may provide computer outputs to grantees to expedite or contribute to the accuracy of reporting. Federal agencies may accept the required information from grantees in machine usable format or computer printouts instead of prescribed forms.

(6) Federal agencies may waive any report required by this section if not needed.

(7) Federal agencies may extend the due date of any financial report upon receiving a justified request from a grantee.

(b) *Financial Status Report*—(1) *Form.* Grantees will use Standard Form 269 or 269A, Financial Status Report, to report the status of funds for all nonconstruction grants and for construction grants when required in accordance with § 92.41(e)(2)(iii).

(2) *Accounting basis.* Each grantee will report program outlays and program income on a cash or accrual basis as prescribed by the awarding agency. If the Federal agency requires accrual information and the grantee's accounting records are not normally kept on the accural basis, the grantee shall not be required to convert its accounting system but shall develop such accrual information through and analysis of the documentation on hand.

(3) *Frequency.* The Federal agency may prescribe the frequency of the report for each project or program. However, the report will not be required more frequently than quarterly. If the Federal agency does not specify the frequency of the report, it will be submitted annually. A final report will be required upon expiration or termination of grant support.

(4) *Due date.* When reports are required on a quarterly or semiannual basis, they will be due 30 days after the reporting period. When required on an annual basis, they will be due 90 days after the grant year. Final reports will be due 90 days after the expiration or termination of grant support.

(c) *Federal Cash Transactions Report*—(1) *Form.* (i) For grants paid by letter or credit, Treasury check advances or electronic transfer of funds, the grantee will submit the Standard Form 272, Federal Cash Transactions Report, and when necessary, its continuation sheet, Standard Form 272a, unless the terms of the award exempt the grantee from this requirement.

(ii) These reports will be used by the Federal agency to monitor cash advanced to grantees and to obtain disbursement or outlay information for each grant from grantees. The format of the report may be adapted as appropriate when reporting is to be accomplished with the assistance of automatic data processing equipment provided that the information to be submitted is not changed in substance.

(2) *Forecasts of Federal cash requirements.* Forecasts of Federal cash requirements may be required in the ''Remarks'' section of the report.

(3) *Cash in hands of subgrantees.* When considered necessary and feasible by the Federal agency, grantees may be required to report the amount of cash advances in excess of three days' needs in the hands of their subgrantees or contractors and to provide short narrative explanations of actions taken by the grantee to reduce the excess balances.

(4) *Frequency and due date.* Grantees must submit the report no later than 15 working days following the end of each quarter. However, where an advance either by letter of credit or electronic transfer of funds is authorized at an annualized rate of one million dollars or more, the Federal agency may require the report to be submitted within 15 working days following the end f each month.

(d) *Request for advance or reimbursement*—(1) *Advance payments.* Requests for Treasury check advance payments will be submitted on Standard Form 270, Request for Advance or Reimbursement. (This form will not be used for drawdowns under a letter of credit, electronic funds transfer or when Treasury check advance payments are made to the grantee automatically on a predetermined basis.)

(2) *Reimbursements.* Requests for reimbursement under nonconstruction grants will also be submitted on Standard Form 270. (For reimbursement requests under construction grants, see paragraph (e)(1) of this section.)

(3) The frequency for submitting payment requests is treated in § 92.41(b)(3).

(e) *Outlay report and request for reimbursement for construction programs*—(1) *Grants that support construction activities paid by reimbursement method.* (i) Requests for reimbursement under construction grants will be submitted on Standard Form 271, Outlay Report and Request for Reimbursement for Construction Programs. Federal agencies may, however, prescribe the Request for Advance or Reimbursement form,

specified in §92.41(d), instead of this form.

(ii) The frequency for submitting reimbursement requests is treated in §92.41(b)(3).

(2) *Grants that support construction activities paid by letter of credit, electronic funds transfer or Treasury check advance.* (i) When a construction grant is paid by letter of credit, electronic funds transfer or Treasury check advances, the grantee will report its outlays to the Federal agency using Standard Form 271, Outlay Report and Request for Reimbursement for Construction Programs. The Federal agency will provide any necessary special instruction. However, frequency and due date shall be governed by §92.41(b)(3) and (4).

(ii) When a construction grant is paid by Treasury check advances based on periodic requests from the grantee, the advances will be requested on the form specified in §92.41(d).

(iii) The Federal agency may substitute the Financial Status Report specified in §92.41(b) for the Outlay Report and Request for Reimbursement for Construction Programs.

(3) *Accounting basis.* The accounting basis for the Outlay Report and Request for Reimbursement for Construction Programs shall be governed by §92.41(b)(2).

§92.42 Retention and access requirements for records.

(a) *Applicability.* (1) This section applies to all financial and programmatic records, supporting documents, statistical records, and other records of grantees or subgrantees which are:

(i) Required to be maintained by the terms of this part, program regulations or the grant agreement, or

(ii) Otherwise reasonably considered as pertinent to program regulations or the grant agreement.

(2) This section does not apply to records maintained by contractors or subcontractors. For a requirement to place a provision concerning records in certain kinds of contracts, see §92.36(i)(10).

(b) *Length of retention period.* (1) Except as otherwise provided, records must be retained for three years from the starting date specified in paragraph (c) of this section.

(2) If any litigation, claim, negotiation, audit or other action involving the records has been started before the expiration of the 3-year period, the records must be retained until completion of the action and resolution of all issues which arise from it, or until the end of the regular 3-year period, whichever is later.

(3) To avoid duplicate recordkeeping, awarding agencies may make special arrangements with grantees and subgrantees to retain any records which are continuously needed for joint use. The awarding agency will request transfer of records to its custody when it determines that the records possess long-term retention value. When the records are transferred to or maintained by the Federal agency, the 3-year retention requirement is not applicable to the grantee or subgrantee.

(c) *Starting date of retention period*—(1) *General.* When grant support is continued or renewed at annual or other intervals, the retention period for the records of each funding period starts on the day the grantee or subgrantee submits to the awarding agency its single or last expenditure report for that period. However, if grant support is continued or renewed quarterly, the retention period for each year's records starts on the day the grantee submits its expenditure report for the last quarter of the Federal fiscal year. In all other cases, the retention period starts on the day the grantee submits its final expenditure report. If an expenditure report has been waived, the retention period starts on the day the report would have been due.

(2) *Real property and equipment records.* The retention period for real property and equipment records starts from the date of the disposition or replacement or transfer at the direction of the awarding agency.

(3) *Records for income transactions after grant or subgrant support.* In some cases grantees must report income after the period of grant support. Where there is such a requirement, the retention period for the records pertaining to the earning of the income starts from the end of the grantee's fiscal year in which the income is earned.

(4) *Indirect cost rate proposals, cost allocations plans, etc.* This paragraph applies to the following types of documents, and their supporting records: indirect cost rate computations or proposals, cost allocation plans, and any similar accounting computations of the rate at which a particular group of costs is chargeable (such as computer usage chargeback rates or composite fringe benefit rates).

(i) *If submitted for negotiation.* If the proposal, plan, or other computation is required to be submitted to the Federal Government (or to the grantee) to form the basis for negotiation of the rate, then the 3-year retention period for its supporting records starts from the date of such submission.

(ii) *If not submitted for negotiation.* If the proposal, plan, or other computation is not required to be submitted to the Federal Government (or to the grantee) for negotiation purposes, then the 3-year retention period for the proposal plan, or computation and its supporting records starts from end of the fiscal year (or other accounting period) covered by the proposal, plan, or other computation.

(d) *Substitution of microfilm.* Copies made by microfilming, photocopying, or similar methods may be substituted for the original records.

(e) *Access to records*—(1) *Records of grantees and subgrantees.* The awarding agency and the Comptroller General of the United States, or any of their authorized representatives, shall have the right of access to any pertinent books, documents, papers, or other records of grantees and subgrantees which are pertinent to the grant, in order to make audits, examinations, excerpts, and transcripts.

(2) *Expiration of right of access.* The rights of access in this section must not be limited to the required retention period but shall last as long as the records are retained.

(f) *Restrictions on public access.* The Federal Freedom of Information Act (5 U.S.C. 552) does not apply to records unless required by Federal, State, or local law, grantees and subgrantees are not required to permit public access to their records.

§ 92.43 Enforcement.

(a) *Remedies for noncompliance.* If a grantee or subgrantee materially fails to comply with any term of an award, whether stated in a Federal statute or regulation, an assurance, in a State plan or application, a notice of award, or elsewhere, the awarding agency may take one or more of the following actions, as appropriate in the circumstances:

(1) Temporarily withhold cash payments pending correction of the deficiency by the grantee or subgrantee or more severe enforcement action by the awarding agency,

(2) Disallow (that is, deny both use of funds and matching credit for) all or part of the cost of the activity or action not in compliance,

(3) Wholly or partly suspend or terminate the current award for the grantee's or subgrantee's program,

(4) Withhold further awards for the program, or

(5) Take other remedies that may be legally available.

(b) *Hearings, appeals.* In taking an enforcement action, the awarding agency will provide the grantee or subgrantee an opportunity for such hearing, appeal, or other administrative proceeding to which the grantee or subgrantee is entitled under any statute or regulation applicable to the action involved.

(c) *Effects of suspension and termination.* Costs of grantee or subgrantee resulting from obligations incurred by the grantee or subgrantee during a suspension or after termination of an award are not allowable unless the awarding agency expressly authorizes them in the notice of suspension or termination or subsequently. Other grantee or subgrantee costs during suspension or after termination which are necessary and not reasonably avoidable are allowable if:

(1) The costs result from obligations which were properly incurred by the grantee or subgrantee before the effective date of suspension or termination, are not in anticipation of it, and, in the case of a termination, are noncancellable, and,

(2) The costs would be allowable if the award were not suspended or expired normally at the end of the funding period in which the termination takes effect.

(d) *Relationship to debarment and suspension.* The enforcement remedies identified in this section, including suspension and termination, do not preclude grantee or subgrantee from being subject to ''Debarment and Suspension'' under E.O. 12549 (see § 92.35).

§ 92.44 Termination for convenience.

Except as provided in § 92.43 awards may be terminated in whole or in part only as follows:

(a) By the awarding agency with the consent of the grantee or subgrantee in which case the two parties shall agree upon the termination conditions, including the effective date and in the case of partial termination, the portion to be terminated, or

(b) By the grantee or subgrantee upon written notification to the awarding agency, setting forth the reasons for such termination, the effective date, and in the case of partial termination, the portion to be terminated. However, if, in the case of a partial termination, the awarding agency determines that the remaining portion of the award will not accomplish the purposes for which the award was made, the awarding agency may terminate the award in its entirety under either § 92.43 or paragraph (a) of this section.

Subpart D—After-the-Grant Requirements

§ 92.50 Closeout.

(a) *General.* The Federal agency will close out the award when it determines that all applicable administrative actions and all required work of the grant has been completed.

(b) *Reports.* Within 90 days after the expiration or termination of the grant, the grantee must submit all financial, performance, and other reports required as a condition of the grant. Upon request by the grantee, Federal agencies may extend this timeframe. These may include but are not limited to:

(1) *Final performance or progress report.*

(2) *Financial Status Report (SF 269) or Outlay Report and Request for Reimbursement for Construction Programs (SF–271) (as applicable).*

(3) *Final request for payment (SF–270) (if applicable).*

(4) *Invention disclosure (if applicable).*

(5) *Federally-owned property report:*

In accordance with § 92.32(f), a grantee must submit an inventory of all federally owned property (as distinct from property acquired with grant funds) for which it is accountable and request disposition instructions from the Federal agency of property no longer needed.

(c) *Cost adjustment.* The Federal agency will, within 90 days after receipt of reports in paragraph (b) of this section, make upward or downward adjustments to the allowable costs.

(d) *Cash adjustments.* (1) The Federal agency will make prompt payment to the grantee for allowable reimbursable costs.

(2) The grantee must immediately refund to the Federal agency any balance of unobligated (unencumbered) cash advanced that is not authorized to be retained for use on other grants.

§ 92.51 Later disallowances and adjustments.

The closeout of a grant does not affect:

(a) The Federal agency's right to disallow costs and recover funds on the basis of a later audit or other review;

(b) The grantee's obligation to return any funds due as a result of later refunds, corrections, or other transactions;

(c) Records retention as required in § 92.42;

(d) Property management requirements in §§ 92.31 and 92.32; and

(e) Audit requirements in § 92.26.

§ 92.52 Collection of amounts due.

(a) Any funds paid to a grantee in excess of the amount to which the grantee is finally determined to be entitled under the terms of the award constitute a debt to the Federal Government. If not paid within a reasonable period after demand, the Federal agency may reduce the debt by:

(1) Making an adminstrative offset against other requests for reimbursements,

(2) Withholding advance payments otherwise due to the grantee, or

(3) Other action permitted by law.

(b) Except where otherwise provided by statutes or regulations, the Federal agency will charge interest on an overdue debt in accordance with the Federal Claims Collection Standards (4 CFR Ch. II). The date from which interest is computed is not extended by litigation or the filing of any form of appeal.

PART 93—NEW RESTRICTIONS ON LOBBYING

Subpart A—General

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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).

CROSS REFERENCE: See also Office of Management and Budget notice published at 54 FR 52306, December 20, 1989.

SOURCE: 55 FR 6754, Feb. 26, 1990, unless otherwise noted.

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 ageement 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 paragraph (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 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.

(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:

(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 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 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) 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.

(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 $100,000 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 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.

§ 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:

(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 required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 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.

APPENDIX B TO PART 93—DISCLOSURE FORM TO REPORT LOBBYING

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

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):*	**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 mintues 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 regarding Investigator financial conflicts of interest.

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 agency) 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.

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:

(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

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:

(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 noncompliance, 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 noncompliance, 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

(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 Institution'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,

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

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.

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.
Title IV-E—Foster Care and Adoption Assistance.
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

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.

§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.

(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

(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 agency 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 approporiate 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.

(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/department 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.

(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 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.

(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 requirements 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.

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 standalone 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

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 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 §§ 1355.54 through 1355.57, § 307.15 and 42 CFR subchapter C, part 433.

(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;

(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]

§ 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 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

enhanced matching rate authorized by § 205.35, Part 307, § 1355.52 or 42 CFR part 433, subpart C, regardless of the acquisition cost.

(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;

(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.

(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 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]

§ 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 State Automated Child Welfare Information System (SACWIS) project, *see* § 1355.56.

[75 FR 66339, Oct. 28, 2010]

§ 95.613 Procurement standards.

(a) *General.* Procurements of ADP equipment and services are subject to the procurement standards prescribed by Part 92 regardless of any conditions for prior approval. The Department retains the authority to provide greater oversight including requiring a State to comply with § 92.36(c) 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]

§ 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 Part 92 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 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]

§ 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 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 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, IV-E, 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 XIX program are contained in 42 CFR Part 433, Subpart C.

[59 FR 30708, June 15, 1994]

§ 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]

§ 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 approved 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 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 part 92.

(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, 75 FR 66341, Oct. 28, 2010]

§ 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 approved APD), the equipment shall be subject to the property disposal rules in § 92.32, Equipment.

(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, 75 FR 66341, Oct. 28, 2010]

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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.

(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. 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–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 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]

§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 prohibitions 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 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]

§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 organization 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 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, 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.

(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 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 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 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 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 authority, 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.

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 energy 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, 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 nonservice 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 reallotment.

(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 reallotment 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 reallotment 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 reallotment.

(c) *Conditions for reallotment.* If the total amount available for reallotment for a fiscal year is less than $25,000, the Department will not reallot such amount. If the total amount available for reallotment for a fiscal year is $25,000 or more, the Department will reallot such amount, except that the Department will not award less than $25 in reallotted 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 section 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 wavier 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 wavier 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 wavier 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 wavier 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 meet 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 preceding 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 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 determine 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 activities 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 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 weatherization 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 preceeding 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 contained 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 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 emergency 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]

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.

§ 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.

§ 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 C.F.R. 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 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:

(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.

(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 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 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 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;

(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 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

(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:

(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 nonprofit 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 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;

(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 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:

(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 C.F.R. 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 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 establishing 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 nonprofit 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 nonprofit 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 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 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.

(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 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.

§ 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 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 nonprofit 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 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 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.

§ 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

1. Adoption Services
2. Case Management Services
3. Congregate Meals
4. Counseling Services
5. Day Care Services—Adults
6. Day Care Services—Children
7. Education and Training Services
8. Employment Services
9. Family Planning Services
10. Foster Care Services for Adults
11. Foster Care Services for Children
12. Health Related and Home Health Services
13. Home Based Services
14. Home Delivered Meals
15. Housing Services
16. Independent and Transitional Living Services
17. Information and Referral Services
18. Legal Services
19. Pregnancy and Parenting Services for Young Parents
20. Prevention and Intervention Services
21. Protective Services for Adults
22. Protective Services for Children
23. Recreational Services
24. Residential Treatment Services
25. Special Services for Persons with Developmental or Physical Disabilities, or Persons with Visual or Auditory Impairments
26. Special Services for Youth Involved in or At Risk of Involvement in Criminal Activity
27. Substance Abuse Services
28. Transportation Services
29. Other Services

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 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.

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 evaluation 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 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 living 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.

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 5¼Prime; or 3½Prime;; 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.

Contact: _____
Title: _____
Date: _____

ANNUAL REPORT OF SERVICES FUNDED BY THE
SOCIAL SERVICES BLOCK GRANT (SSBG)
FOR FISCAL YEAR 19__

STATE:

Report Covers Period of:
_____ to _____
Mo./Yr. Mo./Yr

		Number of Recipients					Expenditures							Provision Method	
	Service	Adults	C	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 Svcs. - Adults														
11	Foster Care Svcs. - Children														
12	Health Related Services														
13	Home Based Services														
14	Home Delivered Meals														
15	Housing Services														
16	Indep./Trans. Living Svcs.														
17	Info. & Referral Services														
18	Legal Services														
19	Pregnancy & Parenting														
20	Prevention/Intervention														
21	Protective Svcs. - Adults														
22	Protective Svcs. - Children														
23	Recreation Services														
24	Residential Treatment														
25	Spec. Svcs. - Youth at Risk														
26	Special Svcs. - Disabled														
27	Substance Abuse Services														
28	Transportation														
29	Other Services														
30	Other Expenditures														
	a. Tranfers In														
	b. Tranfers Out														
	c. Carry Forward														
	d. Carry Over														
	e. Administrative Costs														
	TOTAL →														

[58 FR 60128, Nov. 15, 1993]

PART 97—CONSOLIDATION OF GRANTS TO THE INSULAR AREAS

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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]

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[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

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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 Goals and purposes.

(a) The goals of the CCDF are to:

(1) Allow each State maximum flexibility in developing child care programs and policies that best suit the needs of children and parents within the State;

(2) Promote parental choice to empower working parents to make their own decisions on the child care that best suits their family's needs;

(3) Encourage States to provide consumer education information to help parents make informed choices about child care;

(4) Assist States to provide child care to parents trying to achieve independence from public assistance; and

(5) Assist States in implementing the health, safety, licensing, and registration standards established in State regulations.

(b) The purpose of the CCDF is to increase the availability, affordability, and quality of child care services. The program offers Federal funding to States, Territories, Indian Tribes, and tribal organizations in order to:

(1) Provide low-income families with the financial resources to find and afford quality child care for their children;

(2) Enhance the quality and increase the supply of child care for all families,

including those who receive no direct assistance under the CCDF;

(3) Provide parents with a broad range of options in addressing their child care needs;

(4) Strengthen the role of the family;

(5) Improve the quality of, and coordination among, child care programs and early childhood development programs; and

(6) Increase the availability of early childhood development and before- and after-school care services.

(c) The purpose of these regulations is to provide the basis for administration of the Fund. These regulations provide that Lead Agencies:

(1) Maximize parental choice through the use of certificates and through grants and contracts;

(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) Provide quality child care that meets applicable requirements;

(4) Coordinate planning and delivery of services at all levels;

(5) Design flexible programs that provide for the changing needs of recipient families;

(6) Administer the CCDF responsibly to ensure that statutory requirements are met and that adequate information regarding the use of public funds is provided; and

(7) Design programs that provide uninterrupted service to families and providers, to the extent statutorily possible.

§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, group home 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 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;

Construction means the erection of a facility that does not currently exist;

The Department means the Department of Health and Human Services;

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:

(1) A center-based child care provider, a group home 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, sibling (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;

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 individual who provides child care services for fewer than 24 hours per day per child, as the sole caregiver, 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;

Group home child care provider means two or more individuals 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 designated under §§ 98.10 and 98.16(a) to which a 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: (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, even if such renovation does not include any structural change;

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 and availability activities pursuant to §98.51;

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 §98.42;

State means any of the States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and includes Tribes unless otherwise specified;

Tribal mandatory funds means the child care funds set aside at section 418(a)(4) of the Social Security Act. The funds consist of between one and two percent of the aggregate Mandatory and Matching child care funds reserved by the Secretary in each fiscal year 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 benefiting 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 nonprofit providers, for-profit providers, sectarian providers and relatives who provide care.

§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 expenditure 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, as designated by the chief executive officer 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); and

(e) Coordinate CCDF services pursuant to § 98.12.

§ 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:

(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.

(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 subgrantees and contractors;

(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.

§ 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, with any Indian Tribes in the State receiving CCDF funds in accordance with subpart I of this part.

§ 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 45 CFR 76.500;

(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;

(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.

§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 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. The Lead Agency shall also coordinate with the State, and if applicable, tribal agencies responsible for:

(A) Public health, including the agency responsible for immunizations;

(B) Employment services/workforce development;

(C) Public education; and

(D) Providing Temporary Assistance for Needy Families.

(2) Provide a description of the results of the coordination with each of these agencies in the CCDF Plan.

(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.

§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 regulatory 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 § 98.53(h)(1).

(b) The Lead Agency shall include the following certifications in its CCDF Plan:

(1) In accordance with § 98.31, it 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;

(2) 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;

(3) It will collect and disseminate to parents of eligible children and the general public, consumer education information that will promote informed child care choices, as required by § 98.33;

(4) There are in effect licensing requirements applicable to child care services provided within the State (or area served by Tribal Lead Agency), pursuant to § 98.40;

(5) 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;

(6) In accordance with § 98.41, 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; and

(7) Payment rates for the provision of child care services, in accordance with § 98.43, 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.

§ 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) The assurances and certifications listed under § 98.15;

(c)(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 Sec. 98.53(f);

(d) A description of the coordination and consultation processes involved in the development of the Plan, including a description of public-private partnership activities that promote business involvement in meeting child care needs pursuant to § 98.14(a) and (b);

(e) A description of the public hearing process, pursuant to § 98.14(c);

(f) Definitions of the following terms for purposes of determining eligibility, pursuant to §§ 98.20(a) and 98.44:

(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*.

(g) 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)(iv);

(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 additional eligibility criteria, priority rules and definitions established pursuant to §98.20(b);

(h) A description of the activities to provide comprehensive consumer education, to increase parental choice, and to improve the quality and availability of child care, pursuant to §98.51;

(i) 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, pursuant to §98.42;

(j) 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;

(k) 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);

(l) Payment rates and a summary of the facts, including a biennial local market rate survey, relied upon to determine that the rates provided are sufficient to ensure equal access pursuant to §98.43;

(m) A detailed description of 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;

(n) 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;

(o) A detailed description of the licensing requirements applicable to child care services provided, and a description of how such licensing requirements are effectively enforced, pursuant to §98.40;

(p) Pursuant to §98.33(b), the definitions or criteria used to implement the exception, provided in section 407(e)(2) of the Social Security Act, to individual penalties in the TANF work requirement applicable to a single custodial parent caring for a child under age six;

(q)(1) When any Matching funds under §98.53(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 §98.53(c)(1), or for more than 10% of the funds available at §98.53(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; and

(r) Such other information as specified by the Secretary.

[63 FR 39981, July 24, 1998, as amended at 72 FR 27979, May 18, 2007]

§98.17 Period covered by Plan.

(a) For States, Territories, and Indian Tribes the Plan shall cover a period of two 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.

§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.* 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 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.

(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.

Subpart C—Eligibility for Services

§ 98.20 A child's eligibility for child care services.

(a) In order to be eligible for services under § 98.50, a child shall:

(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) Reside with a family whose income does not exceed 85 percent of the State's median income for a family of the same size; and

(3)(i) Reside with a parent or parents (as defined in § 98.2) who are working or attending a job training or educational program; or

(ii) Receive, or need to receive, protective services and reside with a parent or parents (as defined in § 98.2) 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 and in § 98.42 may be waived for families eligible for child care pursuant to this paragraph, if determined to be necessary on a case-by-case basis by, or in consultation with, an appropriate protective services worker.

(B) At grantee option, the provisions in (A) apply to children in foster care when defined in the Plan, pursuant to § 98.16(f)(7).

(b) Pursuant to § 98.16(g)(5), a grantee or other administering agency may establish eligibility conditions or priority rules in addition to those specified in this section and § 98.44 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; or

(3) Violate the provisions of this section, § 98.44, 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.

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) 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 required 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) Group home child care;

(iii) Family child care; and

(iv) In-home child care, with limitations, if any, imposed by the Lead Agency and described in its Plan at §98.16(g)(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 §98.43, 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; or

(3) Excluding a significant number of providers in any category of care or of any type as defined in §98.2.

§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 of such procedures.

§98.32 Parental complaints.

The State shall:

(a) Maintain a record of substantiated parental complaints;

(b) Make information regarding such parental complaints available to the public on request; and

(c) The Lead Agency shall provide a detailed description of how such record is maintained and is made available.

§98.33 Consumer education.

The Lead Agency shall:

(a) Certify that it will collect and disseminate to parents and the general public consumer education information that will promote informed child care choices including, at a minimum, information about

(1) The full range of providers available, and

(2) Health and safety requirements;

(b) Inform parents who receive TANF benefits about the requirement at section 407(e)(2) of the Social Security Act 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 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 (b) of this section will count toward the time limit on Federal benefits required at section 408(a)(7) of the Social Security Act.

(c) Include in the biennial Plan the definitions or criteria the TANF agency uses in implementing the exception to the work requirement specified in paragraph (b) of this section.

§ 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) Provide a detailed description 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).

§ 98.41 Health and safety requirements.

(a) Although the Act specifically states it does not require the establishment of any new or additional requirements if existing requirements comply with the requirements of the statute, 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 designed to protect the health and safety of children that are applicable to child care providers of services for which assistance is provided under this part. Such requirements shall include:

(1) The prevention and control of infectious diseases (including immunizations). With respect to immunizations, the following provisions apply:

(i) As part of their health and safety provisions in this area, States and Territories 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 immunizations of the respective State or territorial public health agency.

(ii) Notwithstanding paragraph (a)(1)(i) of this section, Lead Agencies may exempt:

(A) Children who are cared for by relatives (defined as grandparents, great grandparents, siblings (if living in a separate residence), aunts, and uncles);

(B) Children who receive care in their own homes;

(C) Children whose parents object to immunization on religious grounds; and

(D) Children whose medical condition contraindicates immunization;

(iii) Lead Agencies shall establish a grace period in which children can receive services while families are taking

the necessary actions to comply with the immunization requirements;

(2) Building and physical premises safety; and

(3) Minimum health and safety training appropriate to the provider setting.

(b) Lead Agencies may not set health and safety standards and requirements under 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 Agency, except the relatives specified in paragraph (e) of this section.

(d) Each Lead Agency shall certify that procedures are in effect to ensure that child care providers of services for which assistance is provided under this part, within the area served by the Lead Agency, comply with all applicable State, local, or tribal health and safety requirements described in paragraph (a) of this section.

(e) For the purposes of this section, the term ''child care providers'' does not include grandparents, great grandparents, siblings (if such providers live in a separate residence), aunts, or uncles, pursuant to §98.2.

§98.42 Sliding fee scales.

(a) Lead Agencies shall establish, and periodically revise, by rule, a sliding fee scale(s) that provides for cost sharing by families that receive CCDF child care services.

(b) A sliding fee scale(s) shall be based on income and the size of the family and may be based on other factors as appropriate.

(c) Lead Agencies may waive contributions from families whose incomes are at or below the poverty level for a family of the same size.

§98.43 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 a summary of the 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, *e.g.*, center, group, family, and in-home care, is made available;

(2) How payment rates are adequate based on a local market rate survey conducted no earlier than two years prior to the effective date of the currently approved Plan;

(3) How copayments based on a sliding fee scale are affordable, as stipulated at §98.42.

(c) A Lead Agency may not establish different payment rates based on a family's eligibility status or circumstances.

(d) Payment rates under paragraph (a) of this section shall be consistent with the parental choice requirements in §98.30.

(e) Nothing in this section shall be construed to create a private right of action.

§98.44 Priority for child care services.

Lead Agencies shall give priority for services provided under §98.50(a) to:

(a) Children of families with very low family income (considering family size); and

(b) Children with special needs.

§98.45 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.

§98.46 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 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.

§ 98.47 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.

Subpart F—Use of Child Care and Development Funds

§ 98.50 Child care services.

(a) Of the funds remaining after applying the provisions of paragraphs (c), (d) and (e) of this section the Lead Agency shall spend a substantial portion to provide child care services to low-income working families.

(b) Child care services shall be provided:

(1) To eligible children, as described in § 98.20;

(2) Using a sliding fee scale, as described in § 98.42;

(3) Using funding methods provided for in § 98.30; and

(4) Based on the priorities in § 98.44.

(c) Of the aggregate amount of funds expended (i.e., Discretionary, Mandatory, and Federal and State share of Matching Funds), no less than four percent shall be used for activities to improve the quality of child care as described at § 98.51.

(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 § 98.52.

(e) Not less than 70 percent of the Mandatory and 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) Pursuant to §98.16(g)(4), the Plan shall specify how the State will meet the child care needs of families described in paragraph (e) of this section.

§98.51 Activities to improve the quality of child care.

(a) No less than four percent of the aggregate funds expended by the Lead Agency for a fiscal year, and including the amounts expended in the State pursuant to §98.53(b), shall be expended for quality activities.

(1) These activities may include but are not limited to:

(i) Activities designed to provide comprehensive consumer education to parents and the public;

(ii) Activities that increase parental choice; and

(iii) Activities designed to improve the quality and availability of child care, including, but not limited to those described in paragraph (2) of this section.

(2) Activities to improve the quality of child care services may include, but are not limited to:

(i) Operating directly or providing financial assistance to organizations (including private non-profit organizations, public organizations, and units of general purpose local government) for the development, establishment, expansion, operation, and coordination of resource and referral programs specifically related to child care;

(ii) Making grants or providing loans to child care providers to assist such providers in meeting applicable State, local, and tribal child care standards, including applicable health and safety requirements, pursuant to §§98.40 and 98.41;

(iii) Improving the monitoring of compliance with, and enforcement of, applicable State, local, and tribal requirements pursuant to §§98.40 and 98.41;

(iv) Providing training and technical assistance in areas appropriate to the provision of child care services, such as training in health and safety, nutrition, first aid, the recognition of communicable diseases, child abuse detection and prevention, and care of children with special needs;

(v) Improving salaries and other compensation (such as fringe benefits) for full-and part-time staff who provide child care services for which assistance is provided under this part; and

(vi) Any other activities that are consistent with the intent of this section.

(b) Pursuant to §98.16(h), the Lead Agency shall describe in its Plan the activities it will fund under this section.

(c) Non-Federal expenditures required by §98.53(c) (i.e., the maintenance-of-effort amount) are not subject to the requirement at paragraph (a) of this section.

§98.52 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 §98.53(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;

(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 § 98.55.

(b) 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.

(c) Non-Federal expenditures required by § 98.53(c) (i.e., the maintenance-of-effort amount) are not subject to the five percent limitation at paragraph (a) of this section.

§ 98.53 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 § 98.53(f) (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 subsection. 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(c)(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 §98.42.

(h) Public pre-kindergarten (pre-K) expenditures:

(1) May be used to meet the maintenance-of-effort requirement only if the 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(q), 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)(3).

[63 FR 39981, July 24, 1998, as amended at 72 FR 27979, May 18, 2007]

§98.54 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 agencies 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.

(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. Pursuant to § 98.2, 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) The CCDF may not be used as the non-Federal share for other Federal grant programs.

§ 98.55 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.

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) Mandatory and Matching Funds are available to States;

(3) Tribal Mandatory Funds are available to Tribes.

(b) Subject to the availability of appropriations, in accordance with the apportionment of funds from the Office of Management and Budget, the Secretary:

(1) May withhold no more than one-quarter of one percent of the CCDF funds made available for a fiscal year for the provision of technical assistance; and

(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 § 98.53 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) 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.

(4) Except for paragraph (d)(5) 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 45 CFR 92.3, Obligations and Outlays (expenditures).

(5) 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.

(6) For purposes of the CCDF, funds for child care services provided through

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.

(7) 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 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, pursuant to §98.51(a)(2)(ii), 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.

§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 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.

(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:

(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:

$$\frac{YCF_t \times APF_t}{\sum\left(YCF_t \times APF_t\right)} \times \begin{array}{c}\text{amount reserved for}\\ \text{Territories at paragraph}\\ \text{(a) of this section.}\end{array}$$

(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*) an amount up to 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 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.

§ 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) of the Social Security Act, less the amounts reserved for technical assistance pursuant to § 98.60(b)(1) and the amount reserved for

Tribes pursuant to paragraph (b) of this section, 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 up to 2 percent of the amount appropriated under section 418(a)(3) 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;

(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.

§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 the Secretary for the second preceding fiscal year.

(b) For purposes of this subsection, the amounts available under section 418(a)(3) of the Social Security Act excludes the amounts reserved and allocated under §98.60(b)(1) for technical assistance and under §98.62(a) and (b) for the Mandatory Fund.

(c) Amounts under this subsection are available pursuant to the requirements at §98.53(c).

§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 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. Funds granted to the Territories are not subject to reallotment. Any 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 § 98.53(c) in the period for which the grant was first made. For purposes of this paragraph 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 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 reallotted to other tribal grantees in proportion to their original allotments. States and Territories may not receive reallotted 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 reallotment reports submitted by Tribes, the Secretary will reallot Tribal Discretionary Funds among the other Tribes.

(i) If the total amount available for reallotment is $25,000 or more, funds will be reallotted 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 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 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 reallotment report by the deadline for report submittal, either:

(i) The Secretary will determine that Tribe does not have any funds available for reallotment; or

(ii) In the case of a report received after the deadline established by the Secretary, any funds reported to be available for reallotment shall revert to the Federal government.

(4) Tribes 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.

§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 OMB Circular A–133 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 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) The Secretary shall require financial reports as necessary.

§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;

(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.

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 December 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).

§98.71 Content of reports.

(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 for determining eligibility;

(2) County of residence;

(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;

(6) The sources of family income, 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, 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 involved was a relative;

(10) The total monthly child care co-payment by the family;

(11) The total expected dollar amount per month to be received by the provider for each child;

(12) The total hours per month of such care;

(13) Social Security Number of the head of the family unit receiving child care assistance;

(14) Reasons for receiving care; and

(15) 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 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; and

(5) Any additional information that the Secretary shall require.

(c) At a minimum, a Tribal Lead Agency's annual report to the Secretary, as required in §98.70(c), shall include the following information on services provided through all CCDF tribal grant awards:

(1) Unduplicated number of families and children receiving services;

(2) Children served by age;

(3) Children served by reason for care;

(4) Children served by payment method (certificate/voucher or contract/grants);

(5) Average number of hours of care provided per week;

(6) Average hourly amount paid for care;

(7) Children served by level of family income; and

(8) Children served by type of child care providers.

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 and childhood development programs subject to the following conditions:

(a) An Indian Tribe applying for or receiving CCDF funds shall be subject to all the requirements under this part, unless otherwise indicated.

(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; and

(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; and

(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.

(f) In determining eligibility for services pursuant to § 98.20(a)(2), a tribal program may use either:

(1) 85 percent of the State median income for a family of the same size; or

(2) 85 percent of the median income for a family of the same size residing in the area served by the Tribal Lead Agency.

§ 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) A Tribal Lead Agency 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 pursuant to § 98.80(f).

(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

(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) Plans for those Tribes specified at § 98.83(f) (i.e., Tribes with small grants) are not subject to the requirements in § 98.16(g)(2) or § 98.16(k) unless the Tribe chooses to include such services, and, therefore, the associated requirements, in its program.

(6) The Plan is not subject to requirements in § 98.16(f)(8) or § 98.16(g)(4).

(7) In its initial Plan, an Indian Tribe shall describe its current service delivery capability pursuant to § 98.80(b)(2).

(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).

(c) When initially applying under paragraph (a) of this section, a Tribal Lead Agency shall include a Plan that meets the provisions of this part and shall be for a two-year period, pursuant to § 98.17(a).

§ 98.82 Coordination.

Tribal applicants shall coordinate 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.

§ 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 shall be carried out on an Indian reservation for the benefit of Indian children.

(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 two-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) Tribal Lead Agencies shall not be subject to the requirements at §§ 98.41(a)(1)(i), 98.44(a), 98.50(e), 98.52(a), 98.53 and 98.63.

(e) The base amount of any tribal grant is not subject to the administrative cost limitation at paragraph (g) of this section or the quality expenditure requirement at § 98.51(a). The base amount may be expended for any costs consistent with the purposes and requirements of the CCDF.

(f) Tribal Lead Agencies whose total CCDF allotment pursuant to §§ 98.61(c)

and 98.62(b) is less than an amount established by the Secretary shall not be subject to the following requirements:

(1) The assurance at § 98.15(a)(2);

(2) The requirement for certificates at § 98.30(a) and (d); and

(3) The requirements for quality expenditures at § 98.51(a).

(g) 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 amount provided under § 98.83(e)) shall be expended for administrative activities. Amounts used for construction and major renovation in accordance with § 98.84 are not considered administrative costs.

(h)(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 (h)(1) of this section is subject to the actual availability of the appropriation.

§ 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.

(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 45 CFR 92.31;

(2) Transfer and disposition of property requirements at 45 CFR 92.31(c);

(3) Title requirements at 45 CFR 92.31(a);

(4) Cost principles and allowable cost requirements at 45 CFR 92.22;

(5) Program income requirements at 45 CFR 92.25;

(6) Procurement procedures at 45 CFR 92.36; 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 liquidate 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.

(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.

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;

(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 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 the improperly expended funds;

(2) An amount equal to or less than the improperly expended funds will be 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.

(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.

§ 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, 370 L'Enfant Promenade,

SW., Washington, DC 20447. 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.

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 payments 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.

(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 administrative costs pursuant to Section 98.52(a).

§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;

(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

(5) Such other information as specified by the Secretary.

PART 99—PROCEDURE FOR HEARINGS FOR THE CHILD CARE AND DEVELOPMENT FUND

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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 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 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;

(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 prevent 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?
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.

§ 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 interagency 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.

(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 detemine 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 finanical assistance or direct Federal development if:

(1) The state has not adopted a process under the Order; or

(2) The assistance or development invovles 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 unusal 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 Department. In addition, if a state process recommendation for a nonselected 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 written 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.

(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.

SUBCHAPTER B—REQUIREMENTS RELATING TO HEALTH CARE ACCESS

PARTS 140–143 [RESERVED]

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

Subpart A—General Provisions

Sec.
144.101 Basis and purpose.
144.102 Scope and applicability.
144.103 Definitions.

Subpart B—Qualified State Long-Term Care Insurance Partnerships: Reporting Requirements for Insurers

144.200 Basis.
144.202 Definitions.
144.204 Applicability of regulations.
144.206 Reporting requirements.
144.208 Deadlines for submission of reports.
144.210 Form and manner of reports.
144.212 Confidentiality of information.
144.214 Notifications of noncompliance with reporting requirements.

AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

SOURCE: 62 FR 16955, Apr. 8, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 144.101 Basis and purpose.

(a) Part 146 of this subchapter implements requirements of Title XXVII of the Public Health Service Act (PHS Act, 42 U.S.C. 300gg, *et seq.*) that apply to group health plans and group health insurance issuers.

(b) Part 147 of this subchapter implements the provisions of the Patient Protection and Affordable Care Act that apply to both group health plans and health insurance issuers in the Group and Individual Markets.

(c) Part 148 of this subchapter implements Individual Health Insurance Market requirements of the PHS Act. Its purpose is to improve access to individual health insurance coverage for certain individuals who previously had group coverage, guarantee the renewability of all health insurance coverage in the individual market, and provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth, and to provide certain protections for patients who elect breast reconstruction in connection with a mastectomy.

(d) Part 150 of this subchapter implements the enforcement provisions of sections 2723 and 2761 of the PHS Act with respect to the following:

(1) States that fail to substantially enforce one or more provisions of part 146 concerning group health insurance or the requirements of part 148 of this subchapter concerning individual health insurance.

(2) Insurance issuers in States described in paragraph (c)(1) of this section.

(3) Group health plans that are non-Federal governmental plans.

(e) Sections 2791 and 2792 of the PHS Act define terms used in the regulations in this subchapter and provide the basis for issuing these regulations.

[64 FR 45795, Aug. 20, 1999, as amended at 74 FR 51688, Oct. 7, 2009; 75 FR 27137, May 13, 2010]

§ 144.102 Scope and applicability.

(a) For purposes of 45 CFR parts 144 through 148, all health insurance coverage is generally divided into two markets—the group market (set forth in 45 CFR part 146) and the individual market (set forth in 45 CFR part 148). 45 CFR part 146 limits the group market to insurance sold to employment-related group health plans and further divides the group market into the large group market and the small group market. Federal law further defines the small group market as insurance sold to employer plans with 2 to 50 employees. State law, however, may expand the definition of the small group market to include certain coverage that would otherwise, under the Federal law, be considered coverage in the large group market or the individual market.

(b) The protections afforded under 45 CFR parts 144 through 148 to individuals and employers (and other sponsors of health insurance offered in connection with a group health plan) are determined by whether the coverage involved is obtained in the small group market, the large group market, or the individual market. Small employers, and individuals who are eligible to enroll under the employer's plan, are guaranteed availability of insurance coverage sold in the small group market. Small and large employers are guaranteed the right to renew their group coverage, subject to certain exceptions. Eligible individuals are guaranteed availability of coverage sold in the individual market, and all coverage in the individual market must be guaranteed renewable. All coverage issued in the small or large group market, and in the individual market, must provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth.

(c) Coverage that is provided to associations, but is not related to employment, is not considered group coverage under 45 CFR parts 144 through 148. The coverage is considered coverage in the individual market, regardless of whether it is considered group coverage under State law.

(d) Provisions relating to CMS enforcement of one or more provisions of part 146 or the requirements of part 148, or both, are contained in part 150 of this subchapter.

[62 FR 16955, Apr. 8, 1997, as amended at 63 FR 57558, Oct. 27, 1998; 64 FR 45795, Aug. 20, 1999]

§ 144.103 Definitions.

For purposes of parts 146 (group market), 148 (individual market), and 150 (enforcement) of this subchapter, the following definitions apply unless otherwise provided:

Affiliation period means a period of time that must expire before health insurance coverage provided by an HMO becomes effective, and during which the HMO is not required to provide benefits.

Applicable State authority means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of 45 CFR parts 146 and 148 for the State involved with respect to the issuer.

Beneficiary has the meaning given the term under section 3(8) of the Employee Retirement Income Security Act of 1974 (ERISA), which states, ''a person designated by a participant, or by the terms of an employee benefit plan, who is or may become entitled to a benefit'' under the plan.

Bona fide association means, with respect to health insurance coverage offered in a State, an association that meets the following conditions:

(1) Has been actively in existence for at least 5 years.

(2) Has been formed and maintained in good faith for purposes other than obtaining insurance.

(3) Does not condition membership in the association on any health status-related factor relating to an individual (including an employee of an employer or a dependent of any employee).

(4) Makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to the members (or individuals eligible for coverage through a member).

(5) Does not make health insurance coverage offered through the association available other than in connection with a member of the association.

(6) Meets any additional requirements that may be imposed under State law.

Church plan means a Church plan within the meaning of section 3(33) of ERISA.

COBRA definitions:

(1) *COBRA* means Title *X* of the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended.

(2) *COBRA continuation coverage* means coverage, under a group health plan, that satisfies an applicable COBRA continuation provision.

(3) *COBRA continuation provision* means sections 601–608 of the Employee Retirement Income Security Act, section 4980B of the Internal Revenue Code of 1986 (other than paragraph (f)(1) of such section 4980B insofar as it relates to pediatric vaccines), or Title XXII of the PHS Act.

(4) *Continuation coverage* means coverage under a COBRA continuation provision or a similar State program. Coverage provided by a plan that is subject to a COBRA continuation provision or similar State program, but that does not satisfy all the requirements of that provision or program, will be deemed to be continuation coverage if it allows an individual to elect to continue coverage for a period of at least 18 months. Continuation coverage does not include coverage under a conversion policy required to be offered to an individual upon exhaustion of continuation coverage, nor does it include continuation coverage under the Federal Employees Health Benefits Program.

(5) *Exhaustion of COBRA continuation coverage* means that an individual's COBRA continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). An individual is considered to have exhausted COBRA continuation coverage if such coverage ceases—

(i) Due to the failure of the employer or other responsible entity to remit premiums on a timely basis;

(ii) When the individual no longer resides, lives, or works in the service area of an HMO or similar program (whether or not within the choice of the individual) and there is no other COBRA continuation coverage available to the individual; or

(iii) When the individual incurs a claim that would meet or exceed a lifetime limit on all benefits and there is no other COBRA continuation coverage available to the individual.

(6) *Exhaustion of continuation coverage* means that an individual's continuation coverage ceases for any reason other than either failure of the individual to pay premiums on a timely basis, or for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). An individual is considered to have exhausted continuation coverage if—

(i) Coverage ceases due to the failure of the employer or other responsible entity to remit premiums on a timely basis;

(ii) When the individual no longer resides, lives or works in a service area of an HMO or similar program (whether or not within the choice of the individual) and there is no other continuation coverage available to the individual; or

(iii) When the individual incurs a claim that would meet or exceed a lifetime limit on all benefits and there is no other continuation coverage available to the individual.

Condition means a *medical condition*.

Creditable coverage has the meaning given the term in 45 CFR 146.113(a).

Dependent means any individual who is or may become eligible for coverage under the terms of a group health plan because of a relationship to a participant.

Eligible individual, for purposes of—

(1) The group market provisions in 45 CFR part 146, subpart E, is defined in 45 CFR 146.150(b); and

(2) The individual market provisions in 45 CFR part 148, is defined in 45 CFR 148.103.

Employee has the meaning given the term under section 3(6) of ERISA, which states, ''any individual employed by an employer.''

Employer has the meaning given the term under section 3(5) of ERISA, which states, ''any person acting directly as an employer, or indirectly in the interest of an employer, in relation to an employee benefit plan; and includes a group or association of employers acting for an employer in such capacity.''

Enroll means to become covered for benefits under a group health plan (that is, when coverage becomes effective), without regard to when the individual may have completed or filed any forms that are required in order to become covered under the plan. For this purpose, an individual who has health coverage under a group health plan is enrolled in the plan regardless of whether the individual elects coverage, the individual is a dependent who becomes covered as a result of an election by a participant, or the individual becomes covered without an election.

Enrollment date definitions (*enrollment date*, *first day of coverage*, and *waiting*

period) are set forth in 45 CFR 146.111(a)(3)(i) through (iii).

ERISA stands for the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*).

Excepted benefits, consistent for purposes of the—

(1) Group market provisions in 45 CFR part 146 subpart D, is defined in 45 CFR 146.145(c); and

(2) Individual market provisions in 45 CFR part 148, is defined in 45 CFR 148.220.

Federal governmental plan means a governmental plan established or maintained for its employees by the Government of the United States or by any agency or instrumentality of such Government.

Genetic information has the meaning specified in §146.122(a) of this subchapter.

Governmental plan means a governmental plan within the meaning of section 3(32) of ERISA.

Group health insurance coverage means health insurance coverage offered in connection with a group health plan.

Group health plan or *plan* means a group health plan within the meaning of 45 CFR 146.145(a).

Group market means the market for health insurance coverage offered in connection with a group health plan. (However, certain very small plans may be treated as being in the individual market, rather than the group market; see the definition of *individual market* in this section.)

Health insurance coverage means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or HMO contract offered by a health insurance issuer. Health insurance coverage includes group health insurance coverage, individual health insurance coverage, and short-term, limited-duration insurance.

Health insurance issuer or *issuer* means an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of ERISA). This term does not include a group health plan.

Health maintenance organization or *HMO* means—

(1) A Federally qualified health maintenance organization (as defined in section 1301(a) of the PHS Act);

(2) An organization recognized under State law as a health maintenance organization; or

(3) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

Health status-related factor is any factor identified as a health factor in 45 CFR 146.121(a).

Individual health insurance coverage means health insurance coverage offered to individuals in the individual market, but does not include short-term, limited-duration insurance. Individual health insurance coverage can include dependent coverage.

Individual market means the market for health insurance coverage offered to individuals other than in connection with a group health plan. Unless a State elects otherwise in accordance with section 2791(e)(1)(B)(ii) of the PHS Act, such term also includes coverage offered in connection with a group health plan that has fewer than two participants who are current employees on the first day of the plan year.

Internal Revenue Code means the Internal Revenue Code of 1986, as amended (Title 26, United States Code).

Issuer means a *health insurance issuer*.

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year, unless otherwise provided under State law.

Large group market means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer, unless otherwise provided under State law.

Late enrollment definitions (*late enrollee* and *late enrollment*) are set forth in 45 CFR 146.111(a)(3)(v) and (vi).

Medical care means amounts paid for—

(1) The diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body;

(2) Transportation primarily for and essential to medical care referred to in paragraph (1) of this definition; and

(3) Insurance covering medical care referred to in paragraphs (1) and (2) of this definition.

Medical condition or *condition* means any condition, whether physical or mental, including, but not limited to, any condition resulting from illness, injury (whether or not the injury is accidental), pregnancy, or congenital malformation. However, genetic information is not a condition.

Network plan means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

Non-Federal governmental plan means a governmental plan that is not a Federal governmental plan.

Participant has the meaning given the term under section 3(7) of ERISA, which States, ''any employee or former employee of an employer, or any member or former member of an employee organization, who is or may become eligible to receive a benefit of any type from an employee benefit plan which covers employees of such employer or members of such organization, or whose beneficiaries may be eligible to receive any such benefit.''

PHS Act stands for the Public Health Service Act (42 U.S.C. 201 *et seq.*).

Placement, or being placed, for adoption means the assumption and retention of a legal obligation for total or partial support of a child by a person with whom the child has been placed in anticipation of the child's adoption. The child's placement for adoption with such person ends upon the termination of such legal obligation.

Plan sponsor has the meaning given the term under section 3(16)(B) of ERISA, which states, ''(i) the employer in the case of an employee benefit plan established or maintained by a single employer, (ii) the employee organization in the case of a plan established or maintained by an employee organization, or (iii) in the case of a plan established or maintained by two or more employers or jointly by one or more employers and one or more employee organizations, the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan.''

Plan year means the year that is designated as the plan year in the plan document of a group health plan, except that if the plan document does not designate a plan year or if there is no plan document, the plan year is—

(1) The deductible or limit year used under the plan;

(2) If the plan does not impose deductibles or limits on a yearly basis, then the plan year is the policy year;

(3) If the plan does not impose deductibles or limits on a yearly basis, and either the plan is not insured or the insurance policy is not renewed on an annual basis, then the plan year is the employer's taxable year; or

(4) In any other case, the plan year is the calendar year.

Policy Year means in the individual health insurance market the 12-month period that is designated as the policy year in the policy documents of the individual health insurance coverage. If there is no designation of a policy year in the policy document (or no such policy document is available), then the policy year is the deductible or limit year used under the coverage. If deductibles or other limits are not imposed on a yearly basis, the policy year is the calendar year.

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant

to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

Public health plan has the meaning given the term in 45 CFR 146.113(a)(1)(ix).

Short-term, limited-duration insurance means health insurance coverage provided pursuant to a contract with an issuer that has an expiration date specified in the contract (taking into account any extensions that may be elected by the policyholder without the issuer's consent) that is less than 12 months after the original effective date of the contract.

Significant break in coverage has the meaning given the term in 45 CFR 146.113(b)(2)(iii).

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year, unless otherwise provided under State law.

Small group market means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer.

Special enrollment means enrollment in a group health plan or group health insurance coverage under the rights described in 45 CFR 146.117.

State means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

State health benefits risk pool has the meaning given the term in 45 CFR § 146.113(a)(1)(vii).

Student health insurance coverage has the meaning given the term in § 147.145.

Waiting period has the meaning given the term in 45 CFR 146.111(a)(3)(iii).

[69 FR 78781, Dec. 30, 2004, as amended at 74 FR 51688, Oct. 7, 2009; 75 FR 27138, May 13, 2010; 75 FR 37235, June 28, 2010; 77 FR 16468, Mar. 21, 2012]

Subpart B—Qualified State Long-Term Care Insurance Partnerships: Reporting Requirements for Insurers

SOURCE: 73 FR 76968, Dec. 18, 2008, unless otherwise noted.

§ 144.200 Basis.

This subpart implements—

(a) Section 1917(b)(1)(C) (iii)(VI) of the Social Security Act, (Act) which requires the issuer of a long-term care insurance policy issued under a qualified State long-term care insurance partnership to provide specified regular reports to the Secretary.

(b) Section 1917(b)(1)(C)(v) of the Act, which specifies that the regulations of the Secretary under section 1917(b)(1)(C)(iii)(VI) of the Act shall be promulgated after consultation with the National Association of Insurance Commissioners, issuers of long-term care insurance policies, States with experience with long-term care insurance partnership plans, other States, and representatives of consumers of long-term care insurance policies, and shall specify the type and format of the data to be reported and the frequency with which such reports are to be made. This section of the statute also provides that the Secretary provide copies of the reports to the States involved.

§ 144.202 Definitions.

As used in this Subpart—

Partnership qualified policy refers to a qualified long-term care insurance policy issued under a qualified State long-term care insurance partnership.

Qualified long-term care insurance policy means an insurance policy that has been determined by a State insurance commissioner to meet the requirements of sections 1917(b)(1)(C)(iii)(I) through (IV) and 1917(b)(5) of the Act. It includes a certificate issued under a group insurance contract.

Qualified State long-term care insurance partnership means an approved Medicaid State plan amendment that provides for the disregard of any assets or resources in an amount equal to the insurance benefit payments that are made to or on behalf of an individual who is a beneficiary under a long-term care insurance policy that has been determined by a State insurance commissioner to meet the requirements of section 1917(b)(1)(C)(iii) of the Act.

§ 144.204 Applicability of regulations.

The regulations contained in this subpart for reporting data apply only to those insurers that have issued qualified long-term care insurance policies to individuals under a qualified State long-term care insurance partnership. They do not apply to the reporting of data by insurers for States with a Medicaid State plan amendment that established a long-term care partnership on or before May 14, 1993.

§ 144.206 Reporting requirements.

(a) *General requirement*. Any insurer that sells a qualified long-term care insurance policy under a qualified State long-term care insurance partnership must submit, in accordance with the requirements of this section, data on insured individuals, policyholders, and claimants who have active partnership qualified policies or certificates for a reporting period.

(b) *Specific requirements*. Insurers of qualified long-term care insurance policies must submit the following data to the Secretary by the deadlines specified in paragraph (c) of this section:

(1) *Registry of active individual and group partnership qualified policies or certificates*. (i) Insurers must submit data on—

(A) Any insured individual who held an active partnership qualified policy or certificate at any point during a reporting period, even if the policy or certificate was subsequently cancelled, lost partnership qualified status, or otherwise terminated during the reporting period; and

(B) All active group long-term care partnership qualified insurance policies, even if the identity of the individual policy/certificate holder is unavailable.

(ii) The data required under paragraph (b)(1)(i) of this section must cover a 6-month reporting period of January through June 30 or July 1 through December 31 of each year; and

(iii) The data must include, but are not limited to—

(A) Current identifying information on the insured individual;

(B) The name of the insurance company and issuing State;

(C) The effective date and terms of coverage under the policy.

(D) The annual premium.

(E) The coverage period.

(F) Other information, as specified by the Secretary in ''State Long-Term Care Partnership Insurer Reporting Requirements.''

(2) *Claims paid under partnership qualified policies or certificates*. Insurers must submit data on all partnership qualified policies or certificates for which the insurer paid at least one claim during the reporting period. This includes data for employer-paid core plans and buy-up plans without individual insured data. The data must—

(i) Cover a quarterly reporting period of 3 months;

(ii) Include, but are not limited to—

(A) Current identifying information on the insured individual;

(B) The type and cash amount of the benefits paid during the reporting period and lifetime to date;

(C) Remaining lifetime benefits;

(D) Other information, as specified by the Secretary in ''State Long-Term Care Partnership Insurer Reporting Requirements.''

§ 144.208 Deadlines for submission of reports.

(a) Transition provision for insurers who have issued or exchanged a qualified partnership policy prior to the effective date of these regulations.

The first reports required for these insurers will be the reports that pertain to the reporting period that begins no more than 120 days after the effective date of the final regulations.

(b) All reports on the registry of qualified long-term care insurance policies issued to individuals or individuals under group coverage specified in § 144.206(b)(1)(ii) must be submitted within 30 days of the end of the 6-month reporting period.

(c) All reports on the claims paid under qualified long-term care insurance policies issued to individual and individuals under group coverage specified in § 144.206(b)(2)(i) must be submitted within 30 days of the end of the 3-month quarterly reporting period.

§ 144.210 Form and manner of reports.

All reports specified in § 144.206 must be submitted in the form and manner specified by the Secretary.

§ 144.212 Confidentiality of information.

Data collected and reported under the requirements of this subpart are subject to the confidentiality of information requirements specified in regulations under 42 CFR Part 401, Subpart B, and 45 CFR Part 5, Subpart F.

§ 144.214 Notifications of noncompliance with reporting requirements.

If an insurer of a qualified long-term care insurance policy does not submit the required reports by the due dates specified in this subpart, the Secretary notifies the appropriate State insurance commissioner within 45 days after the deadline for submission of the information and data specified in § 144.208.

PART 145 [RESERVED]

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

Subpart A—General Provisions

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146.101 Basis and scope.

Subpart B—Requirements Relating to Access and Renewability of Coverage, and Limitations on Preexisting Condition Exclusion Periods

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Subpart F—Exclusion of Plans and Enforcement

146.180 Treatment of non-Federal governmental plans.

AUTHORITY: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act

(42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92).

SOURCE: 62 FR 16958, Apr. 8, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 146.101 Basis and scope.

(a) *Statutory basis.* This part implements the Group Market requirements of the PHS Act. Its purpose is to improve access to group health insurance coverage, to guarantee the renewability of all coverage in the group market, and to provide certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth. Sections 2791 and 2792 of the PHS Act define terms used in the regulations in this subchapter and provide the basis for issuing these regulations, respectively.

(b) *Scope.* A group health plan or health insurance issuer offering group health insurance coverage may provide greater rights to participants and beneficiaries than those set forth in this part.

(1) *Subpart B.* Subpart B of this part sets forth minimum requirements for group health plans and health insurance issuers offering group health insurance coverage concerning:

(i) Limitations on a preexisting condition exclusion period.

(ii) Certificates and disclosure of previous coverage.

(iii) Methods of counting creditable coverage.

(iv) Special enrollment periods.

(v) Use of an affiliation period by an HMO as an alternative to a preexisting condition exclusion.

(vi) Prohibiting discrimination against participants and beneficiaries based on a health factor.

(vii) Additional requirements prohibiting discrimination against participants and beneficiaries based on genetic information.

(2) *Subpart C.* Subpart C of this part sets forth the requirements that apply to plans and issuers with respect to coverage for hospital stays in connection with childbirth. It also sets forth the regulations governing parity between medical/surgical benefits and mental health benefits in group health plans and health insurance coverage offered by issuers in connection with a group health plan.

(3) *Subpart D.* Subpart D of this part sets forth exceptions to the requirements of Subpart B for certain plans and certain types of benefits.

(4) *Subpart E.* Subpart E of this part implements requirements relating to group health plans and issuers in the Group Health Insurance Market.

(5) *Subpart F.* Subpart F of this part addresses the treatment of non-Federal governmental plans, and sets forth enforcement procedures.

[62 FR 16958, Apr. 8, 1997, as amended at 63 FR 57559, Oct. 27, 1998; 71 FR 75046, Dec. 13, 2006; 74 FR 51688, Oct. 7, 2009, as amended at 75 FR 27138, May 13, 2010]

Subpart B—Requirements Relating to Access and Renewability of Coverage, and Limitations on Preexisting Condition Exclusion Periods

§ 146.111 Limitations on preexisting condition exclusion period.

(a) *Preexisting condition exclusion*—(1) *Defined* (i) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning set forth in § 144.103 of this part.

(ii) *Examples.* The rules of this paragraph (a)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *S*. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *T*. Issuer *T*'s policy excludes benefits for any prosthesis if the body part was lost before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1*, the exclusion of benefits for any prosthesis if the body part was lost before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy. (Therefore, the exclusion of benefits is required to comply with the limitations on preexisting condition exclusions in this section. For an example illustrating the application of these limitations to a succeeding insurance policy, see *Example 3* of paragraph (a)(3)(iv) of this section.)

Example 2. (i) *Facts.* A group health plan provides coverage for cosmetic surgery in

cases of accidental injury, but only if the injury occurred while the individual was covered under the plan.

(ii) *Conclusion*. In this *Example 2*, the plan provision excluding cosmetic surgery benefits for individuals injured before enrolling in the plan is a preexisting condition exclusion because it operates to exclude benefits relating to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

Example 3. (i) *Facts*. A group health plan provides coverage for the treatment of diabetes, generally not subject to any lifetime dollar limit. However, if an individual was diagnosed with diabetes before the effective date of coverage under the plan, diabetes coverage is subject to a lifetime limit of $10,000.

(ii) *Conclusion*. In this *Example 3*, the $10,000 lifetime limit is a preexisting condition exclusion because it limits benefits for a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

Example 4. (i) *Facts*. A group health plan provides coverage for the treatment of acne, subject to a lifetime limit of $2,000. The plan counts against this $2,000 lifetime limit acne treatment benefits provided under prior health coverage.

(ii) *Conclusion*. In this *Example 4*, counting benefits for a specific condition provided under prior health coverage against a lifetime limit for that condition is a preexisting condition exclusion because it operates to limit benefits for a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

Example 5. (i) *Facts*. When an individual's coverage begins under a group health plan, the individual generally becomes eligible for all benefits. However, benefits for pregnancy are not available until the individual has been covered under the plan for 12 months.

(ii) *Conclusion*. In this *Example 5*, the requirement to be covered under the plan for 12 months to be eligible for pregnancy benefits is a subterfuge for a preexisting condition exclusion because it is designed to exclude benefits for a condition (pregnancy) that arose before the effective date of coverage. Because a plan is prohibited under paragraph (b)(5) of this section from imposing any preexisting condition exclusion on pregnancy, the plan provision is prohibited. However, if the plan provision included an exception for women who were pregnant before the effective date of coverage under the plan (so that the provision applied only to women who became pregnant on or after the effective date of coverage) the plan provision would not be a preexisting condition exclusion (and would not be prohibited by paragraph (b)(5) of this section).

Example 6. (i) *Facts*. A group health plan provides coverage for medically necessary items and services, generally including treatment of heart conditions. However, the plan does not cover those same items and services when used for treatment of congenital heart conditions.

(ii) *Conclusion*. In this *Example 6*, the exclusion of coverage for treatment of congenital heart conditions is a preexisting condition exclusion because it operates to exclude benefits relating to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

Example 7. (i) *Facts*. A group health plan generally provides coverage for medically necessary items and services. However, the plan excludes coverage for the treatment of cleft palate.

(ii) *Conclusion*. In this *Example 7*, the exclusion of coverage for treatment of cleft palate is not a preexisting condition exclusion because the exclusion applies regardless of when the condition arose relative to the effective date of coverage. The plan provision, therefore, is not subject to the limitations on preexisting condition exclusions in this section.

Example 8. (i) *Facts*. A group health plan provides coverage for treatment of cleft palate, but only if the individual being treated has been continuously covered under the plan from the date of birth.

(ii) *Conclusion*. In this *Example 8*, the exclusion of coverage for treatment of cleft palate for individuals who have not been covered under the plan from the date of birth operates to exclude benefits in relation to a condition based on the fact that the condition was present before the effective date of coverage. The plan provision, therefore, is subject to the limitations on preexisting condition exclusions in this section.

(2) *General rules*. Subject to paragraph (b) of this section (prohibiting the imposition of a preexisting condition exclusion with respect to certain individuals and conditions), a group health plan, and a health insurance issuer offering group health insurance coverage, may impose, with respect to a participant or beneficiary, a preexisting condition exclusion only if the requirements of this paragraph (a)(2) are satisfied.

(i) *6-month look-back rule.* A preexisting condition exclusion must relate to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the 6-month period (or such shorter period as applies under the plan) ending on the enrollment date.

(A) For purposes of this paragraph (a)(2)(i), medical advice, diagnosis, care, or treatment is taken into account only if it is recommended by, or received from, an individual licensed or similarly authorized to provide such services under State law and operating within the scope of practice authorized by State law.

(B) For purposes of this paragraph (a)(2)(i), the 6-month period ending on the enrollment date begins on the 6-month anniversary date preceding the enrollment date. For example, for an enrollment date of August 1, 1998, the 6-month period preceding the enrollment date is the period commencing on February 1, 1998 and continuing through July 31, 1998. As another example, for an enrollment date of August 30, 1998, the 6-month period preceding the enrollment date is the period commencing on February 28, 1998 and continuing through August 29, 1998.

(C) The rules of this paragraph (a)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* is diagnosed with a medical condition 8 months before *A*'s enrollment date in Employer *R*'s group health plan. *A*'s doctor recommends that *A* take a prescription drug for 3 months, and *A* follows the recommendation.

(ii) *Conclusion.* In this *Example 1,* Employer *R*'s plan may impose a preexisting condition exclusion with respect to *A*'s condition because A received treatment during the 6-month period ending on *A*'s enrollment date in Employer *R*'s plan by taking the prescription medication during that period. However, if *A* did not take the prescription drug during the 6-month period, Employer *R*'s plan would not be able to impose a preexisting condition exclusion with respect to that condition.

Example 2. (i) *Facts.* Individual *B* is treated for a medical condition 7 months before the enrollment date in Employer *S*'s group health plan. As part of such treatment, *B*'s physician recommends that a follow-up examination be given 2 months later. Despite this recommendation, *B* does not receive a follow-up examination, and no other medical advice, diagnosis, care, or treatment for that condition is recommended to *B* or received by *B* during the 6-month period ending on *B*'s enrollment date in Employer *S*'s plan.

(ii) *Conclusion.* In this *Example 2,* Employer *S*'s plan may not impose a preexisting condition exclusion with respect to the condition for which *B* received treatment 7 months prior to the enrollment date.

Example 3. (i) *Facts.* Same facts as *Example 2,* except that Employer *S*'s plan learns of the condition and attaches a rider to *B*'s certificate of coverage excluding coverage for the condition. Three months after enrollment, *B*'s condition recurs, and Employer *S*'s plan denies payment under the rider.

(ii) *Conclusion.* In this *Example 3,* the rider is a preexisting condition exclusion and Employer *S*'s plan may not impose a preexisting condition exclusion with respect to the condition for which *B* received treatment 7 months prior to the enrollment date. (In addition, such a rider would violate the provisions of § 146.121, even if *B* had received treatment for the condition within the 6-month period ending on the enrollment date.)

Example 4. (i) *Facts.* Individual *C* has asthma and is treated for that condition several times during the 6-month period before *C*'s enrollment date in Employer *T*'s plan. Three months after the enrollment date, *C* begins coverage under Employer *T*'s plan. Two months later, *C* is hospitalized for asthma.

(ii) *Conclusion.* In this *Example 4,* Employer *T*'s plan may impose a preexisting condition exclusion with respect to *C*'s asthma because care relating to *C*'s asthma was received during the 6-month period ending on *C*'s enrollment date (which, under the rules of paragraph (a)(3)(i) of this section, is the first day of the waiting period).

Example 5. (i) *Facts.* Individual *D,* who is subject to a preexisting condition exclusion imposed by Employer *U*'s plan, has diabetes, as well as retinal degeneration, a foot condition, and poor circulation (all of which are conditions that may be directly attributed to diabetes). *D* receives treatment for these conditions during the 6-month period ending on *D*'s enrollment date in Employer *U*'s plan. After enrolling in the plan, *D* stumbles and breaks a leg.

(ii) *Conclusion.* In this *Example 5,* the leg fracture is not a condition related to D's diabetes, retinal degeneration, foot condition, or poor circulation, even though they may have contributed to the accident. Therefore, benefits to treat the leg fracture cannot be subject to a preexisting condition exclusion. However, any additional medical services that may be needed because of *D*'s preexisting diabetes, poor circulation, or retinal degeneration that would not be needed by another patient with a broken leg who does not have these conditions may be subject to

the preexisting condition exclusion imposed under Employer *U*'s plan.

(ii) *Maximum length of preexisting condition exclusion*. A preexisting condition exclusion is not permitted to extend for more than 12 months (18 months in the case of a late enrollee) after the enrollment date. For example, for an enrollment date of August 1, 1998, the 12-month period after the enrollment date is the period commencing on August 1, 1998 and continuing through July 31, 1999; the 18-month period after the enrollment date is the period commencing on August 1, 1998 and continuing through January 31, 2000.

(iii) *Reducing a preexisting condition exclusion period by creditable coverage*—(A) The period of any preexisting condition exclusion that would otherwise apply to an individual under a group health plan is reduced by the number of days of creditable coverage the individual has as of the enrollment date, as counted under §146.113. Creditable coverage may be evidenced through a certificate of creditable coverage (required under §146.115(a)), or through other means in accordance with the rules of §146.115(c).

(B) The rules of this paragraph (a)(2)(iii) are illustrated by the following example:

Example. (i) *Facts*. Individual *D* works for Employer *X* and has been covered continuously under *X*'s group health plan. *D*'s spouse works for Employer *Y*. *Y* maintains a group health plan that imposes a 12-month preexisting condition exclusion (reduced by creditable coverage) on all new enrollees. *D* enrolls in *Y*'s plan, but also stays covered under *X*'s plan. *D* presents *Y*'s plan with evidence of creditable coverage under *X*'s plan.

(ii) *Conclusion*. In this *Example*, *Y*'s plan must reduce the preexisting condition exclusion period that applies to *D* by the number of days of coverage that *D* had under *X*'s plan as of *D*'s enrollment date in *Y*'s plan (even though *D*'s coverage under *X*'s plan was continuing as of that date).

(iv) *Other standards*. See §146.121 for other standards in this Subpart A that may apply with respect to certain benefit limitations or restrictions under a group health plan. Other laws may also apply, such as the Uniformed Services Employment and Reemployment Rights Act (USERRA), which can affect the application of a preexisting condition exclusion to certain individuals who are reinstated in a group health plan following active military service.

(3) *Enrollment definitions*—(i) *Enrollment date* means the first day of coverage (as described in paragraph (a)(3)(ii) of this section) or, if there is a waiting period, the first day of the waiting period. If an individual receiving benefits under a group health plan changes benefit packages, or if the plan changes group health insurance issuers, the individual's enrollment date does not change.

(ii) *First day of coverage* means, in the case of an individual covered for benefits under a group health plan, the first day of coverage under the plan and, in the case of an individual covered by health insurance coverage in the individual market, the first day of coverage under the policy or contract.

(iii) *Waiting period* means the period that must pass before coverage for an employee or dependent who is otherwise eligible to enroll under the terms of a group health plan can become effective. If an employee or dependent enrolls as a late enrollee or special enrollee, any period before such late or special enrollment is not a waiting period. If an individual seeks coverage in the individual market, a waiting period begins on the date the individual submits a substantially complete application for coverage and ends on—

(A) If the application results in coverage, the date coverage begins;

(B) If the application does not result in coverage, the date on which the application is denied by the issuer or the date on which the offer of coverage lapses.

(iv) The rules of paragraphs (a)(3)(i), (ii), and (iii) of this section are illustrated by the following examples:

Example 1. (i) *Facts*. Employer *V*'s group health plan provides for coverage to begin on the first day of the first payroll period following the date an employee is hired and completes the applicable enrollment forms, or on any subsequent January 1 after completion of the applicable enrollment forms. Employer *V*'s plan imposes a preexisting condition exclusion for 12 months (reduced by the individual's creditable coverage) following an individual's enrollment date. Employee *E* is hired by Employer *V* on October 13, 1998 and on October 14, 1998 *E* completes and files all the forms necessary to enroll in

the plan. *E*'s coverage under the plan becomes effective on October 25, 1998 (which is the beginning of the first payroll period after *E*'s date of hire).

(ii) *Conclusion*. In this *Example 1*, *E*'s enrollment date is October 13, 1998 (which is the first day of the waiting period for *E*'s enrollment and is also *E*'s date of hire). Accordingly, with respect to *E*, the permissible 6-month period in paragraph (a)(2)(i) is the period from April 13, 1998 through October 12, 1998, the maximum permissible period during which Employer *V*'s plan can apply a preexisting condition exclusion under paragraph (a)(2)(ii) is the period from October 13, 1998 through October 12, 1999, and this period must be reduced under paragraph (a)(2)(iii) by *E*'s days of creditable coverage as of October 13, 1998.

Example 2. (i) *Facts*. A group health plan has two benefit package options, Option 1 and Option 2. Under each option a 12-month preexisting condition exclusion is imposed. Individual *B* is enrolled in Option 1 on the first day of employment with the employer maintaining the plan, remains enrolled in Option 1 for more than one year, and then decides to switch to Option 2 at open season.

(ii) *Conclusion*. In this *Example 2*, *B* cannot be subject to any preexisting condition exclusion under Option 2 because any preexisting condition exclusion period would have to begin on *B*'s enrollment date, which is *B*'s first day of coverage, rather than the date that *B* enrolled in Option 2. Therefore, the preexisting condition exclusion period expired before B switched to Option 2.

Example 3. (i) *Facts*. On May 13, 1997, Individual *E* is hired by an employer and enrolls in the employer's group health plan. The plan provides benefits solely through an insurance policy offered by Issuer *S*. On December 27, 1998, *E*'s leg is injured in an accident and the leg is amputated. On January 1, 1999, the plan switches coverage to a policy offered by Issuer *T*. Issuer *T*'s policy excludes benefits for any prosthesis if the body part was lost before the effective date of coverage under the policy.

(ii) *Conclusion*. In this *Example 3*, *E*'s enrollment date is May 13, 1997, *E*'s first day of coverage. Therefore, the permissible 6-month look-back period for the preexisting condition exclusion imposed under Issuer *T*'s policy begins on November 13, 1996 and ends on May 12, 1997. In addition, the 12-month maximum permissible preexisting condition exclusion period begins on May 13, 1997 and ends on May 12, 1998. Accordingly, because no medical advice, diagnosis, care, or treatment was recommended to or received by *E* for the leg during the 6-month look-back period (even though medical care was provided within the 6-month period preceding the effective date of *E*'s coverage under Issuer *T*'s policy), Issuer *T* may not impose any preexisting condition exclusion with respect to *E*. Moreover, even if *E* had received treatment during the 6-month look-back period, Issuer *T* still would not be permitted to impose a preexisting condition exclusion because the 12-month maximum permissible preexisting condition exclusion period expired on May 12, 1998 (before the effective date of *E*'s coverage under Issuer *T*'s policy).

Example 4. (i) *Facts*. A group health plan limits eligibility for coverage to full-time employees of Employer *Y*. Coverage becomes effective on the first day of the month following the date the employee becomes eligible. Employee *C* begins working full-time for Employer *Y* on April 11. Prior to this date, *C* worked part-time for *Y*. *C* enrolls in the plan and coverage is effective May 1.

(ii) *Conclusion*. In this *Example 4*, *C*'s enrollment date is April 11 and the period from April 11 through April 30 is a waiting period. The period while *C* was working part-time, and therefore not in an eligible class of employees, is not part of the waiting period.

Example 5. (i) *Facts*. To be eligible for coverage under a multiemployer group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the previous quarter. If the hours requirement is satisfied, coverage becomes effective on the first day of the current calendar quarter. Employee *D* begins work on January 28 and does not work 250 hours in covered employment during the first quarter (ending March 31). *D* works at least 250 hours in the second quarter (ending June 30) and is enrolled in the plan with coverage effective July 1 (the first day of the third quarter).

(ii) *Conclusion*. In this *Example 5*, *D*'s enrollment date is the first day of the quarter during which *D* satisfies the hours requirement, which is April 1. The period from April 1 through June 30 is a waiting period.

(v) *Late enrollee* means an individual whose enrollment in a plan is a late enrollment.

(vi) (A) *Late enrollment* means enrollment of an individual under a group health plan other than—

(*1*) On the earliest date on which coverage can become effective for the individual under the terms of the plan; or

(*2*) Through special enrollment. (For rules relating to special enrollment, see § 146.117.)

(B) If an individual ceases to be eligible for coverage under the plan, and then subsequently becomes eligible for coverage under the plan, only the individual's most recent period of eligibility is taken into account in determining whether the individual is a late enrollee under the plan with respect to the most recent period of coverage.

Similar rules apply if an individual again becomes eligible for coverage following a suspension of coverage that applied generally under the plan.

(vii) *Examples*. The rules of paragraphs (a)(3)(v) and (vi) of this section are illustrated by the following examples:

Example 1. (i) *Facts*. Employee *F* first becomes eligible to be covered by Employer *W*'s group health plan on January 1, 1999 but elects not to enroll in the plan until a later annual open enrollment period, with coverage effective January 1, 2001. *F* has no special enrollment right at that time.

(ii) *Conclusion*. In this *Example 1*, *F* is a late enrollee with respect to *F*'s coverage that became effective under the plan on January 1, 2001.

Example 2. (i) *Facts*. Same facts as *Example 1*, except that *F* terminates employment with Employer *W* on July 1, 1999 without having had any health insurance coverage under the plan. *F* is rehired by Employer *W* on January 1, 2000 and is eligible for and elects coverage under Employer *W*'s plan effective on January 1, 2000.

(ii) *Conclusion*. In this *Example 2*, *F* would not be a late enrollee with respect to *F*'s coverage that became effective on January 1, 2000.

(b) *Exceptions pertaining to preexisting condition exclusions*—(1) *Newborns*—(i) *In general*. Subject to paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion on a child who, within 30 days after birth, is covered under any creditable coverage. Accordingly, if a child is enrolled in a group health plan (or other creditable coverage) within 30 days after birth and subsequently enrolls in another group health plan without a significant break in coverage (as described in §146.113(b)(2)(iii)), the other plan may not impose any preexisting condition exclusion on the child.

(ii) *Examples*. The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) *Facts*. Individual *E*, who has no prior creditable coverage, begins working for Employer *W* and has accumulated 210 days of creditable coverage under Employer *W*'s group health plan on the date *E* gives birth to a child. Within 30 days after the birth, the child is enrolled in the plan. Ninety days after the birth, both *E* and the child terminate coverage under the plan. Both *E* and the child then experience a break in coverage of 45 days before *E* is hired by Employer *X* and the two are enrolled in Employer *X*'s group health plan.

(ii) *Conclusion*. In this *Example 1*, because *E*'s child is enrolled in Employer *W*'s plan within 30 days after birth, no preexisting condition exclusion may be imposed with respect to the child under Employer *W*'s plan. Likewise, Employer *X*'s plan may not impose any preexisting condition exclusion on *E*'s child because the child was covered under creditable coverage within 30 days after birth and had no significant break in coverage before enrolling in Employer *X*'s plan. On the other hand, because *E* had only 300 days of creditable coverage prior to *E*'s enrollment date in Employer *X*'s plan, Employer *X*'s plan may impose a preexisting condition exclusion on *E* for up to 65 days (66 days if the 12-month period after *E*'s enrollment date in *X*'s plan includes February 29).

Example 2. (i) *Facts*. Individual *F* is enrolled in a group health plan in which coverage is provided through a health insurance issuer. *F* gives birth. Under State law applicable to the health insurance issuer, health care expenses incurred for the child during the 30 days following birth are covered as part of *F*'s coverage. Although *F* may obtain coverage for the child beyond 30 days by timely requesting special enrollment and paying an additional premium, the issuer is prohibited under State law from recouping the cost of any expenses incurred for the child within the 30-day period if the child is not later enrolled.

(ii) *Conclusion*. In this *Example 2*, the child is covered under creditable coverage within 30 days after birth, regardless of whether the child enrolls as a special enrollee under the plan. Therefore, no preexisting condition exclusion may be imposed on the child unless the child has a significant break in coverage.

(2) *Adopted children*. Subject to paragraph (b)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion on a child who is adopted or placed for adoption before attaining 18 years of age and who, within 30 days after the adoption or placement for adoption, is covered under any creditable coverage. Accordingly, if a child is enrolled in a group health plan (or other creditable coverage) within 30 days after adoption or placement for adoption and subsequently enrolls in another group health plan without a significant break in coverage (as described in §146.113(b)(2)(iii)), the other plan may

not impose any preexisting condition exclusion on the child. This rule does not apply to coverage before the date of such adoption or placement for adoption.

(3) *Significant break in coverage.* Paragraphs (b)(1) and (2) of this section no longer apply to a child after a significant break in coverage. (*See* § 146.113(b)(2)(iii) for rules relating to the determination of a significant break in coverage.)

(4) *Special enrollment.* For special enrollment rules relating to new dependents, see § 146.117(b).

(5) *Pregnancy.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not impose a preexisting condition exclusion relating to pregnancy.

(6) *Genetic information*—(i) A group health plan, and a health insurance issuer offering group health insurance coverage, may not impose a preexisting condition exclusion relating to a condition based solely on genetic information. However, if an individual is diagnosed with a condition, even if the condition relates to genetic information, the plan may impose a preexisting condition exclusion with respect to the condition, subject to the other limitations of this section.

(ii) The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) *Facts.* Individual *A* enrolls in a group health plan that imposes a 12-month maximum preexisting condition exclusion. Three months before *A*'s enrollment, *A*'s doctor told *A* that, based on genetic information, *A* has a predisposition towards breast cancer. *A* was not diagnosed with breast cancer at any time prior to *A*'s enrollment date in the plan. Nine months after *A*'s enrollment date in the plan, *A* is diagnosed with breast cancer.

(ii) *Conclusion.* In this *Example,* the plan may not impose a preexisting condition exclusion with respect to *A*'s breast cancer because, prior to *A*'s enrollment date, *A* was not diagnosed with breast cancer.

(c) *General notice of preexisting condition exclusion.* A group health plan imposing a preexisting condition exclusion, and a health insurance issuer offering group health insurance coverage subject to a preexisting condition exclusion, must provide a written general notice of preexisting condition exclusion to participants under the plan and cannot impose a preexisting condition exclusion with respect to a participant or a dependent of the participant until such a notice is provided.

(1) *Manner and timing.* A plan or issuer must provide the general notice of preexisting condition exclusion as part of any written application materials distributed by the plan or issuer for enrollment. If the plan or issuer does not distribute such materials, the notice must be provided by the earliest date following a request for enrollment that the plan or issuer, acting in a reasonable and prompt fashion, can provide the notice.

(2) *Content.* The general notice of preexisting condition exclusion must notify participants of the following:

(i) The existence and terms of any preexisting condition exclusion under the plan. This description includes the length of the plan's look-back period (which is not to exceed 6 months under paragraph (a)(2)(i) of this section); the maximum preexisting condition exclusion period under the plan (which cannot exceed 12 months (or 18-months for late enrollees) under paragraph (a)(2)(ii) of this section); and how the plan will reduce the maximum preexisting condition exclusion period by creditable coverage (described in paragraph (a)(2)(iii) of this section).

(ii) A description of the rights of individuals to demonstrate creditable coverage, and any applicable waiting periods, through a certificate of creditable coverage (as required by § 146.115(a)) or through other means (as described in § 146.115(c)). This must include a description of the right of the individual to request a certificate from a prior plan or issuer, if necessary, and a statement that the current plan or issuer will assist in obtaining a certificate from any prior plan or issuer, if necessary.

(iii) A person to contact (including an address or telephone number) for obtaining additional information or assistance regarding the preexisting condition exclusion.

(3) *Duplicate notices not required.* If a notice satisfying the requirements of this paragraph (c) is provided to an individual, the obligation to provide a general notice of preexisting condition

exclusion with respect to that individual is satisfied for both the plan and the issuer.

(4) *Example with sample language.* The rules of this paragraph (c) are illustrated by the following example, which includes sample language that plans and issuers can use as a basis for preparing their own notices to satisfy the requirements of this paragraph (c):

Example. (i) *Facts.* A group health plan makes coverage effective on the first day of the first calendar month after hire and on each January 1 following an open season. The plan imposes a 12-month maximum preexisting condition exclusion (18 months for late enrollees) and uses a 6-month look-back period. As part of the enrollment application materials, the plan provides the following statement:

This plan imposes a preexisting condition exclusion. This means that if you have a medical condition before coming to our plan, you might have to wait a certain period of time before the plan will provide coverage for that condition. This exclusion applies only to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within a six-month period. Generally, this six-month period ends the day before your coverage becomes effective. However, if you were in a waiting period for coverage, the six-month period ends on the day before the waiting period begins. The preexisting condition exclusion does not apply to pregnancy nor to a child who is enrolled in the plan within 30 days after birth, adoption, or placement for adoption.

This exclusion may last up to 12 months (18 months if you are a late enrollee) from your first day of coverage, or, if you were in a waiting period, from the first day of your waiting period. However, you can reduce the length of this exclusion period by the number of days of your prior ''creditable coverage.'' Most prior health coverage is creditable coverage and can be used to reduce the preexisting condition exclusion if you have not experienced a break in coverage of at least 63 days. To reduce the 12-month (or 18-month) exclusion period by your creditable coverage, you should give us a copy of any certificates of creditable coverage you have. If you do not have a certificate, but you do have prior health coverage, we will help you obtain one from your prior plan or issuer. There are also other ways that you can show you have creditable coverage. Please contact us if you need help demonstrating creditable coverage.

All questions about the preexisting condition exclusion and creditable coverage should be directed to Individual *B* at Address *M* or Telephone Number *N*.

(ii) *Conclusion.* In this *Example,* the plan satisfies the general notice requirement of this paragraph (c), and thus also satisfies this requirement for any issuer providing the coverage.

(d) *Determination of creditable coverage*—(1) *Determination within reasonable time.* If a group health plan or health insurance issuer offering group health insurance coverage receives creditable coverage information under § 146.115, the plan or issuer is required, within a reasonable time following receipt of the information, to make a determination regarding the amount of the individual's creditable coverage and the length of any exclusion that remains. Whether this determination is made within a reasonable time depends on the relevant facts and circumstances. Relevant facts and circumstances include whether a plan's application of a preexisting condition exclusion would prevent an individual from having access to urgent medical care.

(2) *No time limit on presenting evidence of creditable coverage.* A plan or issuer may not impose any limit on the amount of time that an individual has to present a certificate or other evidence of creditable coverage.

(3) *Example.* The rules of this paragraph (d) are illustrated by the following example:

Example. (i) *Facts.* A group health plan imposes a preexisting condition exclusion period of 12 months. After receiving the general notice of preexisting condition exclusion, Individual *H* develops an urgent health condition before receiving a certificate of creditable coverage from *H*'s prior group health plan. *H* attests to the period of prior coverage, presents corroborating documentation of the coverage period, and authorizes the plan to request a certificate on *H*'s behalf in accordance with the rules of § 146.115.

(ii) *Conclusion.* In this *Example,* the plan must review the evidence presented by *H* and make a determination of creditable coverage within a reasonable time that is consistent with the urgency of *H*'s health condition. (This determination may be modified as permitted under paragraph (f) of this section.)

(e) *Individual notice of period of preexisting condition exclusion.* After an individual has presented evidence of creditable coverage and after the plan or issuer has made a determination of creditable coverage under paragraph

(d) of this section, the plan or issuer must provide the individual a written notice of the length of preexisting condition exclusion that remains after offsetting for prior creditable coverage. This individual notice is not required to identify any medical conditions specific to the individual that could be subject to the exclusion. A plan or issuer is not required to provide this notice if the plan or issuer does not impose any preexisting condition exclusion on the individual or if the plan's preexisting condition exclusion is completely offset by the individual's prior creditable coverage.

(1) *Manner and timing*. The individual notice must be provided by the earliest date following a determination that the plan or issuer, acting in a reasonable and prompt fashion, can provide the notice.

(2) *Content*. A plan or issuer must disclose—

(i) Its determination of any preexisting condition exclusion period that applies to the individual (including the last day on which the preexisting condition exclusion applies);

(ii) The basis for such determination, including the source and substance of any information on which the plan or issuer relied;

(iii) An explanation of the individual's right to submit additional evidence of creditable coverage; and

(iv) A description of any applicable appeal procedures established by the plan or issuer.

(3) *Duplicate notices not required*. If a notice satisfying the requirements of this paragraph (e) is provided to an individual, the obligation to provide this individual notice of preexisting condition exclusion with respect to that individual is satisfied for both the plan and the issuer.

(4) *Examples*. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts*. A group health plan imposes a preexisting condition exclusion period of 12 months. After receiving the general notice of preexisting condition exclusion, Individual *G* presents a certificate of creditable coverage indicating 240 days of creditable coverage. Within seven days of receipt of the certificate, the plan determines that *G* is subject to a preexisting condition exclusion of 125 days, the last day of which is March 5. Five days later, the plan notifies *G* that, based on the certificate *G* submitted, *G* is subject to a preexisting condition exclusion period of 125 days, ending on March 5. The notice also explains the opportunity to submit additional evidence of creditable coverage and the plan's appeal procedures. The notice does not identify any of *G*'s medical conditions that could be subject to the exclusion.

(ii) *Conclusion*. In this *Example 1*, the plan satisfies the requirements of this paragraph (e).

Example 2. (i) *Facts*. Same facts as in *Example 1*, except that the plan determines that *G* has 430 days of creditable coverage based on *G*'s certificate indicating 430 days of creditable coverage under *G*'s prior plan.

(ii) *Conclusion*. In this *Example 2*, the plan is not required to notify *G* that *G* will not be subject to a preexisting condition exclusion.

(f) *Reconsideration*. Nothing in this section prevents a plan or issuer from modifying an initial determination of creditable coverage if it determines that the individual did not have the claimed creditable coverage, provided that —

(1) A notice of the new determination (consistent with the requirements of paragraph (e) of this section) is provided to the individual; and

(2) Until the notice of the new determination is provided, the plan or issuer, for purposes of approving access to medical services (such as a pre-surgery authorization), acts in a manner consistent with the initial determination.

[69 FR 78783, Dec. 30, 2004, as amended at 75 FR 37235, June 28, 2010]

§ 146.113 Rules relating to creditable coverage.

(a) *General rules*—(1) *Creditable coverage*. For purposes of this section, except as provided in paragraph (a)(2) of this section, the term *creditable coverage* means coverage of an individual under any of the following:

(i) A group health plan as defined in § 146.145(a).

(ii) Health insurance coverage as defined in § 144.103 of this chapter (whether or not the entity offering the coverage is subject to the requirements of this part and 45 CFR part 148 and without regard to whether the coverage is offered in the group market, the individual market, or otherwise).

(iii) Part A or B of Title XVIII of the Social Security Act (Medicare).

(iv) Title XIX of the Social Security Act (Medicaid), other than coverage consisting solely of benefits under section 1928 of the Social Security Act (the program for distribution of pediatric vaccines).

(v) Title 10 U.S.C. Chapter 55 (medical and dental care for members and certain former members of the uniformed services, and for their dependents; for purposes of Title 10 U.S.C. Chapter 55, *uniformed services* means the armed forces and the Commissioned Corps of the National Oceanic and Atmospheric Administration and of the Public Health Service).

(vi) A medical care program of the Indian Health Service or of a tribal organization.

(vii) A State health benefits risk pool. For purposes of this section, a *State health benefits risk pool* means—

(A) An organization qualifying under section 501(c)(26) of the Internal Revenue Code;

(B) A qualified high risk pool described in section 2744(c)(2) of the PHS Act; or

(C) Any other arrangement sponsored by a State, the membership composition of which is specified by the State and which is established and maintained primarily to provide health coverage for individuals who are residents of such State and who, by reason of the existence or history of a medical condition—

(*1*) Are unable to acquire medical care coverage for such condition through insurance or from an HMO, or

(*2*) Are able to acquire such coverage only at a rate which is substantially in excess of the rate for such coverage through the membership organization.

(viii) A health plan offered under Title 5 U.S.C. Chapter 89 (the Federal Employees Health Benefits Program).

(ix) A public health plan. For purposes of this section, a *public health plan* means any plan established or maintained by a State, the U.S. government, a foreign country, or any political subdivision of a State, the U.S. government, or a foreign country that provides health coverage to individuals who are enrolled in the plan.

(x) A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

(xi) Title XXI of the Social Security Act (State Children's Health Insurance Program).

(2) *Excluded coverage.* Creditable coverage does not include coverage of solely excepted benefits (described in §146.145).

(3) *Methods of counting creditable coverage.* For purposes of reducing any preexisting condition exclusion period, as provided under §146.111(a)(2)(iii), the amount of an individual's creditable coverage generally is determined by using the standard method described in paragraph (b) of this section. A plan or issuer may use the alternative method under paragraph (c) of this section with respect to any or all of the categories of benefits described under paragraph (c)(3) of this section.

(b) *Standard method*—(1) *Specific benefits not considered.* Under the standard method, the amount of creditable coverage is determined without regard to the specific benefits included in the coverage.

(2) *Counting creditable coverage*—(i) *Based on days.* For purposes of reducing the preexisting condition exclusion period that applies to an individual, the amount of creditable coverage is determined by counting all the days on which the individual has one or more types of creditable coverage. Accordingly, if on a particular day an individual has creditable coverage from more than one source, all the creditable coverage on that day is counted as one day. Any days in a waiting period for coverage are not creditable coverage.

(ii) *Days not counted before significant break in coverage.* Days of creditable coverage that occur before a significant break in coverage are not required to be counted.

(iii) *Significant break in coverage defined*—A significant break in coverage means a period of 63 consecutive days during each of which an individual does not have any creditable coverage. (See also §146.143(c)(2)(iii) regarding the applicability to issuers of State insurance laws that require a break of more than

63 days before an individual has a significant break in coverage for purposes of State insurance law.)

(iv) *Periods that toll a significant break.* Days in a waiting period and days in an affiliation period are not taken into account in determining whether a significant break in coverage has occurred. In addition, for an individual who elects COBRA continuation coverage during the second election period provided under the Trade Act of 2002, the days between the date the individual lost group health plan coverage and the first day of the second COBRA election period are not taken into account in determining whether a significant break in coverage has occurred.

(v) *Examples.* The rules of this paragraph (b)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* has creditable coverage under Employer *P*'s plan for 18 months before coverage ceases. *A* is provided a certificate of creditable coverage on *A*'s last day of coverage. Sixty-four days after the last date of coverage under *P*'s plan, *A* is hired by Employer *Q* and enrolls in *Q*'s group health plan. *Q*'s plan has a 12-month preexisting condition exclusion.

(ii) *Conclusion.* In this *Example 1*, *A* has a break in coverage of 63 days. Because *A*'s break in coverage is a significant break in coverage, *Q*'s plan may disregard *A*'s prior coverage and *A* may be subject to a 12-month preexisting condition exclusion.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *A* is hired by *Q* and enrolls in *Q*'s plan on the 63rd day after the last date of coverage under *P*'s plan.

(ii) *Conclusion.* In this *Example 2*, *A* has a break in coverage of 62 days. Because *A*'s break in coverage is not a significant break in coverage, *Q*'s plan must count *A*'s prior creditable coverage for purposes of reducing the plan's preexisting condition exclusion period that applies to *A*.

Example 3. (i) *Facts.* Same facts as *Example 1*, except that *Q*'s plan provides benefits through an insurance policy that, as required by applicable State insurance laws, defines a significant break in coverage as 90 days.

(ii) *Conclusion.* In this *Example 3*, under State law, the issuer that provides group health insurance coverage to *Q*'s plan must count *A*'s period of creditable coverage prior to the 63-day break. (However, if *Q*'s plan was a self-insured plan, the coverage would not be subject to State law. Therefore, the health coverage would not be governed by the longer break rules and *A*'s previous health coverage could be disregarded.)

Example 4. [Reserved]

Example 5. (i) *Facts.* Individual *C* has creditable coverage under Employer *S*'s plan for 200 days before coverage ceases. *C* is provided a certificate of creditable coverage on *C*'s last day of coverage. *C* then does not have any creditable coverage for 51 days before being hired by Employer *T*. *T*'s plan has a 3-month waiting period. *C* works for *T* for 2 months and then terminates employment. Eleven days after terminating employment with *T*, *C* begins working for Employer *U*. *U*'s plan has no waiting period, but has a 6-month preexisting condition exclusion.

(ii) *Conclusion.* In this *Example 5*, *C* does not have a significant break in coverage because, after disregarding the waiting period under *T*'s plan, *C* had only a 62-day break in coverage (51 days plus 11 days). Accordingly, *C* has 200 days of creditable coverage, and *U*'s plan may not apply its 6-month preexisting condition exclusion with respect to *C*.

Example 6. [Reserved]

Example 7. (i) *Facts.* Individual *E* has creditable coverage under Employer *X*'s plan. *E* is provided a certificate of creditable coverage on *E*'s last day of coverage. On the 63rd day without coverage, *E* submits a substantially complete application for a health insurance policy in the individual market. *E*'s application is accepted and coverage is made effective 10 days later.

(ii) *Conclusion.* In this *Example 7*, because *E* applied for the policy before the end of the 63rd day, the period between the date of application and the first day of coverage is a waiting period and no significant break in coverage occurred even though the actual period without coverage was 73 days.

Example 8. (i) *Facts.* Same facts as *Example 7*, except that *E*'s application for a policy in the individual market is denied.

(ii) *Conclusion.* In this *Example 8*, even though *E* did not obtain coverage following application, the period between the date of application and the date the coverage was denied is a waiting period. However, to avoid a significant break in coverage, no later than the day after the application for the policy is denied *E* would need to do one of the following: submit a substantially complete application for a different individual market policy; obtain coverage in the group market; or be in a waiting period for coverage in the group market.

(vi) *Other permissible counting methods*—(A) *Rule.* Notwithstanding any other provisions of this paragraph (b)(2), for purposes of reducing a preexisting condition exclusion period (but not for purposes of issuing a certificate under § 146.115), a group health

plan, and a health insurance issuer offering group health insurance coverage, may determine the amount of creditable coverage in any other manner that is at least as favorable to the individual as the method set forth in this paragraph (b)(2), subject to the requirements of other applicable law.

(B) *Example*. The rule of this paragraph (b)(2)(vi) is illustrated by the following example:

Example. (i) *Facts*. Individual *F* has coverage under Group Health Plan *Y* from January 3, 1997 through March 25, 1997. *F* then becomes covered by Group Health Plan *Z*. *F*'s enrollment date in Plan *Z* is May 1, 1997. Plan *Z* has a 12-month preexisting condition exclusion.

(ii) *Conclusion*. In this *Example*, Plan *Z* may determine, in accordance with the rules prescribed in paragraphs (b)(2)(i), (ii), and (iii) of this section, that *F* has 82 days of creditable coverage (29 days in January, 28 days in February, and 25 days in March). Thus, the preexisting condition exclusion will no longer apply to *F* on February 8, 1998 (82 days before the 12-month anniversary of *F*'s enrollment (May 1)). For administrative convenience, however, Plan *Z* may consider that the preexisting condition exclusion will no longer apply to *F* on the first day of the month (February 1).

(c) *Alternative method*—(1) *Specific benefits considered*. Under the alternative method, a group health plan, or a health insurance issuer offering group health insurance coverage, determines the amount of creditable coverage based on coverage within any category of benefits described in paragraph (c)(3) of this section and not based on coverage for any other benefits. The plan or issuer may use the alternative method for any or all of the categories. The plan or issuer may apply a different preexisting condition exclusion period with respect to each category (and may apply a different preexisting condition exclusion period for benefits that are not within any category). The creditable coverage determined for a category of benefits applies only for purposes of reducing the preexisting condition exclusion period with respect to that category. An individual's creditable coverage for benefits that are not within any category for which the alternative method is being used is determined under the standard method of paragraph (b) of this section.

(2) *Uniform application*. A plan or issuer using the alternative method is required to apply it uniformly to all participants and beneficiaries under the plan or health insurance coverage. The use of the alternative method is required to be set forth in the plan.

(3) *Categories of benefits*. The alternative method for counting creditable coverage may be used for coverage for the following categories of benefits—

(i) Mental health;

(ii) Substance abuse treatment;

(iii) Prescription drugs;

(iv) Dental care; or

(v) Vision care.

(4) *Plan notice*. If the alternative method is used, the plan is required to—

(i) State prominently that the plan is using the alternative method of counting creditable coverage in disclosure statements concerning the plan, and state this to each enrollee at the time of enrollment under the plan; and

(ii) Include in these statements a description of the effect of using the alternative method, including an identification of the categories used.

(5) *Issuer notice*. With respect to health insurance coverage offered by an issuer in the small or large group market, if the insurance coverage uses the alternative method, the issuer states prominently in any disclosure statement concerning the coverage, that the issuer is using the alternative method, and includes in such statements a description of the effect of using the alternative method. This applies separately to each type of coverage offered by the health insurance issuer.

(6) *Disclosure of information on previous benefits*. See § 146.115(b) for special rules concerning disclosure of coverage to a plan, or issuer, using the alternative method of counting creditable coverage under this paragraph (c).

(7) *Counting creditable coverage*—(i) *In general*. Under the alternative method, the group health plan or issuer counts creditable coverage within a category if any level of benefits is provided within the category. Coverage under a reimbursement account or arrangement, such as a flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code),

does not constitute coverage within any category.

(ii) *Special rules.* In counting an individual's creditable coverage under the alternative method, the group health plan, or issuer, first determines the amount of the individual's creditable coverage that may be counted under paragraph (b) of this section, up to a total of 365 days of the most recent creditable coverage (546 days for a late enrollee). The period over which this creditable coverage is determined is referred to as the determination period. Then, for the category specified under the alternative method, the plan or issuer counts within the category all days of coverage that occurred during the determination period (whether or not a significant break in coverage for that category occurs), and reduces the individual's preexisting condition exclusion period for that category by that number of days. The plan or issuer may determine the amount of creditable coverage in any other reasonable manner, uniformly applied, that is at least as favorable to the individual.

(iii) *Example.* The rules of this paragraph (c)(7) are illustrated by the following example:

Example. (i) *Facts.* Individual *D* enrolls in Employer *V*'s plan on January 1, 2001. Coverage under the plan includes prescription drug benefits. On April 1, 2001, the plan ceases providing prescription drug benefits. *D*'s employment with Employer *V* ends on January 1, 2002, after *D* was covered under Employer *V*'s group health plan for 365 days. *D* enrolls in Employer *Y*'s plan on February 1, 2002 (*D*'s enrollment date). Employer *Y*'s plan uses the alternative method of counting creditable coverage and imposes a 12-month preexisting condition exclusion on prescription drug benefits.

(ii) *Conclusion.* In this *Example*, Employer *Y*'s plan may impose a 275-day preexisting condition exclusion with respect to *D* for prescription drug benefits because *D* had 90 days of creditable coverage relating to prescription drug benefits within *D*'s determination period.

[69 FR 78788, Dec. 30, 2004]

§ 146.115 Certification and disclosure of previous coverage.

(a) *Certificate of creditable coverage*—(1) *Entities required to provide certificate*—(i) *In General.* A group health plan, and each health insurance issuer offering group health insurance coverage under a group health plan, is required to furnish certificates of creditable coverage in accordance with this paragraph (a).

(ii) *Duplicate certificates not required.* An entity required to provide a certificate under this paragraph (a) with respect to an individual satisfies that requirement if another party provides the certificate, but only to the extent that the certificate contains the information required in paragraph (a)(3) of this section. For example, in the case of a group health plan funded through an insurance policy, the issuer satisfies the certification requirement with respect to an individual if the plan actually provides a certificate that includes all the information required under paragraph (a)(3) of this section with respect to the individual.

(iii) *Special rule for group health plans.* To the extent coverage under a plan consists of group health insurance coverage, the plan satisfies the certification requirements under this paragraph (a) if any issuer offering the coverage is required to provide the certificates pursuant to an agreement between the plan and the issuer. For example, if there is an agreement between an issuer and a plan sponsor under which the issuer agrees to provide certificates for individuals covered under the plan, and the issuer fails to provide a certificate to an individual when the plan would have been required to provide one under this paragraph (a), then the issuer, but not the plan, violates the certification requirements of this paragraph (a).

(iv) *Special rules for issuers*—(A)(*1*) *Responsibility of issuer for coverage period.* An issuer is not required to provide information regarding coverage provided to an individual by another party.

(*2*) *Example.* The rule of this paragraph (a)(1)(iv)(A) is illustrated by the following example:

Example. (i) *Facts.* A plan offers coverage with an HMO option from one issuer and an indemnity option from a different issuer. The HMO has not entered into an agreement with the plan to provide certificates as permitted under paragraph (a)(1)(iii) of this section.

(ii) *Conclusion.* In this *Example,* if an employee switches from the indemnity option to the HMO option and later ceases to be

covered under the plan, any certificate provided by the HMO is not required to provide information regarding the employee's coverage under the indemnity option.

(B)(*1*) *Cessation of issuer coverage prior to cessation of coverage under a plan.* If an individual's coverage under an issuer's policy or contract ceases before the individual's coverage under the plan ceases, the issuer is required to provide sufficient information to the plan (or to another party designated by the plan) to enable the plan (or other party), after cessation of the individual's coverage under the plan, to provide a certificate that reflects the period of coverage under the policy or contract. By providing that information to the plan, the issuer satisfies its obligation to provide an automatic certificate for that period of creditable coverage with respect to the individual under paragraph (a)(2)(ii) of this section. The issuer, however, must still provide a certificate upon request as required under paragraph (a)(2)(iii) of this section. In addition, the issuer is required to cooperate with the plan in responding to any request made under paragraph (b)(2) of this section (relating to the alternative method of counting creditable coverage). Moreover, if the individual's coverage under the plan ceases at the time the individual's coverage under the issuer's policy or contract ceases, the issuer must still provide an automatic certificate under paragraph (a)(2)(ii) of this section. If an individual's coverage under an issuer's policy or contract ceases on the effective date for changing enrollment options under the plan, the issuer may presume (absent information to the contrary) that the individual's coverage under the plan continues. Therefore, the issuer is required to provide information to the plan in accordance with this paragraph (a)(1)(iv)(B)(*1*) (and is not required to provide an automatic certificate under paragraph (a)(2)(ii) of this section).

(*2*) *Example.* The rule of this paragraph (a)(1)(iv)(B) is illustrated by the following example:

Example. (i) *Facts.* A group health plan provides coverage under an HMO option and an indemnity option through different issuers, and only allows employees to switch on each January 1. Neither the HMO nor the indemnity issuer has entered into an agreement with the plan to provide certificates as permitted under paragraph (a)(1)(iii) of this section.

(ii) *Conclusion.* In this *Example,* if an employee switches from the indemnity option to the HMO option on January 1, the indemnity issuer must provide the plan (or a person designated by the plan) with appropriate information with respect to the individual's coverage with the indemnity issuer. However, if the individual's coverage with the indemnity issuer ceases at a date other than January 1, the issuer is instead required to provide the individual with an automatic certificate.

(2) *Individuals for whom certificate must be provided; timing of issuance*—(i) *Individuals.* A certificate must be provided, without charge, for participants or dependents who are or were covered under a group health plan upon the occurrence of any of the events described in paragraph (a)(2)(ii) or (iii) of this section.

(ii) *Issuance of automatic certificates.* The certificates described in this paragraph (a)(2)(ii) are referred to as automatic certificates.

(A) *Qualified beneficiaries upon a qualifying event.* In the case of an individual who is a qualified beneficiary (as defined in section 607(3) of ERISA, section 4980(B)(g)(1) of the Internal Revenue Code, or section 2208 of the PHS Act) entitled to elect COBRA continuation coverage, an automatic certificate is required to be provided at the time the individual would lose coverage under the plan in the absence of COBRA continuation coverage or alternative coverage elected instead of COBRA continuation coverage. A plan or issuer satisfies this requirement if it provides the automatic certificate no later than the time a notice is required to be furnished for a qualifying event under section 606 of ERISA, section 4980(B)(f)(6) of the Internal Revenue Code, and section 2206 of the PHS Act (relating to notices required under COBRA).

(B) *Other individuals when coverage ceases.* In the case of an individual who is not a qualified beneficiary entitled to elect COBRA continuation coverage, an automatic certificate must be provided at the time the individual ceases to be covered under the plan. A plan or issuer satisfies the requirement to provide an automatic certificate at the

time the individual ceases to be covered if it provides the automatic certificate within a reasonable time after coverage ceases (or after the expiration of any grace period for nonpayment of premiums).

(*1*) The cessation of temporary continuation coverage (TCC) under Title 5 U.S.C. Chapter 89 (the Federal Employees Health Benefit Program) is a cessation of coverage upon which an automatic certificate must be provided.

(*2*) In the case of an individual who is entitled to elect to continue coverage under a State program similar to COBRA and who receives the automatic certificate not later than the time a notice is required to be furnished under the State program, the certificate is deemed to be provided within a reasonable time after coverage ceases under the plan.

(*3*) If an individual's coverage ceases due to the operation of a lifetime limit on all benefits, coverage is considered to cease for purposes of this paragraph (a)(2)(ii)(B) on the earliest date that a claim is denied due to the operation of the lifetime limit.

(C) *Qualified beneficiaries when COBRA ceases.* In the case of an individual who is a qualified beneficiary and has elected COBRA continuation coverage (or whose coverage has continued after the individual became entitled to elect COBRA continuation coverage), an automatic certificate is to be provided at the time the individual' s coverage under the plan ceases. A plan, or issuer, satisfies this requirement if it provides the automatic certificate within a reasonable time after coverage ceases (or after the expiration of any grace period for nonpayment of premiums). An automatic certificate is required to be provided to such an individual regardless of whether the individual has previously received an automatic certificate under paragraph (a)(2)(ii)(A) of this section.

(iii) *Any individual upon request.* A certificate must be provided in response to a request made by, or on behalf of, an individual at any time while the individual is covered under a plan and up to 24 months after coverage ceases. Thus, for example, a plan in which an individual enrolls may, if authorized by the individual, request a certificate of the individual's creditable coverage on behalf of the individual from a plan in which the individual was formerly enrolled. After the request is received, a plan or issuer is required to provide the certificate by the earliest date that the plan or issuer, acting in a reasonable and prompt fashion, can provide the certificate. A certificate is required to be provided under this paragraph (a)(2)(iii) even if the individual has previously received a certificate under this paragraph (a)(2)(iii) or an automatic certificate under paragraph (a)(2)(ii) of this section.

(iv) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* terminates employment with Employer *Q*. *A* is a qualified beneficiary entitled to elect COBRA continuation coverage under Employer *Q*'s group health plan. A notice of the rights provided under COBRA is typically furnished to qualified beneficiaries under the plan within 10 days after a covered employee terminates employment.

(ii) *Conclusion.* In this *Example 1,* the automatic certificate may be provided at the same time that *A* is provided the COBRA notice.

Example 2. (i) *Facts.* Same facts as *Example 1,* except that the automatic certificate for *A* is not completed by the time the COBRA notice is furnished to *A*.

(ii) *Conclusion.* In this *Example 2,* the automatic certificate may be provided after the COBRA notice but must be provided within the period permitted by law for the delivery of notices under COBRA.

Example 3. (i) *Facts.* Employer *R* maintains an insured group health plan. *R* has never had 20 employees and thus *R*'s plan is not subject to the COBRA continuation provisions. However, *R* is in a State that has a State program similar to COBRA. *B* terminates employment with *R* and loses coverage under *R*'s plan.

(ii) *Conclusion.* In this *Example 3,* the automatic certificate must be provided not later than the time a notice is required to be furnished under the State program.

Example 4. (i) *Facts.* Individual *C* terminates employment with Employer *S* and receives both a notice of *C*'s rights under COBRA and an automatic certificate. *C* elects COBRA continuation coverage under Employer *S*'s group health plan. After four months of COBRA continuation coverage and the expiration of a 30-day grace period, *S*'s group health plan determines that *C*'s COBRA continuation coverage has ceased

due to a failure to make a timely payment for continuation coverage.

(ii) *Conclusion*. In this *Example 4*, the plan must provide an updated automatic certificate to *C* within a reasonable time after the end of the grace period.

Example 5. (i) *Facts*. Individual *D* is currently covered under the group health plan of Employer *T*. *D* requests a certificate, as permitted under paragraph (a)(2)(iii) of this section. Under the procedure for *T*'s plan, certificates are mailed (by first class mail) 7 business days following receipt of the request. This date reflects the earliest date that the plan, acting in a reasonable and prompt fashion, can provide certificates.

(ii) *Conclusion*. In this *Example 5*, the plan's procedure satisfies paragraph (a)(2)(iii) of this section.

(3) *Form and content of certificate*—(i) *Written certificate*—(A) *In General*. Except as provided in paragraph (a)(3)(i)(B) of this section, the certificate must be provided in writing (or any other medium approved by the Secretary).

(B) *Other permissible forms*. No written certificate is required to be provided under this paragraph (a) with respect to a particular event described in paragraph (a)(2)(ii) or (iii) of this section, if—

(*1*) An individual who is entitled to receive the certificate requests that the certificate be sent to another plan or issuer instead of to the individual;

(*2*) The plan or issuer that would otherwise receive the certificate agrees to accept the information in this paragraph (a)(3) through means other than a written certificate (such as by telephone); and

(*3*) The receiving plan or issuer receives the information from the sending plan or issuer through such means within the time required under paragraph (a)(2) of this section.

(ii) *Required information*. The certificate must include the following—

(A) The date the certificate is issued;

(B) The name of the group health plan that provided the coverage described in the certificate;

(C) The name of the participant or dependent with respect to whom the certificate applies, and any other information necessary for the plan providing the coverage specified in the certificate to identify the individual, such as the individual's identification number under the plan and the name of the participant if the certificate is for (or includes) a dependent;

(D) The name, address, and telephone number of the plan administrator or issuer required to provide the certificate;

(E) The telephone number to call for further information regarding the certificate (if different from paragraph (a)(3)(ii)(D) of this section);

(F) Either—

(*1*) A statement that an individual has at least 18 months (for this purpose, 546 days is deemed to be 18 months) of creditable coverage, disregarding days of creditable coverage before a significant break in coverage, or

(*2*) The date any waiting period (and affiliation period, if applicable) began and the date creditable coverage began;

(G) The date creditable coverage ended, unless the certificate indicates that creditable coverage is continuing as of the date of the certificate; and

(H) An educational statement regarding HIPAA, which explains:

(*1*) The restrictions on the ability of a plan or issuer to impose a preexisting condition exclusion (including an individual's ability to reduce a preexisting condition exclusion by creditable coverage);

(*2*) Special enrollment rights;

(*3*) The prohibitions against discrimination based on any health factor;

(*4*) The right to individual health coverage;

(*5*) The fact that State law may require issuers to provide additional protections to individuals in that State; and

(*6*) Where to get more information.

(iii) *Periods of coverage under the certificate*. If an automatic certificate is provided pursuant to paragraph (a)(2)(ii) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate pursuant to paragraph (a)(2)(iii) of this section, the certificate provided must include each period of continuous coverage ending within the 24-month period ending on the date of the request (or continuing on the date of the request). A separate certificate may be

provided for each such period of continuous coverage.

(iv) *Combining information for families.* A certificate may provide information with respect to both a participant and the participant's dependents if the information is identical for each individual. If the information is not identical, certificates may be provided on one form if the form provides all the required information for each individual and separately states the information that is not identical.

(v) *Model certificate.* The requirements of paragraph (a)(3)(ii) of this section are satisfied if the plan or issuer provides a certificate in accordance with a model certificate authorized by the Secretary.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in §146.145(c). In addition, the information in the certificate regarding coverage is not required to specify categories of benefits described in §146.113(c) (relating to the alternative method of counting creditable coverage). However, if excepted benefits are provided concurrently with other creditable coverage (so that the coverage does not consist solely of excepted benefits), information concerning the benefits may be required to be disclosed under paragraph (b) of this section.

(4) *Procedures*—(i) *Method of delivery.* The certificate is required to be provided to each individual described in paragraph (a)(2) of this section or an entity requesting the certificate on behalf of the individual. The certificate may be provided by first-class mail. If the certificate or certificates are provided to the participant and the participant's spouse at the participant's last known address, then the requirements of this paragraph (a)(4) are satisfied with respect to all individuals residing at that address. If a dependent's last known address is different than the participant's last known address, a separate certificate is required to be provided to the dependent at the dependent's last known address. If separate certificates are being provided by mail to individuals who reside at the same address, separate mailings of each certificate are not required.

(ii) *Procedure for requesting certificates.* A plan or issuer must establish a written procedure for individuals to request and receive certificates pursuant to paragraph (a)(2)(iii) of this section. The written procedure must include all contact information necessary to request a certificate (such as name and phone number or address).

(iii) *Designated recipients.* If an automatic certificate is required to be provided under paragraph (a)(2)(ii) of this section, and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the plan or issuer responsible for providing the certificate is permitted to provide the certificate to the designated individual or entity. If a certificate is required to be provided upon request under paragraph (a)(2)(iii) of this section and the individual entitled to receive the certificate designates another individual or entity to receive the certificate, the plan or issuer responsible for providing the certificate is required to provide the certificate to the designated individual or entity.

(5) *Special rules concerning dependent coverage*—(i)(A) *Reasonable efforts.* A plan or issuer is required to use reasonable efforts to determine any information needed for a certificate relating to dependent coverage. In any case in which an automatic certificate is required to be furnished with respect to a dependent under paragraph (a)(2)(ii) of this section, no individual certificate is required to be furnished until the plan or issuer knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the plan.

(B) *Example.* The rules of this paragraph (a)(5)(i) are illustrated by the following example:

Example. (i) *Facts.* A group health plan covers employees and their dependents. The plan annually requests all employees to provide updated information regarding dependents, including the specific date on which an employee has a new dependent or on which a person ceases to be a dependent of the employee.

(ii) *Conclusion.* In this *Example*, the plan has satisfied the standard in this paragraph (a)(5)(i) of this section that it make reasonable efforts to determine the cessation of dependents' coverage and the related dependent coverage information.

(ii) *Special rules for demonstrating coverage.* If a certificate furnished by a plan or issuer does not provide the name of any dependent covered by the certificate, the procedures described in paragraph (c)(5) of this section may be used to demonstrate dependent status. In addition, these procedures may be used to demonstrate that a child was covered under any creditable coverage within 30 days after birth, adoption, or placement for adoption. See also § 146.111(b), under which such a child cannot be subject to a preexisting condition exclusion.

(6) *Special certification rules*—(i) *Issuers.* Issuers of group and individual health insurance are required to provide certificates of any creditable coverage they provide in the group or individual health insurance market, even if the coverage is provided in connection with an entity or program that is not itself required to provide a certificate because it is not subject to the group market provisions of this part, part 7 of subtitle B of title I of ERISA, or chapter 100 of subtitle K of the Internal Revenue Code. This would include coverage provided in connection with any of the following:

(A) Creditable coverage described in sections 2701(c)(1)(G), (I) and (J) of the PHS Act (coverage under a State health benefits risk pool, a public health plan, and a health benefit plan under section 5(e) of the Peace Corps Act).

(B) Coverage subject to section 2722(a)(1)(B) of the PHS Act (requiring certificates by issuers offering health insurance coverage in connection with any group health plan, including a church plan or a governmental plan (including the Federal Employees Health Benefits Program).

(C) Coverage subject to section 2743 of the PHS Act applicable to health insurance issuers in the individual market. (However, this section does not require a certificate to be provided with respect to short-term limited duration insurance, which is excluded from the definition of ''individual health insurance coverage'' in 45 CFR 144.103 that is not provided in connection with a group health plan, as described in paragraph (a)(6)(i)(B) of this section.)

(ii) *Other entities.* For special rules requiring that certain other entities, not subject to this part, provide certificates consistent with the rules of this section, see section 2791(a)(3) of the PHS Act applicable to entities described in sections 2701(c)(1)(C), (D), (E), and (F) of the PHS Act (relating to Medicare, Medicaid, TRICARE, and Indian Health Service), section 2722(a)(1)(A) of the PHS Act applicable to non-Federal governmental plans generally, section 2721(b)(2)(C)(ii) of the PHS Act applicable to non-Federal governmental plans that elect to be excluded from the requirements of subparts 1 through 3 of part A of title XXVII of the PHS Act, and section 9805(a) of the Internal Revenue Code applicable to group health plans, which includes church plans (as defined in section 414(e) of the Internal Revenue Code).

(b) *Disclosure of coverage to a plan or issuer using the alternative method of counting creditable coverage*—(1) *In general.* After an individual provides a certificate of creditable coverage to a plan or issuer using the alternative method under § 146.113(c), that plan or issuer (requesting entity) must request that the entity that issued the certificate (prior entity) disclose the information set forth in paragraph (b)(2) of this section. The prior entity is required to disclose this information promptly.

(2) *Information to be disclosed.* The prior entity is required to identify to the requesting entity the categories of benefits with respect to which the requesting entity is using the alternative method of counting creditable coverage, and the requesting entity may identify specific information that the requesting entity reasonably needs in order to determine the individual's creditable coverage with respect to any such category.

(3) *Charge for providing information.* The prior entity may charge the requesting entity for the reasonable cost of disclosing such information.

(c) *Ability of an individual to demonstrate creditable coverage and waiting period information*—(1) *Purpose.* The rules in this paragraph (c) implement section 2701(c)(4) of the PHS Act, which permits individuals to demonstrate the duration of creditable coverage

through means other than certificates, and section 2701(e)(3) of the PHS Act, which requires the Secretary to establish rules designed to prevent an individual's subsequent coverage under a group health plan or health insurance coverage from being adversely affected by an entity's failure to provide a certificate with respect to that individual.

(2) *In general*. If the accuracy of a certificate is contested or a certificate is unavailable when needed by an individual, the individual has the right to demonstrate creditable coverage (and waiting or affiliation periods) through the presentation of documents or other means. For example, the individual may make such a demonstration when—

(i) An entity has failed to provide a certificate within the required time;

(ii) The individual has creditable coverage provided by an entity that is not required to provide a certificate of the coverage pursuant to paragraph (a) of this section;

(iii) The individual has an urgent medical condition that necessitates a determination before the individual can deliver a certificate to the plan; or

(iv) The individual lost a certificate that the individual had previously received and is unable to obtain another certificate.

(3) *Evidence of creditable coverage*—(i) *Consideration of evidence*—(A) A plan or issuer is required to take into account all information that it obtains or that is presented on behalf of an individual to make a determination, based on the relevant facts and circumstances, whether an individual has creditable coverage. A plan or issuer shall treat the individual as having furnished a certificate under paragraph (a) of this section if—

(*1*) The individual attests to the period of creditable coverage;

(*2*) The individual also presents relevant corroborating evidence of some creditable coverage during the period; and

(*3*) The individual cooperates with the plan's or issuer's efforts to verify the individual's coverage.

(B) For purposes of this paragraph (c)(3)(i), cooperation includes providing (upon the plan's or issuer's request) a written authorization for the plan or issuer to request a certificate on behalf of the individual, and cooperating in efforts to determine the validity of the corroborating evidence and the dates of creditable coverage. While a plan or issuer may refuse to credit coverage where the individual fails to cooperate with the plan's or issuer's efforts to verify coverage, the plan or issuer may not consider an individual's inability to obtain a certificate to be evidence of the absence of creditable coverage.

(ii) *Documents*. Documents that corroborate creditable coverage (and waiting or affiliation periods) include explanations of benefits (EOBs) or other correspondence from a plan or issuer indicating coverage, pay stubs showing a payroll deduction for health coverage, a health insurance identification card, a certificate of coverage under a group health policy, records from medical care providers indicating health coverage, third party statements verifying periods of coverage, and any other relevant documents that evidence periods of health coverage.

(iii) *Other evidence*. Creditable coverage (and waiting or affiliation periods) may also be corroborated through means other than documentation, such as by a telephone call from the plan or provider to a third party verifying creditable coverage.

(iv) *Example*. The rules of this paragraph (c)(3) are illustrated by the following example:

Example. (i) *Facts*. Individual *F* terminates employment with Employer *W* and, a month later, is hired by Employer *X*. *X*'s group health plan imposes a preexisting condition exclusion of 12 months on new enrollees under the plan and uses the standard method of determining creditable coverage. *F* fails to receive a certificate of prior coverage from the self-insured group health plan maintained by *F*'s prior employer, *W*, and requests a certificate. However, *F* (and *X*'s plan, on *F*'s behalf and with *F*'s cooperation) is unable to obtain a certificate from *W*'s plan. *F* attests that, to the best of *F*'s knowledge, *F* had at least 12 months of continuous coverage under *W*'s plan, and that the coverage ended no earlier than *F*'s termination of employment from *W*. In addition, *F* presents evidence of coverage, such as an explanation of benefits for a claim that was made during the relevant period.

(ii) *Conclusion*. In this *Example*, based solely on these facts, *F* has demonstrated creditable coverage for the 12 months of coverage

under *W*'s plan in the same manner as if *F* had presented a written certificate of creditable coverage.

(4) *Demonstrating categories of creditable coverage.* Procedures similar to those described in this paragraph (c) apply in order to determine the duration of an individual's creditable coverage with respect to any category under paragraph (b) of this section (relating to determining creditable coverage under the alternative method).

(5) *Demonstrating dependent status.* If, in the course of providing evidence (including a certificate) of creditable coverage, an individual is required to demonstrate dependent status, the group health plan or issuer is required to treat the individual as having furnished a certificate showing the dependent status if the individual attests to such dependency and the period of such status and the individual cooperates with the plan's or issuer's efforts to verify the dependent status.

[69 FR 78790, Dec. 30, 2004, as amended at 75 FR 27138, May 13, 2010]

§ 146.117 Special enrollment periods.

(a) *Special enrollment for certain individuals who lose coverage*—(1) *In General.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, is required to permit current employees and dependents (as defined in § 144.103 of this chapter) who are described in paragraph (a)(2) of this section to enroll for coverage under the terms of the plan if the conditions in paragraph (a)(3) of this section are satisfied. The special enrollment rights under this paragraph (a) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan.

(2) *Individuals eligible for special enrollment*—(i) *When employee loses coverage.* A current employee and any dependents (including the employee's spouse) each are eligible for special enrollment in any benefit package under the plan (subject to plan eligibility rules conditioning dependent enrollment on enrollment of the employee) if—

(A) The employee and the dependents are otherwise eligible to enroll in the benefit package;

(B) When coverage under the plan was previously offered, the employee had coverage under any group health plan or health insurance coverage; and

(C) The employee satisfies the conditions of paragraph (a)(3)(i), (ii), or (iii) of this section and, if applicable, paragraph (a)(3)(iv) of this section.

(ii) *When dependent loses coverage*—(A) A dependent of a current employee (including the employee's spouse) and the employee each are eligible for special enrollment in any benefit package under the plan (subject to plan eligibility rules conditioning dependent enrollment on enrollment of the employee) if—

(*1*) The dependent and the employee are otherwise eligible to enroll in the benefit package;

(*2*) When coverage under the plan was previously offered, the dependent had coverage under any group health plan or health insurance coverage; and

(*3*) The dependent satisfies the conditions of paragraph (a)(3)(i), (ii), or (iii) of this section and, if applicable, paragraph (a)(3)(iv) of this section.

(B) However, the plan or issuer is not required to enroll any other dependent unless that dependent satisfies the criteria of this paragraph (a)(2)(ii), or the employee satisfies the criteria of paragraph (a)(2)(i) of this section.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* works for Employer *X*. *A*, *A*'s spouse, and *A*'s dependent children are eligible but not enrolled for coverage under *X*'s group health plan. *A*'s spouse works for Employer *Y* and at the time coverage was offered under *X*'s plan, *A* was enrolled in coverage under *Y*'s plan. Then, *A* loses eligibility for coverage under *Y*'s plan.

(ii) *Conclusion.* In this *Example 1*, because *A* satisfies the conditions for special enrollment under paragraph (a)(2)(i) of this section, *A*, *A*'s spouse, and *A*'s dependent children are eligible for special enrollment under *X*'s plan.

Example 2. (i) *Facts.* Individual *A* and *A*'s spouse are eligible but not enrolled for coverage under Group Health Plan *P* maintained by *A*'s employer. When *A* was first presented with an opportunity to enroll *A* and *A*'s spouse, they did not have other coverage. Later, *A* and *A*'s spouse enroll in Group Health Plan *Q* maintained by the employer of *A*'s spouse. During a subsequent open enrollment period in *P*, *A* and *A*'s spouse did not enroll because of their coverage under *Q*.

They then lose eligibility for coverage under *Q*.

(ii) *Conclusion*. In this *Example 2*, because *A* and *A*'s spouse were covered under *Q* when they did not enroll in *P* during open enrollment, they satisfy the conditions for special enrollment under paragraphs (a)(2)(i) and (ii) of this section. Consequently, *A* and *A*'s spouse are eligible for special enrollment under *P*.

Example 3. (i) *Facts*. Individual *B* works for Employer *X*. *B* and *B*'s spouse are eligible but not enrolled for coverage under *X*'s group health plan. *B*'s spouse works for Employer *Y* and at the time coverage was offered under *X*'s plan, *B*'s spouse was enrolled in self-only coverage under *Y*'s group health plan. Then, *B*'s spouse loses eligibility for coverage under *Y*'s plan.

(ii) *Conclusion*. In this *Example 3*, because *B*'s spouse satisfies the conditions for special enrollment under paragraph (a)(2)(ii) of this section, both *B* and *B*'s spouse are eligible for special enrollment under *X*'s plan.

Example 4. (i) *Facts*. Individual *A* works for Employer *X*. *X* maintains a group health plan with two benefit packages—an HMO option and an indemnity option. Self-only and family coverage are available under both options. *A* enrolls for self-only coverage in the HMO option. *A*'s spouse works for Employer *Y* and was enrolled for self-only coverage under *Y*'s plan at the time coverage was offered under *X*'s plan. Then, *A*'s spouse loses coverage under *Y*'s plan. *A* requests special enrollment for *A* and *A*'s spouse under the plan's indemnity option.

(ii) *Conclusion*. In this *Example 4*, because *A*'s spouse satisfies the conditions for special enrollment under paragraph (a)(2)(ii) of this section, both *A* and *A*'s spouse can enroll in either benefit package under *X*'s plan. Therefore, if *A* requests enrollment in accordance with the requirements of this section, the plan must allow *A* and *A*'s spouse to enroll in the indemnity option.

(3) *Conditions for special enrollment*—(i) *Loss of eligibility for coverage*. In the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions of this paragraph (a)(3)(i) are satisfied at the time the coverage is terminated as a result of loss of eligibility (regardless of whether the individual is eligible for or elects COBRA continuation coverage). Loss of eligibility under this paragraph (a)(3)(i) does not include a loss due to the failure of the employee or dependent to pay premiums on a timely basis or termination of coverage for cause (such as making a fraudulent claim or an intentional misrepresentation of a material fact in connection with the plan). Loss of eligibility for coverage under this paragraph (a)(3)(i) includes (but is not limited to)—

(A) Loss of eligibility for coverage as a result of legal separation, divorce, cessation of dependent status (such as attaining the maximum age to be eligible as a dependent child under the plan), death of an employee, termination of employment, reduction in the number of hours of employment, and any loss of eligibility for coverage after a period that is measured by reference to any of the foregoing;

(B) In the case of coverage offered through an HMO, or other arrangement, in the individual market that does not provide benefits to individuals who no longer reside, live, or work in a service area, loss of coverage because an individual no longer resides, lives, or works in the service area (whether or not within the choice of the individual);

(C) In the case of coverage offered through an HMO, or other arrangement, in the group market that does not provide benefits to individuals who no longer reside, live, or work in a service area, loss of coverage because an individual no longer resides, lives, or works in the service area (whether or not within the choice of the individual), and no other benefit package is available to the individual;

(D) A situation in which an individual incurs a claim that would meet or exceed a lifetime limit on all benefits; and

(E) A situation in which a plan no longer offers any benefits to the class of similarly situated individuals (as described in §146.121(d)) that includes the individual.

(ii) *Termination of employer contributions*. In the case of an employee or dependent who has coverage that is not COBRA continuation coverage, the conditions of this paragraph (a)(3)(ii) are satisfied at the time employer contributions towards the employee's or dependent's coverage terminate. Employer contributions include contributions by any current or former employer that was contributing to coverage for the employee or dependent.

(iii) *Exhaustion of COBRA continuation coverage.* In the case of an employee or dependent who has coverage that is COBRA continuation coverage, the conditions of this paragraph (a)(3)(iii) are satisfied at the time the COBRA continuation coverage is exhausted. For purposes of this paragraph (a)(3)(iii), an individual who satisfies the conditions for special enrollment of paragraph (a)(3)(i) of this section, does not enroll, and instead elects and exhausts COBRA continuation coverage satisfies the conditions of this paragraph (a)(3)(iii). (*Exhaustion of COBRA continuation coverage* is defined in § 144.103 of this chapter.)

(iv) *Written statement.* A plan may require an employee declining coverage (for the employee or any dependent of the employee) to state in writing whether the coverage is being declined due to other health coverage only if, at or before the time the employee declines coverage, the employee is provided with notice of the requirement to provide the statement (and the consequences of the employee's failure to provide the statement). If a plan requires such a statement, and an employee does not provide it, the plan is not required to provide special enrollment to the employee or any dependent of the employee under this paragraph (a)(3). A plan must treat an employee as having satisfied the plan requirement permitted under this paragraph (a)(3)(iv) if the employee provides a written statement that coverage was being declined because the employee or dependent had other coverage; a plan cannot require anything more for the employee to satisfy the plan's requirement to provide a written statement. (For example, the plan cannot require that the statement be notarized.)

(v) The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *D* enrolls in a group health plan maintained by Employer *Y*. At the time *D* enrolls, *Y* pays 70 percent of the cost of employee coverage and *D* pays the rest. *Y* announces that beginning January 1, *Y* will no longer make employer contributions towards the coverage. Employees may maintain coverage, however, if they pay the total cost of the coverage.

(ii) *Conclusion.* In this *Example 1*, employer contributions towards *D*'s coverage ceased on January 1 and the conditions of paragraph (a)(3)(ii) of this section are satisfied on this date (regardless of whether *D* elects to pay the total cost and continue coverage under *Y*'s plan).

Example 2. (i) *Facts.* A group health plan provides coverage through two options—Option 1 and Option 2. Employees can enroll in either option only within 30 days of hire or on January 1 of each year. Employee *A* is eligible for both options and enrolls in Option 1. Effective July 1 the plan terminates coverage under Option 1 and the plan does not create an immediate open enrollment opportunity into Option 2.

(ii) *Conclusion.* In this *Example 2*, A has experienced a loss of eligibility for coverage that satisfies paragraph (a)(3)(i) of this section, and has satisfied the other conditions for special enrollment under paragraph (a)(2)(i) of this section. Therefore, if *A* satisfies the other conditions of this paragraph (a), the plan must permit *A* to enroll in Option 2 as a special enrollee. (*A* may also be eligible to enroll in another group health plan, such as a plan maintained by the employer of *A*'s spouse, as a special enrollee.) The outcome would be the same if Option 1 was terminated by an issuer and the plan made no other coverage available to *A*.

Example 3. (i) *Facts.* Individual *C* is covered under a group health plan maintained by Employer *X*. While covered under *X*'s plan, *C* was eligible for but did not enroll in a plan maintained by Employer Z, the employer of *C*'s spouse. *C* terminates employment with *X* and loses eligibility for coverage under *X*'s plan. *C* has a special enrollment right to enroll in *Z*'s plan, but *C* instead elects COBRA continuation coverage under *X*'s plan. *C* exhausts COBRA continuation coverage under *X*'s plan and requests special enrollment in *Z*'s plan.

(ii) *Conclusion.* In this *Example 3*, *C* has satisfied the conditions for special enrollment under paragraph (a)(3)(iii) of this section, and has satisfied the other conditions for special enrollment under paragraph (a)(2)(i) of this section. The special enrollment right that *C* had into *Z*'s plan immediately after the loss of eligibility for coverage under *X*'s plan was an offer of coverage under *Z*'s plan. When *C* later exhausts COBRA coverage under *X*'s plan, *C* has a second special enrollment right in *Z*'s plan.

(4) *Applying for special enrollment and effective date of coverage*—(i) A plan or issuer must allow an employee a period of at least 30 days after an event described in paragraph (a)(3) of this section (other than an event described in paragraph (a)(3)(i)(D)) to request enrollment (for the employee or the employee's dependent). In the case of an event described in paragraph

(a)(3)(i)(D) of this section (relating to loss of eligibility for coverage due to the operation of a lifetime limit on all benefits), a plan or issuer must allow an employee a period of at least 30 days after a claim is denied due to the operation of a lifetime limit on all benefits.

(ii) Coverage must begin no later than the first day of the first calendar month beginning after the date the plan or issuer receives the request for special enrollment.

(b) *Special enrollment with respect to certain dependent beneficiaries*—(1) *General.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, that makes coverage available with respect to dependents is required to permit individuals described in paragraph (b)(2) of this section to be enrolled for coverage in a benefit package under the terms of the plan. Paragraph (b)(3) of this section describes the required special enrollment period and the date by which coverage must begin. The special enrollment rights under this paragraph (b) apply without regard to the dates on which an individual would otherwise be able to enroll under the plan.

(2) *Individuals eligible for special enrollment.* An individual is described in this paragraph (b)(2) if the individual is otherwise eligible for coverage in a benefit package under the plan and if the individual is described in paragraph (b)(2)(i), (ii), (iii), (iv), (v), or (vi) of this section.

(i) *Current employee only.* A current employee is described in this paragraph (b)(2)(i) if a person becomes a dependent of the individual through marriage, birth, adoption, or placement for adoption.

(ii) *Spouse of a participant only.* An individual is described in this paragraph (b)(2)(ii) if either—

(A) The individual becomes the spouse of a participant; or

(B) The individual is a spouse of a participant and a child becomes a dependent of the participant through birth, adoption, or placement for adoption.

(iii) *Current employee and spouse.* A current employee and an individual who is or becomes a spouse of such an employee, are described in this paragraph (b)(2)(iii) if either—

(A) The employee and the spouse become married; or

(B) The employee and spouse are married and a child becomes a dependent of the employee through birth, adoption, or placement for adoption.

(iv) *Dependent of a participant only.* An individual is described in this paragraph (b)(2)(iv) if the individual is a dependent (as defined in § 144.103 of this chapter) of a participant and the individual has become a dependent of the participant through marriage, birth, adoption, or placement for adoption.

(v) *Current employee and a new dependent.* A current employee and an individual who is a dependent of the employee, are described in this paragraph (b)(2)(v) if the individual becomes a dependent of the employee through marriage, birth, adoption, or placement for adoption.

(vi) *Current employee, spouse, and a new dependent.* A current employee, the employee's spouse, and the employee's dependent are described in this paragraph (b)(2)(vi) if the dependent becomes a dependent of the employee through marriage, birth, adoption, or placement for adoption.

(3) *Applying for special enrollment and effective date of coverage*—(i) *Request.* A plan or issuer must allow an individual a period of at least 30 days after the date of the marriage, birth, adoption, or placement for adoption (or, if dependent coverage is not generally made available at the time of the marriage, birth, adoption, or placement for adoption, a period of at least 30 days after the date the plan makes dependent coverage generally available) to request enrollment (for the individual or the individual's dependent).

(ii) *Reasonable procedures for special enrollment.* [Reserved]

(iii) *Date coverage must begin*—(A) *Marriage.* In the case of marriage, coverage must begin no later than the first day of the first calendar month beginning after the date the plan or issuer receives the request for special enrollment.

(B) *Birth, adoption, or placement for adoption.* Coverage must begin in the case of a dependent's birth on the date

of birth and in the case of a dependent's adoption or placement for adoption no later than the date of such adoption or placement for adoption (or, if dependent coverage is not made generally available at the time of the birth, adoption, or placement for adoption, the date the plan makes dependent coverage available).

(4) *Examples*. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts*. An employer maintains a group health plan that offers all employees employee-only coverage, employee-plus-spouse coverage, or family coverage. Under the terms of the plan, any employee may elect to enroll when first hired (with coverage beginning on the date of hire) or during an annual open enrollment period held each December (with coverage beginning the following January 1). Employee *A* is hired on September 3. *A* is married to *B*, and they have no children. On March 15 in the following year a child *C* is born to *A* and *B*. Before that date, *A* and *B* have not been enrolled in the plan.

(ii) *Conclusion*. In this *Example 1*, the conditions for special enrollment of an employee with a spouse and new dependent under paragraph (b)(2)(vi) of this section are satisfied. If *A* satisfies the conditions of paragraph (b)(3) of this section for requesting enrollment timely, the plan will satisfy this paragraph (b) if it allows *A* to enroll either with employee-only coverage, with employee-plus-spouse coverage (for *A* and *B*), or with family coverage (for *A*, *B*, and *C*). The plan must allow whatever coverage is chosen to begin on March 15, the date of *C*'s birth.

Example 2. (i) *Facts*. Individual *D* works for Employer *X*. *X* maintains a group health plan with two benefit packages—an HMO option and an indemnity option. Self-only and family coverage are available under both options. *D* enrolls for self-only coverage in the HMO option. Then, a child, *E*, is placed for adoption with *D*. Within 30 days of the placement of *E* for adoption, *D* requests enrollment for *D* and *E* under the plan's indemnity option.

(ii) *Conclusion*. In this *Example 2*, *D* and *E* satisfy the conditions for special enrollment under paragraphs (b)(2)(v) and (b)(3) of this section. Therefore, the plan must allow *D* and *E* to enroll in the indemnity coverage, effective as of the date of the placement for adoption.

(c) *Notice of special enrollment*. At or before the time an employee is initially offered the opportunity to enroll in a group health plan, the plan must furnish the employee with a notice of special enrollment that complies with the requirements of this paragraph (c).

(1) *Description of special enrollment rights*. The notice of special enrollment must include a description of special enrollment rights. The following model language may be used to satisfy this requirement:

If you are declining enrollment for yourself or your dependents (including your spouse) because of other health insurance or group health plan coverage, you may be able to enroll yourself and your dependents in this plan if you or your dependents lose eligibility for that other coverage (or if the employer stops contributing towards your or your dependents' other coverage). However, you must request enrollment within [insert "30 days" or any longer period that applies under the plan] after your or your dependents' other coverage ends (or after the employer stops contributing toward the other coverage).

In addition, if you have a new dependent as a result of marriage, birth, adoption, or placement for adoption, you may be able to enroll yourself and your dependents. However, you must request enrollment within [insert "30 days" or any longer period that applies under the plan] after the marriage, birth, adoption, or placement for adoption.

To request special enrollment or obtain more information, contact [insert the name, title, telephone number, and any additional contact information of the appropriate plan representative].

(2) *Additional information that may be required*. The notice of special enrollment must also include, if applicable, the notice described in paragraph (a)(3)(iv) of this section (the notice required to be furnished to an individual declining coverage if the plan requires the reason for declining coverage to be in writing).

(d) *Treatment of special enrollees*—(1) If an individual requests enrollment while the individual is entitled to special enrollment under either paragraph (a) or (b) of this section, the individual is a special enrollee, even if the request for enrollment coincides with a late enrollment opportunity under the plan. Therefore, the individual cannot be treated as a late enrollee.

(2) Special enrollees must be offered all the benefit packages available to similarly situated individuals who enroll when first eligible. For this purpose, any difference in benefits or cost-

sharing requirements for different individuals constitutes a different benefit package. In addition, a special enrollee cannot be required to pay more for coverage than a similarly situated individual who enrolls in the same coverage when first eligible. The length of any preexisting condition exclusion that may be applied to a special enrollee cannot exceed the length of any preexisting condition exclusion that is applied to similarly situated individuals who enroll when first eligible. For rules prohibiting the application of a preexisting condition exclusion to certain newborns, adopted children, and children placed for adoption, see § 146.111(b).

(3) The rules of this section are illustrated by the following example:

Example. (i) *Facts.* Employer *Y* maintains a group health plan that has an enrollment period for late enrollees every November 1 through November 30 with coverage effective the following January 1. On October 18, Individual *B* loses coverage under another group health plan and satisfies the requirements of paragraphs (a)(2), (3), and (4) of this section. *B* submits a completed application for coverage on November 2.

(ii) *Conclusion.* In this *Example*, *B* is a special enrollee. Therefore, even though *B*'s request for enrollment coincides with an open enrollment period, *B*'s coverage is required to be made effective no later than December 1 (rather than the plan's January 1 effective date for late enrollees).

[69 FR 78794, Dec. 30, 2004]

§ 146.119 HMO affiliation period as an alternative to a preexisting condition exclusion.

(a) *In general.* A group health plan offering health insurance coverage through an HMO, or an HMO that offers health insurance coverage in connection with a group health plan, may impose an affiliation period only if each of the following requirements is satisfied—

(1) No preexisting condition exclusion is imposed with respect to any coverage offered by the HMO in connection with the particular group health plan.

(2) No premium is charged to a participant or beneficiary for the affiliation period.

(3) The affiliation period for the HMO coverage is imposed consistent with the requirements of § 146.121 (prohibiting discrimination based on a health factor).

(4) The affiliation period does not exceed 2 months (or 3 months in the case of a late enrollee).

(5) The affiliation period begins on the enrollment date, or in the case of a late enrollee, the affiliation period begins on the day that would be the first day of coverage but for the affiliation period.

(6) The affiliation period for enrollment in the HMO under a plan runs concurrently with any waiting period.

(b) *Examples.* The rules of paragraph (a) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan. Benefits under the plan are provided through an HMO, which imposes a two-month affiliation period. In order to be eligible under the plan, employees must have worked for the employer for six months. Individual *A* begins working for the employer on February 1.

(ii) *Conclusion.* In this *Example 1*, Individual *A*'s enrollment date is February 1 (see § 146.111(a)(2)), and both the waiting period and the affiliation period begin on this date and run concurrently. Therefore, the affiliation period ends on March 31, the waiting period ends on July 31, and *A* is eligible to have coverage begin on August 1.

Example 2. (i) *Facts.* A group health plan has two benefit package options, a fee-for-service option and an HMO option. The HMO imposes a 1-month affiliation period. Individual *B* is enrolled in the fee-for-service option for more than one month and then decides to switch to the HMO option at open season.

(ii) *Conclusion.* In this *Example 2*, the HMO may not impose the affiliation period with respect to *B* because any affiliation period would have to begin on *B*'s enrollment date in the plan rather than the date that *B* enrolled in the HMO option. Therefore, the affiliation period would have expired before *B* switched to the HMO option.

Example 3. (i) *Facts.* An employer sponsors a group health plan that provides benefits through an HMO. The plan imposes a two-month affiliation period with respect to salaried employees, but it does not impose an affiliation period with respect to hourly employees.

(ii) *Conclusion.* In this *Example 3*, the plan may impose the affiliation period with respect to salaried employees without imposing any affiliation period with respect to hourly employees (unless, under the circumstances, treating salaried and hourly employees differently does not comply with the requirements of § 146.121).

(c) *Alternatives to affiliation period.* An HMO may use alternative methods in lieu of an affiliation period to address adverse selection, as approved by the State insurance commissioner or other official designated to regulate HMOs. However, an arrangement that is in the nature of a preexisting condition exclusion cannot be an alternative to an affiliation period. Nothing in this part requires a State to receive proposals for or approve alternatives to affiliation periods.

[69 FR 78797, Dec. 30, 2004]

§ 146.120 Interaction with the Family and Medical Leave Act. [Reserved]

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) *Health factors.* (1) The term *health factor* means, in relation to an individual, any of the following health status-related factors:

(i) Health status;

(ii) Medical condition (including both physical and mental illnesses), as defined in § 144.103 of this chapter;

(iii) Claims experience;

(iv) Receipt of health care;

(v) Medical history;

(vi) Genetic information, as defined in § 146.122(a) of this subchapter;

(vii) Evidence of insurability; or

(viii) Disability.

(2) Evidence of insurability includes—

(i) Conditions arising out of acts of domestic violence; and

(ii) Participation in activities such as motorcycling, snowmobiling, all-terrain vehicle riding, horseback riding, skiing, and other similar activities.

(3) The decision whether health coverage is elected for an individual (including the time chosen to enroll, such as under special enrollment or late enrollment) is not, itself, within the scope of any health factor. (However, under § 146.117, a plan or issuer must treat special enrollees the same as similarly situated individuals who are enrolled when first eligible.)

(b) *Prohibited discrimination in rules for eligibility*—(1) *In general*—(i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not establish any rule for eligibility (including continued eligibility) of any individual to enroll for benefits under the terms of the plan or group health insurance coverage that discriminates based on any health factor that relates to that individual or a dependent of that individual. This rule is subject to the provisions of paragraph (b)(2) of this section (explaining how this rule applies to benefits), paragraph (b)(3) of this section (allowing plans to impose certain preexisting condition exclusions), paragraph (d) of this section (containing rules for establishing groups of similarly situated individuals), paragraph (e) of this section (relating to nonconfinement, actively-at-work, and other service requirements), paragraph (f) of this section (relating to wellness programs), and paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors).

(ii) For purposes of this section, rules for eligibility include, but are not limited to, rules relating to—

(A) Enrollment;

(B) The effective date of coverage;

(C) Waiting (or affiliation) periods;

(D) Late and special enrollment;

(E) Eligibility for benefit packages (including rules for individuals to change their selection among benefit packages);

(F) Benefits (including rules relating to covered benefits, benefit restrictions, and cost-sharing mechanisms such as coinsurance, copayments, and deductibles), as described in paragraphs (b)(2) and (b)(3) of this section;

(G) Continued eligibility; and

(H) Terminating coverage (including disenrollment) of any individual under the plan.

(iii) The rules of this paragraph (b)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that is available to all employees who enroll within the first 30 days of their employment. However, employees who do not enroll within the first 30 days cannot enroll later unless they pass a physical examination.

(ii) *Conclusion.* In this *Example 1,* the requirement to pass a physical examination in order to enroll in the plan is a rule for eligibility that discriminates based on one or

more health factors and thus violates this paragraph (b)(1).

Example 2. (i) *Facts.* Under an employer's group health plan, employees who enroll during the first 30 days of employment (and during special enrollment periods) may choose between two benefit packages: an indemnity option and an HMO option. However, employees who enroll during late enrollment are permitted to enroll only in the HMO option and only if they provide evidence of good health.

(ii) *Conclusion.* In this *Example 2,* the requirement to provide evidence of good health in order to be eligible for late enrollment in the HMO option is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1). However, if the plan did not require evidence of good health but limited late enrollees to the HMO option, the plan's rules for eligibility would not discriminate based on any health factor, and thus would not violate this paragraph (b)(1), because the time an individual chooses to enroll is not, itself, within the scope of any health factor.

Example 3. (i) *Facts.* Under an employer's group health plan, all employees generally may enroll within the first 30 days of employment. However, individuals who participate in certain recreational activities, including motorcycling, are excluded from coverage.

(ii) *Conclusion.* In this *Example 3,* excluding from the plan individuals who participate in recreational activities, such as motorcycling, is a rule for eligibility that discriminates based on one or more health factors and thus violates this paragraph (b)(1).

Example 4. (i) *Facts.* A group health plan applies for a group health policy offered by an issuer. As part of the application, the issuer receives health information about individuals to be covered under the plan. Individual *A* is an employee of the employer maintaining the plan. *A* and *A*'s dependents have a history of high health claims. Based on the information about *A* and *A*'s dependents, the issuer excludes *A* and *A*'s dependents from the group policy it offers to the employer.

(ii) *Conclusion.* In this *Example 4,* the issuer's exclusion of A and A's dependents from coverage is a rule for eligibility that discriminates based on one or more health factors, and thus violates this paragraph (b)(1). (If the employer is a small employer under 45 CFR 144.103 (generally, an employer with 50 or fewer employees), the issuer also may violate 45 CFR 146.150, which requires issuers to offer all the policies they sell in the small group market on a guaranteed available basis to all small employers and to accept every eligible individual in every small employer group.) If the plan provides coverage through this policy and does not provide equivalent coverage for *A* and *A*'s dependents through other means, the plan will also violate this paragraph (b)(1).

(2) *Application to benefits*—(i) *General rule*—(A) Under this section, a group health plan or group health insurance issuer is not required to provide coverage for any particular benefit to any group of similarly situated individuals.

(B) However, benefits provided under a plan or through group health insurance coverage must be uniformly available to all similarly situated individuals (as described in paragraph (d) of this section). Likewise, any restriction on a benefit or benefits must apply uniformly to all similarly situated individuals and must not be directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries (determined based on all the relevant facts and circumstances). Thus, for example, a plan or issuer may limit or exclude benefits in relation to a specific disease or condition, limit or exclude benefits for certain types of treatments or drugs, or limit or exclude benefits based on a determination of whether the benefits are experimental or not medically necessary, but only if the benefit limitation or exclusion applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In addition, a plan or issuer may impose annual, lifetime, or other limits on benefits and may require the satisfaction of a deductible, copayment, coinsurance, or other cost-sharing requirement in order to obtain a benefit if the limit or cost-sharing requirement applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries. In the case of a cost-sharing requirement, see also paragraph (b)(2)(ii) of this section, which permits variances in the application of a cost-sharing mechanism made available under a wellness program. (Whether

any plan provision or practice with respect to benefits complies with this paragraph (b)(2)(i) does not affect whether the provision or practice is permitted under any other provision of ERISA, the Americans with Disabilities Act, or any other law, whether State or Federal.)

(C) For purposes of this paragraph (b)(2)(i), a plan amendment applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(D) The rules of this paragraph (b)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan applies a $500,000 lifetime limit on all benefits to each participant or beneficiary covered under the plan. The limit is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1,* the limit does not violate this paragraph (b)(2)(i) because $500,000 of benefits are available uniformly to each participant and beneficiary under the plan and because the limit is applied uniformly to all participants and beneficiaries and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts.* A group health plan has a $2 million lifetime limit on all benefits (and no other lifetime limits) for participants covered under the plan. Participant *B* files a claim for the treatment of AIDS. At the next corporate board meeting of the plan sponsor, the claim is discussed. Shortly thereafter, the plan is modified to impose a $10,000 lifetime limit on benefits for the treatment of AIDS, effective before the beginning of the next plan year.

(ii) *Conclusion.* The facts of this *Example 2* strongly suggest that the plan modification is directed at *B* based on *B*'s claim. Absent outweighing evidence to the contrary, the plan violates this paragraph (b)(2)(i).

Example 3. (i) A group health plan applies for a group health policy offered by an issuer. Individual *C* is covered under the plan and has an adverse health condition. As part of the application, the issuer receives health information about the individuals to be covered, including information about *C*'s adverse health condition. The policy form offered by the issuer generally provides benefits for the adverse health condition that *C* has, but in this case the issuer offers the plan a policy modified by a rider that excludes benefits for *C* for that condition. The exclusionary rider is made effective the first day of the next plan year.

(ii) *Conclusion.* In this *Example 3*, the issuer violates this paragraph (b)(2)(i) because benefits for *C*'s condition are available to other individuals in the group of similarly situated individuals that includes *C* but are not available to *C*. Thus, the benefits are not uniformly available to all similarly situated individuals. Even though the exclusionary rider is made effective the first day of the next plan year, because the rider does not apply to all similarly situated individuals, the issuer violates this paragraph (b)(2)(i).

Example 4. (i) *Facts.* A group health plan has a $2,000 lifetime limit for the treatment of temporomandibular joint syndrome (TMJ). The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 4*, the limit does not violate this paragraph (b)(2)(i) because $2,000 of benefits for the treatment of TMJ are available uniformly to all similarly situated individuals and a plan may limit benefits covered in relation to a specific disease or condition if the limit applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries. (This example does not address whether the plan provision is permissible under the Americans with Disabilities Act or any other applicable law.)

Example 5. (i) *Facts.* A group health plan applies a $2 million lifetime limit on all benefits. However, the $2 million lifetime limit is reduced to $10,000 for any participant or beneficiary covered under the plan who has a congenital heart defect.

(ii) *Conclusion.* In this *Example 5,* the lower lifetime limit for participants and beneficiaries with a congenital heart defect violates this paragraph (b)(2)(i) because benefits under the plan are not uniformly available to all similarly situated individuals and the plan's lifetime limit on benefits does not apply uniformly to all similarly situated individuals.

Example 6. (i) *Facts.* A group health plan limits benefits for prescription drugs to those listed on a drug formulary. The limit is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 6*, the exclusion from coverage of drugs not listed on the drug formulary does not violate this paragraph (b)(2)(i) because benefits for prescription drugs listed on the formulary are uniformly available to all similarly situated individuals and because the exclusion of drugs not listed on the formulary applies uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 7. (i) *Facts.* Under a group health plan, doctor visits are generally subject to a

$250 annual deductible and 20 percent coinsurance requirement. However, prenatal doctor visits are not subject to any deductible or coinsurance requirement. These rules are applied uniformly to all similarly situated individuals and are not directed at individual participants or beneficiaries.

(ii) *Conclusion*. In this *Example 7*, imposing different deductible and coinsurance requirements for prenatal doctor visits and other visits does not violate this paragraph (b)(2)(i) because a plan may establish different deductibles or coinsurance requirements for different services if the deductible or coinsurance requirement is applied uniformly to all similarly situated individuals and is not directed at individual participants or beneficiaries.

Example 8. (i) *Facts*. An employer sponsors a group health plan that is available to all current employees. Under the plan, the medical care expenses of each employee (and the employee's dependents) are reimbursed up to an annual maximum amount. The maximum reimbursement amount with respect to an employee for a year is $1500 multiplied by the number of years the employee has participated in the plan, reduced by the total reimbursements for prior years.

(ii) *Conclusion*. In this *Example 8*, the variable annual limit does not violate this paragraph (b)(2)(i). Although the maximum reimbursement amount for a year varies among employees within the same group of similarly situated individuals based on prior claims experience, employees who have participated in the plan for the same length of time are eligible for the same total benefit over that length of time (and the restriction on the maximum reimbursement amount is not directed at any individual participants or beneficiaries based on any health factor).

(ii) *Exception for wellness programs*. A group health plan or group health insurance issuer may vary benefits, including cost-sharing mechanisms (such as a deductible, copayment, or coinsurance), based on whether an individual has met the standards of a wellness program that satisfies the requirements of paragraph (f) of this section.

(iii) *Specific rule relating to source-of-injury exclusions*—(A) If a group health plan or group health insurance coverage generally provides benefits for a type of injury, the plan or issuer may not deny benefits otherwise provided for treatment of the injury if the injury results from an act of domestic violence or a medical condition (including both physical and mental health conditions). This rule applies in the case of an injury resulting from a medical condition even if the condition is not diagnosed before the injury.

(B) The rules of this paragraph (b)(2)(iii) are illustrated by the following examples:

Example 1. (i) *Facts*. A group health plan generally provides medical/surgical benefits, including benefits for hospital stays, that are medically necessary. However, the plan excludes benefits for self-inflicted injuries or injuries sustained in connection with attempted suicide. Because of depression, Individual D attempts suicide. As a result, *D* sustains injuries and is hospitalized for treatment of the injuries. Under the exclusion, the plan denies *D* benefits for treatment of the injuries.

(ii) *Conclusion*. In this Example 1, the suicide attempt is the result of a medical condition (depression). Accordingly, the denial of benefits for the treatments of D's injuries violates the requirements of this paragraph (b)(2)(iii) because the plan provision excludes benefits for treatment of an injury resulting from a medical condition.

Example 2. (i) *Facts*. A group health plan provides benefits for head injuries generally. The plan also has a general exclusion for any injury sustained while participating in any of a number of recreational activities, including bungee jumping. However, this exclusion does not apply to any injury that results from a medical condition (nor from domestic violence). Participant E sustains a head injury while bungee jumping. The injury did not result from a medical condition (nor from domestic violence). Accordingly, the plan denies benefits for *E*'s head injury.

(ii) *Conclusion*. In this *Example 2*, the plan provision that denies benefits based on the source of an injury does not restrict benefits based on an act of domestic violence or any medical condition. Therefore, the provision is permissible under this paragraph (b)(2)(iii) and does not violate this section. (However, if the plan did not allow E to enroll in the plan (or applied different rules for eligibility to *E*) because *E* frequently participates in bungee jumping, the plan would violate paragraph (b)(1) of this section.)

(3) *Relationship to § 146.111*. (i) A preexisting condition exclusion is permitted under this section if it —

(A) Complies with § 146.111;

(B) Applies uniformly to all similarly situated individuals (as described in paragraph (d) of this section); and

(C) Is not directed at individual participants or beneficiaries based on any health factor of the participants or

beneficiaries. For purposes of this paragraph (b)(3)(i)(C), a plan amendment relating to a preexisting condition exclusion applicable to all individuals in one or more groups of similarly situated individuals under the plan and made effective no earlier than the first day of the first plan year after the amendment is adopted is not considered to be directed at any individual participants or beneficiaries.

(ii) The rules of this paragraph (b)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan imposes a preexisting condition exclusion on all individuals enrolled in the plan. The exclusion applies to conditions for which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. In addition, the exclusion generally extends for 12 months after an individual's enrollment date, but this 12-month period is offset by the number of days of an individual's creditable coverage in accordance with §146.111. There is nothing to indicate that the exclusion is directed at individual participants or beneficiaries.

(ii) *Conclusion.* In this *Example 1*, even though the plan's preexisting condition exclusion discriminates against individuals based on one or more health factors, the preexisting condition exclusion does not violate this section because it applies uniformly to all similarly situated individuals, is not directed at individual participants or beneficiaries, and complies with §146.111 (that is, the requirements relating to the six-month look-back period, the 12-month (or 18-month) maximum exclusion period, and the creditable coverage offset).

Example 2. (i) *Facts.* A group health plan excludes coverage for conditions with respect to which medical advice, diagnosis, care, or treatment was recommended or received within the six-month period ending on an individual's enrollment date. Under the plan, the preexisting condition exclusion generally extends for 12 months, offset by creditable coverage. However, if an individual has no claims in the first six months following enrollment, the remainder of the exclusion period is waived.

(ii) *Conclusion.* In this *Example 2*, the plan's preexisting condition exclusions violate this section because they do not meet the requirements of this paragraph (b)(3); specifically, they do not apply uniformly to all similarly situated individuals. The plan provisions do not apply uniformly to all similarly situated individuals because individuals who have medical claims during the first six months following enrollment are not treated the same as similarly situated individuals with no claims during that period. (Under paragraph (d) of this section, the groups cannot be treated as two separate groups of similarly situated individuals because the distinction is based on a health factor.)

(c) *Prohibited discrimination in premiums or contributions*—(1) *In general*—(i) A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, may not require an individual, as a condition of enrollment or continued enrollment under the plan or group health insurance coverage, to pay a premium or contribution that is greater than the premium or contribution for a similarly situated individual (described in paragraph (d) of this section) enrolled in the plan or group health insurance coverage based on any health factor that relates to the individual or a dependent of the individual.

(ii) Discounts, rebates, payments in kind, and any other premium differential mechanisms are taken into account in determining an individual's premium or contribution rate. (For rules relating to cost-sharing mechanisms, see paragraph (b)(2) of this section (addressing benefits).)

(2) *Rules relating to premium rates*—(i) *Group rating based on health factors not restricted under this section.* Nothing in this section restricts the aggregate amount that an employer may be charged for coverage under a group health plan. But *see* §146.122(b) of this part, which prohibits adjustments in group premium or contribution rates based on genetic information.

(ii) *List billing based on a health factor prohibited.* However, a group health insurance issuer, or a group health plan, may not quote or charge an employer (or an individual) a different premium for an individual in a group of similarly situated individuals based on a health factor. (But see paragraph (g) of this section permitting favorable treatment of individuals with adverse health factors.)

(iii) *Examples.* The rules of this paragraph (c)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan and purchases coverage

from a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan. The issuer finds that Individual *F* had significantly higher claims experience than similarly situated individuals in the plan. The issuer quotes the plan a higher per-participant rate because of *F*'s claims experience.

(ii) *Conclusion*. In this *Example 1*, the issuer does not violate the provisions of this paragraph (c)(2) because the issuer blends the rate so that the employer is not quoted a higher rate for *F* than for a similarly situated individual based on *F*'s claims experience. (However, if the issuer used genetic information in computing the group rate, it would violate §146.122(b) of this part.)

Example 2. (i) *Facts*. Same facts as *Example 1*, except that the issuer quotes the employer a higher premium rate for *F*, because of *F*'s claims experience, than for a similarly situated individual.

(ii) *Conclusion*. In this *Example 2*, the issuer violates this paragraph (c)(2). Moreover, even if the plan purchased the policy based on the quote but did not require a higher participant contribution for *F* than for a similarly situated individual, the issuer would still violate this paragraph (c)(2) (but in such a case the plan would not violate this paragraph (c)(2)).

(3) *Exception for wellness programs*. Notwithstanding paragraphs (c)(1) and (c)(2) of this section, a plan or issuer may vary the amount of premium or contribution it requires similarly situated individuals to pay based on whether an individual has met the standards of a wellness program that satisfies the requirements of paragraph (f) of this section.

(d) *Similarly situated individuals*. The requirements of this section apply only within a group of individuals who are treated as similarly situated individuals. A plan or issuer may treat participants as a group of similarly situated individuals separate from beneficiaries. In addition, participants may be treated as two or more distinct groups of similarly situated individuals and beneficiaries may be treated as two or more distinct groups of similarly situated individuals in accordance with the rules of this paragraph (d). Moreover, if individuals have a choice of two or more benefit packages, individuals choosing one benefit package may be treated as one or more groups of similarly situated individuals distinct from individuals choosing another benefit package.

(1) *Participants*. Subject to paragraph (d)(3) of this section, a plan or issuer may treat participants as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of participants is based on a bona fide employment-based classification consistent with the employer's usual business practice. Whether an employment-based classification is bona fide is determined on the basis of all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Subject to paragraph (d)(3) of this section, examples of classifications that, based on all the relevant facts and circumstances, may be bona fide include full-time versus part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and different occupations. However, a classification based on any health factor is not a bona fide employment-based classification, unless the requirements of paragraph (g) of this section are satisfied (permitting favorable treatment of individuals with adverse health factors).

(2) *Beneficiaries*—(i) Subject to paragraph (d)(3) of this section, a plan or issuer may treat beneficiaries as two or more distinct groups of similarly situated individuals if the distinction between or among the groups of beneficiaries is based on any of the following factors:

(A) A bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage;

(B) Relationship to the participant (for example, as a spouse or as a dependent child);

(C) Marital status;

(D) With respect to children of a participant, age or student status; or

(E) Any other factor if the factor is not a health factor.

(ii) Paragraph (d)(2)(i) of this section does not prevent more favorable treatment of individuals with adverse health factors in accordance with paragraph (g) of this section.

(3) *Discrimination directed at individuals*. Notwithstanding paragraphs (d)(1) and (d)(2) of this section, if the creation or modification of an employment or coverage classification is directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries, the classification is not permitted under this paragraph (d), unless it is permitted under paragraph (g) of this section (permitting favorable treatment of individuals with adverse health factors). Thus, if an employer modified an employment-based classification to single out, based on a health factor, individual participants and beneficiaries and deny them health coverage, the new classification would not be permitted under this section.

(4) *Examples*. The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts*. An employer sponsors a group health plan for full-time employees only. Under the plan (consistent with the employer's usual business practice), employees who normally work at least 30 hours per week are considered to be working full-time. Other employees are considered to be working part-time. There is no evidence to suggest that the classification is directed at individual participants or beneficiaries.

(ii) *Conclusion*. In this *Example 1*, treating the full-time and part-time employees as two separate groups of similarly situated individuals is permitted under this paragraph (d) because the classification is bona fide and is not directed at individual participants or beneficiaries.

Example 2. (i) *Facts*. Under a group health plan, coverage is made available to employees, their spouses, and their dependent children. However, coverage is made available to a dependent child only if the dependent child is under age 19 (or under age 25 if the child is continuously enrolled full-time in an institution of higher learning (full-time students)). There is no evidence to suggest that these classifications are directed at individual participants or beneficiaries.

(ii) *Conclusion*. In this *Example 2*, treating spouses and dependent children differently by imposing an age limitation on dependent children, but not on spouses, is permitted under this paragraph (d). Specifically, the distinction between spouses and dependent children is permitted under paragraph (d)(2) of this section and is not prohibited under paragraph (d)(3) of this section because it is not directed at individual participants or beneficiaries. It is also permissible to treat dependent children who are under age 19 (or full-time students under age 25) as a group of similarly situated individuals separate from those who are age 25 or older (or age 19 or older if they are not full-time students) because the classification is permitted under paragraph (d)(2) of this section and is not directed at individual participants or beneficiaries.

Example 3. (i) *Facts*. A university sponsors a group health plan that provides one health benefit package to faculty and another health benefit package to other staff. Faculty and staff are treated differently with respect to other employee benefits such as retirement benefits and leaves of absence. There is no evidence to suggest that the distinction is directed at individual participants or beneficiaries.

(ii) *Conclusion*. In this *Example 3*, the classification is permitted under this paragraph (d) because there is a distinction based on a bona fide employment-based classification consistent with the employer's usual business practice and the distinction is not directed at individual participants and beneficiaries.

Example 4. (i) *Facts*. An employer sponsors a group health plan that is available to all current employees. Former employees may also be eligible, but only if they complete a specified number of years of service, are enrolled under the plan at the time of termination of employment, and are continuously enrolled from that date. There is no evidence to suggest that these distinctions are directed at individual participants or beneficiaries.

(ii) *Conclusion*. In this *Example 4*, imposing additional eligibility requirements on former employees is permitted because a classification that distinguishes between current and former employees is a bona fide employment-based classification that is permitted under this paragraph (d), provided that it is not directed at individual participants or beneficiaries. In addition, it is permissible to distinguish between former employees who satisfy the service requirement and those who do not, provided that the distinction is not directed at individual participants or beneficiaries. (However, former employees who do not satisfy the eligibility criteria may, nonetheless, be eligible for continued coverage pursuant to a COBRA continuation provision or similar State law.)

Example 5. (i) *Facts*. An employer sponsors a group health plan that provides the same benefit package to all seven employees of the employer. Six of the seven employees have the same job title and responsibilities, but

Employee *G* has a different job title and different responsibilities. After *G* files an expensive claim for benefits under the plan, coverage under the plan is modified so that employees with *G*'s job title receive a different benefit package that includes a lower lifetime dollar limit than in the benefit package made available to the other six employees.

(ii) *Conclusion*. Under the facts of this *Example 5*, changing the coverage classification for *G* based on the existing employment classification for *G* is not permitted under this paragraph (d) because the creation of the new coverage classification for *G* is directed at *G* based on one or more health factors.

(e) *Nonconfinement and actively-at-work provisions*—(1) *Nonconfinement provisions*—(i) *General rule*. Under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is confined to a hospital or other health care institution. In addition, under the rules of paragraphs (b) and (c) of this section, a plan or issuer may not establish a rule for eligibility or set any individual's premium or contribution rate based on an individual's ability to engage in normal life activities, except to the extent permitted under paragraphs (e)(2)(ii) and (e)(3) of this section (permitting plans and issuers, under certain circumstances, to distinguish among employees based on the performance of services).

(ii) *Examples*. The rules of this paragraph (e)(1) are illustrated by the following examples:

Example 1. (i) *Facts*. Under a group health plan, coverage for employees and their dependents generally becomes effective on the first day of employment. However, coverage for a dependent who is confined to a hospital or other health care institution does not become effective until the confinement ends.

(ii) *Conclusion*. In this *Example 1*, the plan violates this paragraph (e)(1) because the plan delays the effective date of coverage for dependents based on confinement to a hospital or other health care institution.

Example 2. (i) *Facts*. In previous years, a group health plan has provided coverage through a group health insurance policy offered by Issuer *M*. However, for the current year, the plan provides coverage through a group health insurance policy offered by Issuer *N*. Under Issuer *N*'s policy, items and services provided in connection with the confinement of a dependent to a hospital or other health care institution are not covered if the confinement is covered under an extension of benefits clause from a previous health insurance issuer.

(ii) *Conclusion*. In this *Example 2*, Issuer *N* violates this paragraph (e)(1) because the group health insurance coverage restricts benefits (a rule for eligibility under paragraph (b)(1)) based on whether a dependent is confined to a hospital or other health care institution that is covered under an extension of benefits clause from a previous issuer. State law cannot change the obligation of Issuer *N* under this section. However, under State law Issuer *M* may also be responsible for providing benefits to such a dependent. In a case in which Issuer *N* has an obligation under this section to provide benefits and Issuer *M* has an obligation under State law to provide benefits, any State laws designed to prevent more than 100% reimbursement, such as State coordination-of-benefits laws, continue to apply.

(2) *Actively-at-work and continuous service provisions*—(i) *General rule*—(A) Under the rules of paragraphs (b) and (c) of this section and subject to the exception for the first day of work described in paragraph (e)(2)(ii) of this section, a plan or issuer may not establish a rule for eligibility (as described in paragraph (b)(1)(ii) of this section) or set any individual's premium or contribution rate based on whether an individual is actively at work (including whether an individual is continuously employed), unless absence from work due to any health factor (such as being absent from work on sick leave) is treated, for purposes of the plan or health insurance coverage, as being actively at work.

(B) The rules of this paragraph (e)(2)(i) are illustrated by the following examples:

Example 1. (i) *Facts*. Under a group health plan, an employee generally becomes eligible to enroll 30 days after the first day of employment. However, if the employee is not actively at work on the first day after the end of the 30-day period, then eligibility for enrollment is delayed until the first day the employee is actively at work.

(ii) *Conclusion*. In this *Example 1*, the plan violates this paragraph (e)(2) (and thus also violates paragraph (b) of this section). However, the plan would not violate paragraph (e)(2) or (b) of this section if, under the plan, an absence due to any health factor is considered being actively at work.

Example 2. (i) *Facts.* Under a group health plan, coverage for an employee becomes effective after 90 days of continuous service; that is, if an employee is absent from work (for any reason) before completing 90 days of service, the beginning of the 90-day period is measured from the day the employee returns to work (without any credit for service before the absence).

(ii) *Conclusion.* In this *Example 2*, the plan violates this paragraph (e)(2) (and thus also paragraph (b) of this section) because the 90-day continuous service requirement is a rule for eligibility based on whether an individual is actively at work. However, the plan would not violate this paragraph (e)(2) or paragraph (b) of this section if, under the plan, an absence due to any health factor is not considered an absence for purposes of measuring 90 days of continuous service.

(ii) *Exception for the first day of work*—(A) Notwithstanding the general rule in paragraph (e)(2)(i) of this section, a plan or issuer may establish a rule for eligibility that requires an individual to begin work for the employer sponsoring the plan (or, in the case of a multiemployer plan, to begin a job in covered employment) before coverage becomes effective, provided that such a rule for eligibility applies regardless of the reason for the absence.

(B) The rules of this paragraph (e)(2)(ii) are illustrated by the following examples:

Example 1. (i) *Facts.* Under the eligibility provision of a group health plan, coverage for new employees becomes effective on the first day that the employee reports to work. Individual *H* is scheduled to begin work on August 3. However, *H* is unable to begin work on that day because of illness. *H* begins working on August 4, and *H*'s coverage is effective on August 4.

(ii) *Conclusion.* In this *Example 1*, the plan provision does not violate this section. However, if coverage for individuals who do not report to work on the first day they were scheduled to work for a reason unrelated to a health factor (such as vacation or bereavement) becomes effective on the first day they were scheduled to work, then the plan would violate this section.

Example 2. (i) *Facts.* Under a group health plan, coverage for new employees becomes effective on the first day of the month following the employee's first day of work, regardless of whether the employee is actively at work on the first day of the month. Individual *J* is scheduled to begin work on March 24. However, *J* is unable to begin work on March 24 because of illness. *J* begins working on April 7 and *J*'s coverage is effective May 1.

(ii) *Conclusion.* In this *Example 2*, the plan provision does not violate this section. However, as in *Example 1*, if coverage for individuals absent from work for reasons unrelated to a health factor became effective despite their absence, then the plan would violate this section.

(3) *Relationship to plan provisions defining similarly situated individuals*—(i) Notwithstanding the rules of paragraphs (e)(1) and (e)(2) of this section, a plan or issuer may establish rules for eligibility or set any individual's premium or contribution rate in accordance with the rules relating to similarly situated individuals in paragraph (d) of this section. Accordingly, a plan or issuer may distinguish in rules for eligibility under the plan between full-time and part-time employees, between permanent and temporary or seasonal employees, between current and former employees, and between employees currently performing services and employees no longer performing services for the employer, subject to paragraph (d) of this section. However, other Federal or State laws (including the COBRA continuation provisions and the Family and Medical Leave Act of 1993) may require an employee or the employee's dependents to be offered coverage and set limits on the premium or contribution rate even though the employee is not performing services.

(ii) The rules of this paragraph (e)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* Under a group health plan, employees are eligible for coverage if they perform services for the employer for 30 or more hours per week or if they are on paid leave (such as vacation, sick, or bereavement leave). Employees on unpaid leave are treated as a separate group of similarly situated individuals in accordance with the rules of paragraph (d) of this section.

(ii) *Conclusion.* In this *Example 1*, the plan provisions do not violate this section. However, if the plan treated individuals performing services for the employer for 30 or more hours per week, individuals on vacation leave, and individuals on bereavement leave as a group of similarly situated individuals separate from individuals on sick leave, the plan would violate this paragraph (e) (and thus also would violate paragraph (b) of this section) because groups of similarly situated individuals cannot be established

based on a health factor (including the taking of sick leave) under paragraph (d) of this section.

Example 2. (i) *Facts.* To be eligible for coverage under a bona fide collectively bargained group health plan in the current calendar quarter, the plan requires an individual to have worked 250 hours in covered employment during the three-month period that ends one month before the beginning of the current calendar quarter. The distinction between employees working at least 250 hours and those working less than 250 hours in the earlier three-month period is not directed at individual participants or beneficiaries based on any health factor of the participants or beneficiaries.

(ii) *Conclusion.* In this *Example 2*, the plan provision does not violate this section because, under the rules for similarly situated individuals allowing full-time employees to be treated differently than part-time employees, employees who work at least 250 hours in a three-month period can be treated differently than employees who fail to work 250 hours in that period. The result would be the same if the plan permitted individuals to apply excess hours from previous periods to satisfy the requirement for the current quarter.

Example 3. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the individual's employment is terminated, in accordance with the rules of paragraph (d) of this section. Employee *B* has been covered under the plan. *B* experiences a disabling illness that prevents *B* from working. *B* takes a leave of absence under the Family and Medical Leave Act of 1993. At the end of such leave, *B* terminates employment and consequently loses coverage under the plan. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 3*, the plan provision terminating *B*'s coverage upon *B*'s termination of employment does not violate this section.

Example 4. (i) *Facts.* Under a group health plan, coverage of an employee is terminated when the employee ceases to perform services for the employer sponsoring the plan, in accordance with the rules of paragraph (d) of this section. Employee *C* is laid off for three months. When the layoff begins, *C*'s coverage under the plan is terminated. (This termination of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 4*, the plan provision terminating *C*'s coverage upon the cessation of *C*'s performance of services does not violate this section.

(f) *Wellness programs.* A wellness program is any program designed to promote health or prevent disease. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that satisfies the requirements of this paragraph (f). If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, paragraph (f)(1) of this section clarifies that the wellness program does not violate this section if participation in the program is made available to all similarly situated individuals. If any of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, the wellness program does not violate this section if the requirements of paragraph (f)(2) of this section are met.

(1) *Wellness programs not subject to requirements.* If none of the conditions for obtaining a reward under a wellness program are based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program does not violate this section, if participation in the program is made available to all similarly situated individuals. Thus, for example, the following programs need not satisfy the requirements of paragraph (f)(2) of this section, if participation in the program is made available to all similarly situated individuals:

(i) A program that reimburses all or part of the cost for memberships in a fitness center.

(ii) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

(iii) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits.

(iv) A program that reimburses employees for the costs of smoking cessation programs without regard to whether the employee quits smoking.

(v) A program that provides a reward to employees for attending a monthly health education seminar.

(2) *Wellness programs subject to requirements*. If any of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, the wellness program does not violate this section if the requirements of this paragraph (f)(2) are met.

(i) The reward for the wellness program, coupled with the reward for other wellness programs with respect to the plan that require satisfaction of a standard related to a health factor, must not exceed 20 percent of the cost of employee-only coverage under the plan. However, if, in addition to employees, any class of dependents (such as spouses or spouses and dependent children) may participate in the wellness program, the reward must not exceed 20 percent of the cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(2), the cost of coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward can be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan.

(ii) The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of or preventing disease in participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease.

(iii) The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(iv) The reward under the program must be available to all similarly situated individuals. (A) A reward is not available to all similarly situated individuals for a period unless the program allows —

(1) A reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(2) A reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) A plan or issuer may seek verification, such as a statement from an individual's physician, that a health factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

(v)(A) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under paragraph (f)(2)(iv) of this section. However, if plan materials merely mention that a program is available, without describing its terms, this disclosure is not required.

(B) The following language, or substantially similar language, can be used to satisfy the requirement of this paragraph (f)(2)(v): ''If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert telephone number] and we will work with you to develop another way to qualify for the reward.'' In addition, other examples of language that would satisfy this requirement are set forth in Examples 3, 4, and 5 of paragraph (f)(3) of this section.

(3) *Examples*. The rules of paragraph (f)(2) of this section are illustrated by the following examples:

Example 1. (i) *Facts*. An employer sponsors a group health plan. The annual premium for employee-only coverage is $3,600 (of which the employer pays $2,700 per year and the employee pays $900 per year). The annual premium for family coverage is $9,000 (of which the employer pays $4,500 per year and the employee pays $4,500 per year). The plan offers a wellness program with an annual premium rebate of $360. The program is available only to employees.

(ii) *Conclusion*. In this *Example 1*, the program satisfies the requirements of paragraph (f)(2)(i) of this section because the reward for the wellness program, $360, does not exceed 20 percent of the total annual cost of employee-only coverage, $720. ($3,600 × 20% = $720.) If any class of dependents is allowed to participate in the program and the employee is enrolled in family coverage, the plan could offer the employee a reward of up to 20 percent of the cost of family coverage, $1,800. ($9,000 × 20% = $1,800.)

Example 2. (i) *Facts*. A group health plan gives an annual premium discount of 20 percent of the cost of employee-only coverage to participants who adhere to a wellness program. The wellness program consists solely of giving an annual cholesterol test to participants. Those participants who achieve a count under 200 receive the premium discount for the year.

(ii) *Conclusion*. In this *Example 2*,the program fails to satisfy the requirement of being available to all similarly situated individuals because some participants may be unable to achieve a cholesterol count of under 200 and the plan does not make available a reasonable alternative standard or waive the cholesterol standard. (In addition, plan materials describing the program are required to disclose the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) for obtaining the premium discount. Thus, the premium discount violates paragraph (c) of this section because it may require an individual to pay a higher premium based on a health factor of the individual than is required of a similarly situated individual under the plan.

Example 3. (i) *Facts*. Same facts as *Example 2*, except that the plan provides that if it is unreasonably difficult due to a medical condition for a participant to achieve the targeted cholesterol count (or if it is medically inadvisable for a participant to attempt to achieve the targeted cholesterol count) within a 60-day period, the plan will make available a reasonable alternative standard that takes the relevant medical condition into account. In addition, all plan materials describing the terms of the program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a cholesterol count under 200, or if it is medically inadvisable for you to attempt to achieve a count under 200, call us at the number below and we will work with you to develop another way to get the discount.'' Individual *D* begins a diet and exercise program but is unable to achieve a cholesterol count under 200 within the prescribed period. D's doctor determines D requires prescription medication to achieve a medically advisable cholesterol count. In addition, the doctor determines that D must be monitored through periodic blood tests to continually reevaluate D's health status. The plan accommodates *D* by making the discount available to *D*, but only if *D* follows the advice of D's doctor regarding medication and blood tests.

(ii) *Conclusion*. In this *Example 3*, the program is a wellness program because it satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve the targeted count (or for whom it is medically inadvisable to attempt to achieve the targeted count) in the prescribed period by providing a reasonable alternative standard. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium discount does not violate this section.

Example 4. (i) *Facts*. A group health plan will waive the $250 annual deductible (which is less than 20 percent of the annual cost of employee-only coverage under the plan) for the following year for participants who have a body mass index between 19 and 26, determined shortly before the beginning of the year. However, any participant for whom it is unreasonably difficult due to a medical condition to attain this standard (and any participant for whom it is medically inadvisable to attempt to achieve this standard) during the plan year is given the same discount if the participant walks for 20 minutes three days a week. Any participant for whom it is unreasonably difficult due to a medical condition to attain either standard (and any participant for whom it is medically inadvisable to attempt to achieve either standard) during the year is given the same discount if the individual satisfies an alternative standard that is reasonable in the burden it imposes and is reasonable taking into consideration the individual's medical situation. All

plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a medical condition for you to achieve a body mass index between 19 and 26 (or if it is medically inadvisable for you to attempt to achieve this body mass index) this year, your deductible will be waived if you walk for 20 minutes three days a week. If you cannot follow the walking program, call us at the number above and we will work with you to develop another way to have your deductible waived.'' Due to a medical condition, Individual E is unable to achieve a BMI of between 19 and 26 and is also unable to follow the walking program. *E* proposes a program based on the recommendations of *E*'s physician. The plan agrees to make the discount available to *E* if *E* follows the physician's recommendations.

(ii) *Conclusion*. In this *Example 4*, the program satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it generally accommodates individuals for whom it is unreasonably difficult due to a medical condition to achieve (or for whom it is medically inadvisable to attempt to achieve) the targeted body mass index by providing a reasonable alternative standard (walking) and it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to walk by providing an alternative standard that is reasonable for the individual. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard for every individual. Thus, the waiver of the deductible does not violate this section.

Example 5. (i) *Facts*. In conjunction with an annual open enrollment period, a group health plan provides a form for participants to certify that they have not used tobacco products in the preceding twelve months. Participants who do not provide the certification are assessed a surcharge that is 20 percent of the cost of employee-only coverage. However, all plan materials describing the terms of the wellness program include the following statement: ''If it is unreasonably difficult due to a health factor for you to meet the requirements under this program (or if it is medically inadvisable for you to attempt to meet the requirements of this program), we will make available a reasonable alternative standard for you to avoid this surcharge.'' It is unreasonably difficult for Individual *F* to stop smoking cigarettes due to an addiction to nicotine (a medical condition). The plan accommodates *F* by requiring *F* to participate in a smoking cessation program to avoid the surcharge. *F* can avoid the surcharge for as long as *F* participates in the program, regardless of whether *F* stops smoking (as long as *F* continues to be addicted to nicotine).

(ii) *Conclusion*. In this *Example 5*, the premium surcharge is permissible as a wellness program because it satisfies the five requirements of paragraph (f)(2) of this section. First, the program complies with the limits on rewards under a program. Second, it is reasonably designed to promote health or prevent disease. Third, individuals eligible for the program are given the opportunity to qualify for the reward at least once per year. Fourth, the reward under the program is available to all similarly situated individuals because it accommodates individuals for whom it is unreasonably difficult due to a medical condition (or for whom it is medically inadvisable to attempt) to quit using tobacco products by providing a reasonable alternative standard. Fifth, the plan discloses in all materials describing the terms of the program the availability of a reasonable alternative standard. Thus, the premium surcharge does not violate this section.

Example 6. (i) *Facts*. Same facts as *Example 5*, except the plan accommodates *F* by requiring *F* to view, over a period of 12 months, a 12-hour video series on health problems associated with tobacco use. *F* can avoid the surcharge by complying with this requirement.

(ii) *Conclusion*. In this *Example 6*, the requirement to watch the series of video tapes is a reasonable alternative method for avoiding the surcharge.

(g) *More favorable treatment of individuals with adverse health factors permitted*—(1) In rules for eligibility—(i) Nothing in this section prevents a group health plan or group health insurance issuer from establishing more favorable rules for eligibility (described in paragraph (b)(1) of this section) for individuals with an adverse health factor, such as disability, than for individuals without the adverse health factor. Moreover, nothing in this section prevents a plan or issuer from charging a higher premium or contribution with respect to individuals with an adverse health factor if they would not be eligible for the coverage were it not for the adverse health factor. (However, other laws, including State insurance laws, may set or limit premium rates; these laws are not affected by this section.)

(ii) The rules of this paragraph (g)(1) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that generally is available to employees, spouses of employees, and dependent children until age 23. However, dependent children who are disabled are eligible for coverage beyond age 23.

(ii) *Conclusion.* In this *Example 1*, the plan provision allowing coverage for disabled dependent children beyond age 23 satisfies this paragraph (g)(1) (and thus does not violate this section).

Example 2. (i) *Facts.* An employer sponsors a group health plan, which is generally available to employees (and members of the employee's family) until the last day of the month in which the employee ceases to perform services for the employer. The plan generally charges employees $50 per month for employee-only coverage and $125 per month for family coverage. However, an employee who ceases to perform services for the employer by reason of disability may remain covered under the plan until the last day of the month that is 12 months after the month in which the employee ceased to perform services for the employer. During this extended period of coverage, the plan charges the employee $100 per month for employee-only coverage and $250 per month for family coverage. (This extended period of coverage is without regard to whatever rights the employee (or members of the employee's family) may have for COBRA continuation coverage.)

(ii) *Conclusion.* In this *Example 2*, the plan provision allowing extended coverage for disabled employees and their families satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled employees a higher premium during the extended period of coverage.

Example 3. (i) *Facts.* To comply with the requirements of a COBRA continuation provision, a group health plan generally makes COBRA continuation coverage available for a maximum period of 18 months in connection with a termination of employment but makes the coverage available for a maximum period of 29 months to certain disabled individuals and certain members of the disabled individual's family. Although the plan generally requires payment of 102 percent of the applicable premium for the first 18 months of COBRA continuation coverage, the plan requires payment of 150 percent of the applicable premium for the disabled individual's COBRA continuation coverage during the disability extension if the disabled individual would not be entitled to COBRA continuation coverage but for the disability.

(ii) *Conclusion.* In this *Example 3*, the plan provision allowing extended COBRA continuation coverage for disabled individuals satisfies this paragraph (g)(1) (and thus does not violate this section). In addition, the plan is permitted, under this paragraph (g)(1), to charge the disabled individuals a higher premium for the extended coverage if the individuals would not be eligible for COBRA continuation coverage were it not for the disability. (Similarly, if the plan provided an extended period of coverage for disabled individuals pursuant to State law or plan provision rather than pursuant to a COBRA continuation coverage provision, the plan could likewise charge the disabled individuals a higher premium for the extended coverage.)

(2) *In premiums or contributions*—(i) Nothing in this section prevents a group health plan or group health insurance issuer from charging individuals a premium or contribution that is less than the premium (or contribution) for similarly situated individuals if the lower charge is based on an adverse health factor, such as disability.

(ii) The rules of this paragraph (g)(2) are illustrated by the following example:

Example. (i) *Facts.* Under a group health plan, employees are generally required to pay $50 per month for employee-only coverage and $125 per month for family coverage under the plan. However, employees who are disabled receive coverage (whether employee-only or family coverage) under the plan free of charge.

(ii) *Conclusion.* In this *Example*, the plan provision waiving premium payment for disabled employees is permitted under this paragraph (g)(2) (and thus does not violate this section).

(h) *No effect on other laws.* Compliance with this section is not determinative of compliance with any other provision of the PHS Act (including the COBRA continuation provisions) or any other State or Federal law, such as the Americans with Disabilities Act. Therefore, although the rules of this section would not prohibit a plan or issuer from treating one group of similarly situated individuals differently from another (such as providing different benefit packages to current and former employees), other Federal or State laws may require that two separate groups of similarly situated individuals be treated the same for certain purposes (such as making the same benefit package available to COBRA

qualified beneficiaries as is made available to active employees). In addition, although this section generally does not impose new disclosure obligations on plans and issuers, this section does not affect any other laws, including those that require accurate disclosures and prohibit intentional misrepresentation.

(i) *Applicability dates.* (1) *Generally.* This section applies for plan years beginning on or after July 1, 2007.

(2) *Special rule for self-funded nonfederal governmental plans exempted under 45 CFR 146.180*—(i) If coverage has been denied to any individual because the sponsor of a self-funded nonfederal governmental plan has elected under §146.180 to exempt the plan from the requirements of this section, and the plan sponsor subsequently chooses to bring the plan into compliance with the requirements of this section, the plan—

(A) Must notify the individual that the plan will be coming into compliance with the requirements of this section, specify the effective date of compliance, and inform the individual regarding any enrollment restrictions that may apply under the terms of the plan once the plan is in compliance with this section (as a matter of administrative convenience, the notice may be disseminated to all employees);

(B) Must give the individual an opportunity to enroll that continues for at least 30 days;

(C) Must permit coverage to be effective as of the first day of plan coverage for which an exemption election under §146.180 of this part (with regard to this section) is no longer in effect; and

(D) May not treat the individual as a late enrollee or a special enrollee.

(ii) For purposes of this paragraph (i)(2), an individual is considered to have been denied coverage if the individual failed to apply for coverage because, given an exemption election under §146.180 of this part, it was reasonable to believe that an application for coverage would have been denied based on a health factor.

(iii) The rules of this paragraph (i)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *D* was hired by a nonfederal governmental employer in June 1999. The employer maintains a self-funded group health plan with a plan year beginning on October 1. The plan sponsor elected under §146.180 of this part to exempt the plan from the requirements of this section for the plan year beginning October 1, 2005, and renewed the exemption election for the plan year beginning October 1, 2006. Under the terms of the plan while the exemption was in effect, employees and their dependents were allowed to enroll when the employee was first hired without regard to any health factor. If an individual declines to enroll when first eligible, the individual could enroll effective October 1 of any plan year if the individual could pass a physical examination. The evidence-of-good-health requirement for late enrollees, absent an exemption election under §146.180 of this part, would have been in violation of this section. *D* chose not to enroll for coverage when first hired. In February of 2006, *D* was treated for skin cancer but did not apply for coverage under the plan for the plan year beginning October 1, 2006, because *D* assumed *D* could not meet the evidence-of-good-health requirement. With the plan year beginning October 1, 2007 the plan sponsor chose not to renew its exemption election and brought the plan into compliance with this section. The plan notifies individual *D* (and all other employees) that it will be coming into compliance with the requirements of this section. The notice specifies that the effective date of compliance will be October 1, 2007, explains the applicable enrollment restrictions that will apply under the plan, states that individuals will have at least 30 days to enroll, and explains that coverage for those who choose to enroll will be effective as of October 1, 2007. Individual *D* timely requests enrollment in the plan, and coverage commences under the plan on October 1, 2007.

(ii) *Conclusion.* In this *Example 1*, the plan complies with this paragraph (i)(2).

Example 2. (i) *Facts.* Individual *E* was hired by a nonfederal governmental employer in February 1999. The employer maintains a self-funded group health plan with a plan year beginning on September 1. The plan sponsor elected under §146.180 of this part to exempt the plan from the requirements of this section and ''§146.111 (limitations on preexisting condition exclusion periods) for the plan year beginning September 1, 2002, and renews the exemption election for the plan years beginning September 1, 2003, September 1, 2004, September 1, 2005, and September 1, 2006. Under the terms of the plan while the exemption was in effect, employees and their dependents were allowed to enroll when the employee was first hired without regard to any health factor. If an individual declined to enroll when first eligible, the individual could enroll effective September 1 of any plan year if the individual could pass a physical examination. Also under the terms

of the plan, all enrollees were subject to a 12-month preexisting condition exclusion period, regardless of whether they had creditable coverage. *E* chose not to enroll for coverage when first hired. In June of 2006, *E* is diagnosed as having multiple sclerosis (MS). With the plan year beginning September 1, 2007, the plan sponsor chooses to bring the plan into compliance with this section, but renews its exemption election with regard to limitations on preexisting condition exclusion periods. The plan notifies *E* of her opportunity to enroll, without a physical examination, effective September 1, 2007. The plan gives *E* 30 days to enroll. *E* is subject to a 12-month preexisting condition exclusion period with respect to any treatment *E* receives that is related to *E*'s MS, without regard to any prior creditable coverage *E* may have. Beginning September 1, 2008, the plan will cover treatment of *E*'s MS.

(ii) *Conclusion*. In this *Example 2*, the plan complies with the requirements of this section. (The plan is not required to comply with the requirements of § 146.111 because the plan continues to be exempted from those requirements in accordance with the plan sponsor's election under § 146.180.)

[71 FR 75046, Dec. 13, 2006, as amended at 74 FR 51688, Oct. 7, 2009]

§ 146.122 Additional requirements prohibiting discrimination based on genetic information.

(a) *Definitions*. Unless otherwise provided, the definitions in this paragraph (a) govern in applying the provisions of this section.

(1) *Collect* means, with respect to information, to request, require, or purchase such information.

(2) *Family member* means, with respect to an individual—

(i) A dependent (as defined in § 144.103 of this part) of the individual; or

(ii) Any other person who is a first-degree, second-degree, third-degree, or fourth-degree relative of the individual or of a dependent of the individual. Relatives by affinity (such as by marriage or adoption) are treated the same as relatives by consanguinity (that is, relatives who share a common biological ancestor). In determining the degree of the relationship, relatives by less than full consanguinity (such as half-siblings, who share only one parent) are treated the same as relatives by full consanguinity (such as siblings who share both parents).

(A) First-degree relatives include parents, spouses, siblings, and children.

(B) Second-degree relatives include grandparents, grandchildren, aunts, uncles, nephews, and nieces.

(C) Third-degree relatives include great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.

(D) Fourth-degree relatives include great-great grandparents, great-great grandchildren, and children of first cousins.

(3) *Genetic information* means—

(i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, with respect to an individual, information about—

(A) The individual's genetic tests (as defined in paragraph (a)(5) of this section);

(B) The genetic tests of family members of the individual;

(C) The manifestation (as defined in paragraph (a)(6) of this section) of a disease or disorder in family members of the individual; or

(D) Any request for, or receipt of, genetic services (as defined in paragraph (a)(4) of this section), or participation in clinical research which includes genetic services, by the individual or any family member of the individual.

(ii) The term *genetic information* does not include information about the sex or age of any individual.

(iii) The term *genetic information* includes—

(A) With respect to a pregnant woman (or a family member of the pregnant woman), genetic information of any fetus carried by the pregnant woman; and

(B) With respect to an individual (or a family member of the individual) who is utilizing an assisted reproductive technology, genetic information of any embryo legally held by the individual or family member.

(4) *Genetic services* means —

(i) A genetic test, as defined in paragraph (a)(5) of this section;

(ii) Genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(iii) Genetic education.

(5)(i) *Genetic test* means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, if the analysis detects genotypes, mutations, or chromosomal changes. However, a genetic test does not include an analysis of

proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition. Accordingly, a test to determine whether an individual has a BRCA1 or BRCA2 variant is a genetic test. Similarly, a test to determine whether an individual has a genetic variant associated with hereditary nonpolyposis colorectal cancer is a genetic test. However, an HIV test, complete blood count, cholesterol test, liver function test, or test for the presence of alcohol or drugs is not a genetic test.

(ii) The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts*. Individual *A* is a newborn covered under a group health plan. *A* undergoes a phenylketonuria (PKU) screening, which measures the concentration of a metabolite, phenylalanine, in *A*'s blood. In PKU, a mutation occurs in the phenylalanine hydroxylase (PAH) gene which contains instructions for making the enzyme needed to break down the amino acid phenylalanine. Individuals with the mutation, who have a deficiency in the enzyme to break down phenylalanine, have high concentrations of phenylalanine.

(ii) *Conclusion*. In this *Example*, the PKU screening is a genetic test with respect to *A* because the screening is an analysis of metabolites that detects a genetic mutation.

(6)(i) *Manifestation* or *manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this section, a disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.

(ii) The rules of this paragraph (a)(6) are illustrated by the following examples:

Example 1. (i) *Facts*. Individual *A* has a family medical history of diabetes. *A* begins to experience excessive sweating, thirst, and fatigue. *A*'s physician examines *A* and orders blood glucose testing (which is not a genetic test). Based on the physician's examination, *A*'s symptoms, and test results that show elevated levels of blood glucose, *A*'s physician diagnoses *A* as having adult onset diabetes mellitus (Type 2 diabetes).

(ii) *Conclusion*. In this *Example 1*, *A* has been diagnosed by a health care professional with appropriate training and expertise in the field of medicine involved. The diagnosis is not based principally on genetic information. Thus, Type 2 diabetes is manifested with respect to *A*.

Example 2. (i) *Facts*. Individual *B* has several family members with colon cancer. One of them underwent genetic testing which detected a mutation in the MSH2 gene associated with hereditary nonpolyposis colorectal cancer (HNPCC). *B*'s physician, a health care professional with appropriate training and expertise in the field of medicine involved, recommends that *B* undergo a targeted genetic test to look for the specific mutation found in *B* 's relative to determine if *B* has an elevated risk for cancer. The genetic test with respect to *B* showed that *B* also carries the mutation and is at increased risk to develop colorectal and other cancers associated with HNPCC. *B* has a colonoscopy which indicates no signs of disease, and *B* has no symptoms.

(ii) *Conclusion*. In this *Example 2*, because *B* has no signs or symptoms of colorectal cancer, *B* has not been and could not reasonably be diagnosed with HNPCC. Thus, HNPCC is not manifested with respect to *B*.

Example 3. (i) *Facts*. Same facts as *Example 2*, except that *B*'s colonoscopy and subsequent tests indicate the presence of HNPCC. Based on the colonoscopy and subsequent test results, *B*'s physician makes a diagnosis of HNPCC.

(ii) *Conclusion*. In this *Example 3*, HNPCC is manifested with respect to *B* because a health care professional with appropriate training and expertise in the field of medicine involved has made a diagnosis that is not based principally on genetic information.

Example 4. (i) *Facts*. Individual *C* has a family member that has been diagnosed with Huntington's Disease. A genetic test indicates that *C* has the Huntington's Disease gene variant. At age 42, *C* begins suffering from occasional moodiness and disorientation, symptoms which are associated with Huntington's Disease. *C* is examined by a neurologist (a physician with appropriate training and expertise for diagnosing Huntington's Disease). The examination includes a clinical neurological exam. The results of the examination do not support a diagnosis of Huntington's Disease.

(ii) *Conclusion*. In this *Example 4*, *C* is not and could not reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is not manifested with respect to *C*.

Example 5. (i) *Facts.* Same facts as *Example 4*, except that *C* exhibits additional neurological and behavioral symptoms, and the results of the examination support a diagnosis of Huntington's Disease with respect to *C*.

(ii) *Conclusion.* In this *Example 5, C* could reasonably be diagnosed with Huntington's Disease by a health care professional with appropriate training and expertise. Therefore, Huntington's Disease is manifested with respect to *C*.

(7) *Underwriting purposes* has the meaning given in paragraph (d)(1) of this section.

(b) *No group-based discrimination based on genetic information*—(1) *In general.* For purposes of this section, a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not adjust premium or contribution amounts for the plan, or any group of similarly situated individuals under the plan, on the basis of genetic information. For this purpose, ''similarly situated individuals'' are those described in §146.121(d) of this part.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section (or in paragraph (d)(1) or (d)(2) of this section) limits the ability of a health insurance issuer offering health insurance coverage in connection with a group health plan to increase the premium for a group health plan or a group of similarly situated individuals under the plan based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such a case, however, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members to further increase the premium for a group health plan or a group of similarly situated individuals under the plan.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that three individuals covered under the plan had unusually high claims experience. In addition, the issuer finds that the genetic information of two other individuals indicates the individuals have a higher probability of developing certain illnesses although the illnesses are not manifested at this time. The issuer quotes the plan a higher per-participant rate because of both the genetic information and the higher claims experience.

(ii) *Conclusion.* In this *Example 1*, the issuer violates the provisions of this paragraph (b) because the issuer adjusts the premium based on genetic information. However, if the adjustment related solely to claims experience, the adjustment would not violate the requirements of this section (nor would it violate the requirements of paragraph (c) of §146.121 of this part, which prohibits discrimination in individual premiums or contributions based on a health factor but permits increases in the group rate based on a health factor).

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage through a health insurance issuer. In order to determine the premium rate for the upcoming plan year, the issuer reviews the claims experience of individuals covered under the plan and other health status information of the individuals, including genetic information. The issuer finds that Employee *A* has made claims for treatment of polycystic kidney disease. *A* also has two dependent children covered under the plan. The issuer quotes the plan a higher per-participant rate because of both *A*'s claims experience and the family medical history of *A*'s children (that is, the fact that *A* has the disease).

(ii) *Conclusion.* In this *Example 2*, the issuer violates the provisions of this paragraph (b) because, by taking the likelihood that *A*'s children may develop polycystic kidney disease into account in computing the rate for the plan, the issuer adjusts the premium based on genetic information relating to a condition that has not been manifested in *A*'s children. However, it is permissible for the issuer to increase the premium based on *A*'s claims experience.

(c) *Limitation on requesting or requiring genetic testing*—(1) *General rule.* Except as otherwise provided in this paragraph (c), a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test.* Nothing in paragraph (c)(1) of this section limits the authority of a health care professional

who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples*. The rules of paragraphs (c)(1) and (2) of this section are illustrated by the following examples:

Example 1. (i) *Facts*. Individual *A* goes to a physician for a routine physical examination. The physician reviews *A*'s family medical history and *A* informs the physician that *A*'s mother has been diagnosed with Huntington's Disease. The physician advises *A* that Huntington's Disease is hereditary and recommends that *A* undergo a genetic test.

(ii) *Conclusion*. In this *Example 1*, the physician is a health care professional who is providing health care services to *A*. Therefore, the physician's recommendation that *A* undergo the genetic test does not violate this paragraph (c).

Example 2. (i) *Facts*. Individual *B* is covered by a health maintenance organization (HMO). *B* is a child being treated for leukemia. *B*'s physician, who is employed by the HMO, is considering a treatment plan that includes six-mercaptopurine, a drug for treating leukemia in most children. However, the drug could be fatal if taken by a small percentage of children with a particular gene variant. *B*'s physician recommends that *B* undergo a genetic test to detect this variant before proceeding with this course of treatment.

(ii) *Conclusion*. In this *Example 2*, even though the physician is employed by the HMO, the physician is nonetheless a health care professional who is providing health care services to *B*. Therefore, the physician's recommendation that *B* undergo the genetic test does not violate this paragraph (c).

(4) *Determination regarding payment*.

(i) *In general*. As provided in this paragraph (c)(4), nothing in paragraph (c)(1) of this section precludes a plan or issuer from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in §164.501 of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if a plan or issuer conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on the genetic makeup of a patient, then the plan or issuer is permitted to condition payment for the item or service on the outcome of a genetic test. The plan or issuer may also refuse payment if the patient does not undergo the genetic test.

(ii) *Limitation*. A plan or issuer is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in §164.502(b) of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples*. *See* paragraph (e) of this section for examples illustrating the rules of this paragraph (c)(4), as well as other provisions of this section.

(5) *Research exception*. Notwithstanding paragraph (c)(1) of this section, a plan or issuer may request, but not require, that a participant or beneficiary undergo a genetic test if all of the conditions of this paragraph (c)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations*. The plan or issuer makes the request pursuant to research, as defined in §46.102(d) of this subtitle, that complies with part 46 of this subtitle or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research*. The plan or issuer makes the request in writing, and the request clearly indicates to each participant or beneficiary (or, in the case of a minor child, to the legal guardian of the beneficiary) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in §146.121(b)(1) of this part) or premium or contribution amounts.

(iii) *Prohibition on underwriting*. No genetic information collected or acquired under this paragraph (c)(5) can be used for underwriting purposes (as described in paragraph (d)(1) of this section).

(iv) *Notice to Federal agencies*. The plan or issuer completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and provides the notice to

the address specified in the instructions thereto.

(d) *Prohibitions on collection of genetic information.*

(1) *For underwriting purposes.*

(i) *General rule.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect (as defined in paragraph (a)(1) of this section) genetic information for underwriting purposes. *See* paragraph (e) of this section for examples illustrating the rules of this paragraph (d)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (d)(1)(iii) of this section, *underwriting purposes* means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage as described in §146.121(b)(1)(ii) of this part (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(B) The computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(C) The application of any preexisting condition exclusion under the plan or coverage; and

(D) Other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(iii) *Medical appropriateness.* If an individual seeks a benefit under a group health plan or health insurance coverage, the plan or coverage may limit or exclude the benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an individual seeks a benefit under the plan and the plan or issuer conditions the benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on genetic information of the individual, then the plan or issuer is permitted to condition the benefit on the genetic information. A plan or issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness. The plan or issuer may deny the benefit if the patient does not provide the genetic information required to determine medical appropriateness. If an individual is not seeking a benefit, the medical appropriateness exception of this paragraph (d)(1)(iii) to the definition of underwriting purposes does not apply. *See* paragraph (e) of this section for examples illustrating the medical appropriateness provisions of this paragraph (d)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment.* (i) *In general.* A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect genetic information with respect to any individual prior to that individual's effective date of coverage under that plan or coverage, nor in connection with the rules for eligibility (as defined in §146.121(b)(1)(ii) of this part) that apply to that individual. Whether or not an individual's information is collected prior to that individual's effective date of coverage is determined at the time of collection.

(ii) *Incidental collection exception.*

(A) *In general.* If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (d)(2), as long as the collection is not for underwriting purposes in violation of paragraph (d)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (d)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly states that genetic information should not be provided.

(3) *Examples*. The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts*. A group health plan provides a premium reduction to enrollees who complete a health risk assessment. The health risk assessment is requested to be completed after enrollment. Whether or not it is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The health risk assessment includes questions about the individual's family medical history.

(ii) *Conclusion*. In this *Example 1*, the health risk assessment includes a request for genetic information (that is, the individual's family medical history). Because completing the health risk assessment results in a premium reduction, the request for genetic information is for underwriting purposes. Consequently, the request violates the prohibition on the collection of genetic information in paragraph (d)(1) of this section.

Example 2. (i) *Facts*. The same facts as *Example 1*, except there is no premium reduction or any other reward for completing the health risk assessment.

(ii) *Conclusion*. In this *Example 2*, the request is not for underwriting purposes, nor is it prior to or in connection with enrollment. Therefore, it does not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 3. (i) *Facts*. A group health plan requests that enrollees complete a health risk assessment prior to enrollment, and includes questions about the individual's family medical history. There is no reward or penalty for completing the health risk assessment.

(ii) *Conclusion*. In this *Example 3*, because the health risk assessment includes a request for genetic information (that is, the individual's family medical history), and requests the information prior to enrollment, the request violates the prohibition on the collection of genetic information in paragraph (d)(2) of this section. Moreover, because it is a request for genetic information, it is not an incidental collection under paragraph (d)(2)(ii) of this section.

Example 4. (i) *Facts*. The facts are the same as in *Example 1*, except there is no premium reduction or any other reward given for completion of the health risk assessment. However, certain people completing the health risk assessment may become eligible for additional benefits under the plan by being enrolled in a disease management program based on their answers to questions about family medical history. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history.

(ii) *Conclusion*. In this *Example 4*, the request for information about an individual's family medical history could result in the individual being eligible for benefits for which the individual would not otherwise be eligible. Therefore, the questions about family medical history on the health risk assessment are a request for genetic information for underwriting purposes and are prohibited under this paragraph (d). Although the plan conditions eligibility for the disease management program based on determinations of medical appropriateness, the exception for determinations of medical appropriateness does not apply because the individual is not seeking benefits.

Example 5. (i) *Facts*. A group health plan requests enrollees to complete two distinct health risk assessments (HRAs) after and unrelated to enrollment. The first HRA instructs the individual to answer only for the individual and not for the individual's family. The first HRA does not ask about any genetic tests the individual has undergone or any genetic services the individual has received. The plan offers a reward for completing the first HRA. The second HRA asks about family medical history and the results of genetic tests the individual has undergone. The plan offers no reward for completing the second HRA and the instructions make clear that completion of the second HRA is wholly voluntary and will not affect the reward given for completion of the first HRA.

(ii) *Conclusion*. In this *Example 5*, no genetic information is collected in connection with the first HRA, which offers a reward, and no benefits or other rewards are conditioned on the request for genetic information in the second HRA. Consequently, the request for genetic information in the second HRA is not for underwriting purposes, and the two HRAs do not violate the prohibition on the collection of genetic information in this paragraph (d).

Example 6. (i) *Facts*. A group health plan waives its annual deductible for enrollees who complete an HRA. The HRA is requested to be completed after enrollment. Whether or not the HRA is completed or what responses are given on it has no effect on an individual's enrollment status, or on the enrollment status of members of the individual's family. The HRA does not include any direct questions about the individual's genetic information (including family medical history). However, the last question reads, ''Is there anything else relevant to your health that you would like us to know or discuss with you?''

(ii) *Conclusion*. In this *Example 6*, the plan's request for medical information does not explicitly state that genetic information should not be provided. Therefore, any genetic information collected in response to

the question is not within the incidental collection exception and is prohibited under this paragraph (d).

Example 7. (i) *Facts.* Same facts as *Example 6*, except that the last question goes on to state, ''In answering this question, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk.''

(ii) *Conclusion.* In this *Example 7*, the plan's request for medical information explicitly states that genetic information should not be provided. Therefore, any genetic information collected in response to the question is within the incidental collection exception. However, the plan may not use any genetic information it obtains incidentally for underwriting purposes.

Example 8. (i) *Facts.* Issuer *M* acquires Issuer *N*. *M* requests *N*'s records, stating that *N* should not provide genetic information and should review the records to excise any genetic information. *N* assembles the data requested by *M* and, although *N* reviews it to delete genetic information, the data from a specific region included some individuals' family medical history. Consequently, *M* receives genetic information about some of *N*'s covered individuals.

(ii) *Conclusion.* In this *Example 8*, *M*'s request for health information explicitly stated that genetic information should not be provided. Therefore, the collection of genetic information was within the incidental collection exception. However, *M* may not use the genetic information it obtained incidentally for underwriting purposes.

(e) *Examples regarding determinations of medical appropriateness.* The application of the rules of paragraphs (c) and (d) of this section to plan or issuer determinations of medical appropriateness is illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* group health plan covers genetic testing for celiac disease for individuals who have family members with this condition. After *A*'s son is diagnosed with celiac disease, *A* undergoes a genetic test and promptly submits a claim for the test to *A*'s issuer for reimbursement. The issuer asks *A* to provide the results of the genetic test before the claim is paid.

(ii) *Conclusion.* In this *Example 1*, under the rules of paragraph (c)(4) of this section the issuer is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for the issuer to make a decision regarding the payment of *A*'s claim, the issuer's request for the results of the genetic test violates paragraph (c) of this section.

Example 2. (i) *Facts.* Individual *B*'s group health plan covers a yearly mammogram for participants and beneficiaries starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. *B* is 33 years old and has the BRCA2 mutation. *B* undergoes a mammogram and promptly submits a claim to *B*'s plan for reimbursement. Following an established policy, the plan asks *B* for evidence of increased risk of breast cancer, such as the results of a genetic test or a family history of breast cancer, before the claim for the mammogram is paid. This policy is applied uniformly to all similarly situated individuals and is not directed at individuals based on any genetic information.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate paragraphs (c) or (d) of this section. Under paragraph (c), the plan is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the plan requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the genetic makeup of the patient, the minimum amount of information necessary includes the results of the genetic test. Similarly, the plan does not violate paragraph (d) of this section because the plan is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and if the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts.* Individual *C* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *C*'s physician, *C* has been taking a regular dose of tamoxifen to help prevent a recurrence. *C*'s group health plan adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients, those with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, the plan does not pay for the tamoxifen prescription.

(ii) *Conclusion.* In this *Example 3*, the plan does not violate paragraph (c) of this section if it conditions future payments for the tamoxifen prescription on *C*'s undergoing a genetic test to determine what genetic markers *C* has for making the CYP_2D6 enzyme. Nor does the plan violate paragraph (c) of this section if the plan refuses future

payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *C*.

Example 4. (i) *Facts*. A group health plan offers a diabetes disease management program to all similarly situated individuals for whom it is medically appropriate based on whether the individuals have or are at risk for diabetes. The program provides enhanced benefits related only to diabetes for individuals who qualify for the program. The plan sends out a notice to all participants that describes the diabetes disease management program and explains the terms for eligibility. Individuals interested in enrolling in the program are advised to contact the plan to demonstrate that they have diabetes or that they are at risk for diabetes. For individuals who do not currently have diabetes, genetic information may be used to demonstrate that an individual is at risk.

(ii) *Conclusion*. In this *Example 4*, the plan may condition benefits under the disease management program upon a showing by an individual that the individual is at risk for diabetes, even if such showing may involve genetic information, provided that the plan requests genetic information only when necessary to make a determination regarding whether the disease management program is medically appropriate for the individual and only requests the minimum amount of information necessary to make that determination.

Example 5. (i) *Facts*. Same facts as *Example 4*, except that the plan includes a questionnaire that asks about the occurrence of diabetes in members of the individual's family as part of the notice describing the disease management program.

(ii) *Conclusion*. In this *Example 5*, the plan violates the requirements of paragraph (d)(1) of this section because the requests for genetic information are not limited to those situations in which it is necessary to make a determination regarding whether the disease management program is medically appropriate for the individuals.

Example 6. (i) *Facts*. Same facts as *Example 4*, except the disease management program provides an enhanced benefit in the form of a lower annual deductible to individuals under the program; the lower deductible applies with respect to all medical expenses incurred by the individual. Thus, whether or not a claim relates to diabetes, the individual is provided with a lower deductible based on the individual providing the plan with genetic information.

(ii) *Conclusion*. In this *Example 6*, because the enhanced benefits include benefits not related to the determination of medical appropriateness, making available the enhanced benefits is within the meaning of underwriting purposes. Accordingly, the plan may not request or require genetic information (including family history information) in determining eligibility for enhanced benefits under the program because such a request would be for underwriting purposes and would violate paragraph (d)(1) of this section.

(f) *Applicability date*. This section applies for plan years beginning on or after December 7, 2009.

[74 FR 51688, Oct. 7, 2009]

§ 146.125 Applicability dates.

Section 144.103, §§ 146.111 through 146.119, § 146.143, and § 146.145 are applicable for plan years beginning on or after July 1, 2005. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144 and 146, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2004.

[69 FR 78797, Dec. 30, 2004; 70 FR 21147, Apr. 25, 2005]

Subpart C—Requirements Related to Benefits

§ 146.130 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule*. Except as provided in paragraph (a)(5) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital*. If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital*. If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection

with childbirth is a medical decision to be made by the attending provider.

(3) *Examples.* The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In each example, the group health plan provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A pregnant woman covered under a group health plan goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion.* In this *Example 1,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts.* A woman covered under a group health plan gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion.* In this *Example 2,* the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts.* A woman covered under a group health plan gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion.* In this *Example 3,* the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general.* A plan or issuer is prohibited from requiring that a physician or other health care provider obtain authorization from the plan or issuer for prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example.* The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts.* In the case of a delivery by cesarean section, a group health plan subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the plan requires an attending provider to complete a certificate of medical necessity. The plan then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion.* In this *Example,* the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother.* If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, a plan, hospital, managed care organization, or other issuer is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a group health plan subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The plan pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example,* the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital

stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll or renew coverage under the terms of the plan solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under the plan are discharged within 24 hours after the delivery, the plan will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1*, because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the plan violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the plan provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2*, because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, a group health plan, and a health insurance issuer offering group health insurance coverage, may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* A group health plan subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the plan automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the participant or beneficiary must call the plan to obtain precertification from a utilization reviewer, who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the plan will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion.* In this *Example*, the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit a plan from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the plan based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers.* A group health plan, and a health insurance issuer offering group health insurance coverage, may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a participant or beneficiary in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a participant or beneficiary in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction.* With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory.* This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated.* This section does not apply to any group health plan, or any group health insurance coverage, that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the plan or coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples.* The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* A group health plan provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The plan covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion.* In this *Example 1*, the plan violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the plan also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts.* A group health plan generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the plan will cover 80 percent of the cost of the stay if the participant or beneficiary notifies the plan of the pregnancy in advance of admission and uses whatever hospital the plan may designate.

(ii) *Conclusion.* In this *Example 2*, the plan does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the plan does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider.* This section does not prevent a group health plan or a health insurance issuer offering group health insurance coverage from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(d) *Notice requirement.* Except as provided in paragraph (d)(4) of this section, a group health plan that provides benefits for hospital lengths of stay in connection with childbirth must meet the following requirements:

(1) *Required statement.* The plan document that provides a description of plan benefits to participants and beneficiaries, or that notifies participants and beneficiaries of plan benefit changes, must disclose information that notifies participants and beneficiaries of their rights under this section.

(2) *Disclosure notice.* To meet the disclosure requirement set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

STATEMENT OF RIGHTS UNDER THE NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT

Under federal law, group health plans and health insurance issuers offering group health insurance coverage generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the plan or issuer may pay for a shorter stay if the attending provider (*e.g.*, your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, plans and issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, a plan or issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up

to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your plan administrator.

(3) *Timing of disclosure*. The disclosure notice in paragraph (d)(2) of this section shall be furnished to each participant covered under a group health plan, and each beneficiary receiving benefits under a group health plan, not later than 60 days after the first day of the first plan year beginning on or after January 1, 2009. Each time a plan distributes one or both of the documents described in paragraph (d)(1) to participants and beneficiaries after providing this initial notice, the disclosure notice in paragraph (d)(2) must appear in at least one of those documents.

(4) *Exceptions*. The requirements of this paragraph (d) do not apply in the following situations.

(i) *Self-insured plans that have already provided notice*. If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has already provided an initial notice that complies with paragraphs (d)(1) and (d)(2) of this section, the group health plan is not automatically required to provide another such notice to participants and beneficiaries who have been provided with the initial notice. However, following the effective date of these regulations, whenever such a plan provides one or both of the documents described in paragraph (d)(1) of this section to participants and beneficiaries, the disclosure notice in paragraph (d)(2) of this section must appear in at least one of those documents.

(ii) *Self-insured plans that have elected exemption from this section*. If benefits for hospital lengths of stay in connection with childbirth are not provided through health insurance coverage, and the group health plan has made the election described in Sec. 146.180 to be exempted from the requirements of this section, the group health plan is not subject to this paragraph (d).

(iii) *Insured plans*. If benefits for hospital lengths of stay in connection with childbirth are provided through health insurance coverage, and the coverage is regulated under a State law described in paragraph (e) of this section, the group health plan is not subject to this paragraph (d).

(e) *Applicability in certain states*—(1) *Health insurance coverage*. The requirements of section 2725 of the PHS Act and this section do not apply with respect to health insurance coverage offered in connection with a group health plan if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Group health plans*—(i) *Fully-insured plans*. For a group health plan that provides benefits solely through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2725 of the PHS Act and this section do not apply.

(ii) *Self-insured plans*. For a group health plan that provides all benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the requirements of section 2725 of the PHS Act and this section apply.

(iii) *Partially-insured plans*. For a group health plan that provides some

benefits through health insurance coverage, if the state law regulating the health insurance coverage meets any of the criteria in paragraph (e)(1) of this section, then the requirements of section 2725 of the PHS Act and this section apply only to the extent the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage.

(3) *Relation to section 2724 (a) of the PHS Act*. The preemption provisions contained in section 2724 (a)(1) of the PHS Act and Sec. 146.143(a) do not supersede a state law described in paragraph (e)(1) of this section.

(4) *Examples*. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts*. A group health plan buys group health insurance coverage in a state that requires that the coverage provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) *Conclusion*. In this Example 1, the coverage is subject to state law, and the requirements of section 2725 of the PHS Act and this section do not apply.

Example 2. (i) *Facts*. A self-insured group health plan covers hospital lengths of stay in connection with childbirth in a state that requires health insurance coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics.

(ii) *Conclusion*. In this Example 2, even though the state law satisfies the criterion of paragraph (e)(1)(ii) of this section, because the plan provides benefits for hospital lengths of stay in connection with childbirth other than through health insurance coverage, the plan is subject to the requirements of section 2725 of the PHS Act and this section.

(f) *Applicability date*. Section 2725 of the PHS Act applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 1998. This section applies to group health plans, and health insurance issuers offering group health insurance coverage, for plan years beginning on or after January 1, 2009.

[73 FR 62424, Oct. 20, 2008, as amended at 75 FR 27138, May 13, 2010]

§ 146.136 Parity in mental health and substance use disorder benefits.

(a) *Meaning of terms*. For purposes of this section, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a group health plan (or health insurance coverage offered in connection with such a plan) for any coverage unit.

Coverage unit means coverage unit as described in paragraph (c)(1)(iv) of this section.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Cumulative quantitative treatment limitations are treatment limitations that determine whether or to what extent benefits are provided based on accumulated amounts, such as annual or lifetime day or visit limits.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for medical or surgical services, as defined under the terms of the plan or health insurance coverage, but does not include mental health or substance use disorder benefits. Any condition defined by the plan as being or as not being a medical/surgical condition

must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

Mental health benefits means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any condition defined by the plan as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines).

Substance use disorder benefits means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law. Any disorder defined by the plan as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines).

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan. (*See* paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation.

(b) *Parity requirements with respect to aggregate lifetime and annual dollar limits*—(1)—*General*—(i) *General parity requirement.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits must comply with paragraph (b)(2), (b)(3), or (b)(6) of this section.

(ii) *Exception.* The rule in paragraph (b)(1)(i) of this section does not apply if a plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(2) *Plan with no limit or limits on less than one-third of all medical/surgical benefits.* If a plan (or health insurance coverage) does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(3) *Plan with a limit on at least two-thirds of all medical/surgical benefits.* If a plan (or health insurance coverage) includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits, it must either—

(i) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(ii) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is less than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits. (For cumulative limits other than aggregate lifetime or annual dollar limits, see paragraph (c)(3)(v) of this section prohibiting separately accumulating cumulative financial requirements or cumulative quantitative treatment limitations.)

(4) *Examples.* The rules of paragraphs (b)(2) and (b)(3) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan has no annual limit on medical/surgical benefits and a $10,000 annual limit on mental health and substance use disorder benefits. To comply with the requirements of this paragraph (b), the plan sponsor is considering each of the following options—

(A) Eliminating the plan's annual dollar limit on mental health and substance use disorder benefits;

(B) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $500,000 annual limit on all benefits (including medical/surgical and mental health and substance use disorder benefits); and

(C) Replacing the plan's annual dollar limit on mental health and substance use disorder benefits with a $250,000 annual limit on medical/surgical benefits and a $250,000 annual limit on mental health and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 1,* each of the three options being considered by the plan sponsor would comply with the requirements of this paragraph (b).

Example 2. (i) *Facts.* A plan has a $100,000 annual limit on medical/surgical inpatient benefits and a $50,000 annual limit on medical/surgical outpatient benefits. To comply with the parity requirements of this paragraph (b), the plan sponsor is considering each of the following options—

(A) Imposing a $150,000 annual limit on mental health and substance use disorder benefits; and

(B) Imposing a $100,000 annual limit on mental health and substance use disorder inpatient benefits and a $50,000 annual limit on mental health and substance use disorder outpatient benefits.

(ii) *Conclusion.* In this *Example 2,* each option under consideration by the plan sponsor would comply with the requirements of this section.

(5) *Determining one-third and two-thirds of all medical/surgical benefits.* For purposes of this paragraph (b), the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the dollar amount of all plan payments for medical/surgical benefits expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the plan will constitute one-third or two-thirds of the dollar amount of all plan payments for medical/surgical benefits.

(6) *Plan not described in paragraph (b)(2) or (b)(3) of this section*—(i) *In general.* A group health plan (or health insurance coverage) that is not described in paragraph (b)(2) or (b)(3) of this section with respect to aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(A) Impose no aggregate lifetime or annual dollar limit, as appropriate, on mental health or substance use disorder benefits; or

(B) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no less than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery systems, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (b)(6)(i)(B). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the plan are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a plan may reasonably be expected to incur with respect to such benefits, taking into account any other applicable restrictions under the plan.

(ii) *Weighting.* For purposes of this paragraph (b)(6), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (b)(5) of this section for determining one-third or two-thirds of all medical/surgical benefits.

(iii) *Example.* The rules of this paragraph (b)(6) are illustrated by the following example:

Example. (i) *Facts.* A group health plan that is subject to the requirements of this section includes a $100,000 annual limit on medical/

surgical benefits related to cardio-pulmonary diseases. The plan does not include an annual dollar limit on any other category of medical/surgical benefits. The plan determines that 40% of the dollar amount of plan payments for medical/surgical benefits are related to cardio-pulmonary diseases. The plan determines that $1,000,000 is a reasonable estimate of the upper limit on the dollar amount that the plan may incur with respect to the other 60% of payments for medical/surgical benefits.

(ii) *Conclusion.* In this *Example,* the plan is not described in paragraph (b)(3) of this section because there is not one annual dollar limit that applies to at least two-thirds of all medical/surgical benefits. Further, the plan is not described in paragraph (b)(2) of this section because more than one-third of all medical/surgical benefits are subject to an annual dollar limit. Under this paragraph (b)(6), the plan sponsor can choose either to include no annual dollar limit on mental health or substance use disorder benefits, or to include an annual dollar limit on mental health or substance use disorder benefits that is not less than the weighted average of the annual dollar limits applicable to each category of medical/surgical benefits. In this example, the minimum weighted average annual dollar limit that can be applied to mental health or substance use disorder benefits is $640,000 (40% × $100,000 + 60% × $1,000,000 = $640,000).

(c) *Parity requirements with respect to financial requirements and treatment limitations*—(1) *Clarification of terms*—(i) *Classification of benefits.* When reference is made in this paragraph (c) to a classification of benefits, the term ''classification'' means a classification as described in paragraph (c)(2)(ii) of this section.

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative list of nonquantitative treatment limitations.

(iii) *Level of a type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation. For example, different levels of coinsurance include 20 percent and 30 percent; different levels of a copayment include $15 and $20; different levels of a deductible include $250 and $500; and different levels of an episode limit include 21 inpatient days per episode and 30 inpatient days per episode.

(iv) *Coverage unit.* When reference is made in this paragraph (c) to a coverage unit, coverage unit refers to the way in which a plan (or health insurance coverage) groups individuals for purposes of determining benefits, or premiums or contributions. For example, different coverage units include self-only, family, and employee-plus-spouse.

(2) *General parity requirement*—(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) *Classifications of benefits used for applying rules*—(A) *In general.* If a plan (or health insurance coverage) provides mental health or substance use disorder benefits in any classification of benefits described in this paragraph (c)(2)(ii), mental health or substance use disorder benefits must be provided

in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c):

(*1*) *Inpatient, in-network.* Benefits furnished on an inpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.

(*2*) *Inpatient, out-of-network.* Benefits furnished on an inpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes inpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(*3*) *Outpatient, in-network.* Benefits furnished on an outpatient basis and within a network of providers established or recognized under a plan or health insurance coverage.

(*4*) *Outpatient, out-of-network.* Benefits furnished on an outpatient basis and outside any network of providers established or recognized under a plan or health insurance coverage. This classification includes outpatient benefits under a plan (or health insurance coverage) that has no network of providers.

(*5*) *Emergency care.* Benefits for emergency care.

(*6*) *Prescription drugs.* Benefits for prescription drugs. See special rules for multi-tiered prescription drug benefits in paragraph (c)(3)(iii) of this section.

(B) *Application to out-of-network providers.* See paragraph (c)(2)(ii)(A) of this section, under which a plan (or health insurance coverage) that provides mental health or substance use disorder benefits in any classification of benefits must provide mental health or substance use disorder benefits in every classification in which medical/surgical benefits are provided, including out-of-network classifications.

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a $500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 1,* because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

Example 2. (i) *Facts.* A plan imposes a $500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 2,* because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

Example 3. (i) *Facts.* Same facts as *Example 2,* except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this *Example 3,* because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for—

(A) Benefits in the emergency classification; and

(B) All other benefits.

Example 4. (i) *Facts.* Same facts as *Example 2*, except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this *Example 4*, because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for—

(A) Inpatient, out-of-network benefits; and

(B) All other benefits.

(3) *Financial requirements and quantitative treatment limitations*—(i) *Determining ''substantially all'' and ''predominant''*—(A) *Substantially all.* For purposes of this paragraph (c), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For this purpose, benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(B) *Predominant*—(*1*) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(3)(i)(A) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(*2*) If, with respect to a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the plan (or health insurance issuer) may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a plan may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(C) *Portion based on plan payments.* For purposes of this paragraph (c), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been

made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes.

(E) *Determining the dollar amount of plan payments.* Subject to paragraph (c)(3)(i)(D) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(ii) *Application to different coverage units.* If a plan (or health insurance coverage) applies different levels of a financial requirement or quantitative treatment limitation to different coverage units in a classification of medical/surgical benefits, the predominant level that applies to substantially all medical/surgical benefits in the classification is determined separately for each coverage unit.

(iii) *Special rule for multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(iv) *Examples.* The rules of paragraphs (c)(3)(i), (c)(3)(ii), and (c)(3)(iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts.* For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Coinsurance rate	0%	10%	15%	20%	30%	Total
Projected payments	$200x	$100x	$450x	$100x	$150x	$1,000x
Percent of total plan costs	20%	10%	45%	10%	15%	
Percent subject to coinsurance level.	N/A	12.5% (100x/800x)	56.25% (450x/800x)	12.5% (100x/800x)	18.75% (150x/800x)	

The plan projects plan costs of $800x to be subject to coinsurance ($100x + $450x + $100x + $150x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(ii) *Conclusion.* In this *Example 1,* the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

Example 2. (i) *Facts.* For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Copayment amount	$0	$10	$15	$20	$50	Total
Projected payments	$200x	$200x	$200x	$300x	$100x	$1,000x
Percent of total plan costs	20%	20%	20%	30%	10%	
Percent subject to copayments.	N/A	25% (200x/800x)	25% (200x/800x)	37.5% (300x/800x)	12.5% (100x/800x)	

The plan projects plan costs of $800x to be subject to copayments ($200x + $200x + $300x + $100x = $800x). Thus, 80 percent ($800x/$1,000x) of the benefits are projected to be subject to a copayment.

(ii) *Conclusion*. In this *Example 2*, the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the $10 copayment, 25%; for the $15 copayment, 25%; for the $20 copayment, 37.5%; and for the $50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the $50 copayment and the $20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($300x + $100x = $400x; $400x/$800x = 50%). The combined projected payments for the three highest copayment levels—the $50 copayment, the $20 copayment, and the $15 copayment—are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($100x + $300x + $200x = $600x; $600x/$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the $15 copayment.

Example 3. (i) *Facts*. A plan imposes a $250 deductible on all medical/surgical benefits for self-only coverage and a $500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion*. In this *Example 3*, because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

Example 4. (i) *Facts*. A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as ''generic'', ''preferred brand name'', ''non-preferred brand name'', or ''specialty'' complies with the rules of paragraph (c)(4)(i) of this section (relating to requirements for nonquantitative treatment limitations).

Tier description	Tier 1	Tier 2	Tier 3	Tier 4
	Generic drugs	Preferred brand name drugs	Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives)	Specialty drugs
Percent paid by plan	90%	80%	60%	50%

(ii) *Conclusion*. In this *Example 4*, the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(v) *No separate cumulative financial requirements or cumulative quantitative treatment limitations*—(A) A group health plan (or health insurance coverage offered in connection with a group health plan) may not apply any cumulative financial requirement or cumulative quantitative treatment limitation for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(B) The rules of this paragraph (c)(3)(v) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan imposes a combined annual $500 deductible on all medical/surgical, mental health, and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 1*, the combined annual deductible complies with the requirements of this paragraph (c)(3)(v).

Example 2. (i) *Facts.* A plan imposes an annual $250 deductible on all medical/surgical benefits and a separate annual $250 deductible on all mental health and substance use disorder benefits.

(ii) *Conclusion.* In this *Example 2*, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 3. (i) *Facts.* A plan imposes an annual $300 deductible on all medical/surgical benefits and a separate annual $100 deductible on all mental health or substance use disorder benefits.

(ii) *Conclusion.* In this *Example 3*, the separate annual deductible on mental health and substance use disorder benefits violates the requirements of this paragraph (c)(3)(v).

Example 4. (i) *Facts.* A plan generally imposes a combined annual $500 deductible on all benefits (both medical/surgical benefits and mental health and substance use disorder benefits) except prescription drugs. Certain benefits, such as preventive care, are provided without regard to the deductible. The imposition of other types of financial requirements or treatment limitations varies with each classification. Using reasonable methods, the plan projects its payments for medical/surgical benefits in each classification for the upcoming year as follows:

Classification	Benefits subject to deductible	Total benefits	Percent subject to deductible
Inpatient, in-network	$1,800x	$2,000x	90
Inpatient, out-of-network	1,000x	1,000x	100
Outpatient, in-network	1,400x	2,000x	70
Outpatient, out-of-network	1,880x	2,000x	94
Emergency care	300x	500x	60

(ii) *Conclusion.* In this *Example 4*, the two-thirds threshold of the substantially all standard is met with respect to each classification except emergency care because in each of those other classifications at least two-thirds of medical/surgical benefits are subject to the $500 deductible. Moreover, the $500 deductible is the predominant level in each of those other classifications because it is the only level. However, emergency care mental health and substance use disorder benefits cannot be subject to the $500 deductible because it does not apply to substantially all emergency care medical/surgical benefits.

(4) *Nonquantitative treatment limitations*—(i) *General rule.* A group health plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation with respect to medical surgical/benefits in the classification, except to the extent that recognized clinically appropriate standards of care may permit a difference.

(ii) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include—

(A) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) Standards for provider admission to participate in a network, including reimbursement rates;

(D) Plan methods for determining usual, customary, and reasonable charges;

(E) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols); and

(F) Exclusions based on failure to complete a course of treatment.

(iii) *Examples*. The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

Example 1. (i) *Facts*. A group health plan limits benefits to treatment that is medically necessary. The plan requires concurrent review for inpatient, in-network mental health and substance use disorder benefits but does not require it for any inpatient, in-network medical/surgical benefits. The plan conducts retrospective review for inpatient, in-network medical/surgical benefits.

(ii) *Conclusion*. In this *Example 1*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical necessity—applies to both mental health and substance use disorder benefits and to medical/surgical benefits for inpatient, in-network services, the concurrent review process does not apply to medical/surgical benefits. The concurrent review process is not comparable to the retrospective review process. While such a difference might be permissible in certain individual cases based on recognized clinically appropriate standards of care, it is not permissible for distinguishing between all medical/surgical benefits and all mental health or substance use disorder benefits.

Example 2. (i) *Facts*. A plan requires prior approval that a course of treatment is medically necessary for outpatient, in-network medical/surgical, mental health, and substance use disorder benefits. For mental health and substance use disorder treatments that do not have prior approval, no benefits will be paid; for medical/surgical treatments that do not have prior approval, there will only be a 25 percent reduction in the benefits the plan would otherwise pay.

(ii) *Conclusion*. In this *Example 2*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical necessity—is applied both to mental health and substance use disorder benefits and to medical/surgical benefits for outpatient, in-network services, the penalty for failure to obtain prior approval for mental health and substance use disorder benefits is not comparable to the penalty for failure to obtain prior approval for medical/surgical benefits.

Example 3. (i) *Facts*. A plan generally covers medically appropriate treatments. For both medical/surgical benefits and mental health and substance use disorder benefits, evidentiary standards used in determining whether a treatment is medically appropriate (such as the number of visits or days of coverage) are based on recommendations made by panels of experts with appropriate training and experience in the fields of medicine involved. The evidentiary standards are applied in a manner that may differ based on clinically appropriate standards of care for a condition.

(ii) *Conclusion*. In this *Example 3*, the plan complies with the rules of this paragraph (c)(4) because the nonquantitative treatment limitation—medical appropriateness—is the same for both medical/surgical benefits and mental health and substance use disorder benefits, and the processes for developing the evidentiary standards and the application of them to mental health and substance use disorder benefits are comparable to and are applied no more stringently than for medical/surgical benefits. This is the result even if, based on clinically appropriate standards of care, the application of the evidentiary standards does not result in similar numbers of visits, days of coverage, or other benefits utilized for mental health conditions or substance use disorders as it does for any particular medical/surgical condition.

Example 4. (i) *Facts*. A plan generally covers medically appropriate treatments. In determining whether prescription drugs are medically appropriate, the plan automatically excludes coverage for antidepressant drugs that are given a black box warning label by the Food and Drug Administration (indicating the drug carries a significant risk of serious adverse effects). For other drugs with a black box warning (including those prescribed for other mental health conditions and substance use disorders, as well as for medical/surgical conditions), the plan will provide coverage if the prescribing physician obtains authorization from the plan that the drug is medically appropriate for the individual, based on clinically appropriate standards of care.

(ii) *Conclusion*. In this *Example 4*, the plan violates the rules of this paragraph (c)(4). Although the same nonquantitative treatment limitation—medical appropriateness—is applied to both mental health and substance use disorder benefits and medical/surgical benefits, the plan's unconditional exclusion of antidepressant drugs given a black box warning is not comparable to the conditional exclusion for other drugs with a black box warning.

Example 5. (i) *Facts*. An employer maintains both a major medical program and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. Participants are eligible for mental health or substance use disorder benefits under the major medical program only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with

respect to medical/surgical benefits provided under the major medical program.

(ii) *Conclusion*. In this *Example 5*, limiting eligibility for mental health and substance use disorder benefits only after EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c). Because no comparable requirement applies to medical/surgical benefits, the requirement may not be applied to mental health or substance use disorder benefits.

(5) *Exemptions*. The rules of this paragraph (c) do not apply if a group health plan (or health insurance coverage) satisfies the requirements of paragraph (f) or (g) of this section (relating to exemptions for small employers and for increased cost).

(d) *Availability of plan information*—(1) *Criteria for medical necessity determinations*. The criteria for medical necessity determinations made under a group health plan with respect to mental health or substance use disorder benefits (or health insurance coverage offered in connection with the plan with respect to such benefits) must be made available by the plan administrator (or the health insurance issuer offering such coverage) to any current or potential participant, beneficiary, or contracting provider upon request.

(2) *Reason for denial*. The reason for any denial under a non-Federal governmental plan (or health insurance coverage offered in connection with such plan) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary must be made available within a reasonable time and in a reasonable manner by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary upon request. For this purpose, a non-Federal governmental plan (or health insurance coverage offered in connection with such plan) that provides the reason for the claim denial in a form and manner consistent with the requirements of 29 CFR 2560.503–1 for group health plans complies with the requirements of this paragraph (d)(2).

(e) *Applicability*—(1) *Group health plans*. The requirements of this section apply to a group health plan offering medical/surgical benefits and mental health or substance use disorder benefits. If, under an arrangement or arrangements to provide medical care benefits by an employer or employee organization (including for this purpose a joint board of trustees of a multiemployer trust affiliated with one or more multiemployer plans), any participant (or beneficiary) can simultaneously receive coverage for medical/surgical benefits and coverage for mental health or substance use disorder benefits, then the requirements of this section (including the exemption provisions in paragraph (g) of this section) apply separately with respect to each combination of medical/surgical benefits and of mental health or substance use disorder benefits that any participant (or beneficiary) can simultaneously receive from that employer's or employee organization's arrangement or arrangements to provide medical care benefits, and all such combinations are considered for purposes of this section to be a single group health plan.

(2) *Health insurance issuers*. The requirements of this section apply to a health insurance issuer offering health insurance coverage for mental health or substance use disorder benefits in connection with a group health plan subject to paragraph (e)(1) of this section.

(3) *Scope*. This section does not—

(i) Require a group health plan (or health insurance issuer offering coverage in connection with a group health plan) to provide any mental health benefits or substance use disorder benefits, and the provision of benefits by a plan (or health insurance coverage) for one or more mental health conditions or substance use disorders does not require the plan (or health insurance coverage) under this section to provide benefits for any other mental health condition or substance use disorder; or

(ii) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the plan (or health insurance coverage) except as specifically provided in paragraphs (b) and (c) of this section.

(f) *Small employer exemption*—(1) *In general*. The requirements of this section do not apply to a group health

plan (or health insurance issuer offering coverage in connection with a group health plan) for a plan year of a small employer. For purposes of this paragraph (f), the term *small employer* means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least two but not more than 50 employees on business days during the preceding calendar year and who employs at least two employees on the first day of the plan year (except that for purposes of this paragraph, a small employer shall include an employer with one employee in the case of an employer residing in a State that permits small groups to include a single individual). See also section 2721(a) of the PHS Act and § 146.145(b) of this Part, which provide that this section (and certain other sections) does not apply to any group health plan (and health insurance issuer offering coverage in connection with a group health plan) for any plan year if, on the first day of the plan year, the plan has fewer than two participants who are current employees.

(2) *Rules in determining employer size.* For purposes of paragraph (f)(1) of this section—

(i) All persons treated as a single employer under subsections (b), (c), (m), and (o) of section 414 of the Internal Revenue Code of 1986 (26 U.S.C. 414) are treated as one employer;

(ii) If an employer was not in existence throughout the preceding calendar year, whether it is a small employer is determined based on the average number of employees the employer reasonably expects to employ on business days during the current calendar year; and

(iii) Any reference to an employer for purposes of the small employer exemption includes a reference to a predecessor of the employer.

(g) *Increased cost exemption* [Reserved]

(h) *Sale of nonparity health insurance coverage.* A health insurance issuer may not sell a policy, certificate, or contract of insurance that fails to comply with paragraph (b) or (c) of this section, except to a plan for a year for which the plan is exempt from the requirements of this section because the plan meets the requirements of paragraph (f) or (g) of this section.

(i) *Applicability dates*—(1) *In general.* Except as provided in paragraph (i)(2) of this section, the requirements of this section are applicable for plan years beginning on or after July 1, 2010.

(2) *Special effective date for certain collectively-bargained plans.* For a group health plan maintained pursuant to one or more collective bargaining agreements ratified before October 3, 2008, the requirements of this section do not apply to the plan (or health insurance coverage offered in connection with the plan) for plan years beginning before the later of either—

(i) The date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension agreed to after October 3, 2008); or

(ii) July 1, 2010.

[75 FR 5444, Feb. 2, 2010]

Subpart D—Preemption and Special Rules

§ 146.143 Preemption; State flexibility; construction.

(a) *Continued applicability of State law with respect to health insurance issuers.* Subject to paragraph (b) of this section and except as provided in paragraph (c) of this section, part A of title XXVII of the PHS Act is not to be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part.

(b) *Continued preemption with respect to group health plans.* Nothing in part A of title XXVII of the PHS Act affects or modifies the provisions of section 514 of ERISA with respect to group health plans.

(c) *Special rules*—(1) *In general.* Subject to paragraph (c)(2) of this section, the provisions of part A of title XXVII of the PHS Act relating to health insurance coverage offered by a health

insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 2701 of the PHS Act which differs from the standards or requirements specified in section 2701 of the PHS Act.

(2) *Exceptions.* Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

(i) Shortens the period of time from the ''6-month period'' described in section 2701(a)(1) of the PHS Act and §146.111(a)(2)(i) (for purposes of identifying a preexisting condition);

(ii) Shortens the period of time from the ''12 months'' and ''18 months'' described in section 2701(a)(2) of the PHS Act and §146.111(a)(2)(ii) (for purposes of applying a preexisting condition exclusion period);

(iii) Provides for a greater number of days than the ''63-day period'' described in sections 2701(c)(2)(A) and (d)(4)(A) of the PHS Act and §§146.111(a)(2)(iii) and 146.113 (for purposes of applying the break in coverage rules);

(iv) Provides for a greater number of days than the ''30-day period'' described in sections 2701(b)(2) and (d)(1) of the PHS Act and §146.111(b) (for purposes of the enrollment period and preexisting condition exclusion periods for certain newborns and children that are adopted or placed for adoption);

(v) Prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) of the PHS Act or expands the exceptions described therein;

(vi) Requires special enrollment periods in addition to those required under section 2701(f) of the PHS Act; or

(vii) Reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B) of the PHS Act.

(d) *Definitions*—(1) *State law.* For purposes of this section the term *State law* includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia is treated as a State law rather than a law of the United States.

(2) *State.* For purposes of this section the term *State* includes a State (as defined in §144.103), any political subdivisions of a State, or any agency or instrumentality of either.

[69 FR 78797, Dec. 30, 2004; 70 FR 21147, Apr. 25, 2005]

§146.145 Special rules relating to group health plans.

(a) *Group health plan*—(1) *Definition.* A group health plan means an employee welfare benefit plan to the extent that the plan provides medical care (including items and services paid for as medical care) to employees (including both current and former employees) or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

(2) *Determination of number of plans.* [Reserved]

(b) *General exception for certain small group health plans.* The requirements of this part, other than §146.130 and the provisions with respect to genetic nondiscrimination (found in §146.111(b)(6), §146.121(b), §146.121(c), §146.121(e), §146.122(b), §146.122(c), §146.122(d), and §146.122(e)) do not apply to any group health plan (and group health insurance coverage) for any plan year, if on the first day of the plan year, the plan has fewer than two participants who are current employees.

(c) *Excepted benefits*—(1) *In general.* The requirements of subparts B and C of this part do not apply to any group health plan (or any group health insurance coverage) in relation to its provision of the benefits described in paragraph (c)(2), (3), (4), or (5) of this section (or any combination of these benefits).

(2) *Benefits excepted in all circumstances.* The following benefits are excepted in all circumstances—

(i) Coverage only for accident (including accidental death and dismemberment);

(ii) Disability income coverage;

(iii) Liability insurance, including general liability insurance and automobile liability insurance;

(iv) Coverage issued as a supplement to liability insurance;

(v) Workers' compensation or similar coverage;

(vi) Automobile medical payment insurance;

(vii) Credit-only insurance (for example, mortgage insurance); and

(viii) Coverage for on-site medical clinics.

(3) *Limited excepted benefits*—(i) *In general*. Limited-scope dental benefits, limited-scope vision benefits, or long-term care benefits are excepted if they are provided under a separate policy, certificate, or contract of insurance, or are otherwise not an integral part of a group health plan as described in paragraph (c)(3)(ii) of this section. In addition, benefits provided under a health flexible spending arrangement are excepted benefits if they satisfy the requirements of paragraph (c)(3)(v) of this section.

(ii) *Not an integral part of a group health plan*. For purposes of this paragraph (c)(3), benefits are not an integral part of a group health plan (whether the benefits are provided through the same plan or a separate plan) only if the following two requirements are satisfied—

(A) Participants must have the right to elect not to receive coverage for the benefits; and

(B) If a participant elects to receive coverage for the benefits, the participant must pay an additional premium or contribution for that coverage.

(iii) *Limited scope*—(A) *Dental benefits*. Limited scope dental benefits are benefits substantially all of which are for treatment of the mouth (including any organ or structure within the mouth).

(B) *Vision benefits*. Limited scope vision benefits are benefits substantially all of which are for treatment of the eye.

(iv) *Long-term care*. Long-term care benefits are benefits that are either—

(A) Subject to State long-term care insurance laws;

(B) For qualified long-term care services, as defined in section 7702B(c)(1) of the Internal Revenue Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Internal Revenue Code; or

(C) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(v) *Health flexible spending arrangements*. Benefits provided under a health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) are excepted for a class of participants only if they satisfy the following two requirements—

(A) Other group health plan coverage, not limited to excepted benefits, is made available for the year to the class of participants by reason of their employment; and

(B) The arrangement is structured so that the maximum benefit payable to any participant in the class for a year cannot exceed two times the participant's salary reduction election under the arrangement for the year (or, if greater, cannot exceed $500 plus the amount of the participant's salary reduction election). For this purpose, any amount that an employee can elect to receive as taxable income but elects to apply to the health flexible spending arrangement is considered a salary reduction election (regardless of whether the amount is characterized as salary or as a credit under the arrangement).

(4) *Noncoordinated benefits*—(i) *Excepted benefits that are not coordinated*. Coverage for only a specified disease or illness (for example, cancer-only policies) or hospital indemnity or other fixed indemnity insurance is excepted only if it meets each of the conditions specified in paragraph (c)(4)(ii) of this section. To be hospital indemnity or other fixed indemnity insurance, the insurance must pay a fixed dollar amount per day (or per other period) of hospitalization or illness (for example, $100/day) regardless of the amount of expenses incurred.

(ii) *Conditions*. Benefits are described in paragraph (c)(4)(i) of this section only if—

(A) The benefits are provided under a separate policy, certificate, or contract of insurance;

(B) There is no coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor; and

(C) The benefits are paid with respect to an event without regard to whether

benefits are provided with respect to the event under any group health plan maintained by the same plan sponsor.

(iii) *Example.* The rules of this paragraph (c)(4) are illustrated by the following example:

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage through an insurance policy. The policy provides benefits only for hospital stays at a fixed percentage of hospital expenses up to a maximum of $100 a day.

(ii) *Conclusion.* In this *Example,* even though the benefits under the policy satisfy the conditions in paragraph (c)(4)(ii) of this section, because the policy pays a percentage of expenses incurred rather than a fixed dollar amount, the benefits under the policy are not excepted benefits under this paragraph (c)(4). This is the result even if, in practice, the policy pays the maximum of $100 for every day of hospitalization.

(5) *Supplemental benefits.* (i) The following benefits are excepted only if they are provided under a separate policy, certificate, or contract of insurance—

(A) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act; also known as Medigap or MedSupp insurance);

(B) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as TRICARE supplemental programs); and

(C) Similar supplemental coverage provided to coverage under a group health plan. To be similar supplemental coverage, the coverage must be specifically designed to fill gaps in primary coverage, such as coinsurance or deductibles. Similar supplemental coverage does not include coverage that becomes secondary or supplemental only under a coordination-of-benefits provision.

(ii) The rules of this paragraph (c)(5) are illustrated by the following example:

Example. (i) *Facts.* An employer sponsors a group health plan that provides coverage for both active employees and retirees. The coverage for retirees supplements benefits provided by Medicare, but does not meet the requirements for a supplemental policy under section 1882(g)(1) of the Social Security Act.

(ii) *Conclusion.* In this *Example,* the coverage provided to retirees does not meet the definition of supplemental excepted benefits under this paragraph (c)(5) because the coverage is not Medicare supplemental insurance as defined under section 1882(g)(1) of the Social Security Act, is not a TRICARE supplemental program, and is not supplemental to coverage provided under a group health plan.

(d) *Treatment of partnerships.* For purposes of this part:

(1) *Treatment as a group health plan.* Any plan, fund, or program that would not be (but for this paragraph (d)) an employee welfare benefit plan and that is established or maintained by a partnership, to the extent that the plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, is treated (subject to paragraph (d)(2) of this section) as an employee welfare benefit plan that is a group health plan.

(2) *Employment relationship.* In the case of a group health plan, the term *employer* also includes the partnership in relation to any bona fide partner. In addition, the term *employee* also includes any bona fide partner. Whether or not an individual is a bona fide partner is determined based on all the relevant facts and circumstances, including whether the individual performs services on behalf of the partnership.

(3) *Participants of group health plans.* In the case of a group health plan, the term *participant* also includes any individual described in paragraph (d)(3)(i) or (ii) of this section if the individual is, or may become, eligible to receive a benefit under the plan or the individual's beneficiaries may be eligible to receive any such benefit.

(i) In connection with a group health plan maintained by a partnership, the individual is a partner in relation to the partnership.

(ii) In connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the individual is the self-employed individual.

(e) *Determining the average number of employees.* [Reserved]

[69 FR 78798, Dec. 30, 2004, as amended at 74 FR 51692, Oct. 7, 2009]

Subpart E—Provisions Applicable to Only Health Insurance Issuers

§ 146.150 Guaranteed availability of coverage for employers in the small group market.

(a) *Issuance of coverage in the small group market.* Subject to paragraphs (c) through (f) of this section, each health insurance issuer that offers health insurance coverage in the small group market in a State must—

(1) Offer, to any small employer in the State, all products that are approved for sale in the small group market and that the issuer is actively marketing, and must accept any employer that applies for any of those products; and

(2) Accept for enrollment under the coverage every eligible individual (as defined in paragraph (b) of this section) who applies for enrollment during the period in which the individual first becomes eligible to enroll under the terms of the group health plan, or during a special enrollment period, and may not impose any restriction on an eligible individual's being a participant or beneficiary, which is inconsistent with the nondiscrimination provisions of § 146.121.

(b) *Eligible individual defined.* For purposes of this section, the term ''eligible individual'' means an individual who is eligible—

(1) To enroll in group health insurance coverage offered to a group health plan maintained by a small employer, in accordance with the terms of the group health plan;

(2) For coverage under the rules of the health insurance issuer which are uniformly applicable in the State to small employers in the small group market; and

(3) For coverage in accordance with all applicable State laws governing the issuer and the small group market.

(c) *Special rules for network plans.* (1) In the case of a health insurance issuer that offers health insurance coverage in the small group market through a network plan, the issuer may—

(i) Limit the employers that may apply for the coverage to those with eligible individuals who live, work, or reside in the service area for the network plan; and

(ii) Within the service area of the plan, deny coverage to employers if the issuer has demonstrated to the applicable State authority (if required by the State authority) that—

(A) It will not have the capacity to deliver services adequately to enrollees of any additional groups because of its obligations to existing group contract holders and enrollees; and

(B) It is applying this paragraph (c)(1) uniformly to all employers without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies health insurance coverage to an employer in any service area, in accordance with paragraph (c)(1)(ii) of this section, may not offer coverage in the small group market within the service area to any employer for a period of 180 days after the date the coverage is denied. This paragraph (c)(2) does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(3) Coverage offered within a service area after the 180-day period specified in paragraph (c)(2) of this section is subject to the requirements of this section.

(d) *Application of financial capacity limits.* (1) A health insurance issuer may deny health insurance coverage in the small group market if the issuer has demonstrated to the applicable State authority (if required by the State authority) that it—

(i) Does not have the financial reserves necessary to underwrite additional coverage; and

(ii) Is applying this paragraph (d)(1) uniformly to all employers in the small group market in the State consistent with applicable State law and without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to those employees and dependents.

(2) An issuer that denies group health insurance coverage to any small employer in a State under paragraph (d)(1) of this section may not offer coverage in connection with group health plans

in the small group market in the State before the later of the following dates:

(i) The 181st day after the date the issuer denies coverage.

(ii) The date the issuer demonstrates to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage.

(3) Paragraph (d)(2) of this section does not limit the issuer's ability to renew coverage already in force or relieve the issuer of the responsibility to renew that coverage.

(4) Coverage offered after the 180-day period specified in paragraph (d)(2) of this section is subject to the requirements of this section.

(5) An applicable State authority may provide for the application of this paragraph (d) on a service-area-specific basis.

(e) *Exception to requirement for failure to meet certain minimum participation or contribution rules.* (1) Paragraph (a) of this section does not preclude a health insurance issuer from establishing employer contribution rules or group participation rules for the offering of health insurance coverage in connection with a group health plan in the small group market, as allowed under applicable State law.

(2) For purposes of paragraph (e)(1) of this section—

(i) The term ''employer contribution rule'' means a requirement relating to the minimum level or amount of employer contribution toward the premium for enrollment of participants and beneficiaries; and

(ii) The term ''group participation rule'' means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

(f) *Exception for coverage offered only to bona fide association members.* Paragraph (a) of this section does not apply to health insurance coverage offered by a health insurance issuer if that coverage is made available in the small group market only through one or more bona fide associations (as defined in 45 CFR 144.103).

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§ 146.152 Guaranteed renewability of coverage for employers in the group market.

(a) *General rule.* Subject to paragraphs (b) through (d) of this section, a health insurance issuer offering health insurance coverage in the small or large group market is required to renew or continue in force the coverage at the option of the plan sponsor.

(b) *Exceptions.* An issuer may nonrenew or discontinue group health insurance coverage offered in the small or large group market based only on one or more of the following:

(1) *Nonpayment of premiums.* The plan sponsor has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud.* The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact in connection with the coverage.

(3) *Violation of participation or contribution rules.* The plan sponsor has failed to comply with a material plan provision relating to any employer contribution or group participation rules permitted under § 146.150(e) in the case of the small group market or under applicable State law in the case of the large group market.

(4) *Termination of plan.* The issuer is ceasing to offer coverage in the market in accordance with paragraphs (c) and (d) of this section and applicable State law.

(5) *Enrollees' movement outside service area.* For network plans, there is no longer any enrollee under the group health plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business); and in the case of the small group market, the issuer applies the same criteria it would apply in denying enrollment in the plan under § 146.150(c).

(6) *Association membership ceases.* For coverage made available in the small or large group market only through one or more bona fide associations, if the employer's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor relating to any covered individual.

(c) *Discontinuing a particular product.* In any case in which an issuer decides to discontinue offering a particular product offered in the small or large group market, that product may be discontinued by the issuer in accordance with applicable State law in the particular market only if—

(1) The issuer provides notice in writing to each plan sponsor provided that particular product in that market (and to all participants and beneficiaries covered under such coverage) of the discontinuation at least 90 days before the date the coverage will be discontinued;

(2) The issuer offers to each plan sponsor provided that particular product the option, on a guaranteed issue basis, to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in that market; and

(3) In exercising the option to discontinue that product and in offering the option of coverage under paragraph (c)(2) of this section, the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(d) *Discontinuing all coverage.* An issuer may elect to discontinue offering all health insurance coverage in the small or large group market or both markets in a State in accordance with applicable State law only if—

(1) The issuer provides notice in writing to the applicable State authority and to each plan sponsor (and all participants and beneficiaries covered under the coverage) of the discontinuation at least 180 days prior to the date the coverage will be discontinued; and

(2) All health insurance policies issued or delivered for issuance in the State in the market (or markets) are discontinued and not renewed.

(e) *Prohibition on market reentry.* An issuer who elects to discontinue offering all health insurance coverage in a market (or markets) in a State as described in paragraph (d) of this section may not issue coverage in the market (or markets) and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(f) *Exception for uniform modification of coverage.* Only at the time of coverage renewal may issuers modify the health insurance coverage for a product offered to a group health plan in the—

(1) Large group market; and

(2) Small group market if, for coverage available in this market (other than only through one or more bona fide associations), the modification is consistent with State law and is effective uniformly among group health plans with that product.

(g) *Application to coverage offered only through associations.* In the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, the reference to ''plan sponsor'' is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

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§ 146.160 Disclosure of information.

(a) *General rule.* In connection with the offering of any health insurance coverage to a small employer, a health insurance issuer is required to—

(1) Make a reasonable disclosure to the employer, as part of its solicitation and sales materials, of the availability of information described in paragraph (b) of this section; and

(2) Upon request of the employer, provide that information to the employer.

(b) *Information described.* Subject to paragraph (d) of this section, information that must be provided under paragraph (a)(2) of this section is information concerning the following:

(1) Provisions of coverage relating to the following:

(i) The issuer's right to change premium rates and the factors that may affect changes in premium rates.

(ii) Renewability of coverage.

(iii) Any preexisting condition exclusion, including use of the alternative method of counting creditable coverage.

(iv) Any affiliation periods applied by HMOs.

(v) The geographic areas served by HMOs.

(2) The benefits and premiums available under all health insurance coverage for which the employer is qualified, under applicable State law. See §146.150(b) through (f) for allowable limitations on product availability.

(c) *Form of information.* The information must be described in language that is understandable by the average small employer, with a level of detail that is sufficient to reasonably inform small employers of their rights and obligations under the health insurance coverage. This requirement is satisfied if the issuer provides each of the following with respect to each product offered:

(1) An outline of coverage. For purposes of this section, outline of coverage means a description of benefits in summary form.

(2) The rate or rating schedule that applies to the product (with and without the preexisting condition exclusion or affiliation period).

(3) The minimum employer contribution and group participation rules that apply to any particular type of coverage.

(4) In the case of a network plan, a map or listing of counties served.

(5) Any other information required by the State.

(d) *Exception.* An issuer is not required to disclose any information that is proprietary and trade secret information under applicable law.

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[62 FR 16958, Apr. 8, 1997, as amended at 62 FR 35906, July 2, 1997]

Subpart F—Exclusion of Plans and Enforcement

§ 146.180 Treatment of non-Federal governmental plans.

(a) *Requirements subject to exemption*—(1) *Basic rule.* A sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent that the plan is not provided through health insurance coverage, (that is, it is self-funded), from any or all of the following requirements:

(i) Limitations on preexisting condition exclusion periods described in §146.111.

(ii) Special enrollment periods for individuals and dependents described in §146.117.

(iii) Prohibitions against discriminating against individual participants and beneficiaries based on health status described in §146.121, except that the sponsor of a self-funded non-Federal governmental plan cannot elect to exempt its plan from the requirements in §146.121(a)(1)(vi) and §146.122 that prohibit discrimination with respect to genetic information.

(iv) Standards relating to benefits for mothers and newborns described in §146.130.

(v) Parity in the application of certain limits to mental health benefits described in §146.136.

(vi) Required coverage for reconstructive surgery and certain other services following a mastectomy under section 2706 of the PHS Act.

(2) *Limitations.* (i) An election under this section cannot circumvent a requirement of this part to the extent the requirement applied to the plan before the effective date of the election.

(A) *Example 1.* A plan is subject to requirements of section 2706 of the PHS Act, under which a plan that covers medical and surgical benefits with respect to a mastectomy must cover reconstructive surgery and certain other services following a mastectomy. An

enrollee who has had a mastectomy receives reconstructive surgery on August 24. Claims with respect to the surgery are submitted to and processed by the plan in September. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from section 2706 of the PHS Act. The plan cannot, on the basis of its exemption election, decline to pay for the claims incurred on August 24.

(B) *Example 2.* An individual is hired by a non-Federal governmental employer and reports to work on August 6. The individual has diabetes. Under the terms of the plan in effect on August 6, if an individual files an enrollment application within the first 30 days of employment, enrollment in the plan is effective as of the first day of employment. The individual timely files an enrollment application. The application is processed on September 10. The group health plan commences a new plan year each September 1. Effective September 1, the plan sponsor elects to exempt its plan from §146.121, which prohibits enrollment discrimination based on health status-related factors, by requiring new enrollees to pass medical underwriting. The plan cannot decline to enroll the individual effective August 6, even if he would not pass medical underwriting under the terms of the plan in effect on September 1.

(ii) If a group health plan is co-sponsored by two or more employers, then only plan enrollees of the non-Federal governmental employer(s) with a valid election under this section are affected by the election.

(3) *Stop-loss or excess risk coverage.* For purposes of this section. (i) Subject to paragraph (a)(3)(ii), the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

(ii) Regardless of whether coverage offered by an issuer is designated as ''stop-loss'' coverage or ''excess risk'' coverage, if it is regulated as group health insurance under an applicable State law, then for purposes of this section, a non-Federal governmental plan that purchases the coverage is considered to be fully insured. In that event, a plan may not be exempted under this section from the requirements of this part.

(4) *Construction.* Nothing in this part should be construed as imposing collective bargaining obligations on any party to the collective bargaining process.

(b) *Form and manner of election*—(1) *Election requirements.* The election must meet the following requirements:

(i) Be made in writing.

(ii) Be made in conformance with all of the plan sponsor's rules, including any public hearing requirements.

(iii) Specify the beginning and ending dates of the period to which the election is to apply. This period can be either of the following periods:

(A) A single specified plan year, as defined in §144.103 of this subchapter.

(B) The ''term of the agreement,'' as specified in paragraph (b)(2) of this section, in the case of a plan governed by collective bargaining.

(iv) Specify the name of the plan and the name and address of the plan administrator, and include the name and telephone number of a person CMS may contact regarding the election.

(v) State that the plan does not include health insurance coverage, or identify which portion of the plan is not funded through health insurance coverage.

(vi) Specify each requirement described in paragraph (a) of this section from which the plan sponsor elects to exempt the plan.

(vii) Certify that the person signing the election document, including (if applicable) a third party plan administrator, is legally authorized to do so by the plan sponsor.

(viii) Include, as an attachment, a copy of the notice described in paragraph (f) of this section.

(2) *''Term of the agreement'' defined.* Except as provided in paragraphs (b)(2)(i) and (b)(2)(ii), for purposes of this section ''term of the agreement'' means all group health plan years governed by a single collective bargaining agreement.

(i) In the case of a group health plan for which the last plan year governed by a prior collective bargaining agreement expires during the bargaining process for a new agreement, the term

of the prior agreement includes all plan years governed by the agreement plus the period of time that precedes the latest of the following dates, as applicable, with respect to the new agreement:

(A) The date of an agreement between the governmental employer and union officials.

(B) The date of ratification of an agreement between the governmental employer and the union.

(C) The date impasse resolution, arbitration or other closure of the collective bargaining process is finalized when agreement is not reached.

(ii) In the case of a group health plan governed by a collective bargaining agreement for which closure is not reached before the last plan year under the immediately preceding agreement expires, the term of the new agreement includes all plan years governed by the agreement excluding the period that precedes the latest applicable date specified in paragraph (b)(2)(i) of this section.

(3) *Construction*—(i) *Dispute resolution.* Nothing in paragraph (b)(1)(ii) of this section should be construed to mean that CMS arbitrates disputes between plan sponsors, participants, beneficiaries, or their representatives regarding whether an election complies with all of a plan sponsor's rules.

(ii) *Future elections not preempted.* If a plan must comply with one or more requirements of this part for a given plan year or period of plan coverage, nothing in this section should be construed as preventing a plan sponsor from submitting an election in accordance with this section for a subsequent plan year or period of plan coverage.

(c) *Mailing address.* The plan sponsor should mail the election to: Centers for Medicare & Medicaid Services, Private Health Insurance Group, CMSO, 7500 Security Boulevard, S3–16–16, Baltimore, MD 21244–1850.

(d) *Filing a timely election*—(1) *Plan not governed by collective bargaining.* Subject to paragraph (d)(4) of this section, if a plan is not governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the plan year.

(2) *Plan governed by a collective bargaining agreement.* Subject to paragraph (d)(4) of this section, if a plan is governed by a collective bargaining agreement, a plan sponsor or entity acting on behalf of a plan sponsor must file an election with CMS before the first day of the first plan year governed by a collective bargaining agreement, or by the 45th day after the latest applicable date specified in paragraph (b)(2)(i) of this section, if the 45th day falls on or after the first day of the plan year.

(3) *Verifying timely filing.* CMS uses the postmark on the envelope in which the election is submitted to determine that the election is timely filed as specified under paragraphs (d)(1) or (d)(2) of this section, as applicable. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(4) *Filing extension based on good cause.* CMS may extend the deadlines specified in paragraphs (d)(1) and (d)(2) of this section for good cause if the plan substantially complies with the requirements of paragraph (f) of this section.

(5) *Failure to file a timely election.* Absent an extension under paragraph (d)(4) of this section, a plan sponsor's failure to file a timely election under paragraph (d)(1) or (d)(2) of this section makes the plan subject to all requirements of this part for the entire plan year to which the election would have applied, or, in the case of a plan governed by a collective bargaining agreement, for any plan years under the agreement for which the election is not timely filed.

(e) *Additional information required*—(1) *Written notification.* If an election is timely filed, but CMS determines that the election document (or the notice to plan enrollees) does not meet all of the requirements of this section, CMS may notify the plan sponsor, or other entity that filed the election, that it must submit any additional information that CMS has determined is necessary to meet those requirements. The additional information must be filed with CMS by the later of the following dates:

(i) The last day of the plan year.

(ii) The 45th day after the date of CMS's written notification requesting additional information.

(2) *Timely response.* CMS uses the postmark on the envelope in which the additional information is submitted to determine that the information is timely filed as specified under paragraph (e)(1) of this section. If the latest filing date falls on a Saturday, Sunday, or a State or Federal holiday, CMS accepts a postmark on the next business day.

(3) *Failure to respond timely.* CMS may invalidate an election if the plan sponsor, or other entity that filed the election, fails to timely submit the additional information as specified under paragraph (e)(1) of this section.

(f) *Notice to enrollees*—(1) *Mandatory notification.* (i) A plan that makes the election described in this section must notify each affected enrollee of the election, and explain the consequences of the election. For purposes of this paragraph (f), if the dependent(s) of a participant reside(s) with the participant, a plan need only provide notice to the participant.

(ii) The notice must be in writing and, except as provided in paragraph (f)(2) of this section with regard to initial notices, must be provided to each enrollee at the time of enrollment under the plan, and on an annual basis no later than the last day of each plan year (as defined in §144.103 of this subchapter) for which there is an election.

(iii) A plan may meet the notification requirements of this paragraph (f) by prominently printing the notice in a summary plan description, or equivalent description, that it provides to each enrollee at the time of enrollment, and annually. Also, when a plan provides a notice to an enrollee at the time of enrollment, that notice may serve as the initial annual notice for that enrollee.

(2) *Initial notices.* (i) If a plan is not governed by a collective bargaining agreement, with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of that plan year, and notice at the time of enrollment to all individuals who enroll during that plan year.

(ii) In the case of a collectively bargained plan (including a self-funded non-Federal governmental plan that has been exempted from requirements of this part under §146.125(a)(2)), with regard to the initial plan year to which an election under this section applies, the plan must provide the initial annual notice of the election to all enrollees before the first day of the plan year, or within 30 days after the latest applicable date specified in paragraph (b)(2)(i) of this section if the 30th day falls on or after the first day of the plan year. Also, the plan must provide a notice at the time of enrollment to individuals who—

(A) Enroll on or after the first day of the plan year, when closure of the collective bargaining process is reached before the plan year begins; or

(B) Enroll on or after the latest applicable date specified in paragraph (b)(2)(i) of this section if that date falls on or after the first day of the plan year.

(3) *Notice content.* The notice must include at least the following information:

(i) The specific requirements described in paragraph (a)(1) of this section from which the plan sponsor is electing to exempt the plan, and a statement that, in general, Federal law imposes these requirements upon group health plans.

(ii) A statement that Federal law gives the plan sponsor of a self-funded non-Federal governmental plan the right to exempt the plan in whole, or in part, from the listed requirements, and that the plan sponsor has elected to do so.

(iii) A statement identifying which parts of the plan are subject to the election.

(iv) A statement identifying which of the listed requirements, if any, apply under the terms of the plan, or as required by State law, without regard to an exemption under this section.

(v) A statement informing plan enrollees that the plan provides for certification and disclosure of creditable coverage for covered employees and their dependents who lose coverage under the plan.

(g) *Subsequent elections*—(1) *Election renewal.* A plan sponsor may renew an

election under this section through subsequent elections. The timeliness standards described in paragraph (d) apply to election renewals under this paragraph (g).

(2) *Form and manner of renewal.* Except for the requirement to forward to CMS a copy of the notice to enrollees under paragraph (b)(1)(viii) of this section, the plan sponsor must comply with the election requirements of paragraph (b)(1) of this section. In lieu of providing a copy of the notice under (b)(1)(viii), the plan sponsor may include a statement that the notice has been, or will be, provided to enrollees as specified under paragraph (f) of this section.

(3) *Election renewal includes provisions from which plan not previously exempted.* If an election renewal includes a requirement described in paragraph (a) of this section from which the plan sponsor did not elect to exempt the plan for the preceding plan year, the advance notification requirements of paragraph (f)(2) of this section apply with respect to the additional requirement(s) of paragraph (a) from which the plan sponsor is electing to exempt the plan.

(4) *Special rules regarding renewal of an election under a collective bargaining agreement.* (i) If protracted negotiations with respect to a new agreement result in an extension of the term of the prior agreement (as provided under paragraph (b)(2)(i)) under which an election under this section was in effect, the plan must comply with the enrollee notification requirements of paragraph (f)(1), and, following closure of the collective bargaining process, must file an election renewal with CMS as provided under paragraph (d)(2) of this section.

(ii) If a single plan applies to more than one bargaining unit, and the plan is governed by collective bargaining agreements of varying lengths, paragraph (d)(2) of this section, with respect to an election renewal, applies to the plan as governed by the agreement that results in the earliest filing date.

(h) *Requirements not subject to exemption.*

(1) *Certification and disclosure of creditable coverage.* Without regard to an election under this section, a non-Federal governmental plan must provide for certification and disclosure of creditable coverage under the plan with respect to participants and their dependents as specified under §146.115 of this part.

(2) *Genetic information.* Without regard to an election under this section that exempts a non-Federal governmental plan from any or all of the provisions of §146.111 and §146.121 of this part, the exemption election must not be construed to exempt the plan from any provisions of this part 146 that pertain to genetic information.

(3) *Enforcement.* CMS enforces these requirements as provided under paragraph (k) of this section.

(4) *Examples.*

(i)

Example 1. (A) Individual *A* is hired by a county that has elected to exempt its self-funded group health plan from certain requirements of paragraph (a)(1) of this section, including prohibitions against enrollment discrimination based on health status-related factors. Individual *A* applies for enrollment in the county's group health plan. Applicants must pass medical underwriting before being allowed to enroll in the plan. The plan requires an applicant to complete a medical history form and to authorize the plan to contact physicians regarding any medical treatments the applicant has received in the past 5 years. Individual *A* has Type 2 diabetes. He submits the required form, which reflects that condition. The plan also receives information from Individual *A*'s physicians. While the plan's request to Individual *A's* physicians did not include a request for genetic information, the plan received information from a physician in response to its request for health information about Individual *A*, that one of Individual *A*'s parents has Huntington's Disease. The Plan denies enrollment to Individual *A*.

(B) Individual *A* files a complaint with CMS that he has been denied enrollment in the plan because of genetic information the plan received. CMS investigates the complaint and determines that the plan uniformly denies enrollment to anyone who has Type II diabetes. CMS resolves the complaint in favor of the plan on the basis that the plan permissibly denied enrollment to Individual *A* under its exemption election because of the existence of a medical condition that uniformly disqualifies individuals from participating in the plan.

(ii)

Example 2. (A) Same facts as in *Example 1*, except Individual *A* does not have diabetes or any other preexisting medical condition; that is, there is no manifestation of a disease

or disorder with respect to Individual *A* at the time of his application for enrollment in the county's group health plan.

(B) In these circumstances, CMS resolves the complaint in favor of Individual *A* because CMS determines that the plan impermissibly denied enrollment to Individual *A* on the basis of genetic information. CMS instructs the plan to permit Individual *A* to enroll in the plan retroactive to the earliest date coverage would be effective under the terms of the plan based on the date of Individual *A*'s enrollment application or hire, as applicable. CMS may impose a civil money penalty, as determined under subpart C of part 150.

(i) *Effect of failure to comply with certification and notification requirements*—(1) *Substantial failure.* (i) *General rule.* Except as provided in paragraph (i)(1)(iii) of this section, a substantial failure to comply with paragraphs (f) or (h)(1) of this section results in the invalidation of an election under this section with respect to all plan enrollees for the entire plan year. That is, the plan is subject to all requirements of this part for the entire plan year to which the election otherwise would have applied.

(ii) *Determination of substantial failure.* CMS determines whether a plan has substantially failed to comply with a requirement of paragraph (f) or paragraph (h)(1) of this section based on all relevant facts and circumstances, including previous record of compliance, gravity of the violation and whether a plan corrects the failure, as warranted, within 30 days of learning of the violation. However, in general, a plan's failure to provide a notice of the fact and consequences of an election under this section to an individual at the time of enrollment, or on an annual basis before a given plan year expires, constitutes a substantial failure.

(iii) *Exceptions*—(A) *Multiple employers.* If the plan is sponsored by multiple employers, and only certain employers substantially fail to comply with the requirements of paragraphs (f) or (h)(1) of this section, then the election is invalidated with respect to those employers only, and not with respect to other employers that complied with those requirements, unless the plan chooses to cancel its election entirely.

(B) *Limited failure to provide notice.* If a substantial failure to notify enrollees of the fact and consequences of an election is limited to certain individuals, the election under this section is valid only if, for the plan year with respect to which the failure has occurred, the plan agrees not to apply the election with respect to the individuals who were not notified and so informs those individuals in writing.

(2) *Examples.* (i) *Example 1:* A self-funded non-Federal group health plan is co-sponsored by 10 school districts. Nine of the school districts have fully complied with the requirements of paragraph (f) of this section, including providing notice to new employees at the time of their enrollment in the plan, regarding the group health plan's exemption under this section from requirements of this part. One school district, which hired 10 new teachers during the summer for the upcoming school year, neglected to notify three of the new hires about the group health plan's exemption election at the time they enrolled in the plan. The school district has substantially failed to comply with a requirement of paragraph (f) with respect to these individuals.

The school district learned of the oversight six weeks into the school year, and promptly (within 30 days of learning of the oversight) provided notice to the three teachers regarding the plan's exemption under this section and that the exemption does not apply to them, or their dependents, during the plan year of their enrollment because of the plan's failure to timely notify them of its exemption. The plan complies with the requirements of this part for these individuals for the plan year of their enrollment. CMS would not require the plan to come into compliance with the requirements of this part for other enrollees.

(ii) *Example 2:* Same facts as in Example 1, except the noncompliant school district failed to notify any enrollees regarding an election under this section. That is, the school district failed to provide the annual notice to current plan enrollees as well as the notice at the time of enrollment to new enrollees. The school district has substantially failed to comply with the requirements of paragraph (f) of this section. At a minimum, the election is invalidated with respect to all enrollees

of the noncompliant school district for the plan year for which the substantial failure has occurred. In this example, the plan decides not to cancel its election entirely. The election with regard to the other nine school districts remains in effect.

(iii) *Example 3.* Two non-Federal governmental employers cosponsor a self-funded group health plan. One employer substantially fails to comply with the requirements of paragraph (f) of this section. While the plan may limit the invalidation of the election to enrollees of the plan sponsor that is responsible for the substantial failure, the plan sponsors determine that administering the plan in that manner would be too burdensome. Accordingly, in this example, the plan sponsors choose to cancel the election entirely. Both plan sponsors come into compliance with the requirements of this part with respect to all enrollees for the plan year for which the substantial failure has occurred.

(iv) *Example 4:* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from certain requirements of this part. The collective bargaining agreement applies to five plan years, 2001 through 2005. For the first three plan years, enrollees are notified annually and at the time of enrollment of the election under this section. The notice specifies that the election applies to the period January 1, 2001 through December 31, 2005. Prior to the dissemination of the annual notice for the 2004 plan year, the individual responsible for disseminating the notice terminates employment. His replacement, who is unaware of the requirement that plan enrollees be notified annually, continues to notify new enrollees at the time of enrollment but fails to disseminate the annual notice. CMS does not consider that failure to be a substantial failure because enrollees previously had actual notice that the election under this section applies for the period January 1, 2001 through December 31, 2005. Accordingly, CMS would not invalidate the election for the 2004 plan year.

(v) *Example 5:* A non-Federal governmental employer has elected to exempt its self-funded plan from certain requirements of this part. An individual terminates employment with the governmental employer, which fails to automatically provide a certificate of creditable coverage within the period specified in §146.115(a)(2)(ii)(A). (The governmental employer generally provides certificates to terminated employees on an automatic basis, but neglected to do so in this case.) The oversight is brought to the employer's attention when the individual inquires as to why he has not received his certificate of creditable coverage. The governmental employer promptly (within 30 days) forwards a certificate to the individual. CMS would not view that situation as constituting a substantial failure and would not invalidate the election under this section.

(j) *Election invalidated.* If CMS finds cause to invalidate an election under this section, the following rules apply:

(1) CMS notifies the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) in writing that CMS has made a preliminary determination that an election is invalid, and states the basis for that determination.

(2) CMS's notice informs the plan sponsor that it has 45 days after the date of CMS's notice to explain in writing why it believes its election is valid. The plan sponsor should provide applicable statutory and regulatory citations to support its position.

(3) CMS verifies that the plan sponsor's response is timely filed as provided under paragraph (d)(3) of this section. CMS will not consider a response that is not timely filed.

(4) If CMS's preliminary determination that an election is invalid remains unchanged after CMS considers the plan sponsor's timely response (or in the event that the plan sponsor fails to respond timely), CMS provides written notice to the plan sponsor (and the plan administrator if other than the plan sponsor and the administrator's address is known to CMS) of CMS's final determination that the election is invalid. Also, CMS informs the plan sponsor that, within 45 days of the date of the notice of final determination, the plan, subject to paragraph (i)(1)(iii) of this section, must comply with all

requirements of this part for the specified period for which CMS has determined the election to be invalid.

(k) *Enforcement*. To the extent that an election under this section has not been filed or a non-Federal governmental plan otherwise is subject to one or more requirements of this part, CMS enforces those requirements under part 150 of this subchapter. This may include imposing a civil money penalty against the plan or plan sponsor, as determined under subpart C of part 150.

(l) *Construction*. Nothing in this section should be construed to prevent a State from taking the following actions:

(1) Establishing, and enforcing compliance with, the requirements of State law (as defined in § 146.143(d)(1)), including requirements that parallel provisions of title XXVII of the PHS Act, that apply to non-Federal governmental plans or sponsors.

(2) Prohibiting a sponsor of a non-Federal governmental plan within the State from making an election under this section.

[67 FR 48811, July 26, 2002, as amended at 74 FR 51693, Oct. 7, 2009]

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

Sec.

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AUTHORITY: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

SOURCE: 75 FR 27138, May 13, 2010, unless otherwise noted.

§ 147.100 Basis and scope.

Part 147 of this subchapter implements the requirements of the Patient Protection and Affordable Care Act that apply to group health plans and health insurance issuers in the Group and Individual markets.

§ 147.108 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions*—(1) *In general*. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 144.103).

(2) *Examples*. The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, *see* § 146.111(a)(1)(ii)):

Example 1. (i) *Facts*. A group health plan provides benefits solely through an insurance policy offered by Issuer *P*. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N*. *N*'s policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion*. In this *Example 1*, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) *Facts*. Individual *C* applies for individual health insurance coverage with Issuer *M*. *M* denies *C*'s application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion*. In this *Example 2*, *M*'s denial of *C*'s application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) *Applicability*—(1) *General applicability date*. Except as provided in paragraph (b)(2) of this section, the rules of this section apply for plan years beginning on or after January 1, 2014; in the case of individual health insurance coverage, for policy years beginning, or

applications denied, on or after January 1, 2014.

(2) *Early applicability date for children.* The rules of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010; in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) *Applicability to grandfathered health plans. See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704).

(4) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *F* commences employment and enrolls *F* and *F*'s 16-year-old child in the group health plan maintained by *F*'s employer, with a first day of coverage of October 15, 2010. *F*'s child had a significant break in coverage because of a lapse of more than 63 days without creditable coverage immediately prior to enrolling in the plan. *F*'s child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) *Conclusion.* In this *Example 1,* the plan year beginning January 1, 2011, is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) *Facts.* Individual *G* applies for a policy of family coverage in the individual market for *G*, *G*'s spouse, and *G*'s 13-year-old child. The issuer denies the application for coverage on March 1, 2011 because *G*'s 13-year-old child has autism.

(ii) *Conclusion.* In this *Example 2,* the issuer's denial of *G*'s application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the child is under 19 years of age and the March 1, 2011, denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to *G*'s 13-year-old child.

[75 FR 37235, June 28, 2010]

§ 147.120 Eligibility of children until at least age 26.

(a) *In general*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, that makes available dependent coverage of children must make such coverage available for children until attainment of 26 years of age.

(2) The rule of this paragraph (a) is illustrated by the following example:

Example. (i) *Facts.* For the plan year beginning January 1, 2011, a group health plan provides health coverage for employees, employees' spouses, and employees' children until the child turns 26. On the birthday of a child of an employee, July 17, 2011, the child turns 26. The last day the plan covers the child is July 16, 2011.

(ii) *Conclusion.* In this *Example,* the plan satisfies the requirement of this paragraph (a) with respect to the child.

(b) *Restrictions on plan definition of dependent.* With respect to a child who has not attained age 26, a plan or issuer may not define dependent for purposes of eligibility for dependent coverage of children other than in terms of a relationship between a child and the participant (in the individual market, the primary subscriber). Thus, for example, a plan or issuer may not deny or restrict coverage for a child who has not attained age 26 based on the presence or absence of the child's financial dependency (upon the participant or primary subscriber, or any other person), residency with the participant (in the individual market, the primary subscriber) or with any other person, student status, employment, or any combination of those factors. In addition, a plan or issuer may not deny or restrict coverage of a child based on eligibility for other coverage, except that paragraph (g) of this section provides a special rule for plan years beginning before January 1, 2014 for grandfathered health plans that are group health

plans. (Other requirements of Federal or State law, including section 609 of ERISA or section 1908 of the Social Security Act, may mandate coverage of certain children.)

(c) *Coverage of grandchildren not required.* Nothing in this section requires a plan or issuer to make coverage available for the child of a child receiving dependent coverage.

(d) *Uniformity irrespective of age.* The terms of the plan or health insurance coverage providing dependent coverage of children cannot vary based on age (except for children who are age 26 or older).

(e) *Examples.* The rules of paragraph (d) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan offers a choice of self-only or family health coverage. Dependent coverage is provided under family health coverage for children of participants who have not attained age 26. The plan imposes an additional premium surcharge for children who are older than age 18.

(ii) *Conclusion.* In this *Example 1,* the plan violates the requirement of paragraph (d) of this section because the plan varies the terms for dependent coverage of children based on age.

Example 2. (i) *Facts.* A group health plan offers a choice among the following tiers of health coverage: Self-only, self-plus-one, self-plus-two, and self-plus-three-or-more. The cost of coverage increases based on the number of covered individuals. The plan provides dependent coverage of children who have not attained age 26.

(ii) *Conclusion.* In this *Example 2,* the plan does not violate the requirement of paragraph (d) of this section that the terms of dependent coverage for children not vary based on age. Although the cost of coverage increases for tiers with more covered individuals, the increase applies without regard to the age of any child.

Example 3. (i) *Facts.* A group health plan offers two benefit packages—an HMO option and an indemnity option. Dependent coverage is provided for children of participants who have not attained age 26. The plan limits children who are older than age 18 to the HMO option.

(ii) *Conclusion.* In this *Example 3,* the plan violates the requirement of paragraph (d) of this section because the plan, by limiting children who are older than age 18 to the HMO option, varies the terms for dependent coverage of children based on age.

(f) *Transitional rules for individuals whose coverage ended by reason of reaching a dependent eligibility threshold*—(1) *In general.* The relief provided in the transitional rules of this paragraph (f) applies with respect to any child—

(i) Whose coverage ended, or who was denied coverage (or was not eligible for coverage) under a group health plan or group or individual health insurance coverage because, under the terms of the plan or coverage, the availability of dependent coverage of children ended before the attainment of age 26 (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for coverage under a group health plan or group or individual health insurance coverage on the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010 by reason of the application of this section.

(2) *Opportunity to enroll required*—(i) If a group health plan, or group or individual health insurance coverage, in which a child described in paragraph (f)(1) of this section is eligible to enroll (or is required to become eligible to enroll) is the plan or coverage in which the child's coverage ended (or did not begin) for the reasons described in paragraph (f)(1)(i) of this section, and if the plan, or the issuer of such coverage, is subject to the requirements of this section, the plan and the issuer are required to give the child an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). This opportunity (including the written notice) must be provided beginning not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(ii) The written notice must include a statement that children whose coverage ended, or who were denied coverage (or were not eligible for coverage), because the availability of dependent coverage of children ended before attainment of age 26 are eligible to enroll in the plan or coverage. The notice may be provided to an employee on behalf of the employee's child (in the individual market, to the primary subscriber on behalf of the primary subscriber's child). In addition, for a group

health plan or group health insurance coverage, the notice may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (f)(2) is provided to an employee whose child is entitled to an enrollment opportunity under this paragraph (f), the obligation to provide the notice of enrollment opportunity under this paragraph (f)(2) with respect to that child is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (f)(2) of this section, coverage must take effect not later than the first day of the first plan year (in the individual market, the first day of the first policy year) beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* For purposes of this Part, any child enrolling in a group health plan pursuant to paragraph (f)(2) of this section must be treated as if the child were a special enrollee, as provided under the rules of 45 CFR 146.117(d). Accordingly, the child (and, if the child would not be a participant once enrolled in the plan, the participant through whom the child is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of cessation of dependent status. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The child also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of cessation of dependent status.

(5) *Examples.* The rules of this paragraph (f) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *Y* maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For the 2010 plan year, the plan allows children of employees to be covered under the plan until age 19, or until age 23 for children who are full-time students. Individual *B*, an employee of *Y*, and Individual *C*, *B*'s child and a full-time student, were enrolled in *Y*'s group health plan at the beginning of the 2010 plan year. On June 10, 2010, *C* turns 23 years old and loses dependent coverage under *Y*'s plan. On or before January 1, 2011, *Y*'s group health plan gives *B* written notice that individuals who lost coverage by reason of ceasing to be a dependent before attainment of age 26 are eligible to enroll in the plan, and that individuals may request enrollment for such children through February 14, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan has complied with the requirements of this paragraph (f) by providing an enrollment opportunity to *C* that lasts at least 30 days.

Example 2. (i) *Facts.* Employer *Z* maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan allows children of employees to be covered under the plan until age 22. Individual *D*, an employee of *Z*, and Individual *E*, *D*'s child, are enrolled in family coverage under *Z*'s group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, *E* turns 22 years old and ceases to be eligible as a dependent under *Z*'s plan and loses coverage. *D* drops coverage but remains an employee of *Z*.

(ii) *Conclusion.* In this *Example 2*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that *D* did not drop coverage. Instead, *D* switched to a lower-cost benefit package option.

(ii) *Conclusion.* In this *Example 3*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible.

Example 4. (i) *Facts.* Same facts as *Example 2*, except that *E* elected COBRA continuation coverage.

(ii) *Conclusion.* In this *Example 4*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll other than as a COBRA qualified beneficiary (and must provide, by that date, written notice of the opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 5. (i) *Facts.* Employer *X* maintains a group health plan with a calendar year plan year. Prior to 2011, the plan allows children of employees to be covered under the plan until the child attains age 22. During the 2009 plan year, an individual with a 22-year old child joins the plan; the child is denied coverage because the child is 22.

(ii) *Conclusion.* In this *Example 5*, notwithstanding that the child was not previously

covered under the plan, the plan must provide the child, not later than January 1, 2011, an opportunity to enroll (including written notice to the employee of an opportunity to enroll the child) that continues for at least 30 days, with enrollment effective not later than January 1, 2011.

(g) *Special rule for grandfathered group health plans*—(1) For plan years beginning before January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act and that makes available dependent coverage of children may exclude an adult child who has not attained age 26 from coverage only if the adult child is eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a group health plan of a parent.

(2) For plan years beginning on or after January 1, 2014, a group health plan that qualifies as a grandfathered health plan under section 1251 of the Patient Protection and Affordable Care Act must comply with the requirements of paragraphs (a) through (f) of this section.

(h) *Applicability date*. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans.

[75 FR 27138, May 13, 2010, as amended at 75 FR 34566, June 17, 2010]

§ 147.126 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits*. Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) *Annual limits*—(i) *General rule*. Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) *Exception for health flexible spending arrangements*. A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits*. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions*. The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits*. The term ''essential health benefits'' means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) *Restricted annual limits permissible prior to 2014*—(1) *In general*. With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year (in the individual market, policy year) beginning on or after September 23, 2010, but before September 23, 2011, $750,000.

(ii) For a plan year (in the individual market, policy year) beginning on or after September 23, 2011, but before September 23, 2012, $1,250,000.

(iii) For plan years (in the individual market, policy years) beginning on or after September 23, 2012, but before January 1, 2014, $2,000,000.

(2) *Only essential health benefits taken into account.* In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) *Waiver authority of the Secretary.* For plan years (in the individual market, policy years) beginning before January 1, 2014, the Secretary may establish a program under which the requirements of paragraph (d)(1) of this section relating to annual limits may be waived (for such period as is specified by the Secretary) for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under paragraph (d)(1) of this section if compliance with paragraph (d)(1) of this section would result in a significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage.

(e) *Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit*—(1) *In general.* The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits under a group health plan or group or individual health insurance coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a lifetime limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, by reason of the application of this section.

(2) *Notice and enrollment opportunity requirements*—(i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan—or group or individual health insurance coverage—described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual written notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, or if an enrolled individual is eligible for but not enrolled in any benefit package under the plan or health insurance coverage, then the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.

(ii) The notices required under paragraph (e)(2)(i) of this section may be provided to an employee on behalf of the employee's dependent (in the individual market, to the primary subscriber on behalf of the primary subscriber's dependent). In addition, for a group health plan or group health insurance coverage, the notices may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For either notice, with respect to a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an individual, the obligation to provide the notice with respect to that individual is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be

treated as if the individual were a special enrollee, as provided under the rules of § 146.117(d). Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) *Examples*. The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts*. Employer *Y* maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For plan years beginning before September 23, 2010, the plan has a lifetime limit on the dollar value of all benefits. Individual *B*, an employee of *Y*, was enrolled in *Y*'s group health plan at the beginning of the 2008 plan year. On June 10, 2008, *B* incurred a claim for benefits that exceeded the lifetime limit under *Y*'s plan and ceased to be enrolled in the plan. *B* is still eligible for coverage under *Y*'s group health plan. On or before January 1, 2011, *Y*'s group health plan gives *B* written notice informing *B* that the lifetime limit on the dollar value of all benefits no longer applies, that individuals whose coverage ended by reason of reaching a lifetime limit under the plan are eligible to enroll in the plan, and that individuals can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion*. In this *Example 1*, the plan has complied with the requirements of this paragraph (e) by providing a timely written notice and enrollment opportunity to *B* that lasts at least 30 days.

Example 2. (i) *Facts*. Employer *Z* maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual *D*, an employee of *Z*, and Individual *E*, *D*'s child, were enrolled in family coverage under *Z*'s group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, *E* incurred a claim for benefits that exceeded the lifetime limit under *Z*'s plan. *D* dropped family coverage but remains an employee of *Z* and is still eligible for coverage under *Z*'s group health plan.

(ii) *Conclusion*. In this *Example 2*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts*. Same facts as *Example 2*, except that *Z*'s plan had two benefit packages (a low-cost and a high-cost option). Instead of dropping coverage, *D* switched to the low-cost benefit package option.

(ii) *Conclusion*. In this *Example 3*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible. The plan would have to provide *D* and *E* the opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible, even if *D* had not switched to the low-cost benefit package option.

Example 4. (i) *Facts*. Employer *Q* maintains a group health plan with a plan year beginning October 1 and ending September 30. For the plan year beginning on October 1, 2009, *Q* has an annual limit on the dollar value of all benefits of $500,000.

(ii) *Conclusion*. In this *Example 4*, *Q* must raise the annual limit on the dollar value of essential health benefits to at least $750,000 for the plan year beginning October 1, 2010. For the plan year beginning October 1, 2011, *Q* must raise the annual limit to at least $1.25 million. For the plan year beginning October 1, 2012, *Q* must raise the annual limit to at least $2 million. *Q* may also impose a restricted annual limit of $2 million for the plan year beginning October 1, 2013. After the conclusion of that plan year, *Q* cannot impose an overall annual limit.

Example 5. (i) *Facts*. Same facts as *Example 4*, except that the annual limit for the plan year beginning on October 1, 2009, is $1 million and *Q* lowers the annual limit for the plan year beginning October 1, 2010 to $750,000.

(ii) *Conclusion*. In this *Example 5*, *Q* complies with the requirements of this paragraph (e). However, *Q*'s choice to lower its annual limit means that under § 147.140(g)(1)(vi)(C), the group health plan will cease to be a grandfathered health plan and will be generally subject to all of the provisions of PHS Act sections 2701 through 2719A.

Example 6. (i) *Facts*. For a policy year that began on October 1, 2009, Individual *T* has individual health insurance coverage with a lifetime limit on the dollar value of all benefits of $1 million. For the policy year beginning October 1, 2010, the issuer of *T*'s health

insurance coverage eliminates the lifetime limit and replaces it with an annual limit of $1 million dollars. In the policy year beginning October 1, 2011, the issuer of *T*'s health insurance coverage maintains the annual limit of $1 million dollars.

(ii) *Conclusion.* In this *Example 6,* the issuer's replacement of a lifetime limit with an equal dollar annual limit allows it to maintain status as a grandfathered health policy under §147.140(g)(1)(vi)(B). Since grandfathered health plans that are individual health insurance coverage are not subject to the requirements of this section relating to annual limits, the issuer does not have to comply with this paragraph (e).

(f) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* §147.140 of this part for determining the application of this section to grandfathered health plans (providing that the prohibitions on lifetime and annual limits apply to all grandfathered health plans that are group health plans and group health insurance coverage, including the special rules regarding restricted annual limits, and the prohibition on lifetime limits apply to individual health insurance coverage that is a grandfathered health plan but the rules on annual limits do not apply to individual health insurance coverage that is a grandfathered health plan).

[75 FR 37236, June 28, 2010]

§147.128 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if—

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A*'s prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part and part 146. The questionnaire includes the following question: ''Is there anything else relevant to your health that we should know?'' *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A*'s visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion*. In this *Example 1*, the plan cannot rescind *A*'s coverage because *A*'s failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts*. An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B*. After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B*'s coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion*. In this *Example 2*, the plan cannot rescind *B*'s coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements*. Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date*. The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

[75 FR 37238, June 28, 2010]

§ 147.130 Coverage of preventive health services.

(a) *Services*—(1) *In general*. Beginning at the time described in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or deductible) with respect to those items or services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration; and

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration.

(A) In developing the binding health plan coverage guidelines specified in this paragraph (a)(1)(iv), the Health Resources and Services Administration shall be informed by evidence and may establish exemptions from such guidelines with respect to group health plans established or maintained by religious employers and health insurance coverage provided in connection with group health plans established or maintained by religious employers with respect to any requirement to cover contraceptive services under such guidelines.

(B) For purposes of this subsection, a ''religious employer'' is an organization that meets all of the following criteria:

(*1*) The inculcation of religious values is the purpose of the organization.

(*2*) The organization primarily employs persons who share the religious tenets of the organization.

(*3*) The organization serves primarily persons who share the religious tenets of the organization.

(*4*) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from

using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

[75 FR 41759, July 19, 2010; 76 FR 46626, Aug. 3, 2011]

§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 147.140 of this part. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section. Paragraph (g) of this section sets forth the applicability date for this section.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as

any rescission of coverage, as described in §147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) or (b)(3)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision,* as used in paragraph (d) of this section, means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an ''adverse benefit determination'' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular

benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128 of this part.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The plan and issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination

includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes*—(*1*) In the case of a plan or issuer that fails to adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(3) *Requirements for individual health insurance issuers.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of this paragraph (b)(3).

(i) *Minimum internal claims and appeals standards.* A health insurance issuer offering individual health insurance coverage must comply with all

the requirements of the ERISA internal claims and appeals procedures applicable to group health plans under 29 CFR 2560.503–1 except for the requirements with respect to multiemployer plans, and except to the extent those requirements are modified by paragraph (b)(3)(ii) of this section. Accordingly, under this paragraph (b), with respect to individual health insurance coverage, the issuer is subject to the requirements in 29 CFR 2560.503–1 as if the issuer were a group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(3)(i) of this section, the internal claims and appeals processes of a health insurance issuer offering individual health insurance coverage must meet the requirements of this paragraph (b)(3)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(3), an adverse benefit determination includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as other provisions of this paragraph (b)(3), an issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) and any decision to deny coverage in an initial eligibility determination as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of 45 CFR 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the issuer's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the issuer. For purposes of this paragraph (b)(3)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* An issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the issuer (or at the direction of the issuer) in connection with the claim; such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* An issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the name of the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(*2*) The issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes*—(*1*) In the case of an issuer that fails to adhere to all the requirements of this paragraph (b)(3) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(3)(ii)(F)(*2*) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under State law, as applicable, on the basis that the issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim.

(*2*) Notwithstanding paragraph (b)(3)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the issuer demonstrates that the violation was for good cause or due to matters beyond the control of the issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the issuer and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the issuer. The claimant may request a written explanation of the violation from the issuer, and the issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(3)(ii)(F)(*1*) of this section on the basis that the issuer met the standards for the exception under this paragraph (b)(3)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the issuer shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(G) *One level of internal appeal.* Notwithstanding the requirements in 29

CFR §2560.503–1(c)(3), a health insurance issuer offering individual health insurance coverage must provide for only one level of internal appeal before issuing a final determination.

(H) *Recordkeeping requirements.* A health insurance issuer offering individual health insurance coverage must maintain for six years records of all claims and notices associated with the internal claims and appeals process, including the information detailed in paragraph (b)(3)(ii)(E) of this section and any other information specified by the Secretary. An issuer must make such records available for examination by the claimant or State or Federal oversight agency upon request.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* An issuer subject to the requirements of this paragraph (b)(3) is required to provide continued coverage pending the outcome of an appeal. For this purpose, the issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii) as if the issuer were a group health plan, so that the issuer cannot reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group or individual health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement, the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) or (b)(3) of this section), or the claimant has applied for expedited external review at

the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, the State external review process may require a nominal filing fee from the claimant requesting an external review. For this purpose, to be considered nominal, a filing fee must not exceed $25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year (in the individual market, policy year) must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.

(vii) The State process must provide that IROs will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IRO qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to

seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the claimant and the issuer (or, if applicable, the plan) of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes.* (i) Through December 31, 2011, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2011, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) For final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2012, the Federal external review process will apply unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section.

(ii) For final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided after the first day of the first plan year (in the individual market, policy year) beginning on or after July 1, 2011, the Federal external review process will apply unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section as of the first day of the plan year (in the individual market, policy year).

(d) *Federal external review process*—A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan

is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the Federal external review process of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage.

(1) *Scope*—(i) *In general.* Subject to the suspension provision in paragraph (d)(1)(ii) of this section and except to the extent provided otherwise by the Secretary in guidance, the Federal external review process established pursuant to this paragraph (d) applies to any adverse benefit determination or final internal adverse benefit determination (as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section), except that a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan is not eligible for the Federal external review process under this paragraph (d).

(ii) *Suspension of general rule.* Unless or until this suspension is revoked in guidance by the Secretary, with respect to claims for which external review has not been initiated before September 20, 2011, the Federal external review process established pursuant to this paragraph (d) applies only to:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; or its determination that a treatment is experimental or investigational), as determined by the external reviewer; and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(iii) *Examples.* This rules of paragraph (d)(1)(ii) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1,* the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion.* In this *Example 2,* the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review during the suspension period under paragraph (d)(1)(ii) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining

effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) will be similar to the process set forth in the NAIC Uniform Model Act and will meet standards issued by the Secretary. These standards will comply with all of the requirements described in this paragraph (d)(2).

(i) These standards will describe how a claimant initiates an external review, procedures for preliminary reviews to determine whether a claim is eligible for external review, minimum qualifications for IROs, a process for approving IROs eligible to be assigned to conduct external reviews, a process for random assignment of external reviews to approved IROs, standards for IRO decision-making, and rules for providing notice of a final external review decision.

(ii) These standards will provide an expedited external review process for—

(A) An adverse benefit determination, if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under paragraph (b) of this section would seriously jeopardize the life or health of the claimant, or would jeopardize the claimant's ability to regain maximum function and the claimant has filed a request for an expedited internal appeal under paragraph (b) of this section; or

(B) A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review pursuant to paragraph (d)(3) of this section would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay or health care service for which the claimant received emergency services, but has not been discharged from a facility.

(iii) With respect to claims involving experimental or investigational treatments, these standards will also provide additional consumer protections to ensure that adequate clinical and scientific experience and protocols are taken into account as part of the external review process.

(iv) These standards will provide that an external review decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide any benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(v) These standards may establish external review reporting requirements for IROs.

(vi) These standards will establish additional notice requirements for plans and issuers regarding disclosures to participants, beneficiaries, and enrollees describing the Federal external review procedures (including the right to file a request for an external review of an adverse benefit determination or a final internal adverse benefit determination in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees.

(vii) These standards will require plans and issuers to provide information relevant to the processing of the external review, including, but not limited to, the information considered and relied on in making the adverse benefit determination or final internal adverse benefit determination.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group or individual health insurance coverage are considered to provide relevant notices in a

culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements*—(i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) The plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer.

(3) *Applicable non-English language*. With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

(f) *Secretarial authority*. The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date*. The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding internal claims and appeals and external review processes do not apply to grandfathered health plans).

[75 FR 43350, July 23, 2010, as amended at 76 FR 37232, June 24, 2011; 76 FR 44492, July 26, 2011]

§ 147.138 Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general*. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Example*. The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts*. A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion*. In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general*. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician

(allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network.

(ii) *Conclusion.* In this *Example 1,* the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts.* Same facts as *Example 1,* except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2,* the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that *A* seeks gynecological services from *C*, an out-of-network provider.

(ii) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider.

You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope*. If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules*. A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance*. Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency

service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1,* the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2,* by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the

plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: one has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3,* the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) *Facts.* Same facts as *Example 3.* Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4,* the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) *Facts.* Same facts as *Example 4.* An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5,* the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—$116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5.* The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6,* the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize,* with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to grandfathered health plans).

[75 FR 37238, June 28, 2010]

§ 147.140 Preservation of right to maintain existing coverage.

(a) *Definition of grandfathered health plan coverage*—(1) *In general*—(i) *Grandfathered health plan coverage. Grandfathered health plan coverage* means coverage provided by a group health plan, or a group or individual health insurance issuer, in which an individual was enrolled on March 23, 2010 (for as long as it maintains that status under the rules of this section). A group health plan or group health insurance coverage does not cease to be grandfathered health plan coverage merely because one or more (or even all) individuals enrolled on March 23, 2010 cease to be covered, provided that the plan has continuously covered someone since March 23, 2010 (not necessarily the same person, but at all times at least one person). In addition, subject to the limitation set forth in paragraph (a)(1)(ii) of this section, a group health plan (and any health insurance coverage offered in connection with the group health plan) does not cease to be a grandfathered health plan merely because the plan (or its sponsor) enters into a new policy, certificate, or contract of insurance after March 23, 2010 (for example, a plan enters into a contract with a new issuer or a new policy is issued with an existing issuer). For purposes of this section, a plan or health insurance coverage that provides grandfathered health plan coverage is referred to as a grandfathered health plan. The rules of this section apply separately to each benefit package made available under a group health plan or health insurance coverage.

(ii) *Changes in group health insurance coverage.* Subject to paragraphs (f) and (g)(2) of this section, if a group health plan (including a group health plan that was self-insured on March 23, 2010) or its sponsor enters into a new policy, certificate, or contract of insurance after March 23, 2010 that is effective before November 15, 2010, then the plan ceases to be a grandfathered health plan.

(2) *Disclosure of grandfather status*—(i) To maintain status as a grandfathered health plan, a plan or health insurance coverage must include a statement, in any plan materials provided to a participant or beneficiary (in the individual market, primary subscriber) describing the benefits provided under the plan or health insurance coverage, that the plan or coverage believes it is a grandfathered health plan within the meaning of section 1251 of the Patient Protection and Affordable Care Act and must provide contact information for questions and complaints.

(ii) The following model language can be used to satisfy this disclosure requirement:

This [group health plan or health insurance issuer] believes this [plan or coverage] is a ''grandfathered health plan'' under the Patient Protection and Affordable Care Act (the Affordable Care Act). As permitted by the Affordable Care Act, a grandfathered health plan can preserve certain basic health coverage that was already in effect when that law was enacted. Being a grandfathered health plan means that your [plan or policy] may not include certain consumer protections of the Affordable Care Act that apply to other plans, for example, the requirement for the provision of preventive health services without any cost sharing. However, grandfathered health plans must comply with certain other consumer protections in the Affordable Care Act, for example, the elimination of lifetime limits on benefits.

Questions regarding which protections apply and which protections do not apply to a grandfathered health plan and what might cause a plan to change from grandfathered health plan status can be directed to the

plan administrator at [insert contact information]. [For ERISA plans, insert: You may also contact the Employee Benefits Security Administration, U.S. Department of Labor at 1–866–444–3272 or *www.dol.gov/ebsa/healthreform*. This Web site has a table summarizing which protections do and do not apply to grandfathered health plans.] [For individual market policies and nonfederal governmental plans, insert: You may also contact the U.S. Department of Health and Human Services at *www.healthreform.gov*.]

(3)(i) *Documentation of plan or policy terms on March 23, 2010*. To maintain status as a grandfathered health plan, a group health plan, or group or individual health insurance coverage, must, for as long as the plan or health insurance coverage takes the position that it is a grandfathered health plan—

(A) Maintain records documenting the terms of the plan or health insurance coverage in connection with the coverage in effect on March 23, 2010, and any other documents necessary to verify, explain, or clarify its status as a grandfathered health plan; and

(B) Make such records available for examination upon request.

(ii) *Change in group health insurance coverage*. To maintain status as a grandfathered health plan, a group health plan that enters into a new policy, certificate, or contract of insurance must provide to the new health insurance issuer (and the new health insurance issuer must require) documentation of plan terms (including benefits, cost sharing, employer contributions, and annual limits) under the prior health coverage sufficient to determine whether a change causing a cessation of grandfathered health plan status under paragraph (g)(1) of this section has occurred.

(4) *Family members enrolling after March 23, 2010*. With respect to an individual who is enrolled in a group health plan or health insurance coverage on March 23, 2010, grandfathered health plan coverage includes coverage of family members of the individual who enroll after March 23, 2010 in the grandfathered health plan coverage of the individual.

(b) *Allowance for new employees to join current plan*—(1) *In general*. Subject to paragraph (b)(2) of this section, a group health plan (including health insurance coverage provided in connection with the group health plan) that provided coverage on March 23, 2010 and has retained its status as a grandfathered health plan (consistent with the rules of this section, including paragraph (g) of this section) is grandfathered health plan coverage for new employees (whether newly hired or newly enrolled) and their families enrolling in the plan after March 23, 2010.

(2) *Anti-abuse rules*—(i) *Mergers and acquisitions*. If the principal purpose of a merger, acquisition, or similar business restructuring is to cover new individuals under a grandfathered health plan, the plan ceases to be a grandfathered health plan.

(ii) *Change in plan eligibility*. A group health plan or health insurance coverage (including a benefit package under a group health plan) ceases to be a grandfathered health plan if—

(A) Employees are transferred into the plan or health insurance coverage (the transferee plan) from a plan or health insurance coverage under which the employees were covered on March 23, 2010 (the transferor plan);

(B) Comparing the terms of the transferee plan with those of the transferor plan (as in effect on March 23, 2010) and treating the transferee plan as if it were an amendment of the transferor plan would cause a loss of grandfather status under the provisions of paragraph (g)(1) of this section; and

(C) There was no bona fide employment-based reason to transfer the employees into the transferee plan. For this purpose, changing the terms or cost of coverage is not a bona fide employment-based reason.

(3) *Examples*. The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts*. A group health plan offers two benefit packages on March 23, 2010, Options *F* and *G*. During a subsequent open enrollment period, some of the employees enrolled in Option *F* on March 23, 2010 switch to Option *G*.

(ii) *Conclusion*. In this *Example 1*, the group health coverage provided under Option *G* remains a grandfathered health plan under the rules of paragraph (b)(1) of this section because employees previously enrolled in Option *F* are allowed to enroll in Option *G* as new employees.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that the plan sponsor eliminates Option *F* because of its high cost and transfers employees covered under Option *F* to Option *G*. If instead of transferring employees from Option *F* to Option *G*, Option *F* was amended to match the terms of Option *G*, then Option *F* would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 2*, the plan did not have a bona fide employment-based reason to transfer employees from Option *F* to Option *G*. Therefore, Option *G* ceases to be a grandfathered health plan with respect to all employees. (However, any other benefit package maintained by the plan sponsor is analyzed separately under the rules of this section.)

Example 3. (i) *Facts.* A group health plan offers two benefit packages on March 23, 2010, Options *H* and *I*. On March 23, 2010, Option *H* provides coverage only for employees in one manufacturing plant. Subsequently, the plant is closed, and some employees in the closed plant are moved to another plant. The employer eliminates Option *H* and the employees that are moved are transferred to Option *I*. If instead of transferring employees from Option *H* to Option *I*, Option *H* was amended to match the terms of Option *I*, then Option *H* would cease to be a grandfathered health plan.

(ii) *Conclusion.* In this *Example 3*, the plan has a bona fide employment-based reason to transfer employees from Option *H* to Option *I*. Therefore, Option *I* does not cease to be a grandfathered health plan.

(c) *General grandfathering rule*—(1) Except as provided in paragraphs (d) and (e) of this section, subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) do not apply to grandfathered health plan coverage. Accordingly, the provisions of PHS Act sections 2701, 2702, 2703, 2705, 2706, 2707, 2709 (relating to coverage for individuals participating in approved clinical trials, as added by section 10103 of the Patient Protection and Affordable Care Act), 2713, 2715A, 2716, 2717, 2719, and 2719A, as added or amended by the Patient Protection and Affordable Care Act, do not apply to grandfathered health plans. In addition, the provisions of PHS Act section 2704, and PHS Act section 2711 insofar as it relates to annual limits, do not apply to grandfathered health plans that are individual health insurance coverage.

(2) To the extent not inconsistent with the rules applicable to a grandfathered health plan, a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Internal Revenue Code applicable prior to the changes enacted by the Patient Protection and Affordable Care Act.

(d) *Provisions applicable to all grandfathered health plans.* The provisions of PHS Act section 2711 insofar as it relates to lifetime limits, and the provisions of PHS Act sections 2712, 2714, 2715, and 2718, apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The provisions of PHS Act section 2708 apply to grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

(e) *Applicability of PHS Act sections 2704, 2711, and 2714 to grandfathered group health plans and group health insurance coverage*—(1) The provisions of PHS Act section 2704 as it applies with respect to enrollees who are under 19 years of age, and the provisions of PHS Act section 2711 insofar as it relates to annual limits, apply to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after September 23, 2010. The provisions of PHS Act section 2704 apply generally to grandfathered health plans that are group health plans (including group health insurance coverage) for plan years beginning on or after January 1, 2014.

(2) For plan years beginning before January 1, 2014, the provisions of PHS Act section 2714 apply in the case of an adult child with respect to a grandfathered health plan that is a group health plan only if the adult child is not eligible to enroll in an eligible employer-sponsored health plan (as defined in section 5000A(f)(2) of the Internal Revenue Code) other than a grandfathered health plan of a parent. For plan years beginning on or after January 1, 2014, the provisions of PHS Act section 2714 apply with respect to a grandfathered health plan that is a

group health plan without regard to whether an adult child is eligible to enroll in any other coverage.

(f) *Effect on collectively bargained plans— In general.* In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before March 23, 2010, the coverage is grandfathered health plan coverage at least until the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage that amends the coverage solely to conform to any requirement added by subtitles A and C of title I of the Patient Protection and Affordable Care Act (and the amendments made by those subtitles, and the incorporation of those amendments into ERISA section 715 and Internal Revenue Code section 9815) is not treated as a termination of the collective bargaining agreement. After the date on which the last of the collective bargaining agreements relating to the coverage that was in effect on March 23, 2010 terminates, the determination of whether health insurance coverage maintained pursuant to a collective bargaining agreement is grandfathered health plan coverage is made under the rules of this section other than this paragraph (f) (comparing the terms of the health insurance coverage after the date the last collective bargaining agreement terminates with the terms of the health insurance coverage that were in effect on March 23, 2010).

(g) *Maintenance of grandfather status*—(1) *Changes causing cessation of grandfather status.* Subject to paragraph (g)(2) of this section, the rules of this paragraph (g)(1) describe situations in which a group health plan or health insurance coverage ceases to be a grandfathered health plan.

(i) *Elimination of benefits.* The elimination of all or substantially all benefits to diagnose or treat a particular condition causes a group health plan or health insurance coverage to cease to be a grandfathered health plan. For this purpose, the elimination of benefits for any necessary element to diagnose or treat a condition is considered the elimination of all or substantially all benefits to diagnose or treat a particular condition.

(ii) *Increase in percentage cost-sharing requirement.* Any increase, measured from March 23, 2010, in a percentage cost-sharing requirement (such as an individual's coinsurance requirement) causes a group health plan or health insurance coverage to cease to be a grandfathered health plan.

(iii) *Increase in a fixed-amount cost-sharing requirement other than a copayment.* Any increase in a fixed-amount cost-sharing requirement other than a copayment (for example, deductible or out-of-pocket limit), determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total percentage increase in the cost-sharing requirement measured from March 23, 2010 exceeds the maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section).

(iv) *Increase in a fixed-amount copayment.* Any increase in a fixed-amount copayment, determined as of the effective date of the increase, causes a group health plan or health insurance coverage to cease to be a grandfathered health plan, if the total increase in the copayment measured from March 23, 2010 exceeds the greater of:

(A) An amount equal to $5 increased by medical inflation, as defined in paragraph (g)(3)(i) of this section (that is, $5 times medical inflation, plus $5), or

(B) The maximum percentage increase (as defined in paragraph (g)(3)(ii) of this section), determined by expressing the total increase in the copayment as a percentage.

(v) *Decrease in contribution rate by employers and employee organizations*—(A) *Contribution rate based on cost of coverage.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on cost of coverage (as defined in paragraph (g)(3)(iii)(A) of this section) towards the cost of any tier of coverage

for any class of similarly situated individuals (as described in section 146.121(d) of this subchapter) by more than 5 percentage points below the contribution rate for the coverage period that includes March 23, 2010.

(B) *Contribution rate based on a formula.* A group health plan or group health insurance coverage ceases to be a grandfathered health plan if the employer or employee organization decreases its contribution rate based on a formula (as defined in paragraph (g)(3)(iii)(B) of this section) towards the cost of any tier of coverage for any class of similarly situated individuals (as described in section 146.121(d) of this subchapter) by more than 5 percent below the contribution rate for the coverage period that includes March 23, 2010.

(vi) *Changes in annual limits*—(A) *Addition of an annual limit.* A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits.

(B) *Decrease in limit for a plan or coverage with only a lifetime limit.* A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010.

(C) *Decrease in limit for a plan or coverage with an annual limit.* A group health plan, or group or individual health insurance coverage, that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

(2) *Transitional rules*—(i) *Changes made prior to March 23, 2010.* If a group health plan or health insurance issuer makes the following changes to the terms of the plan or health insurance coverage, the changes are considered part of the terms of the plan or health insurance coverage on March 23, 2010 even though they were not effective at that time and such changes do not cause a plan or health insurance coverage to cease to be a grandfathered health plan:

(A) Changes effective after March 23, 2010 pursuant to a legally binding contract entered into on or before March 23, 2010;

(B) Changes effective after March 23, 2010 pursuant to a filing on or before March 23, 2010 with a State insurance department; or

(C) Changes effective after March 23, 2010 pursuant to written amendments to a plan that were adopted on or before March 23, 2010.

(ii) *Changes made after March 23, 2010 and adopted prior to issuance of regulations.* If, after March 23, 2010, a group health plan or health insurance issuer makes changes to the terms of the plan or health insurance coverage and the changes are adopted prior to June 14, 2010, the changes will not cause the plan or health insurance coverage to cease to be a grandfathered health plan if the changes are revoked or modified effective as of the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, and the terms of the plan or health insurance coverage on that date, as modified, would not cause the plan or coverage to cease to be a grandfathered health plan under the rules of this section, including paragraph (g)(1) of this section. For this purpose, changes will be considered to have been adopted prior to June 14, 2010 if:

(A) The changes are effective before that date;

(B) The changes are effective on or after that date pursuant to a legally binding contract entered into before that date;

(C) The changes are effective on or after that date pursuant to a filing before that date with a State insurance department; or

(D) The changes are effective on or after that date pursuant to written amendments to a plan that were adopted before that date.

(3) *Definitions*—(i) *Medical inflation defined*. For purposes of this paragraph (g), the term *medical inflation* means the increase since March 2010 in the overall medical care component of the Consumer Price Index for All Urban Consumers (CPI–U) (unadjusted) published by the Department of Labor using the 1982–1984 base of 100. For this purpose, the increase in the overall medical care component is computed by subtracting 387.142 (the overall medical care component of the CPI–U (unadjusted) published by the Department of Labor for March 2010, using the 1982–1984 base of 100) from the index amount for any month in the 12 months before the new change is to take effect and then dividing that amount by 387.142.

(ii) *Maximum percentage increase defined*. For purposes of this paragraph (g), the term *maximum percentage increase* means medical inflation (as defined in paragraph (g)(3)(i) of this section), expressed as a percentage, plus 15 percentage points.

(iii) *Contribution rate defined*. For purposes of paragraph (g)(1)(v) of this section:

(A) *Contribution rate based on cost of coverage*. The term *contribution rate based on cost of coverage* means the amount of contributions made by an employer or employee organization compared to the total cost of coverage, expressed as a percentage. The total cost of coverage is determined in the same manner as the applicable premium is calculated under the COBRA continuation provisions of section 604 of ERISA, section 4980B(f)(4) of the Internal Revenue Code, and section 2204 of the PHS Act. In the case of a self-insured plan, contributions by an employer or employee organization are equal to the total cost of coverage minus the employee contributions towards the total cost of coverage.

(B) *Contribution rate based on a formula*. The term *contribution rate based on a formula* means, for plans that, on March 23, 2010, made contributions based on a formula (such as hours worked or tons of coal mined), the formula.

(4) *Examples*. The rules of this paragraph (g) are illustrated by the following examples:

Example 1. (i) *Facts*. On March 23, 2010, a grandfathered health plan has a coinsurance requirement of 20% for inpatient surgery. The plan is subsequently amended to increase the coinsurance requirement to 25%.

(ii) *Conclusion*. In this *Example 1*, the increase in the coinsurance requirement from 20% to 25% causes the plan to cease to be a grandfathered health plan.

Example 2. (i) *Facts*. Before March 23, 2010, the terms of a group health plan provide benefits for a particular mental health condition, the treatment for which is a combination of counseling and prescription drugs. Subsequently, the plan eliminates benefits for counseling.

(ii) *Conclusion*. In this *Example 2*, the plan ceases to be a grandfathered health plan because counseling is an element that is necessary to treat the condition. Thus the plan is considered to have eliminated substantially all benefits for the treatment of the condition.

Example 3. (i) *Facts*. On March 23, 2010, a grandfathered health plan has a copayment requirement of $30 per office visit for specialists. The plan is subsequently amended to increase the copayment requirement to $40. Within the 12-month period before the $40 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 475.

(ii) *Conclusion*. In this *Example 3*, the increase in the copayment from $30 to $40, expressed as a percentage, is 33.33% (40 − 30 = 10; 10 ÷ 30 = 0.3333; 0.3333 = 33.33%). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2269 (475 − 387.142 = 87.858; 87.858 ÷ 387.142 = 0.2269). The maximum percentage increase permitted is 37.69% (0.2269 = 22.69%; 22.69% + 15% = 37.69%). Because 33.33% does not exceed 37.69%, the change in the copayment requirement at that time does not cause the plan to cease to be a grandfathered health plan.

Example 4. (i) *Facts*. Same facts as *Example 3*, except the grandfathered health plan subsequently increases the $40 copayment requirement to $45 for a later plan year. Within the 12-month period before the $45 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 485.

(ii) *Conclusion*. In this *Example 4*, the increase in the copayment from $30 (the copayment that was in effect on March 23, 2010) to $45, expressed as a percentage, is 50% (45 − 30

= 15; 15 ÷ 30 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.2527 (485 − 387.142 = 97.858; 97.858 ÷ 387.142 = 0.2527). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 40.27% (0.2527 = 25.27%; 25.27% + 15% = 40.27%), or $6.26 ($5 × 0.2527 = $1.26; $1.26 + $5 = $6.26). Because 50% exceeds 40.27% and $15 exceeds $6.26, the change in the copayment requirement at that time causes the plan to cease to be a grandfathered health plan.

Example 5. (i) *Facts*. On March 23, 2010, a grandfathered health plan has a copayment of $10 per office visit for primary care providers. The plan is subsequently amended to increase the copayment requirement to $15. Within the 12-month period before the $15 copayment takes effect, the greatest value of the overall medical care component of the CPI–U (unadjusted) is 415.

(ii) *Conclusion*. In this *Example 5*, the increase in the copayment, expressed as a percentage, is 50% (15 − 10 = 5; 5 ÷ 10 = 0.5; 0.5 = 50%). Medical inflation (as defined in paragraph (g)(3) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv) of this section is the greater of the maximum percentage increase of 22.20% (0.0720 = 7.20%; 7.20% + 15% = 22.20), or $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 5* would not cause the plan to cease to be a grandfathered health plan pursuant to paragraph (g)(1)(iv) this section, which would permit an increase in the copayment of up to $5.36.

Example 6. (i) *Facts*. The same facts as *Example 5*, except on March 23, 2010, the grandfathered health plan has no copayment ($0) for office visits for primary care providers. The plan is subsequently amended to increase the copayment requirement to $5.

(ii) *Conclusion*. In this *Example 6*, medical inflation (as defined in paragraph (g)(3)(i) of this section) from March 2010 is 0.0720 (415.0 − 387.142 = 27.858; 27.858 ÷ 387.142 = 0.0720). The increase that would cause a plan to cease to be a grandfathered health plan under paragraph (g)(1)(iv)(A) of this section is $5.36 ($5 × 0.0720 = $0.36; $0.36 + $5 = $5.36). The $5 increase in copayment in this *Example 6* is less than the amount calculated pursuant to paragraph (g)(1)(iv)(A) of this section of $5.36. Thus, the $5 increase in copayment does not cause the plan to cease to be a grandfathered health plan.

Example 7. (i) *Facts*. On March 23, 2010, a self-insured group health plan provides two tiers of coverage—self-only and family. The employer contributes 80% of the total cost of coverage for self-only and 60% of the total cost of coverage for family. Subsequently, the employer reduces the contribution to 50% for family coverage, but keeps the same contribution rate for self-only coverage.

(ii) *Conclusion*. In this *Example 7*, the decrease of 10 percentage points for family coverage in the contribution rate based on cost of coverage causes the plan to cease to be a grandfathered health plan. The fact that the contribution rate for self-only coverage remains the same does not change the result.

Example 8. (i) *Facts*. On March 23, 2010, a self-insured grandfathered health plan has a COBRA premium for the 2010 plan year of $5000 for self-only coverage and $12,000 for family coverage. The required employee contribution for the coverage is $1000 for self-only coverage and $4000 for family coverage. Thus, the contribution rate based on cost of coverage for 2010 is 80% ((5000 − 1000)/5000) for self-only coverage and 67% ((12,000 − 4000)/12,000) for family coverage. For a subsequent plan year, the COBRA premium is $6000 for self-only coverage and $15,000 for family coverage. The employee contributions for that plan year are $1200 for self-only coverage and $5000 for family coverage. Thus, the contribution rate based on cost of coverage is 80% ((6000 − 1200)/6000) for self-only coverage and 67% ((15,000 − 5000)/15,000) for family coverage.

(ii) *Conclusion*. In this *Example 8*, because there is no change in the contribution rate based on cost of coverage, the plan retains its status as a grandfathered health plan. The result would be the same if all or part of the employee contribution was made pre-tax through a cafeteria plan under section 125 of the Internal Revenue Code.

Example 9. (i) *Facts*. A group health plan not maintained pursuant to a collective bargaining agreement offers three benefit packages on March 23, 2010. Option *F* is a self-insured option. Options *G* and *H* are insured options. Beginning July 1, 2013, the plan increases coinsurance under Option *H* from 10% to 15%.

(ii) *Conclusion*. In this *Example 9*, the coverage under Option *H* is not grandfathered health plan coverage as of July 1, 2013, consistent with the rule in paragraph (g)(1)(ii) of this section. Whether the coverage under Options *F* and *G* is grandfathered health plan coverage is determined separately under the rules of this paragraph (g).

[75 FR 34566, June 17, 2010, as amended at 75 FR 70121, Nov. 15, 2010]

§ 147.145 Student health insurance coverage.

(a) *Definition*. Student health insurance coverage is a type of individual health insurance coverage (as defined in § 144.103 of this subchapter) that is provided pursuant to a written agreement between an institution of higher

education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students enrolled in that institution of higher education and their dependents, that meets the following conditions:

(1) Does not make health insurance coverage available other than in connection with enrollment as a student (or as a dependent of a student) in the institution of higher education.

(2) Does not condition eligibility for the health insurance coverage on any health status-related factor (as defined in § 146.121(a) of this subchapter) relating to a student (or a dependent of a student).

(3) Meets any additional requirement that may be imposed under State law.

(b) *Exemptions from the Public Health Service Act.* (1) *Guaranteed availability and guaranteed renewability.* For purposes of sections 2741(e)(1) and 2742(b)(5) of the Public Health Service Act, student health insurance coverage is deemed to be available only through a bona fide association.

(2) *Annual limits.* (i) Notwithstanding the annual dollar limits requirements of § 147.126, for policy years beginning before September 23, 2012, a health insurance issuer offering student health insurance coverage may not establish an annual dollar limit on essential health benefits that is lower than $100,000.

(ii) Notwithstanding the annual dollar limits requirements of § 147.126, for policy years beginning on or after September 23, 2012, but before January 1, 2014, a health insurance issuer offering student health insurance coverage may not establish an annual dollar limit on essential health benefits that is lower than $500,000.

(iii) For policy years beginning on or after January 1, 2014, a health insurance issuer offering student health insurance coverage must comply with the annual dollar limits requirements in § 147.126.

(c) *Student administrative health fees.* (1) *Definition.* A student administrative health fee is a fee charged by the institution of higher education on a periodic basis to students of the institution of higher education to offset the cost of providing health care through health clinics regardless of whether the students utilize the health clinics or enroll in student health insurance coverage.

(2) *Preventive services.* Notwithstanding the requirements under section 2713 of the Public Health Service Act and its implementing regulations, student administrative health fees as defined in paragraph (c)(1) of this section are not considered cost-sharing requirements with respect to specified recommended preventive services.

(d) *Notice.* (1) *Requirements.* (i) A health insurance issuer that provides student health insurance coverage, and does not meet the annual dollar limits requirements under section 2711 of the Public Health Service Act, must provide a notice informing students that the policy does not meet the minimum annual limits requirements under section 2711 of the Public Health Service Act. The notice must include the dollar amount of the annual limit along with a description of the plan benefits to which the limit applies for the student health insurance coverage.

(ii) The notice must state that the student may be eligible for coverage as a dependent in a group health plan of a parent's employer or under the parent's individual market coverage if the student is under the age of 26.

(iii) The notice must be prominently displayed in clear, conspicuous 14-point bold type on the front of the insurance policy or certificate and in any other plan materials summarizing the terms of the coverage (such as a summary description document).

(iv) The notice must be provided for policy years beginning before January 1, 2014.

(2) *Model language.* The following model language, or substantially similar language, can be used to satisfy the notice requirement of this paragraph (d): ''Your student health insurance coverage, offered by [name of health insurance issuer], may not meet the minimum standards required by the health care reform law for the restrictions on annual dollar limits. The annual dollar limits ensure that consumers have sufficient access to medical benefits throughout the annual term of the policy. Restrictions for annual dollar limits for group and individual health insurance coverage are

$1.25 million for policy years before September 23, 2012; and $2 million for policy years beginning on or after September 23, 2012 but before January 1, 2014. Restrictions for annual dollar limits for student health insurance coverage are $100,000 for policy years before September 23, 2012, and $500,000 for policy years beginning on or after September 23, 2012, but before January 1, 2014. Your student health insurance coverage put an annual limit of: [Dollar amount] on [which covered benefits—notice should describe all annual limits that apply]. If you have any questions or concerns about this notice, contact [provide contact information for the health insurance issuer]. Be advised that you may be eligible for coverage under a group health plan of a parent's employer or under a parent's individual health insurance policy if you are under the age of 26. Contact the plan administrator of the parent's employer plan or the parent's individual health insurance issuer for more information.''

(e) *Applicability*. The provisions of this section apply for policy years beginning on or after July 1, 2012.

[77 FR 16468, Mar. 21, 2012]

§ 147.200 Summary of benefits and coverage and uniform glossary.

(a) *Summary of benefits and coverage*–(1) *In general*. A group health plan (and its administrator as defined in section 3(16)(A) of ERISA), and a health insurance issuer offering group or individual health insurance coverage, is required to provide a written summary of benefits and coverage (SBC) for each benefit package without charge to entities and individuals described in this paragraph (a)(1) in accordance with the rules of this section.

(i) *SBC provided by a group health insurance issuer to a group health plan*—(A) *Upon application*. A health insurance issuer offering group health insurance coverage must provide the SBC to a group health plan (or its sponsor) upon application for health coverage, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application.

(B) *By first day of coverage (if there are changes)*. If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the plan (or its sponsor) no later than the first day of coverage.

(C) *Upon renewal*. If the issuer renews or reissues the policy, certificate, or contract of insurance (for example, for a succeeding policy year), the issuer must provide a new SBC as follows:

(*1*) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date the written application materials are distributed.

(*2*) If renewal or reissuance is automatic, the SBC must be provided no later than 30 days prior to the first day of the new plan or policy year; however, with respect to an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) *Upon request*. If a group health plan (or its sponsor) requests an SBC or summary information about a health insurance product from a health insurance issuer offering group health insurance coverage, an SBC must be provided as soon as practicable, but in no event later than seven business days following receipt of the request.

(ii) *SBC provided by a group health insurance issuer and a group health plan to participants and beneficiaries*—(A) *In general*. A group health plan (including its administrator, as defined under section 3(16) of ERISA), and a health insurance issuer offering group health insurance coverage, must provide an SBC to a participant or beneficiary (as defined under sections 3(7) and 3(8) of ERISA), and consistent with paragraph (a)(1)(iii) of this section, with respect to each benefit package offered by the plan or issuer for which the participant or beneficiary is eligible.

(B) *Upon application*. The SBC must be provided as part of any written application materials that are distributed

by the plan or issuer for enrollment. If the plan or issuer does not distribute written application materials for enrollment, the SBC must be distributed no later than the first date on which the participant is eligible to enroll in coverage for the participant or any beneficiaries.

(C) *By first day of coverage (if there are changes).* If there is any change to the information required to be in the SBC that was provided upon application and before the first day of coverage, the plan or issuer must update and provide a current SBC to a participant or beneficiary no later than the first day of coverage.

(D) *Special enrollees.* The plan or issuer must provide the SBC to special enrollees (as described in 45 CFR 146.117) no later than the date by which a summary plan description is required to be provided under the timeframe set forth in ERISA section 104(b)(1)(A) and its implementing regulations, which is 90 days from enrollment.

(E) *Upon renewal.* If the plan or issuer requires participants or beneficiaries to renew in order to maintain coverage (for example, for a succeeding plan year), the plan or issuer must provide a new SBC when the coverage is renewed, as follows:

(*1*) If written application is required for renewal (in either paper or electronic form), the SBC must be provided no later than the date on which the written application materials are distributed.

(*2*) If renewal is automatic, the SBC must be provided no later than 30 days prior to the first day of the new plan or policy year; however, with respect to an insured plan, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(F) *Upon request.* A plan or issuer must provide the SBC to participants or beneficiaries upon request for an SBC or summary information about the health coverage, as soon as practicable, but in no event later than seven business days following receipt of the request.

(iii) *Special rules to prevent unnecessary duplication with respect to group health coverage*—(A) An entity required to provide an SBC under this paragraph (a)(1) with respect to an individual satisfies that requirement if another party provides the SBC, but only to the extent that the SBC is timely and complete in accordance with the other rules of this section. Therefore, for example, in the case of a group health plan funded through an insurance policy, the plan satisfies the requirement to provide an SBC with respect to an individual if the issuer provides a timely and complete SBC to the individual.

(B) If a single SBC is provided to a participant and any beneficiaries at the participant's last known address then the requirement to provide the SBC to the participant and any beneficiaries is generally satisfied. However, if a beneficiary's last known address is different than the participant's last known address, a separate SBC is required to be provided to the beneficiary at the beneficiary's last known address.

(C) With respect to a group health plan that offers multiple benefit packages, the plan or issuer is required to provide a new SBC automatically upon renewal only with respect to the benefit package in which a participant or beneficiary is enrolled; SBCs are not required to be provided automatically upon renewal with respect to benefit packages in which the participant or beneficiary is not enrolled. However, if a participant or beneficiary requests an SBC with respect to another benefit package (or more than one other benefit package) for which the participant or beneficiary is eligible, the SBC (or SBCs, in the case of a request for SBCs relating to more than one benefit package) must be provided upon request as soon as practicable, but in no event later than seven business days following receipt of the request.

(iv) *SBC provided by a health insurance issuer offering individual health insurance coverage*—(A) *Upon application.* A health insurance issuer offering individual health insurance coverage must provide an SBC to an individual covered under the policy (including every

dependent) upon receiving an application for any health insurance policy, as soon as practicable following receipt of the application, but in no event later than seven business days following receipt of the application.

(B) *By first day of coverage (if there are changes).* If there is any change in the information required to be in the SBC that was provided upon application and before the first day of coverage, the issuer must update and provide a current SBC to the individual no later than the first day of coverage.

(C) *Upon renewal.* The issuer must provide the SBC to policyholders annually at renewal. The SBC must reflect any modified policy terms that would be effective on the first day of the new policy year. The SBC must be provided as follows:

(*1*) If written application is required (in either paper or electronic form) for renewal or reissuance, the SBC must be provided no later than the date on which the written application materials are distributed.

(*2*) If renewal or reissuance is automatic, the SBC must be provided no later than 30 days prior to the first day of the new policy year; however, if the policy, certificate, or contract of insurance has not been issued or renewed before such 30-day period, the SBC must be provided as soon as practicable but in no event later than seven business days after issuance of the new policy, certificate, or contract of insurance, or the receipt of written confirmation of intent to renew, whichever is earlier.

(D) *Upon request.* A health insurance issuer offering individual health insurance coverage must provide an SBC to any individual or dependent anytime an individual requests an SBC or summary information about a health insurance product as soon as practicable, but in no event later than seven business days following receipt of the request. For purposes of this paragraph (a)(1)(iv)(D), a request for an SBC or summary information about a health insurance product includes a request made both before and after an individual submits an application for coverage.

(v) *Special rule to prevent unnecessary duplication with respect to individual health insurance coverage.* If a single SBC is provided to an individual and any dependents at the individual's last known address, then the requirement to provide the SBC to the individual and any dependents is generally satisfied. However, if a dependent's last known address is different than the individual's last known address, a separate SBC is required to be provided to the dependent at the dependents' last known address.

(2) *Content*—(i) *In general.* Subject to paragraph (a)(2)(iii) of this section, the SBC must include the following:

(A) Uniform definitions of standard insurance terms and medical terms so that consumers may compare health coverage and understand the terms of (or exceptions to) their coverage, in accordance with guidance as specified by the Secretary;

(B) A description of the coverage, including cost sharing, for each category of benefits identified by the Secretary in guidance;

(C) The exceptions, reductions, and limitations of the coverage;

(D) The cost-sharing provisions of the coverage, including deductible, coinsurance, and copayment obligations;

(E) The renewability and continuation of coverage provisions;

(F) Coverage examples, in accordance with paragraph (a)(2)(ii) of this section;

(G) With respect to coverage beginning on or after January 1, 2014, a statement about whether the plan or coverage provides minimum essential coverage as defined under section 5000A(f) of the Internal Revenue Code and whether the plan's or coverage's share of the total allowed costs of benefits provided under the plan or coverage meets applicable requirements;

(H) A statement that the SBC is only a summary and that the plan document, policy, certificate, or contract of insurance should be consulted to determine the governing contractual provisions of the coverage;

(I) Contact information for questions and obtaining a copy of the plan document or the insurance policy, certificate, or contract of insurance (such as a telephone number for customer service and an Internet address for obtaining a copy of the plan document or the insurance policy, certificate, or contract of insurance);

(J) For plans and issuers that maintain one or more networks of providers, an Internet address (or similar contact information) for obtaining a list of network providers;

(K) For plans and issuers that use a formulary in providing prescription drug coverage, an Internet address (or similar contact information) for obtaining information on prescription drug coverage; and

(L) An Internet address for obtaining the uniform glossary, as described in paragraph (c) of this section, as well as a contact phone number to obtain a paper copy of the uniform glossary, and a disclosure that paper copies are available.

(ii) *Coverage examples.* The SBC must include coverage examples specified by the Secretary in guidance that illustrate benefits provided under the plan or coverage for common benefits scenarios (including pregnancy and serious or chronic medical conditions) in accordance with this paragraph (a)(2)(ii).

(A) *Number of examples.* The Secretary may identify up to six coverage examples that may be required in an SBC.

(B) *Benefits scenarios.* For purposes of this paragraph (a)(2)(ii), a benefits scenario is a hypothetical situation, consisting of a sample treatment plan for a specified medical condition during a specific period of time, based on recognized clinical practice guidelines as defined by the National Guideline Clearinghouse, Agency for Healthcare Research and Quality. The Secretary will specify, in guidance, the assumptions, including the relevant items and services and reimbursement information, for each claim in the benefits scenario.

(C) *Illustration of benefit provided.* For purposes of this paragraph (a)(2)(ii), to illustrate benefits provided under the plan or coverage for a particular benefits scenario, a plan or issuer simulates claims processing in accordance with guidance issued by the Secretary to generate an estimate of what an individual might expect to pay under the plan, policy, or benefit package. The illustration of benefits provided will take into account any cost sharing, excluded benefits, and other limitations on coverage, as specified by the Secretary in guidance.

(iii) *Coverage provided outside the United States.* In lieu of summarizing coverage for items and services provided outside the United States, a plan or issuer may provide an Internet address (or similar contact information) for obtaining information about benefits and coverage provided outside the United States. In any case, the plan or issuer must provide an SBC in accordance with this section that accurately summarizes benefits and coverage available under the plan or coverage within the United States.

(3) *Appearance.* A group health plan and a health insurance issuer must provide an SBC in the form, and in accordance with the instructions for completing the SBC, that are specified by the Secretary in guidance. The SBC must be presented in a uniform format, use terminology understandable by the average plan enrollee (or, in the case of individual market coverage, the average individual covered under a health insurance policy), not exceed four double-sided pages in length, and not include print smaller than 12-point font. A health insurance issuer offering individual health insurance coverage must provide the SBC as a stand-alone document.

(4) *Form*—(i) An SBC provided by an issuer offering group health insurance coverage to a plan (or its sponsor), may be provided in paper form. Alternatively, the SBC may be provided electronically (such as by email or an Internet posting) if the following three conditions are satisfied—

(A) The format is readily accessible by the plan (or its sponsor);

(B) The SBC is provided in paper form free of charge upon request; and

(C) If the electronic form is an Internet posting, the issuer timely advises the plan (or its sponsor) in paper form or email that the documents are available on the Internet and provides the Internet address.

(ii) An SBC provided by a group health plan or health insurance issuer to a participant or beneficiary may be provided in paper form. Alternatively, for non-Federal governmental plans, the SBC may be provided electronically if the plan conforms to either the substance of the ERISA provisions at

29 CFR 2590.715–2715(a)(4)(ii), or the provisions governing electronic disclosure for individual health insurance issuers set forth in paragraph (a)(4)(iii) of this section.

(iii) An issuer offering individual health insurance coverage must provide an SBC in a manner that can reasonably be expected to provide actual notice in paper or electronic form.

(A) An issuer satisfies the requirements of this paragraph (a)(4)(iii) if the issuer:

(*1*) Hand-delivers a printed copy of the SBC to the individual or dependent;

(*2*) Mails a printed copy of the SBC to the mailing address provided to the issuer by the individual or dependent;

(*3*) Provides the SBC by email after obtaining the individual's or dependent's agreement to receive the SBC or other electronic disclosures by email;

(*4*) Posts the SBC on the Internet and advises the individual or dependent in paper or electronic form, in a manner compliant with paragraphs (a)(4)(iii)(A)(*1*) through (*3*), that the SBC is available on the Internet and includes the applicable Internet address; or

(*5*) Provides the SBC by any other method that can reasonably be expected to provide actual notice.

(B) An SBC may not be provided electronically unless:

(*1*) The format is readily accessible;

(*2*) The SBC is placed in a location that is prominent and readily accessible;

(*3*) The SBC is provided in an electronic form which can be electronically retained and printed;

(*4*) The SBC is consistent with the appearance, content, and language requirements of this section;

(*5*) The issuer notifies the individual or dependent that the SBC is available in paper form without charge upon request and provides it upon request.

(C) *Deemed compliance.* A health insurance issuer offering individual health insurance coverage that provides the content required under paragraph (a)(2) of this section, as specified in guidance published by the Secretary, to the federal health reform Web portal described in 45 CFR 159.120 will be deemed to satisfy the requirements of paragraph (a)(1)(iv)(D) of this section with respect to a request for summary information about a health insurance product made prior to an application for coverage. However, nothing in this paragraph should be construed as otherwise limiting such issuer's obligations under this section.

(5) *Language.* A group health plan or health insurance issuer must provide the SBC in a culturally and linguistically appropriate manner. For purposes of this paragraph (a)(5), a plan or issuer is considered to provide the SBC in a culturally and linguistically appropriate manner if the thresholds and standards of § 147.136(e) of this chapter are met as applied to the SBC.

(b) *Notice of modification.* If a group health plan, or health insurance issuer offering group or individual health insurance coverage, makes any material modification (as defined under section 102 of ERISA) in any of the terms of the plan or coverage that would affect the content of the SBC, that is not reflected in the most recently provided SBC, and that occurs other than in connection with a renewal or reissuance of coverage, the plan or issuer must provide notice of the modification to enrollees (or, in the case of individual market coverage, an individual covered under a health insurance policy) not later than 60 days prior to the date on which the modification will become effective. The notice of modification must be provided in a form that is consistent with paragraph (a)(4) of this section.

(c) *Uniform glossary*—(1) *In general.* A group health plan, and a health insurance issuer offering group health insurance coverage, must make available to participants and beneficiaries, and a health insurance issuer offering individual health insurance coverage must make available to applicants, policyholders, and covered dependents, the uniform glossary described in paragraph (c)(2) of this section in accordance with the appearance and form and manner requirements of paragraphs (c)(3) and (4) of this section.

(2) *Health-coverage-related terms and medical terms.* The uniform glossary must provide uniform definitions, specified by the Secretary in guidance, of the following health-coverage-related terms and medical terms:

(i) Allowed amount, appeal, balance billing, co-insurance, complications of pregnancy, co-payment, deductible, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, in-network co-insurance, in-network co-payment, medically necessary, network, non-preferred provider, out-of-network co-insurance, out-of-network co-payment, out-of-pocket limit, physician services, plan, preauthorization, preferred provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, reconstructive surgery, rehabilitation services, skilled nursing care, specialist, usual customary and reasonable (UCR), and urgent care; and

(ii) Such other terms as the Secretary determines are important to define so that individuals and employers may compare and understand the terms of coverage and medical benefits (including any exceptions to those benefits), as specified in guidance.

(3) *Appearance*. A group health plan, and a health insurance issuer, must provide the uniform glossary with the appearance specified by the Secretary in guidance to ensure the uniform glossary is presented in a uniform format and uses terminology understandable by the average plan enrollee (or, in the case of individual market coverage, an average individual covered under a health insurance policy).

(4) *Form and manner*. A plan or issuer must make the uniform glossary described in this paragraph (c) available upon request, in either paper or electronic form (as requested), within seven business days after receipt of the request.

(d) *Preemption*. For purposes of this section, the provisions of section 2724 of the PHS Act continue to apply with respect to preemption of State law. In addition, State laws that require a health insurance issuer to provide an SBC that supplies less information than required under paragraph (a) of this section are preempted.

(e) *Failure to provide*. A health insurance issuer or a non-federal governmental health plan that willfully fails to provide information required under this section is subject to a fine of not more than $1,000 for each such failure. A failure with respect to each covered individual constitutes a separate offense for purposes of this paragraph (e). HHS will enforce these provisions in a manner consistent with 45 CFR 150.101 through 150.465.

(f) *Applicability date*—(1) This section is applicable to group health plans and group health insurance issuers in accordance with this paragraph (f). (*See* §147.140(d), providing that this section applies to grandfathered health plans.)

(i) For disclosures with respect to participants and beneficiaries who enroll or re-enroll through an open enrollment period (including re-enrollees and late enrollees), this section applies beginning on the first day of the first open enrollment period that begins on or after September 23, 2012; and

(ii) For disclosures with respect to participants and beneficiaries who enroll in coverage other than through an open enrollment period (including individuals who are newly eligible for coverage and special enrollees), this section applies beginning on the first day of the first plan year that begins on or after September 23, 2012.

(2) For disclosures with respect to plans, and to individuals and dependents in the individual market, this section is applicable to health insurance issuers beginning September 23, 2012.

[77 FR 8702, Feb 14, 2012]

PART 148—REQUIREMENTS FOR THE INDIVIDUAL HEALTH INSURANCE MARKET

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AUTHORITY: Secs. 2741 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg–41 through 300gg–63, 300gg–91, and 300gg–92).

SOURCE: 62 FR 16995, Apr. 8, 1997, unless otherwise noted.

Subpart A—General Provisions

§ 148.101 Basis and purpose.

This part implements sections 2741 through 2763 and 2791 and 2792 of the PHS Act. Its purpose is to improve access to individual health insurance coverage for certain eligible individuals who previously had group coverage, and to guarantee the renewability of all coverage in the individual market. It also provides certain protections for mothers and newborns with respect to coverage for hospital stays in connection with childbirth and protects all individuals and family members who have, or seek, individual health insurance coverage from discrimination based on genetic information.

[63 FR 57561, Oct. 27, 1998, as amended at 74 FR 51693, Oct. 7, 2009]

§ 148.102 Scope, applicability, and effective dates.

(a) *Scope and applicability.* (1) Individual health insurance coverage includes all health insurance coverage (as defined in § 144.103) that is neither health insurance coverage sold in connection with an employment-related group health plan, nor short-term, limited-duration coverage as defined in § 144.103 of this subchapter. In some cases, coverage that may be considered group coverage under State law (such as coverage sold through certain associations) is considered individual coverage.

(2) The requirements of this part that pertain to guaranteed availability of individual health insurance coverage for certain eligible individuals apply to all issuers of individual health insurance coverage in a State, unless the State implements an acceptable alternative mechanism as described in § 148.128. The requirements that pertain to guaranteed renewability for all individuals, to protections for mothers and newborns with respect to hospital stays in connection with childbirth, and to protections against discrimination based on genetic information apply to all issuers of individual health insurance coverage in the State, regardless of whether a State implements an alternative mechanism under § 148.128 of this part.

(b) *Effective date.* Except as provided in § 148.124 (certificate of creditable coverage), § 148.128 (alternative State mechanisms), § 148.170 (standards relating to benefits for mothers and newborns), and § 148.180 (prohibition of health discrimination based on genetic information) of this part, the requirements of this part apply to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs.

[62 FR 16995, Apr. 8, 1997; 62 FR 31695, June 10, 1997, as amended at 63 FR 57562, Oct. 27, 1998; 74 FR 51693, Oct. 7, 2009]

§ 148.103 Definitions.

Unless otherwise provided, the following definition applies:

Eligible individual means an individual who meets the following conditions:

(1) The individual has at least 18 months of creditable coverage (as determined under § 146.113 of this subchapter) as of the date on which the individual seeks coverage under this part.

(2) The individual's most recent prior creditable coverage was under a group health plan, governmental plan, or church plan (or health insurance coverage offered in connection with any of these plans).

(3) The individual is not eligible for coverage under any of the following:

(i) A group health plan.

(ii) Part A or Part B of Title XVIII (Medicare) of the Social Security Act.

(iii) A State plan under Title XIX (Medicaid) of the Social Security Act (or any successor program).

(4) The individual does not have other health insurance coverage.

(5) The individual's most recent coverage was not terminated because of nonpayment of premiums or fraud. (For more information about nonpayment of premiums or fraud, see § 146.152(b)(1) and (b)(2) of this subchapter.)

(6) If the individual has been offered the option of continuing coverage under a COBRA continuation provision or a similar State program, the individual has both elected and exhausted the continuation coverage.

Subpart B—Requirements Relating to Access and Renewability of Coverage

§ 148.120 Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage.

(a) *General rule*. Except as provided for in paragraph (c) of this section, an issuer that furnishes health insurance coverage in the individual market must meet the following requirements with respect to any eligible individual who requests coverage:

(1) May not decline to offer coverage or deny enrollment under any policy forms that it actively markets in the individual market, except as permitted in paragraph (c) of this section concerning alternative coverage when no State mechanism exists. An issuer is deemed to meet this requirement if, upon the request of an eligible individual, it acts promptly to do the following:

(i) Provide information about all available coverage options.

(ii) Enroll the individual in any coverage option the individual selects.

(2) May not impose any preexisting condition exclusion on the individual.

(b) *Exception*. The requirements of paragraph (a) of this section do not apply to health insurance coverage offered in the individual market in a State that chooses to implement an acceptable alternative mechanism described in § 148.128.

(c) *Alternative coverage permitted where no State mechanism exists*—(1) *General rule*. If the State does not implement an acceptable alternative mechanism under § 148.128, an issuer may elect to limit the coverage required under paragraph (a) of this section if it offers eligible individuals at least two policy forms that meet the following requirements:

(i) Each policy form must be designed for, made generally available to, and actively marketed to, and enroll, both eligible and other individuals.

(ii) The policy forms must be either the issuer's two most popular policy forms (as described in paragraph (c)(2) of this section) or representative samples of individual health insurance offered by the issuer in the State (as described in paragraph (c)(3) of this section).

(2) *Most popular policies*. The *two most popular policy forms* means the policy forms with the largest, and the second largest, premium volume for the last reporting year, for policies offered in that State. In the absence of applicable State standards, *premium volume* means earned premiums for the last reporting year. In the absence of applicable State standards, the last reporting year is the period from October 1 through September 30 of the preceding year. Blocks of business closed under applicable State law are not included in calculating premium volume.

(3) *Representative policy forms*—(i) *Definition of weighted average.* Weighted average means the average actuarial value of the benefits provided by all the health insurance coverage issued by one of the following:

(A) An issuer in the individual market in a State during the previous calendar year, weighted by enrollment for each policy form, but not including coverage issued to eligible individuals.

(B) All issuers in the individual market in a State if the data are available for the previous calendar year, weighted by enrollment for each policy form.

(ii) *Requirements.* The two representative policy forms must meet the following requirements:

(A) Include a lower-level coverage policy form under which the actuarial value of benefits under the coverage is at least 85 percent but not greater than 100 percent of the weighted average.

(B) Include a higher-level coverage policy form under which the actuarial value of the benefits under the coverage is at least 15 percent greater than the actuarial value of the lower-level coverage policy form offered by an issuer in that State and at least 100 percent, but not greater than 120 percent, of the weighted average.

(C) Include benefits substantially similar to other individual health insurance coverage offered by the issuer in the State.

(D) Provide for risk adjustment, risk spreading, or a risk spreading mechanism, or otherwise provide some financial subsidization for eligible individuals.

(E) Meet all applicable State requirements.

(iii) *Actuarial value of benefits.* The actuarial value of benefits provided under individual health insurance coverage must be calculated based on a standardized population, and a set of standardized utilization and cost factors under applicable State law.

(4) *Election.* All issuer elections must be applied uniformly to all eligible individuals in the State and must be effective for all policies offered during a period of at least 2 years.

(5) *Documentation.* The issuer must document the actuarial calculations it makes as follows:

(i) *Enforcement by State.* In a State that elects to enforce the provisions of this section in lieu of an alternative mechanism under § 148.128, the issuer must provide the appropriate State authorities with the documentation required by the State.

(ii) *Enforcement by CMS.* If CMS acts to enforce the provisions of this section under part 150, the issuer must provide to CMS, within the following time frames, any documentation CMS requests:

(A) For policy forms already being marketed as of July 1, 1997—no later than September 1, 1997.

(B) For other policy forms—90 days before the beginning of the calendar year in which the issuer wants to market the policy form.

(d) *Special rules for network plans.* (1) An issuer that offers coverage in the individual market through a network plan may take the following actions:

(i) Specify that an eligible individual may only enroll if he or she lives, resides, or works within the service area for the network plan.

(ii) Deny coverage to an eligible individual if the issuer has demonstrated the following to the applicable State authority (if required by the State):

(A) It does not have the capacity to deliver services adequately to additional individual enrollees because of its obligations to provide services to current group contract holders and enrollees, and to current individual enrollees.

(B) It uniformly denies coverage to individuals without regard to any health status-related factor, and without regard to whether the individuals are eligible individuals.

(iii) Not offer any coverage in the individual market, within the service area identified for purposes of paragraph (d)(1)(ii) of this section, for a period of 180 days after the coverage is denied.

(2) In those States in which CMS is enforcing the individual market provisions of this part in accordance with part 150, the issuer must make the demonstration described in paragraph (d)(1)(ii) of this section to CMS rather than to the State, and the issuer may

not deny coverage to any eligible individual until 30 days after CMS receives and approves the information.

(e) *Application of financial capacity limits*. (1) An issuer may deny coverage to an eligible individual if the issuer has demonstrated the following to the applicable State authority (if required by the State):

(i) It does not have the financial reserves necessary to underwrite additional coverage.

(ii) It uniformly denies coverage to all individuals in the individual market, consistent with applicable State law, without regard to any health status-related factor of the individuals, and without regard to whether the individuals are eligible individuals.

(2) In those States in which CMS is enforcing the individual market provisions of this part in accordance with part 150, the issuer must make the demonstration described in paragraph (e)(1) of this section to CMS rather than to the State, and the issuer may not deny coverage to any eligible individual until 30 days after CMS receives and approves the information.

(3) An issuer that denies coverage in any service area according to paragraph (e)(1) of this section is prohibited from offering that coverage in the individual market for a period of 180 days after the later of the date—

(i) The coverage is denied; or

(ii) The issuer demonstrates to the applicable State authority (if required under applicable State law) that the issuer has sufficient financial reserves to underwrite additional coverage.

(4) A State may apply the 180-day suspension described in paragraph (e)(3) of this section on a service-area-specific basis.

(f) *Rules for dependents*—(1) *General rule*. Except as prohibited by § 148.180, if an eligible individual elects to enroll in individual health insurance coverage that provides coverage for dependents, the issuer may apply a preexisting condition exclusion on any dependent who is not an eligible individual.

(2) *Exception for certain children*. A child is deemed to be an eligible individual if the following conditions are met:

(i) The child was covered under any creditable coverage within 30 days of birth, adoption, or placement for adoption (or longer if the State provides for a longer special enrollment period than required under § 146.117(a)(6) of this subchapter).

(ii) The child has not had a significant break in coverage.

(3) *Examples*. The following examples illustrate the requirements of this paragraph (f) for certain children:

Example 1: Individual *A* had self-only coverage under his employer's group health plan for five years. *A* has two children, ages 11 and 15, but never enrolled in family coverage. *A* leaves his job to become self-employed, and qualifies as an eligible individual because he is not entitled to any continuation coverage, Medicare or Medicaid, and has no other health insurance coverage. He applies to Issuer *R* for coverage in the individual market under a policy with family coverage that *R* makes available to eligible individuals. *R* must sell *A* the policy, but he may refuse coverage to *A*'s children, or may apply a preexisting condition exclusion to them if allowed under applicable State law, because they did not have prior creditable coverage, and therefore do not qualify as eligible individuals.

Example 2: Individual *B* was also covered under a group health plan for 5 years before losing his job. He originally had coverage only for himself and his wife, but 3 months before his employment ended, his wife had a baby. *B* took advantage of the special enrollment period that applied, changed to family coverage, and enrolled the baby in the group health plan within 20 days. Immediately after losing his job, *B* applied to Issuer *R* for family coverage. *B* and his wife qualify as eligible individuals, and the baby is deemed to be an eligible individual even though she has less than 3 months of creditable coverage. Therefore *R* must make the policy available to all three members of the family, and cannot impose any preexisting condition exclusions.

(g) *Clarification of applicability*. (1) An issuer in the individual market is not required to offer a family coverage option with any policy form.

(2) An issuer offering health insurance coverage only in connection with group health plans, or only through one or more bona fide associations, or both, is not required to offer that type of coverage in the individual market.

(3) An issuer offering health insurance coverage in connection with a group health plan is not deemed to be a health insurance issuer offering individual health insurance coverage solely

because the issuer offers a conversion policy.

(4) Except as prohibited by § 148.180, this section does not restrict the amount of the premium rates that an issuer may charge an individual under State law for health insurance coverage provided in the individual market.

(5) This section does not prevent an issuer offering health insurance coverage in the individual market from establishing premium discounts or rebates, or modifying otherwise applicable copayments or deductibles, in return for adherence to programs of health promotion and disease prevention.

(6) This section does not require issuers to reopen blocks of business closed under applicable State law.

(Approved by the Office of Management and Budget under control number 0938–0703)

[62 FR 16996, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997; 74 FR 51693, Oct. 7, 2009]

§ 148.122 Guaranteed renewability of individual health insurance coverage.

(a) *Applicability*. This section applies to all health insurance coverage in the individual market.

(b) *General rules*. (1) Except as provided in paragraph (c) of this section, an issuer must renew or continue in force the coverage at the option of the individual.

(2) Medicare eligibility or entitlement is not a basis for nonrenewal or termination of an individual's health insurance coverage in the individual market.

(c) *Exceptions to renewing coverage*. An issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market based only on one or more of the following:

(1) *Nonpayment of premiums*. The individual has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage, including any timeliness requirements.

(2) *Fraud*. The individual has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

(3) *Termination of plan*. The issuer is ceasing to offer coverage in the individual market in accordance with paragraphs (d) and (e) of this section and applicable State law.

(4) *Movement outside the service area*. For network plans, the individual no longer resides, lives, or works in the service area of the issuer, or area for which the issuer is authorized to do business, but only if coverage is terminated uniformly without regard to any health status-related factor of covered individuals.

(5) *Association membership ceases*. For coverage made available in the individual market only through one or more bona fide associations, the individual's membership in the association ceases, but only if the coverage is terminated uniformly without regard to any health status-related factor of covered individuals.

(d) *Discontinuing a particular type of coverage*. An issuer may discontinue offering a particular type of health insurance coverage offered in the individual market only if it meets the following requirements:

(1) Provides notice in writing to each individual provided coverage of that type of health insurance at least 90 days before the date the coverage will be discontinued.

(2) Offers to each covered individual, on a guaranteed issue basis, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in that market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(e) *Discontinuing all coverage*. An issuer may discontinue offering all health insurance coverage in the individual market in a State only if it meets the following requirements.

(1) Provides notice in writing to the applicable State authority and to each individual of the discontinuation at least 180 days before the date the coverage will expire.

(2) Discontinues and does not renew all health insurance policies it issues or delivers for issuance in the State in the individual market.

(3) Acts uniformly without regard to any health status-related factor of covered individuals or dependents of covered individuals who may become eligible for coverage.

(f) *Prohibition on market reentry*. An issuer who elects to discontinue offering all health insurance coverage under paragraph (e) of this section may not issue coverage in the market and State involved during the 5-year period beginning on the date of discontinuation of the last coverage not renewed.

(g) *Exception for uniform modification of coverage*. An issuer may, only at the time of coverage renewal, modify the health insurance coverage for a policy form offered in the individual market if the modification is consistent with State law and is effective uniformly for all individuals with that policy form.

(h) *Application to coverage offered only through associations*. In the case of health insurance coverage that is made available by a health insurance issuer in the individual market only through one or more associations, any reference in this section to an ''individual'' is deemed to include a reference to the association of which the individual is a member.

(Approved by the Office of Management and Budget under control number 0938–0703)

[62 FR 16998, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 148.124 Certification and disclosure of coverage.

(a) *Applicability*—(1) *General rule*. Except as provided in paragraph (a)(2) of this section, this section applies to all issuers of health insurance coverage.

(2) *Exception*. The provisions of this section do not apply to issuers of the following types of coverage:

(i) Health insurance coverage furnished in connection with a group health plan defined in § 144.103 of this subchapter. (These issuers are required under § 146.115 of this subchapter to provide a certificate of coverage.)

(ii) Excepted benefits described in § 148.220.

(iii) Short-term, limited duration coverage defined in § 144.103 of this subchapter.

(b) *General rules*—(1) *Individuals for whom a certificate must be provided; timing of issuance*. A certificate must be provided, without charge, for individuals and dependents who are or were covered under an individual health insurance policy as follows:

(i) *Issuance of automatic certificates*. An automatic certificate must be provided within a reasonable time period consistent with State law after the individual ceases to be covered under the policy.

(ii) *Any individual upon request*. Requests for certificates may be made by, or on behalf of, an individual within 24 months after coverage ends. For example, an entity that provides coverage to an individual in the future may, if authorized by the individual, request a certificate of the individual's creditable coverage on behalf of the individual from the issuer of the individual's prior coverage. After the request is received, an issuer must provide the certificate by the earliest date the issuer, acting in a reasonable and prompt fashion, can provide the certificate. A certificate must be provided under this paragraph even if the individual has previously received a certificate under this paragraph (b)(1)(ii) or an automatic certificate under paragraph (a)(1)(i) of this section.

(2) *Form and content of certificate*—(i) *Written certificate*—(A) *General rule*. Except as provided in paragraph (b)(2)(i)(B) of this section, the issuer must provide the certificate in writing (including any form approved by CMS).

(B) *Other permissible forms*. No written certificate must be provided if all of the following occur:

(*1*) An individual is entitled to receive a certificate.

(*2*) The individual requests that the certificate be sent to another plan or issuer instead of to the individual.

(*3*) The plan or issuer that would otherwise receive the certificate agrees to accept the information in paragraph (a)(3) of this section through means other than a written certificate (for example, by telephone).

(*4*) The receiving plan or issuer receives the information from the sending issuer in the prescribed form within the time periods required under paragraph (b)(1) of this section.

(ii) *Required information*. The certificate must include the following:

(A) The date the certificate is issued.

(B) The name of the individual or dependent for whom the certificate applies, and any other information necessary for the issuer providing the coverage specified in the certificate to identify the individual, such as the individual's identification number under the policy and the name of the policyholder if the certificate is for (or includes) a dependent.

(C) The name, address, and telephone number of the issuer required to provide the certificate.

(D) The telephone number to call for further information regarding the certificate (if different from paragraph (b)(2)(ii)(C) of this section).

(E) Either one of the following:

(*1*) A statement that the individual has at least 18 months (for this purpose, 546 days is deemed to be 18 months) of creditable coverage, disregarding days of creditable coverage before a significant break in coverage as defined in §146.113(b)(2)(iii) of this subchapter.

(*2*) Both the date the individual first sought coverage, as evidenced by a substantially complete application, and the date creditable coverage began.

(F) The date creditable coverage ended, unless the certificate indicates that creditable coverage is continuing as of the date of the certificate.

(iii) *Periods of coverage under a certificate.* If an automatic certificate is provided under paragraph (b)(1)(i) of this section, the period that must be included on the certificate is the last period of continuous coverage ending on the date coverage ceased. If an individual requests a certificate under paragraph (b)(1)(ii) of this section, a certificate must be provided for each period of continuous coverage ending within the 24-month period ending on the date of the request (or continuing on the date of the request). A separate certificate may be provided for each period of continuous coverage.

(iv) *Single certificate permitted for families.* An issuer may provide a single certificate for both an individual and the individual's dependents if it provides all the required information for each individual and dependent, and separately states the information that is not identical.

(v) *Model certificate.* The requirements of paragraph (b)(2)(ii) of this section are satisfied if the issuer provides a certificate in accordance with a model certificate as provided by CMS.

(vi) *Excepted benefits; categories of benefits.* No certificate is required to be furnished with respect to excepted benefits described in §148.220. If excepted benefits are provided concurrently with other creditable coverage (so that the coverage does not consist solely of excepted benefits), information concerning the benefits may be required to be disclosed under paragraph (c) of this section.

(3) *Procedures*—(i) *Method of delivery.* The certificate is required to be provided, without charge, to each individual described in paragraph (b)(1) of this section or an entity requesting the certificate on behalf of the individual. The certificate may be provided by first-class mail. If the certificate or certificates are provided to the individual and the individual's spouse at the individual's last known address, the requirements of this paragraph (b)(3) are satisfied with respect to all individuals and dependents residing at that address. If a dependent's last known address is different than the individual's last known address, a separate certificate must be provided to the dependent at the dependent's last known address. If separate certificates are provided by mail to individuals and dependents who reside at the same address, separate mailings of each certificate are not required.

(ii) *Procedure for requesting certificates.* An issuer must establish a procedure for individuals and dependents to request and receive certificates under paragraph (b)(1)(ii) of this section.

(iii) *Designated recipients.* If an automatic certificate is required to be provided under paragraph (b)(1)(i) of this section, and the individual or dependent entitled to receive the certificate designates another individual or entity to receive the certificate, the issuer responsible for providing the certificate may provide the certificate to the designated party. If a certificate must be provided upon request under paragraph (b)(1)(ii) of this section, and the individual entitled to receive the certificate designates another individual or

entity to receive the certificate, the issuer responsible for providing the certificates must provide the certificate to the designated party.

(4) *Special rules concerning dependent coverage*—(i) *Reasonable efforts*. An issuer must use reasonable efforts to determine any information needed for a certificate relating to dependent coverage. If an automatic certificate must be furnished with respect to a dependent under paragraph (b)(1)(i) of this section, no individual certificate must be furnished until the issuer knows (or making reasonable efforts should know) of the dependent's cessation of coverage under the policy.

(ii) *Special rules for demonstrating coverage*. If a certificate furnished by an issuer does not provide the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (d)(3) of this section for demonstrating dependent status. An individual may, if necessary, use these procedures to demonstrate that a child was enrolled within 30 days of birth, adoption, or placement for adoption, in which case the child would not be subject to a preexisting condition exclusion under § 148.120(f)(2).

(iii) *Transition rule for dependent coverage through June 30, 1998*—(A) *General rule*. An issuer that cannot provide the names of dependents (or related coverage information) for purposes of providing a certificate of coverage for a dependent may satisfy the requirements of paragraph (b)(2)(ii)(C) of this section by providing the name of the policyholder and specifying that the type of coverage described in the certificate is for dependent coverage (for example, family coverage or individual-plus-spouse coverage).

(B) *Certificates provided on request*. For purposes of certificates provided on the request of, or on behalf of, an individual under paragraph (b)(1)(ii) of this section, an issuer must make reasonable efforts to obtain and provide the names of any dependent covered by the certificate if the information is requested. If a certificate does not include the name of any dependent of an individual covered by the certificate, the individual may, if necessary, use the procedures described in paragraph (d)(3) of this section for submitting documentation to establish that the creditable coverage in the certificate applies to the dependent.

(C) *Demonstrating a dependent's creditable coverage*. See paragraph (d)(3) of this section for special rules to demonstrate dependent status.

(D) *Duration*. The transitional rules of this paragraph (b)(4)(iii) are effective for certifications provided with respect to an event occurring before July 1, 1998.

(5) *Optional notice*. This paragraph applies to events described in paragraph (b)(1)(i) of this section, that occur after September 30, 1996, but before June 30, 1997. An issuer offering individual health insurance coverage is deemed to satisfy paragraphs (b)(1) and (b)(2) of this section if a notice is provided in accordance with the provisions of § 146.125(e)(3)(ii) through (e)(3)(iv) of this subchapter.

(c) *Disclosure of coverage to a plan, or issuer, electing the alternative method of creating coverage*—(1) *General rule*. If an individual enrolls in a group health plan and the plan or issuer uses the alternative method of determining creditable coverage described in § 146.113(c) of this subchapter, the individual provides a certificate of coverage under paragraph (b) of this section or demonstrates creditable coverage under paragraph (d) of this section, and the plan or coverage in which the individual enrolls requests from the prior entity, the prior entity must disclose promptly to the requesting plan or issuer (''requesting entity'') the information set forth in paragraph (c)(2) of this section.

(2) *Information to be disclosed*. The prior entity must identify to the requesting entity the categories of benefits under which the individual was covered and with respect to which the requesting entity is using the alternative method of counting creditable coverage, and the requesting entity may identify specific information that the requesting entity reasonably needs to determine the individual's creditable coverage with respect to any of those categories. The prior entity must promptly disclose to the requesting entity the creditable coverage information that was requested.

(3) *Charge for providing information.* The prior entity furnishing the information under paragraph (c)(2) of this section may charge the requesting entity for the reasonable cost of disclosing the information.

(d) *Ability of an individual to demonstrate creditable coverage and waiting period information*—(1) *General rule.* Individuals may establish creditable coverage through means other than certificates. If the accuracy of a certificate is contested or a certificate is unavailable when needed by the individual, the individual has the right to demonstrate creditable coverage (and waiting or affiliation periods) through the presentation of documents or other means. For example, the individual may make a demonstration if one of the following occurs:

(i) An entity has failed to provide a certificate within the required time period.

(ii) The individual has creditable coverage but an entity may not be required to provide a certificate of the coverage.

(iii) The coverage is for a period before July 1, 1996.

(iv) The individual has an urgent medical condition that necessitates a determination before the individual can deliver a certificate to the plan.

(v) The individual lost a certificate that the individual had previously received and is unable to obtain another certificate.

(2) *Evidence of creditable coverage*—(i) *Consideration of evidence.* An issuer must take into account all information that it obtains or that is presented on behalf of an individual to make a determination, based on the relevant facts and circumstances, whether or not an individual has 18 months of creditable coverage. An issuer must treat the individual as having furnished a certificate if the individual attests to the period of creditable coverage, the individual presents relevant corroborating evidence of some creditable coverage during the period, and the individual cooperates with the issuer's efforts to verify the individual's coverage. For this purpose, cooperation includes providing (upon the issuer's request) a written authorization for the issuer to request a certificate on behalf of the individual, and cooperating in efforts to determine the validity of the corroborating evidence and the dates of creditable coverage. While an issuer may refuse to credit coverage if the individual fails to cooperate with the issuer's efforts to verify coverage, the issuer may not consider an individual's inability to obtain a certificate to be evidence of the absence of creditable coverage.

(ii) *Documents.* Documents that may establish creditable coverage (and waiting periods or affiliation periods) in the absence of a certificate include explanations of benefit claims (EOB) or other correspondence from a plan or issuer indicating coverage, pay stubs showing a payroll deduction for health coverage, a health insurance identification card, a certificate of coverage under a group health policy, records from medical care providers indicating health coverage, third party statements verifying periods of coverage, and any other relevant documents that evidence periods of health coverage.

(iii) *Other evidence.* Creditable coverage (and waiting period or affiliation period information) may be established through means other than documentation, such as by a telephone call from the issuer to a third party verifying creditable coverage.

(3) *Demonstrating dependent status.* If, in the course of providing evidence (including a certificate) of creditable coverage, an individual is required to demonstrate dependent status, the issuer must treat the individual as having furnished a certificate showing the dependent status if the individual attests to the dependency and the period of the status and the individual cooperates with the issuer's efforts to verify the dependent status.

(Approved by the Office of Management and Budget under control number 0938–0703)

[62 FR 16998, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

§ 148.126 Determination of an eligible individual.

(a) *General rule.* Each issuer offering health insurance coverage in the individual market is responsible for determining whether an applicant for coverage is an eligible individual as defined in § 148.103.

(b) *Specific requirements.* (1) The issuer must exercise reasonable diligence in making this determination.

(2) The issuer must promptly determine whether an applicant is an eligible individual.

(3) If an issuer determines that an individual is an eligible individual, the issuer must promptly issue a policy to that individual.

(c) *Insufficient information*—(1) *General rule.* If the information presented in or with an application is substantially insufficient for the issuer to make the determination described in paragraph (b)(2) of this section, the issuer may immediately request additional information from the individual, and must act promptly to make its determination after receipt of the requested information

(2) *Failure to provide a certification of creditable coverage.* If an entity fails to provide the certificate that is required under this part or part 146 of this subchapter to the applicant, the issuer is subject to the procedures set forth in § 148.124(d)(1) concerning an individual's right to demonstrate creditable coverage.

[62 FR 17000, Apr. 8, 1997]

EFFECTIVE DATE NOTE: At 62 FR 17000, Apr. 8, 1997, § 148.126 was added. This section contains information collection and recordkeeping requirements and will not become effective until approval has been given by the Office of Management and Budget.

§ 148.128 State flexibility in individual market reforms—alternative mechanisms.

(a) *Waiver of requirements.* The requirements of § 148.120, which set forth Federal requirements for guaranteed availability in the individual market, do not apply in a State that implements an acceptable alternative mechanism in accordance with the following criteria:

(1) The alternative mechanism meets the following conditions:

(i) Offers health insurance coverage to all eligible individuals.

(ii) Prohibits imposing preexisting condition exclusions and affiliation periods for coverage of an eligible individual.

(iii) Offers an eligible individual a choice of coverage that includes at least one policy form of coverage that is comparable to either one of the following:

(A) Comprehensive coverage offered in the individual market in the State.

(B) A standard option of coverage available under the group or individual health insurance laws of the State.

(2) The State is implementing one of the following provisions relating to risk:

(i) One of the following model acts, as adopted by the NAIC on June 3, 1996, but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

(A) The Small Employer and Individual Health Insurance Availability Model Act to the extent it applies to individual health insurance coverage.

(B) The Individual Health Insurance Portability Model Act.

(ii) A qualified high risk pool, which, for purposes of this section, is a high risk pool that meets the following conditions:

(A) Provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion or affiliation periods for coverage of an eligible individual.

(B) Provides for premium rates and covered benefits for the coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect as of August 21, 1996), but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

(iii) One of the following mechanisms:

(A) Any other mechanism that provides for risk adjustment, risk spreading, or a risk-spreading mechanism (among issuers or policies of an issuer) or otherwise provides for some financial subsidization for eligible individuals, including through assistance to participating issuers.

(B) A mechanism that provides a choice for each eligible individual of all individual health insurance coverage otherwise available.

(b) *Permissible forms of mechanisms.* A private or public individual health insurance mechanism (such as a health

insurance coverage pool or program, a mandatory group conversion policy, guaranteed issue of one or more plans of individual health insurance coverage, or open enrollment by one or more health insurance issuers), or combination of these mechanisms, that is designed to provide access to health benefits for individuals in the individual market in the State, in accordance with this section, may constitute an acceptable alternative mechanism.

(c) *Establishing an acceptable alternative mechanism—transition rules.* CMS presumes a State to be implementing an acceptable alternative mechanism as of July 1, 1997 if the following conditions are met:

(1) By not later than April 1, 1997, as evidenced by a postmark date, or other such date, the chief executive officer of the State takes the following actions:

(i) Notifies CMS that the State has enacted or intends to enact by not later than January 1, 1998 (unless it is a State described in paragraph (d) of this section), any legislation necessary to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998.

(ii) Provides CMS with the information necessary to review the mechanism and its implementation (or proposed implementation).

(2) CMS has not made a determination, in accordance with the procedure in paragraph (e)(4) of this section, that the State will not be implementing a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998.

(d) *Delay permitted for certain States.* If a State notifies CMS that its legislature is not meeting in a regular session between August 21, 1996 and August 20, 1997, CMS continues to presume until July 1, 1998 that the State is implementing an acceptable alternative mechanism, if the chief executive officer of the State takes the following actions:

(1) Notifies CMS by April 1, 1997, that the State intends to submit an alternative mechanism and intends to enact any necessary legislation to provide for the implementation of an acceptable alternative mechanism as of July 1, 1998.

(2) Notifies CMS by April 1, 1998, that the State has enacted any necessary legislation to provide for the implementation of an acceptable alternative mechanism as of July 1, 1998.

(3) Provides CMS with the information necessary to review the mechanism and its implementation (or proposed implementation).

(e) *Submitting an alternative mechanism after April 1, 1997*—(1) *Notice with information.* A State that wishes to implement an acceptable alternative mechanism must take the following actions:

(i) Notify CMS that it has enacted legislation necessary to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism, and

(ii) Provide CMS with the information necessary for CMS to review the mechanism and its implementation (or proposed implementation).

(2) *An acceptable alternative mechanism.* If the State takes the actions described in paragraph (e)(1) of this section, the mechanism is considered to be an acceptable alternative mechanism unless CMS makes a preliminary determination (under paragraph (e)(4)(i) of this section), within the review period (defined in paragraph (e)(3) of this section), that the mechanism is not an acceptable alternative mechanism.

(3) *Review period*—(i) *General.* The review period begins on the date the State's notice and information are received by CMS, and ends 90 days later, not counting any days during which the review period is suspended under paragraph (e)(3)(ii) of this section.

(ii) *Suspension of review period.* During any review period, if CMS notifies the State of the need for additional information or further discussion on its submission, CMS suspends the review period until the State provides the necessary information.

(4) *Determination by CMS*—(i) *Preliminary determination.* If CMS finds after reviewing the submitted information, and after consultation with the chief executive officer of the State and the chief insurance regulatory official of the State, that the mechanism is not an acceptable alternative mechanism, CMS takes the following actions:

(A) Notifies the State, in writing, of the preliminary determination.

(B) Informs the State that if it fails to implement an acceptable alternative mechanism, the Federal guaranteed availability provisions of § 148.120 will take effect.

(C) Permits the State a reasonable opportunity to modify the mechanism (or to adopt another mechanism).

(ii) *Final determination*. If, after providing notice and a reasonable opportunity for the State to modify its mechanism, CMS makes a final determination that the design of the State's alternative mechanism is not acceptable or that the State is not substantially enforcing an acceptable alternative mechanism, CMS notifies the State in writing of the following:

(A) CMS's final determination.

(B) That the requirements of § 148.120 concerning guaranteed availability apply to health insurance coverage offered in the individual market in the State as of a date specified in the notice from CMS.

(iii) *State request for early notice*. A State may request that CMS notify the State before the end of the review period if CMS is not making a preliminary determination.

(5) *Effective date*. If CMS does not make a preliminary determination within the review period, the acceptable alternative mechanism is effective 90 days after the end of the 90-day review period described in paragraph (e)(3)(i) of this section.

(f) *Continued application*. A State alternative mechanism may continue to be presumed to be acceptable, if the State provides information to CMS that meets the following requirements:

(1) If the State makes a significant change to its alternative mechanism, it provides the information before making a change.

(2) Every 3 years from the later of implementing the alternative mechanism or implementing a significant change, it provides CMS with information.

(g) *Review criteria*. CMS reviews each State's submission to determine whether it addresses all of the following requirements:

(1) Is the mechanism reasonably designed to provide all eligible individuals with a choice of health insurance coverage?

(2) Does the choice offered to eligible individuals include at least one policy form that meets one of the following requirements?

(i) Is the policy form comparable to comprehensive health insurance coverage offered in the individual market in the State?

(ii) Is the policy form comparable to a standard option of coverage available under the group or individual health insurance laws of the State?

(3) Does the mechanism prohibit preexisting condition exclusions for all eligible individuals?

(4) Is the State implementing one of the following:

(i) The NAIC Small Employer and Individual Health Insurance Availability Model Act (Availability Model), adopted on June 3, 1996, revised to reflect HIPAA requirements.

(ii) The Individual Health Insurance Portability Model Act (Portability Model), adopted on June 3, 1996, revised to reflect HIPAA requirements.

(iii) A qualified high-risk pool that provides eligible individuals health insurance or comparable coverage without a preexisting condition exclusion, and with premiums and benefits consistent with the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect August 21, 1996), revised to reflect HIPAA requirements.

(iv) A mechanism that provides for risk spreading or provides eligible individuals with a choice of all available individual health insurance coverage.

(5) Has the State enacted all legislation necessary for implementing the alternative mechanism?

(6) If the State has not enacted all legislation necessary for implementing the alternative mechanism, will the necessary legislation be enacted by January 1, 1998?

(h) *Limitation of CMS's authority*. CMS does not make a preliminary or final determination on any basis other than that a mechanism is not considered an

acceptable alternative mechanism or is not being implemented.

(Approved by the Office of Management and Budget under control number 0938–0703)

[62 FR 16995, Apr. 8, 1997; 62 FR 17005, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 62 FR 35906, July 2, 1997]

Subpart C—Requirements Related to Benefits

§ 148.170 Standards relating to benefits for mothers and newborns.

(a) *Hospital length of stay*—(1) *General rule*. Except as provided in paragraph (a)(5) of this section, an issuer offering health insurance coverage in the individual market that provides benefits for a hospital length of stay in connection with childbirth for a mother or her newborn may not restrict benefits for the stay to less than—

(i) 48 hours following a vaginal delivery; or

(ii) 96 hours following a delivery by cesarean section.

(2) *When stay begins*—(i) *Delivery in a hospital*. If delivery occurs in a hospital, the hospital length of stay for the mother or newborn child begins at the time of delivery (or in the case of multiple births, at the time of the last delivery).

(ii) *Delivery outside a hospital*. If delivery occurs outside a hospital, the hospital length of stay begins at the time the mother or newborn is admitted as a hospital inpatient in connection with childbirth. The determination of whether an admission is in connection with childbirth is a medical decision to be made by the attending provider.

(3) *Examples*. The rules of paragraphs (a)(1) and (2) of this section are illustrated by the following examples. In each example, the issuer provides benefits for hospital lengths of stay in connection with childbirth and is subject to the requirements of this section, as follows:

Example 1. (i) *Facts*. A pregnant woman covered under a policy issued in the individual market goes into labor and is admitted to the hospital at 10 p.m. on June 11. She gives birth by vaginal delivery at 6 a.m. on June 12.

(ii) *Conclusion*. In this *Example 1*, the 48-hour period described in paragraph (a)(1)(i) of this section ends at 6 a.m. on June 14.

Example 2. (i) *Facts*. A woman covered under a policy issued in the individual market gives birth at home by vaginal delivery. After the delivery, the woman begins bleeding excessively in connection with the childbirth and is admitted to the hospital for treatment of the excessive bleeding at 7 p.m. on October 1.

(ii) *Conclusion*. In this *Example 2*, the 48-hour period described in paragraph (a)(1)(i) of this section ends at 7 p.m. on October 3.

Example 3. (i) *Facts*. A woman covered under a policy issued in the individual market gives birth by vaginal delivery at home. The child later develops pneumonia and is admitted to the hospital. The attending provider determines that the admission is not in connection with childbirth.

(ii) *Conclusion*. In this *Example 3*, the hospital length-of-stay requirements of this section do not apply to the child's admission to the hospital because the admission is not in connection with childbirth.

(4) *Authorization not required*—(i) *In general*. An issuer is prohibited from requiring that a physician or other health care provider obtain authorization from the issuer for prescribing the hospital length of stay specified in paragraph (a)(1) of this section. (See also paragraphs (b)(2) and (c)(3) of this section for rules and examples regarding other authorization and certain notice requirements.)

(ii) *Example*. The rule of this paragraph (a)(4) is illustrated by the following example:

Example. (i) *Facts*. In the case of a delivery by cesarean section, an issuer subject to the requirements of this section automatically provides benefits for any hospital length of stay of up to 72 hours. For any longer stay, the issuer requires an attending provider to complete a certificate of medical necessity. The issuer then makes a determination, based on the certificate of medical necessity, whether a longer stay is medically necessary.

(ii) *Conclusion*. In this *Example*, the requirement that an attending provider complete a certificate of medical necessity to obtain authorization for the period between 72 hours and 96 hours following a delivery by cesarean section is prohibited by this paragraph (a)(4).

(5) *Exceptions*—(i) *Discharge of mother*. If a decision to discharge a mother earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother, the requirements of paragraph (a)(1) of this section do not

apply for any period after the discharge.

(ii) *Discharge of newborn.* If a decision to discharge a newborn child earlier than the period specified in paragraph (a)(1) of this section is made by an attending provider, in consultation with the mother (or the newborn's authorized representative), the requirements of paragraph (a)(1) of this section do not apply for any period after the discharge.

(iii) *Attending provider defined.* For purposes of this section, attending provider means an individual who is licensed under applicable state law to provide maternity or pediatric care and who is directly responsible for providing maternity or pediatric care to a mother or newborn child. Therefore, an issuer, plan, hospital, or managed care organization is not an attending provider.

(iv) *Example.* The rules of this paragraph (a)(5) are illustrated by the following example:

Example. (i) *Facts.* A pregnant woman covered under a policy offered by an issuer subject to the requirements of this section goes into labor and is admitted to a hospital. She gives birth by cesarean section. On the third day after the delivery, the attending provider for the mother consults with the mother, and the attending provider for the newborn consults with the mother regarding the newborn. The attending providers authorize the early discharge of both the mother and the newborn. Both are discharged approximately 72 hours after the delivery. The issuer pays for the 72-hour hospital stays.

(ii) *Conclusion.* In this *Example*, the requirements of this paragraph (a) have been satisfied with respect to the mother and the newborn. If either is readmitted, the hospital stay for the readmission is not subject to this section.

(b) *Prohibitions*—(1) *With respect to mothers*—(i) *In general.* An issuer subject to the requirements of this section may not—

(A) Deny a mother or her newborn child eligibility or continued eligibility to enroll in or renew coverage solely to avoid the requirements of this section; or

(B) Provide payments (including payments-in-kind) or rebates to a mother to encourage her to accept less than the minimum protections available under this section.

(ii) *Examples.* The rules of this paragraph (b)(1) are illustrated by the following examples. In each example, the issuer is subject to the requirements of this section, as follows:

Example 1. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. If a mother and newborn covered under a policy issued in the individual market are discharged within 24 hours after the delivery, the issuer will waive the copayment and deductible.

(ii) *Conclusion.* In this *Example 1,* because waiver of the copayment and deductible is in the nature of a rebate that the mother would not receive if she and her newborn remained in the hospital, it is prohibited by this paragraph (b)(1). (In addition, the issuer violates paragraph (b)(2) of this section because, in effect, no copayment or deductible is required for the first portion of the stay and a double copayment and a deductible are required for the second portion of the stay.)

Example 2. (i) *Facts.* An issuer provides benefits for at least a 48-hour hospital length of stay following a vaginal delivery. In the event that a mother and her newborn are discharged earlier than 48 hours and the discharges occur after consultation with the mother in accordance with the requirements of paragraph (a)(5) of this section, the issuer provides for a follow-up visit by a nurse within 48 hours after the discharges to provide certain services that the mother and her newborn would otherwise receive in the hospital.

(ii) *Conclusion.* In this *Example 2,* because the follow-up visit does not provide any services beyond what the mother and her newborn would receive in the hospital, coverage for the follow-up visit is not prohibited by this paragraph (b)(1).

(2) *With respect to benefit restrictions*—(i) *In general.* Subject to paragraph (c)(3) of this section, an issuer may not restrict the benefits for any portion of a hospital length of stay specified in paragraph (a) of this section in a manner that is less favorable than the benefits provided for any preceding portion of the stay.

(ii) *Example.* The rules of this paragraph (b)(2) are illustrated by the following example:

Example. (i) *Facts.* An issuer subject to the requirements of this section provides benefits for hospital lengths of stay in connection with childbirth. In the case of a delivery by cesarean section, the issuer automatically pays for the first 48 hours. With respect to each succeeding 24-hour period, the covered individual must call the issuer to obtain precertification from a utilization reviewer,

who determines if an additional 24-hour period is medically necessary. If this approval is not obtained, the issuer will not provide benefits for any succeeding 24-hour period.

(ii) *Conclusion*. In this *Example*, the requirement to obtain precertification for the two 24-hour periods immediately following the initial 48-hour stay is prohibited by this paragraph (b)(2) because benefits for the latter part of the stay are restricted in a manner that is less favorable than benefits for a preceding portion of the stay. (However, this section does not prohibit an issuer from requiring precertification for any period after the first 96 hours.) In addition, the requirement to obtain precertification from the issuer based on medical necessity for a hospital length of stay within the 96-hour period would also violate paragraph (a) of this section.

(3) *With respect to attending providers*. An issuer may not directly or indirectly—

(i) Penalize (for example, take disciplinary action against or retaliate against), or otherwise reduce or limit the compensation of, an attending provider because the provider furnished care to a covered individual in accordance with this section; or

(ii) Provide monetary or other incentives to an attending provider to induce the provider to furnish care to a covered individual in a manner inconsistent with this section, including providing any incentive that could induce an attending provider to discharge a mother or newborn earlier than 48 hours (or 96 hours) after delivery.

(c) *Construction*. With respect to this section, the following rules of construction apply:

(1) *Hospital stays not mandatory*. This section does not require a mother to—

(i) Give birth in a hospital; or

(ii) Stay in the hospital for a fixed period of time following the birth of her child.

(2) *Hospital stay benefits not mandated*. This section does not apply to any issuer that does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) *Cost-sharing rules*—(i) *In general*. This section does not prevent an issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or a newborn under the coverage, except that the coinsurance or other cost-sharing for any portion of the hospital length of stay specified in paragraph (a) of this section may not be greater than that for any preceding portion of the stay.

(ii) *Examples*. The rules of this paragraph (c)(3) are illustrated by the following examples. In each example, the issuer is subject to the requirements of this section, as follows:

Example 1. (i) *Facts*. An issuer provides benefits for at least a 48-hour hospital length of stay in connection with vaginal deliveries. The issuer covers 80 percent of the cost of the stay for the first 24-hour period and 50 percent of the cost of the stay for the second 24-hour period. Thus, the coinsurance paid by the patient increases from 20 percent to 50 percent after 24 hours.

(ii) *Conclusion*. In this *Example 1*, the issuer violates the rules of this paragraph (c)(3) because coinsurance for the second 24-hour period of the 48-hour stay is greater than that for the preceding portion of the stay. (In addition, the issuer also violates the similar rule in paragraph (b)(2) of this section.)

Example 2. (i) *Facts*. An issuer generally covers 70 percent of the cost of a hospital length of stay in connection with childbirth. However, the issuer will cover 80 percent of the cost of the stay if the covered individual notifies the issuer of the pregnancy in advance of admission and uses whatever hospital the issuer may designate.

(ii) *Conclusion*. In this *Example 2*, the issuer does not violate the rules of this paragraph (c)(3) because the level of benefits provided (70 percent or 80 percent) is consistent throughout the 48-hour (or 96-hour) hospital length of stay required under paragraph (a) of this section. (In addition, the issuer does not violate the rules in paragraph (a)(4) or (b)(2) of this section.)

(4) *Compensation of attending provider*. This section does not prevent an issuer from negotiating with an attending provider the level and type of compensation for care furnished in accordance with this section (including paragraph (b) of this section).

(5) *Applicability*. This section applies to all health insurance coverage issued in the individual market, and is not limited in its application to coverage that is provided to eligible individuals as defined in section 2741(b) of the PHS Act.

(d) *Notice requirement*. Except as provided in paragraph (d)(4) of this section, an issuer offering health insurance in the individual market must

meet the following requirements with respect to benefits for hospital lengths of stay in connection with childbirth:

(1) Required statement. The insurance contract must disclose information that notifies covered individuals of their rights under this section.

(2) Disclosure notice. To meet the disclosure requirements set forth in paragraph (d)(1) of this section, the following disclosure notice must be used:

STATEMENT OF RIGHTS UNDER THE NEWBORNS' AND MOTHERS' HEALTH PROTECTION ACT

Under federal law, health insurance issuers generally may not restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a delivery by cesarean section. However, the issuer may pay for a shorter stay if the attending provider (*e.g.* , your physician, nurse midwife, or physician assistant), after consultation with the mother, discharges the mother or newborn earlier.

Also, under federal law, issuers may not set the level of benefits or out-of-pocket costs so that any later portion of the 48-hour (or 96-hour) stay is treated in a manner less favorable to the mother or newborn than any earlier portion of the stay.

In addition, an issuer may not, under federal law, require that a physician or other health care provider obtain authorization for prescribing a length of stay of up to 48 hours (or 96 hours). However, to use certain providers or facilities, or to reduce your out-of-pocket costs, you may be required to obtain precertification. For information on precertification, contact your issuer.

(3) *Timing of disclosure*. The disclosure notice in paragraph (d)(2) of this section shall be furnished to the covered individuals in the form of a copy of the contract, or a rider (or equivalent amendment to the contract) no later than December 19, 2008. To the extent an issuer has already provided the disclosure notice in paragraph (d)(2) of this section to covered individuals, it need not provide another such notice by December 19, 2008.

(4) *Exception*. The requirements of this paragraph (d) do not apply with respect to coverage regulated under a state law described in paragraph (e) of this section.

(e) *Applicability in certain states*—(1) *Health insurance coverage*. The requirements of section 2751 of the PHS Act and this section do not apply with respect to health insurance coverage in the individual market if there is a state law regulating the coverage that meets any of the following criteria:

(i) The state law requires the coverage to provide for at least a 48-hour hospital length of stay following a vaginal delivery and at least a 96-hour hospital length of stay following a delivery by cesarean section.

(ii) The state law requires the coverage to provide for maternity and pediatric care in accordance with guidelines that relate to care following childbirth established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or any other established professional medical association.

(iii) The state law requires, in connection with the coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or is required to be made by) the attending provider in consultation with the mother. State laws that require the decision to be made by the attending provider with the consent of the mother satisfy the criterion of this paragraph (e)(1)(iii).

(2) *Relation to section 2762(a) of the PHS Act*. The preemption provisions contained in section 2762(a) of the PHS Act and § 148.210(b) do not supersede a state law described in paragraph (e)(1) of this section.

(f) *Applicability date*. Section 2751 of the PHS Act applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998. This section applies to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 2009.

[73 FR 62427, Oct. 20, 2008]

§ 148.180 Prohibition of discrimination based on genetic information.

(a) *Definitions*. For purposes of this section, the following definitions as set forth in § 146.122 of this subchapter pertain to health insurance issuers in the individual market to the extent that those definitions are not inconsistent with respect to health insurance coverage offered, sold, issued, renewed, in

effect or operated in the individual market:

Collect has the meaning set forth at § 146.122(a).

Family member has the meaning set forth at § 146.122(a).

Genetic information has the meaning set forth at § 146.122(a).

Genetic services has the meaning set forth at § 146.122(a).

Genetic test has the meaning set forth at § 146.122(a).

Manifestation or manifested has the meaning set forth at § 146.122(a).

Preexisting condition exclusion has the meaning set forth at § 144.103.

Underwriting purposes has the meaning set forth at § 148.180(f)(1).

(b) *Prohibition on genetic information as a condition of eligibility.*

(1) *In general.* An issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information.

(2) *Rule of construction.* Nothing in paragraph (b)(1) of this section precludes an issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of that individual when the family member is covered under the policy that covers the individual.

(3) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* A State implements the HIPAA guaranteed availability requirement in the individual health insurance market in accordance with § 148.120. Individual *A* and his spouse *S* are not ''eligible individuals'' as that term is defined at § 148.103 and, therefore, they are not entitled to obtain individual health insurance coverage on a guaranteed available basis. They apply for individual coverage with Issuer *M*. As part of the application for coverage, *M* receives health information about *A* and *S*. Although *A* has no known medical conditions, *S* has high blood pressure. *M* declines to offer coverage to *S*.

(ii) *Conclusion.* In this *Example 1, M* permissibly may decline to offer coverage to *S* because *S* has a manifested disorder (high blood pressure) that makes her ineligible for coverage under the policy's rules for eligibility.

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *S* does not have high blood pressure or any other known medical condition. The only health information relevant to *S* that *M* receives in the application indicates that both of *S*'s parents are overweight and have high blood pressure. *M* declines to offer coverage to *S*.

(ii) *Conclusion.* In this *Example 2, M* cannot decline to offer coverage to *S* because *S* does not have a manifested disease or disorder. The only health information *M* has that relates to her pertains to a manifested disease or disorder of family members, which as family medical history constitutes genetic information with respect to *S*. If *M* denies eligibility to *S* based on genetic information, the denial will violate this paragraph (b).

(c) *Prohibition on genetic information in setting premium rates.*

(1) *In general.* An issuer offering health insurance coverage in the individual market must not adjust premium amounts for an individual on the basis of genetic information regarding the individual or a family member of the individual.

(2) *Rule of construction.* (i) Nothing in paragraph (c)(1) of this section precludes an issuer from adjusting premium amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or on the basis of a manifestation of a disease or disorder in a family member of that individual when the family member is covered under the policy that covers the individual.

(ii) The manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to that individual and to further increase premium amounts.

(3) *Examples.* The rules of this paragraph (c) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *B* is covered under an individual health insurance policy through Issuer *N*. Every other policy year, before renewal, *N* requires policyholders to submit updated health information before the policy renewal date for purposes of determining an appropriate premium, in excess of any increases due to inflation, based on the policyholders' health status. *B* complies with that requirement. During the past year, *B*'s blood glucose levels have increased significantly. *N* increases its premium for renewing *B*'s policy to account for *N*'s increased risk associated with *B*'s elevated blood glucose levels.

(ii) *Conclusion*. In this *Example 1*, *N* is permitted to increase the premium for *B*'s policy on the basis of a manifested disorder (elevated blood glucose) in *B*.

Example 2. (i) *Facts*. Same facts as *Example 1*, except that *B*'s blood glucose levels have not increased and are well within the normal range. In providing updated health information to *N*, *B* indicates that both his mother and sister are being treated for adult onset diabetes mellitus (Type 2 diabetes). *B* provides this information voluntarily and not in response to a specific request for family medical history or other genetic information. *N* increases *B*'s premium to account for *B*'s genetic predisposition to develop Type 2 diabetes in the future.

(ii) *Conclusion*. In this *Example 2*, *N* cannot increase *B*'s premium on the basis of *B*'s family medical history of Type 2 diabetes, which is genetic information with respect to *B*. Since there is no manifestation of the disease in *B* at this point in time, *N* cannot increase *B*'s premium.

(d) *Prohibition on genetic information as preexisting condition*.

(1) *In general*. An issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion with respect to that coverage.

(2) *Rule of construction*. Nothing in paragraph (d)(1) of this section precludes an issuer from imposing any preexisting condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

(3) *Examples:* The rules of this paragraph (d) are illustrated by the following examples:

Example 1. (i) *Facts*. Individual *C* has encountered delays in receiving payment from the issuer of his individual health insurance policy for covered services. He decides to switch carriers and applies for an individual health insurance policy through Issuer *O*. *C* is generally in good health, but has arthritis for which he has received medical treatment. *O* offers *C* an individual policy that excludes coverage for a 12-month period for any services related to *C*'s arthritis.

(ii) *Conclusion*. In this *Example 1*, *O* is permitted to impose a preexisting condition exclusion with respect to *C* because *C* has a manifested disease (arthritis).

Example 2. (i) *Facts*. Individual *D* applies for individual health insurance coverage through Issuer *P*. *D* has no known medical conditions. However, in response to *P*'s request for medical information about *D*, *P* receives information from *D*'s physician that indicates that both of *D*'s parents have adult onset diabetes mellitus (Type 2 diabetes). *P* offers *D* an individual policy with a rider that permanently excludes coverage for any treatment related to diabetes that *D* may receive while covered by the policy, based on the fact that both of *D*'s parents have the disease.

(ii) *Conclusion*. In this *Example 2*, the rider violates this paragraph (d) because the preexisting condition exclusion is based on genetic information with respect to *D* (family medical history of Type 2 diabetes).

(e) *Limitation on requesting or requiring genetic testing*.

(1) *General rule*. Except as otherwise provided in this paragraph (e), an issuer offering health insurance coverage in the individual market must not request or require an individual or a family member of the individual to undergo a genetic test.

(2) *Health care professional may recommend a genetic test*. Nothing in paragraph (e)(1) of this section limits the authority of a health care professional who is providing health care services to an individual to request that the individual undergo a genetic test.

(3) *Examples*. The rules of paragraphs (e)(1) and (e)(2) of this section are illustrated by the following examples:

Example 1. (i) *Facts*. Individual *E* goes to a physician for a routine physical examination. The physician reviews *E*'s family medical history, and *E* informs the physician that *E*'s mother has been diagnosed with Huntington's Disease. The physician advises *E* that Huntington's Disease is hereditary, and recommends that E undergo a genetic test.

(ii) *Conclusion*. In this *Example 1*, the physician is a health care professional who is providing health care services to *E*. Therefore, the physician's recommendation that *E* undergo the genetic test does not violate this paragraph (e).

Example 2. (i) *Facts*. Individual *F* is covered by a health maintenance organization (HMO). *F* is a child being treated for leukemia. *F*'s physician, who is employed by the HMO, is considering a treatment plan that includes six-mercaptopurine, a drug for treating leukemia in most children. However, the drug could be fatal if taken by a small percentage of children with a particular gene variant. *F*'s physician recommends that *F* undergo a genetic test to detect this variant before proceeding with this course of treatment.

(ii) *Conclusion*. In this *Example 2*, even though the physician is employed by the

HMO, the physician is nonetheless a health care professional who is providing health care services to *F*. Therefore, the physician's recommendation that *F* undergo the genetic test does not violate this paragraph (e).

(4) *Determination regarding payment.* (i) *In general.* As provided in this paragraph (e)(4), nothing in paragraph (e)(1) of this section precludes an issuer offering health insurance in the individual market from obtaining and using the results of a genetic test in making a determination regarding payment. For this purpose, ''payment'' has the meaning given such term in § 164.501 of this subtitle of the privacy regulations issued under the Health Insurance Portability and Accountability Act. Thus, if an issuer conditions payment for an item or service based on its medical appropriateness and the medical appropriateness of the item or service depends on a covered individual's genetic makeup, the issuer is permitted to condition payment on the outcome of a genetic test, and may refuse payment if the covered individual does not undergo the genetic test.

(ii) *Limitation.* An issuer in the individual market is permitted to request only the minimum amount of information necessary to make a determination regarding payment. The minimum amount of information necessary is determined in accordance with the minimum necessary standard in § 164.502(b) of this subtitle of the privacy regulations issued under the Health Insurance Portability and Accountability Act.

(iii) *Examples. See* paragraph (g) of this section for examples illustrating the rules of this paragraph (e)(4), as well as other provisions of this section.

(5) *Research exception.* Notwithstanding paragraph (e)(1) of this section, an issuer may request, but not require, that an individual or family member covered under the same policy undergo a genetic test if all of the conditions of this paragraph (e)(5) are met:

(i) *Research in accordance with Federal regulations and applicable State or local law or regulations.* The issuer makes the request pursuant to research, as defined in § 46.102(d) of this subtitle, that complies with Part 46 of this subtitle or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(ii) *Written request for participation in research.* The issuer makes the request in writing, and the request clearly indicates to each individual (or, in the case of a minor child, to the child's legal guardian) that—

(A) Compliance with the request is voluntary; and

(B) Noncompliance will have no effect on eligibility for benefits (as described in paragraph (b) of this section) or premium amounts (as described in paragraph (c) of this section).

(iii) *Prohibition on underwriting.* No genetic information collected or acquired under this paragraph (e)(5) can be used for underwriting purposes (as described in paragraph (f)(1) of this section).

(iv) *Notice to Federal agencies.* The issuer completes a copy of the ''Notice of Research Exception under the Genetic Information Nondiscrimination Act'' authorized by the Secretary and provides the notice to the address specified in the instructions thereto.

(f) *Prohibitions on collection of genetic information.*

(1) *For underwriting purposes.*

(i) *General rule.* An issuer offering health insurance coverage in the individual market must not collect (as defined in paragraph (a) of this section) genetic information for underwriting purposes. *See* paragraph (g) of this section for examples illustrating the rules of this paragraph (f)(1), as well as other provisions of this section.

(ii) *Underwriting purposes defined.* Subject to paragraph (f)(1)(iii) of this section, *underwriting purposes* means, with respect to any issuer offering health insurance coverage in the individual market—

(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the coverage;

(B) The computation of premium amounts under the coverage;

(C) The application of any preexisting condition exclusion under the coverage; and

(D) Other activities related to the creation, renewal, or replacement of a contract of health insurance.

(iii) *Medical appropriateness.* An issuer in the individual market may limit or exclude a benefit based on whether the benefit is medically appropriate, and the determination of whether the benefit is medically appropriate is not within the meaning of underwriting purposes. Accordingly, if an issuer conditions a benefit based on its medical appropriateness and the medical appropriateness of the benefit depends on a covered individual's genetic information, the issuer is permitted to condition the benefit on the genetic information. An issuer is permitted to request only the minimum amount of genetic information necessary to determine medical appropriateness, and may deny the benefit if the covered individual does not provide the genetic information required to determine medical appropriateness. *See* paragraph (g) of this section for examples illustrating the applicability of this paragraph (f)(1)(iii), as well as other provisions of this section.

(2) *Prior to or in connection with enrollment.*

(i) *In general.* An issuer offering health insurance coverage in the individual market must not collect genetic information with respect to any individual prior to that individual's enrollment under the coverage or in connection with that individual's enrollment. Whether or not an individual's information is collected prior to that individual's enrollment is determined at the time of collection.

(ii) *Incidental collection exception.*

(A) *In general.* If an issuer offering health insurance coverage in the individual market obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (f)(2), as long as the collection is not for underwriting purposes in violation of paragraph (f)(1) of this section.

(B) *Limitation.* The incidental collection exception of this paragraph (f)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly provides that genetic information should not be provided.

(iii) *Examples.* The rules of this paragraph (f)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *G* applies for a health insurance policy through Issuer *Q*. *Q*'s application materials ask for the applicant's medical history, but not for family medical history. The application's instructions state that no genetic information, including family medical history, should be provided. *G* answers the questions in the application completely and truthfully, but volunteers certain health information about diseases his parents had, believing that *Q* also needs this information.

(ii) *Conclusion.* In this *Example 1*, *G*'s family medical history is genetic information with respect to *G*. However, since *Q* did not request this genetic information, and *Q*'s instructions stated that no genetic information should be provided, *Q*'s collection is an incidental collection under paragraph (f)(2)(ii). However, *Q* may not use the genetic information it obtained incidentally for underwriting purposes.

Example 2. (i) *Facts.* Individual *H* applies for a health insurance policy through Issuer *R*. *R*'s application materials request that an applicant provide information on his or her individual medical history, including the names and contact information of physicians from whom the applicant sought treatment. The application includes a release which authorizes the physicians to furnish information to *R*. *R* forwards a request for health information about *H*, including the signed release, to his primary care physician. Although the request for information does not ask for genetic information, including family medical history, it does not state that no genetic information should be provided. The physician's office administrator includes part of *H*'s family medical history in the package to *R*.

(ii) *Conclusion.* In this *Example 2*, *R*'s request was for health information solely about its applicant, *H*, which is not genetic information with respect to *H*. However, *R*'s materials did not state that genetic information should not be provided. Therefore, *R*'s collection of *H*'s family medical history (which is genetic information with respect to *H*), violates the rule against collection of genetic information and does not qualify for the incidental collection exception under paragraph (f)(2)(ii).

Example 3. (i) *Facts.* Issuer *S* acquires Issuer *T*. *S* requests *T*'s records, stating that *S* should not provide genetic information and should review the records to excise any genetic information. *T* assembles the data requested by *S* and, although *T* reviews it to delete genetic information, the data from a specific region included some individuals'

family medical history. Consequently, *S* receives genetic information about some of *T*'s covered individuals.

(ii) *Conclusion*. In this *Example 3*, *S*'s request for health information explicitly stated that genetic information should not be provided. Therefore, its collection of genetic information was within the incidental collection exception. However, *S* may not use the genetic information it obtained incidentally for underwriting purposes.

(g) *Examples regarding determinations of medical appropriateness*. The application of the rules of paragraphs (e) and (f) of this section to issuer determinations of medical appropriateness is illustrated by the following examples:

Example 1. (i) *Facts*. Individual *I* has an individual health insurance policy through Issuer *U* that covers genetic testing for celiac disease for individuals who have family members with this condition. *I*'s policy includes dependent coverage. After *I*'s son is diagnosed with celiac disease, *I* undergoes a genetic test and promptly submits a claim for the test to *U* for reimbursement. *U* asks *I* to provide the results of the genetic test before the claim is paid.

(ii) *Conclusion*. In this *Example 1*, under the rules of paragraph (e)(4) of this section, *U* is permitted to request only the minimum amount of information necessary to make a decision regarding payment. Because the results of the test are not necessary for *U* to make a decision regarding the payment of *I*'s claim, *U*'s request for the results of the genetic test violates paragraph (e) of this section.

Example 2. (i) *Facts*. Individual *J* has an individual health insurance policy through Issuer *V* that covers a yearly mammogram for participants starting at age 40, or at age 30 for those with increased risk for breast cancer, including individuals with BRCA1 or BRCA2 gene mutations. *J* is 33 years old and has the BRCA2 mutation. *J* undergoes a mammogram and promptly submits a claim to *V* for reimbursement. *V* asks *J* for evidence of increased risk of breast cancer, such as the results of a genetic test, before the claim for the mammogram is paid.

(ii) *Conclusion*. In this *Example 2*, *V* does not violate paragraphs (e) or (f) of this section. Under paragraph (e), an issuer is permitted to request and use the results of a genetic test to make a determination regarding payment, provided the issuer requests only the minimum amount of information necessary. Because the medical appropriateness of the mammogram depends on the covered individual's genetic makeup, the minimum amount of information necessary includes the results of the genetic test. Similarly, *V* does not violate paragraph (f) of this section because an issuer is permitted to request genetic information in making a determination regarding the medical appropriateness of a claim if the genetic information is necessary to make the determination (and the genetic information is not used for underwriting purposes).

Example 3. (i) *Facts*. Individual *K* was previously diagnosed with and treated for breast cancer, which is currently in remission. In accordance with the recommendation of *K*'s physician, *K* has been taking a regular dose of tamoxifen to help prevent a recurrence. *K* has an individual health insurance policy through Issuer *W* which adopts a new policy requiring patients taking tamoxifen to undergo a genetic test to ensure that tamoxifen is medically appropriate for their genetic makeup. In accordance with, at the time, the latest scientific research, tamoxifen is not helpful in up to 7 percent of breast cancer patients with certain variations of the gene for making the CYP_2D6 enzyme. If a patient has a gene variant making tamoxifen not medically appropriate, *W* does not pay for the tamoxifen prescription.

(ii) *Conclusion*. In this *Example 3*, *W* does not violate paragraph (e) of this section if it conditions future payments for the tamoxifen prescription on *K*'s undergoing a genetic test to determine the genetic markers *K* has for making the CYP_2D6 enzyme. *W* also does not violate paragraph (e) of this section if it refuses future payment if the results of the genetic test indicate that tamoxifen is not medically appropriate for *K*.

(h) *Applicability date*. The provisions of this section are effective with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after December 7, 2009.

[74 FR 51693, Oct. 7, 2009]

Subpart D—Preemption; Excepted Benefits

§ 148.210 Preemption.

(a) *Scope*. (1) This section describes the effect of sections 2741 through 2763 and 2791 of the PHS Act on a State's authority to regulate health insurance issuers in the individual market. This section makes clear that States remain subject to section 514 of ERISA, which generally preempts State law that relates to ERISA-covered plans.

(2) Sections 2741 through 2763 and 2791 of the PHS Act cannot be construed to affect or modify the provisions of section 514 of ERISA.

(b) *Regulation of insurance issuers*. The individual market rules of this part do not prevent a State law from establishing, implementing, or continuing in effect standards or requirements unless the standards or requirements prevent the application of a requirement of this part.

§ 148.220 Excepted benefits.

The requirements of this part do not apply to individual health insurance coverage in relation to its provision of the benefits described in paragraphs (a) and (b) of this section (or any combination of the benefits).

(a) *Benefits excepted in all circumstances*. The following benefits are excepted in all circumstances:

(1) Coverage only for accident (including accidental death and dismemberment).

(2) Disability income insurance.

(3) Liability insurance, including general liability insurance and automobile liability insurance.

(4) Coverage issued as a supplement to liability insurance.

(5) Workers' compensation or similar insurance.

(6) Automobile medical payment insurance.

(7) Credit-only insurance (for example, mortgage insurance).

(8) Coverage for on-site medical clinics.

(b) *Other excepted benefits*. The requirements of this part do not apply to individual health insurance coverage described in paragraphs (b)(1) through (b)(6) of this section if the benefits are provided under a separate policy, certificate, or contract of insurance. These benefits include the following:

(1) Limited scope dental or vision benefits. These benefits are dental or vision benefits that are limited in scope to a narrow range or type of benefits that are generally excluded from benefit packages that combine hospital, medical, and surgical benefits.

(2) Long-term care benefits. These benefits are benefits that are either—

(i) Subject to State long-term care insurance laws;

(ii) For qualified long-term care insurance services, as defined in section 7702B(c)(1) of the Code, or provided under a qualified long-term care insurance contract, as defined in section 7702B(b) of the Code; or

(iii) Based on cognitive impairment or a loss of functional capacity that is expected to be chronic.

(3) Coverage only for a specified disease or illness (for example, cancer policies), or hospital indemnity or other fixed indemnity insurance (for example, $100/day) if the policies meet the requirements of § 146.145(b)(4)(ii)(B) and (b)(4)(ii)(C) of this subchapter regarding noncoordination of benefits.

(4) Medicare supplemental health insurance (as defined under section 1882(g)(1) of the Social Security Act. 42 U.S.C. 1395ss, also known as Medigap or MedSupp insurance). The requirements of this part 148 (including genetic nondiscrimination requirements), do not apply to Medicare supplemental health insurance policies. However, Medicare supplemental health insurance policies are subject to similar genetic nondiscrimination requirements under section 104 of the Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110–233), as incorporated into the NAIC Model Regulation relating to sections 1882(s)(2)(e) and (x) of the Act (The NAIC Model Regulation can be accessed at *http://www.naic.org*.).

(5) Coverage supplemental to the coverage provided under Chapter 55, Title 10 of the United States Code (also known as CHAMPUS supplemental programs).

(6) Similar supplemental coverage provided to coverage under a group health plan.

[62 FR 16995, Apr. 8, 1997; 62 FR 31696, June 10, 1997, as amended at 74 FR 51696, Oct. 7, 2009]

Subpart E—Grants to States for Operation of Qualified High Risk Pools

SOURCE: 68 FR 23414, May 2, 2003, unless otherwise noted.

§ 148.306 Basis and scope.

This subpart implements section 2745 of the Public Health Service Act (PHS Act). It extends grants to States that have qualified high risk pools that meet the specific requirements described in § 148.310. It also provides specific instructions on how to apply for

the grants and outlines the grant review and grant award processes.

[73 FR 22285, Apr. 25, 2008]

§ 148.308 Definitions.

For the purposes of this subpart, the following definitions apply:

Bonus grants means funds that the Secretary provides from the appropriated grant funds to be used to provide supplemental consumer benefits to enrollees or potential enrollees in qualified high risk pools.

CMS stands for Centers for Medicare & Medicaid Services.

Loss means the difference between expenses incurred by a qualified high risk pool, including payment of claims and administrative expenses, and the premiums collected by the pool.

Qualified high risk pool as defined in sections 2744(c)(2) and 2745(g) of the PHS Act means a risk pool that—

(1) Provides to all eligible individuals health insurance coverage (or comparable coverage) that does not impose any preexisting condition exclusion with respect to such coverage for all eligible individuals, except that it may provide for enrollment of eligible individuals through an acceptable alternative mechanism (as defined for purposes of section 2744 of the PHS Act) that includes a high risk pool as a component; and

(2) Provides for premium rates and covered benefits for such coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act that was in effect at the time of the enactment of the Health Insurance Portability and Accountability Act of 1996 (August 21, 1996) but only if the model has been revised in State regulations to meet all of the requirements of this part and title 27 of the PHS Act.

Standard risk rate means a rate developed by a State using reasonable actuarial techniques and taking into account the premium rates charged by other insurers offering health insurance coverage to individuals in the same geographical service area to which the rate applies. The standard rate may be adjusted based upon age, sex, and geographical location.

State means any of the 50 States and the District of Columbia and includes the U.S. Territories of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

State fiscal year, for purposes of this subpart, means the fiscal year used for accounting purposes by either a State or a risk pool entity to which a State has delegated the authority to conduct risk pool operations.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004; 72 FR 41236, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.310 Eligibility requirements for a grant.

A State must meet all of the following requirements to be eligible for a grant:

(a) The State has a qualified high risk pool as defined in § 148.308.

(b) The pool restricts premiums charged under the pool to no more than 200 percent of the premium for applicable standard risk rates for the State.

(c) The pool offers a choice of two or more coverage options through the pool.

(d) The pool has in effect a mechanism reasonably designed to ensure continued funding of losses incurred by the State after the end of each fiscal year for which the State applies for Federal Funding in fiscal year (FY) 2005 through FY 2010 in connection with the operation of the pool.

(e) The pool has incurred a loss in a period described in § 148.314.

(f) In the case of a qualified high risk pool in a State that charges premiums that exceed 150 percent of the premium for applicable standard risks, the State will use at least 50 percent of the amount of the grant provided to the State to reduce premiums for enrollees.

(g) In no case will the aggregate amount allotted and made available to the U.S. Territories for a fiscal year exceed $1,000,000 in total.

(h) Bonus grant funding must be used for one or more of the following benefits:

(1) Low income premium subsidies;

(2) Reduction in premium trends, actual premium or other cost-sharing requirements;

(3) An expansion or broadening of the pool of individuals eligible for coverage, such as through eliminating

waiting lists, increasing enrollment caps, or providing flexibility in enrollment rules;

(4) Less stringent rules or additional waiver authority with respect to coverage of pre-existing conditions;

(5) Increased benefits; and

(6) The establishment of disease management programs.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41236, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.312 Amount of grant payment.

(a) An eligible State may receive a grant to fund up to 100 percent of the losses incurred in the operation of its qualified high risk pool during the period for which it is applying or a lesser amount based on the limits of the allotment under the formula.

(b) Funds will be allocated in accordance with this paragraph to each State that meets the eligibility requirements of § 148.310 and files an application in accordance with § 148.316. The amount will be divided among the States that apply and are awarded grants according to the allotment rules that generally provide that: 40 percent will be equally divided among those States; 30 percent will be divided among States and territories based on their number of uninsured residents in the State during the specified year as compared to all States that apply; and 30 percent will be divided among States and territories based on the number of people in State high risk pools during the specified year as compared to all States that apply.

For purposes of this paragraph:

(1) The number of uninsured individuals is calculated for each eligible State by taking a 3-year average of the number of uninsured individuals in that State in the Current Population Survey (CPS) of the Census Bureau during the period for which it is applying. The 3-year average will be calculated using numbers available as of March 1 of each year.

(2) The number of individuals enrolled in health care coverage through the qualified high risk pool of the State will be determined by attestation by the State in its grant application and verified for reasonability by the Secretary through acceptable industry data sources.

(c) The amount awarded to each eligible State will be the lesser of the 50 percent of losses incurred by its qualified risk pool for the fiscal year in question or its allotment under the formula.

(d) One-third of the total appropriation will be available for the bonus grants. In no case will a State for a fiscal year receive bonus grants that exceed 10 percent of the total allotted funds for bonus grants.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15700, Mar. 26, 2004; 72 FR 41237, July 27, 2007; 73 FR 22285, Apr. 25, 2008]

§ 148.314 Periods during which eligible States may apply for a grant.

(a) *General rule.* A State that meets the eligibility requirements in § 148.310 may apply for a grant to fund losses that were incurred during the State's FYs 2005, 2006, 2007, 2008 and 2009 in connection with the operation of its qualified high risk pool. Funding for FY 2007 through FY 2010 under the Extension Act requires subsequent enactment of appropriations authority. States will be unable to apply for grants unless and until such funding becomes available. Grants funding is on a retrospective basis and applies to the States previous fiscal year. If a State becomes eligible for a grant in the middle of its fiscal year, a State may apply for losses incurred in a partial fiscal year if a partial year audit is done. Only losses that are incurred after eligibility is established will qualify for a grant.

(b) *Maximum number of grants.* An eligible State may only be awarded a maximum of five grants, with one grant per fiscal year. A grant for a partial fiscal year counts as a full grant.

(c) *Deadline for submitting grant applications.* The deadlines for submitting grant applications are stated in § 148.316(d).

(d) *Distribution of grant funds.* States that meet all of the eligibility requirements in § 148.310 and submit timely requests in accordance with paragraph (c) of this section will receive an initial distribution of grant funds using the

following methodology: Grant applications for losses will be on a retrospective basis. For example, grant applications for 2006 funds are based on the State's FY 2005 incurred losses. Grant funding was appropriated for Federal FY 2006 and is authorized to be appropriated for Federal FYs 2008 through 2010.

(e) *Grant allocations.* Grant allocations for each fiscal year will be determined by taking all grant applications during the period for which States are applying and allocating the funds in accordance with § 148.312.

(1) In no case will a State receive funds greater than 100 percent of their losses.

(2) If any excess funds remain after the initial calculation, these excess funds will be proportionately redistributed to the States whose allocations have not exceeded 100 percent of their losses.

[73 FR 22285, Apr. 25, 2008]

§ 148.316 Grant application instructions.

Funding for FY 2008, FY 2009, and FY 2010 under the Extension Act requires the subsequent enactment of appropriations authority. Funding was appropriated for Federal FY 2006. States will be unable to apply for FY 2008 through FY 2010 grants unless and until such funding becomes available.

(a) *Application for operational losses.* Each State must compile an application package that documents that it has met the requirements for a grant. If a risk pool entity applies on behalf of a State, it must provide documentation that it has been delegated appropriate authority by the State. At a minimum, the application package must include a completed standard form application kit (see paragraph (b) of this section) along with the following information:

(1) *History and description of the qualified high risk pool.* Provide a detailed description of the qualified high risk pool that includes the following:

(i) Brief history, including date of inception.

(ii) Enrollment criteria (including provisions for the admission of eligible individuals as defined in § 148.103) and number of enrollees.

(iii) Description of how coverage is provided administratively in the qualified high risk pool (that is, self-insured, through a private carrier, etc.).

(iv) Benefits options and packages offered in the qualified high risk pool to both eligible individual (as defined in § 148.103) and other applicants.

(v) Outline of plan benefits and coverage offered in the pool. Provide evidence that the level of plan benefits is consistent with either Alternative One or Alternative Two in Section 8 of the NAIC Model Health Plan for Uninsurable Individuals Act. See appendix for the text of Section 8 of the NAIC Model.

(vi) Premiums charged (in terms of dollars and in percentage of standard risk rate) and other cost-sharing mechanisms, such as co-pays and deductibles, imposed on enrollees (both eligible individuals (as defined in § 148.103) and non-eligible individuals if a distinction is made).

(vii) How the standard risk rate for the State is calculated and when it was last calculated.

(viii) Revenue sources for the qualified high risk pool, including current funding mechanisms and, if different, future funding mechanisms. Provide current projections of future income.

(ix) Copies of all governing authorities of the pool, including statutes, regulations and plan of operation.

(2) *Accounting of risk pool losses.* Provide a detailed accounting of claims paid, administrative expenses, and premiums collected for the fiscal year for which the grant is being requested. Indicate the timing of the fiscal year upon which the accounting is based. Provide the methodology of projecting losses and expenses, and include current projections of future operating losses (this information is needed to judge compliance with the requirements in § 148.310(d)).

(3) *Bonus grants for supplemental consumer benefits.* Provide detailed information about the following supplemental consumer benefits for which the entity is applying:

(i) A narrative description of one or more of the following of the supplemental consumer benefits to be provided to enrollees and/or potential enrollees in the high risk pool:

(A) Low income premium subsidies;

(B) Reduction in premium trends, actual premium or other cost-sharing requirements;

(C) An expansion or broadening of the pool of individuals eligible for coverage, such as through eliminating waiting lists, increasing enrollment caps, or providing flexibility in enrollment;

(D) Less stringent rules, or additional waiver authority with respect to coverage of pre-existing conditions;

(E) Increased benefits; and

(F) The establishment of disease management programs.

(ii) A description of the population or subset population that will be eligible for the supplemental consumer benefits.

(iii) A projected budget for the use of bonus grant funds using the SF 424 A.

(4) *Contact person*. Identify the name, position title, address, e-mail address, and telephone number of the person to contact for further information and questions.

(b) Standard form application kit—(1) Forms. (i) The following standard forms must be completed with an original signature and enclosed as part of the application package:

SF–424 Application for Federal Assistance.

SF–424A Budget Information.

SF–424B Assurances Non-Construction Programs.

SF–LLL Disclosure of Lobbying Activities Biographical Sketch.

(ii) These forms can be accessed from the following Web site: *http://www.grants.gov*.

(2) *Other narrative*. All other narrative in the application must be submitted on 8½ × 11 inches white paper.

(c) *Application submission*. Submission of application package is through *http://www.grants.gov*. Submissions by facsimile (fax) transmissions will not be accepted.

(d) *Application deadlines*. (1) The deadline for States to submit an application for losses incurred in a State fiscal year is June 30 of the next Federal fiscal year that begins after the end of the State fiscal year. Funding for FY 2008, FY 2009, and FY 2010 under the Extension Act requires the subsequent enactment of appropriations authority. Funding was appropriated for Federal FY 2006. States will be unable to apply for FY 2008 through FY 2010 grants unless and until such funding becomes available.

(2) *Deadline for States to submit an application for losses incurred in their fiscal year 2005*. States had to submit an application to CMS no later than June 30, 2006.

(3) *Deadline for States to submit an application for losses incurred in their fiscal year 2006*. States must submit an application to CMS by no later than June 30, 2007.

(4) *Deadline for States to submit an application for losses incurred in their fiscal year 2007*. States must submit an application to CMS by no later than June 30, 2008.

(5) *Deadline for States to submit an application for losses incurred in their fiscal year 2008*. States must submit an application to CMS by no later than June 30, 2009.

(6) *Deadline for States to submit an application for losses incurred in their fiscal year 2009*. States must submit an application to CMS by no later than June 30, 2010.

(e) *Where to submit an application*. Applications must be submitted to *http://www.grants.gov*. Submissions by facsimile (fax) transmissions will not be accepted.

[68 FR 23414, May 2, 2003, as amended at 69 FR 15701, Mar. 26, 2004; 72 FR 41237, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

§ 148.318 Grant application review.

(a) *Executive Order 12372*. This grant program is not listed by the Secretary under § 100.3 of this title, and therefore the grant program is not subject to review by States under part 100 of this title, which implements Executive Order 12372, ''Intergovernmental Review of Federal Programs'' (see part 100 of this title).

(b) *Review team*. A team consisting of staff from CMS and the Department of Health and Human Services will review all applications. The team will meet as necessary on an ongoing basis as applications are received.

(c) *Eligibility criteria*. To be eligible for a grant, a State must submit sufficient documentation that its high risk pool meets the eligibility requirements

described in § 148.310. A State must include sufficient documentation of the losses incurred in the operation of the qualified high risk pool in the period for when it is applying.

(d) *Review criteria.* If the review team determines that a State meets the eligibility requirements described in § 148.310, the review team will use the following additional criteria in reviewing the applications:

(1) *Documentation of expenses incurred during operation of the qualified high risk pool.* The losses and expenses incurred in the operation of a State's pool are sufficiently documented.

(2) *Funding mechanism.* The State has outlined funding sources, such as assessments and State general revenues, which can cover the projected costs and are reasonably designed to ensure continued funding of losses a State incurs in connection with the operation of the qualified high risk pool after each fiscal year for which it is applying for grant funds.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

§ 148.320 Grant awards.

(a) *Notification and award letter.* (1) Each State applicant will be notified in writing of CMS's decision on its application.

(2) If the State applicant is awarded a grant, the award letter will contain the following terms and conditions:

(i) All funds awarded to the grantee under this program must be used exclusively for the operation of a qualified high risk pool that meets the eligibility requirements for this program.

(ii) The grantee must keep sufficient records of the grant expenditures for audit purposes (see part 92 of this title).

(iii) The grantee will be required to submit quarterly progress and financial reports under part 92 of this title and in accordance with section 2745(f) of the Public Health Service Act, requiring the Secretary to make an annual report to Congress that includes information on the use of these grant funds by States.

(b) *Grantees letter of acceptance.* Grantees must submit a letter of acceptance to CMS' Acquisition and Grants Group within 30 days of the date of the award agreeing to the terms and conditions of the award letter.

[68 FR 23414, May 2, 2003, as amended at 72 FR 41238, July 27, 2007; 73 FR 22286, Apr. 25, 2008]

PART 149—REQUIREMENTS FOR THE EARLY RETIREE REINSURANCE PROGRAM

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AUTHORITY: Section 1102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 24466, May 5, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 149.1 Purpose and basis.

This part implements the Early Retiree Reinsurance Program, as required by section 1102 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

§ 149.2 Definitions.

For purposes of this part, the following definitions apply:

Authorized representative means an individual with legal authority to sign and bind a sponsor to the terms of a contract or agreement.

Benefit option means a particular benefit design, category of benefits, or cost-sharing arrangement offered within an employment-based plan.

Certified means that the sponsor and its employment-based plan or plans meet the requirements of this part and the sponsor's application to participate in the program has been approved by the Secretary.

Chronic and high-cost condition means a condition for which $15,000 or more in health benefit claims are likely to be incurred during a plan year by one plan participant.

Claim or *medical claim* means documentation, in a form and manner to be specified by the Secretary, indicating the health benefit provided, the provider or supplier, the incurred date, the individual for whom the health benefit was provided, the date and amount of payment net any known negotiated price concessions, and the employment-based plan and benefit option under which the health benefit was provided. The terms *claim* or *medical claim* include medical, surgical, hospital, prescription drug and other such claims as determined by the Secretary.

Early retiree means a plan participant who is age 55 and older who is enrolled for health benefits in a certified employment-based plan, who is not eligible for coverage under title XVIII of the Act, and who is not an active employee of an employer maintaining, or currently contributing to, the employment-based plan or of any employer that has made substantial contributions to fund such plan. In this part, the term *early retiree* also includes the enrolled spouse, surviving spouse, and dependents of such individuals. The determination of whether an individual is not an active employee is made by the sponsor in accordance with the rules of its plan. For purposes of this subpart, however, an individual is presumed to be an active employee if, under the Medicare Secondary Payer rules in 42 CFR 411.104 and related guidance published by the Centers for Medicare & Medicaid Services, the person is considered to be receiving coverage by reason of current employment status. This presumption applies whether or not the Medicare Secondary Payer rules actually apply to the sponsor. For this purpose, a sponsor may also treat a person receiving coverage under its employment-based plan as a dependent in accordance with the rules of its plan, regardless of whether that individual is considered a dependent for Federal or state tax purposes. For purposes of this definition of early retiree, an employer maintaining, or currently contributing to, the employment-based plan or any employer that has made substantial contributions to fund such plan, means a plan sponsor (as defined in this section).

Employment-based plan means a group health plan as defined in this section of the regulation.

Good cause means:

(1) New and material evidence exists that was not readily available at the time the reimbursement determination was made;

(2) A clerical error in the computation of the reimbursement determination was made by the Secretary; or

(3) The evidence that was considered in making the reimbursement determination clearly shows on its face that an error was made.

Group health plan means group health plan as defined in 42 CFR 423.882 that provides health benefits to early retirees, but excludes Federal governmental plans.

Health benefits means medical, surgical, hospital, prescription drug, and other benefits that may be specified by the Secretary, whether self-funded or delivered through the purchase of health insurance or otherwise. Such benefits include benefits for the diagnosis, cure, mitigation, or prevention of physical or mental disease or condition with respect to any structure or function of the body. Health benefits do not include benefits specified at 45 CFR 146.145(c)(2) through (4).

Incurred means the point in time when the sponsor, health insurance issuer (as defined in 45 CFR 160.103), employment-based plan, plan participant, or a combination of these or similar stakeholders, become responsible for payment of the claim.

Negotiated price concession means any direct or indirect remuneration (including discounts, direct or indirect subsidies, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits) offered to some or all purchasers, which may include a sponsor, a health insurance issuer, or an employment-based plan) that would serve to decrease the costs incurred under the employment-based plan.

Plan participant means anyone enrolled in an applicable plan including an early retiree, as defined in this section, a retiree, a retiree's spouse and dependent, an active employee and an active employee's spouse and dependent.

Plan year means the year that is designated as the plan year in the plan document of an employment-based plan, except that if the plan document does not designate a plan year, if the plan year is not a 12-month plan year, or if there is no plan document, the plan year is:

(1) The deductible or limit year used under the plan;

(2) The policy year, if the plan does not impose deductibles or limits on a 12-month basis;

(3) The sponsor's taxable year, If the plan does not impose deductibles or limits on a 12-month basis, and either the plan is not insured or the insurance policy is not renewed on a 12-month basis, or;

(4) The calendar year, in any other case.

Post point-of-sale negotiated price concession means any negotiated price concession that an employment-based plan or insurer receives with respect to a given health benefit, after making payment for that health benefit.

Program means the Early Retiree Reinsurance Program established in section 1102 of the Patient Protection and Affordable Care Act.

Secretary means the Secretary of the United States Department of Health & Human Services or the Secretary's designee.

Sponsor means a plan sponsor as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1002(16)(B), except that in the case of a plan maintained jointly by one employer and an employee organization and for which the employer is the primary source of financing, the term means the employer.

Sponsor agreement means an agreement between the sponsor and the United States Department of Health & Human Services, or its designee, which is made to comply with the provisions of this part.

Subpart B—Requirements for Eligible Employment-Based Plans

§ 149.30 General requirements.

A sponsor is eligible to participate in the program if it meets the requirements of section 1102 of the Patient Protection and Affordable Care Act, this part, and guidance developed by the Secretary.

§ 149.35 Requirements to participate.

(a) A sponsor's employment-based plan must—

(1) Be certified by the Secretary.

(2) Include programs and procedures that have generated or have the potential to generate cost-savings with respect to plan participants with chronic and high-cost conditions.

(b) A sponsor must—

(1) Make available information, data, documents, and records as specified in § 149.350.

(2) Have a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan (as applicable) regarding disclosure of information, data, documents, and records, to the Secretary, and the health insurance issuer or employment-based plan must disclose to the Secretary, on behalf of the sponsor, at a time and in a manner specified by the Secretary in guidance, the information, data, documents and records necessary for the sponsor to comply with the program, this part, and program guidance.

(3) Ensure that policies and procedures to protect against fraud, waste and abuse under this program are in place, and must comply timely with requests from the Secretary to produce the policies and procedures and any documents or data to substantiate the implementation of the policies and procedures and their effectiveness.

(4) Submit an application to the Secretary in the manner, and at the time, required by the Secretary as specified in § 149.40.

§ 149.40 Application.

(a) The applicant must submit an application to participate in this program to the Secretary, which is signed by an authorized representative of the applicant who certifies that the information contained in the application is true and accurate to the best of the authorized representative's knowledge and belief.

(b) Applications will be processed in the order in which they are received.

(c) An application that fails to meet all the requirements of this part will be denied and the applicant must submit another application if it wishes to participate in the program. The new application will be processed based on when the new submission is received.

(d) An applicant need not submit a separate application for each plan year but must identify in its application the plan year start and end date cycle (starting month and day, and ending month and day) for which it is applying.

(e) An applicant must submit an application for each plan for which it will submit a reimbursement request.

(f) In connection with each application the applicant must submit the following:

(1) Applicant's Tax Identification Number.

(2) Applicant's name and address.

(3) Contact name, telephone number and email address.

(4) Plan sponsor agreement signed by an authorized representative, which includes—

(i) An assurance that the sponsor has a written agreement with its health insurance issuer (as defined in 45 CFR 160.103) or employment-based plan, as applicable, regarding disclosure of information to the Secretary, and the health insurance issuer or employment-based plan must disclose to the Secretary, on behalf of the sponsor, at a time and in a manner specified by the Secretary in guidance, information, data, documents, and records necessary for the sponsor to comply with the requirements of the program.

(ii) An acknowledgment that the information in the application is being provided to obtain Federal funds, and that all subcontractors acknowledge that information provided in connection with a subcontract is used for purposes of obtaining Federal funds.

(iii) An attestation that policies and procedures are in place to detect and reduce fraud, waste, and abuse, and that the sponsor will produce the policies and procedures, and necessary information, records and data, upon request by the Secretary, to substantiate existence of the policies and procedures and their effectiveness.

(iv) Other terms and conditions required by the Secretary.

(5) A summary indicating how the applicant will use any reimbursement received under the program to meet the requirements of the program, including:

(i) How the reimbursement will be used to reduce premium contributions, co-payments, deductibles, coinsurance, or other out-of-pocket costs for plan

participants, to reduce health benefit or health benefit premium costs for the sponsor, or to reduce any combination of these costs;

(ii) What procedures or programs the sponsor has in place that have generated or have the potential to generate cost savings with respect to plan participants with chronic and high-cost conditions; and

(iii) How the sponsor will use the reimbursement to maintain its level of contribution to the applicable plan.

(6) Projected amount of reimbursement to be received under the program for the first two plan year cycles with specific amounts for each of the two cycles.

(7) A list of all benefit options under the employment-based plan that any early retiree for whom the sponsor receives program reimbursement may be claimed.

(8) Any other information the Secretary requires.

(g) An application must be approved, and the plan and the sponsor certified, by the Secretary before a sponsor may request reimbursement under the program.

(h) The Secretary may reopen a determination under which an application had been approved or denied:

(1) Within 1 year of the determination for any reason;

(2) Within 4 years of the determination if the evidence that was considered in making the determination shows on its face that an error was made; or

(3) At any time in instances of fraud or similar fault.

§ 149.41 Consequences of Non-Compliance, Fraud, or Similar Fault.

Upon failure to comply with the requirements of this part, or if fraud, waste, and abuse, or similar fault are found, the Secretary may recoup or withhold funds, terminate or deny a sponsor's application, or take a combination of these actions.

§ 149.45 Funding limitation.

(a) Based on the projected or actual availability of program funding, the Secretary may deny applications that otherwise meet the requirements of this part, and if an application is approved, may deny all or part of a sponsor's reimbursement request.

(b) The Secretary's decision to stop accepting applications or satisfying reimbursement requests based on the availability of funding is final and binding, and is not appealable.

Subpart C—Reinsurance Amounts

§ 149.100 Amount of reimbursement.

(a) For each early retiree enrolled in a certified plan in a plan year, the sponsor receives reimbursement in the amount of 80 percent of the costs for health benefits (net of negotiated price concessions for health benefits) for claims incurred during the plan year that are attributed to health benefits costs between the cost threshold and cost limit, and that are paid by the employment-based plan or by the insurer (if an insured plan), and by the early retiree.

(b) Costs are considered paid by an early retiree, if paid by that individual or another person on behalf of the early retiree, and the early retiree (or person paying on behalf of the early retiree) is not reimbursed through insurance or otherwise, or other third party payment arrangement.

(c) Reimbursement is calculated by first determining the costs for health benefits net of negotiated price concessions, within the applicable plan year for each early retiree, and then subtracting amounts below the cost threshold and above the cost limit within the applicable plan year for each such individual.

(d) For purposes of determining amounts below the cost threshold and above the cost limit for any given early retiree, all costs for health benefits paid by the employment-based plan (or by the insurer, if applicable), or by or on behalf of, an early retiree, for all benefit options the early retiree is enrolled in with respect to a given certified employment-based plan for a given plan year, will be combined. For each early retiree enrolled in an employment-based plan, there is only one cost threshold and one cost limit per plan year regardless of the number of benefit options the early retiree is enrolled in during that plan year.

§ 149.105 Transition provision.

For a certified plan that has a plan year that begins before June 1, 2010 and ends on any date thereafter, the reinsurance amount for the plan year must be determined as follows:

(a) With respect to claims incurred before June 1, 2010, the amount of such claims up to $15,000 count toward the cost threshold and the cost limit. The amount of claims incurred before June 1, 2010 that exceed $15,000 are not eligible for reimbursement and do not count toward the cost limit.

(b) The reinsurance amount to be paid is based only on claims incurred on and after June 1, 2010, that fall between the cost threshold and cost limit for the plan year.

§ 149.110 Negotiated price concessions.

(a) The amount of negotiated price concessions that will be taken into account in determining the reinsurance amount will reflect negotiated price concessions that have already been subtracted from the amount the employment-based plan or insurer paid for the cost of health benefits and the amount of post-point-of-sale negotiated price concessions received.

(b) At a time specified by the Secretary, sponsors are required to disclose the amount of post-point-of-sale price concessions that were received but not accounted for in their submitted claims.

§ 149.115 Cost threshold and cost limit.

The following cost threshold and cost limits apply individually, to each early retiree as defined in § 149.2:

(a) The cost threshold is equal to $15,000 for plan years that start on any date before October 1, 2011.

(b) The cost limit is equal to $90,000 for plan years that start on any date before October 1, 2011.

(c) The cost threshold and cost limit specified in paragraphs (a) and (b) of this section, for plan years that start on or after October 1, 2011, will be adjusted each fiscal year based on the percentage increase in the Medical Care Component of the Consumer Price Index for all urban consumers (rounded to the nearest multiple of $1,000) for the year involved.

Subpart D—Use of Reimbursements

§ 149.200 Use of reimbursements.

(a) A sponsor must use the proceeds under this program:

(1) To reduce the sponsor's health benefit premiums or health benefit costs,

(2) To reduce health benefit premium contributions, copayments, deductibles, coinsurance, or other out-of-pocket costs, or any combination of these costs, for plan participants, or

(3) To reduce any combination of the costs in (a)(1) and (a)(2) of this section.

(b) Proceeds under this program must not be used as general revenue for the sponsor.

Subpart E—Reimbursement Methods

§ 149.300 General reimbursement rules.

Reimbursement under this program is conditioned on provision of accurate information by the sponsor or its designee. The information must be submitted, in a form and manner and at the times provided in this subpart and other guidance specified by the Secretary. A sponsor must provide the information specified in section § 149.335.

§ 149.310 Timing.

(a) An employment-based plan and a sponsor must be certified by the Secretary before claims can be submitted and a reimbursement request may be made. Reimbursement will be made with respect to submitted claims for health benefits at a time and in a manner to be specified by the Secretary, after the sponsor or its designee submits the claims to the Secretary. Claims must satisfy the requirements of this subpart in order to be eligible for reimbursement.

(b) Claims for health benefits may be submitted for a given plan year only upon the approval of an application that references that plan year cycle. Claims for an early retiree for a plan year cannot be submitted until the total paid costs for health benefits for that early retiree incurred for that

plan year exceed the applicable cost threshold.

(c) For employment-based plans for which a provider in the normal course of business does not produce a claim, such as a staff-model health maintenance organization, the information required in a claim must be produced and provided to the Secretary, as set out in this regulation and applicable guidance.

§ 149.315 Reimbursement conditioned upon available funds.

Notwithstanding a sponsor's compliance with this part, reimbursement is conditioned upon the availability of program funds.

§ 149.320 Universe of claims that must be submitted.

(a) Claims submitted for an early retiree, as defined in § 149.2, must include claims below the applicable cost threshold for the plan year.

(b) Claims must not be submitted until claims are submitted for amounts that exceed the applicable cost threshold for the plan year for the early retiree.

(c) Sponsors must not submit claims for health benefits for an early retiree to the extent the sponsor has already submitted claims for the early retiree that total more than the applicable cost limit for the applicable plan year.

§ 149.325 Requirements for eligibility of claims.

A claim may be submitted only if it represents costs for health benefits for an early retiree, as defined in § 149.2, has been incurred during the applicable plan year, and has been paid.

§ 149.330 Content of claims.

Each claim on its face must include the information specified in, and meet, the definition of claim or medical claim found at § 149.2.

§ 149.335 Documentation of costs of actual claims involved.

(a) A submission of claims consists of a list of early retirees for whom claims are being submitted, and documentation of the actual costs of the items and services for claims being submitted, in a form and manner specified by the Secretary.

(b) In order for a sponsor to receive reimbursement for the portion of a claim that an early retiree paid, the sponsor must submit prima facie evidence that the early enrollee paid his or her portion of the claim.

§ 149.340 Rule for insured plans.

With respect to insured plans, the claims and data specified in the subpart may be submitted directly to the Secretary by the insurer.

§ 149.345 Use of information provided.

The Secretary may use data and information collected under this section only for the purpose of, and to the extent necessary in, carrying out this part including, but not limited to, determining reimbursement and reimbursement-related oversight and program integrity activities, or as otherwise allowed by law. Nothing in this section limits the Office of the Inspector General's authority to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

§ 149.350 Maintenance of records.

(a) The sponsor of the certified plan (or a subcontractor, as applicable) must maintain and furnish to the Secretary, upon request the records enumerated in paragraph (b) of this section. The records must be maintained for 6 years after the expiration of the plan year in which the costs were incurred, or longer if otherwise required by law.

(b) The records that must be retained are as follows—

(1) All documentation, data, and other information related to this part.

(2) Any other records specified by the Secretary.

(c) The Secretary may issue additional guidance addressing recordkeeping requirements, including (but not limited to) the use of electronic media.

(d) The sponsor must require its health insurance issuer or employment-based plan, as applicable, to maintain and produce upon request records to satisfy subparagraph (a) of this regulation.

(e) The sponsor is responsible for ensuring that the records are maintained and provided according to this subpart.

Subpart F—Appeals

§ 149.500 Appeals.

(a) An adverse reimbursement determination is final and binding unless appealed pursuant to paragraph (e) of this section.

(b) Except as provided in paragraph (c) of this section, a sponsor may request an appeal of an adverse reimbursement determination.

(c) A sponsor may not appeal an adverse reimbursement determination if the denial is based on the unavailability of funds.

(d) An adverse reimbursement determination is a determination constituting a complete or partial denial of a reimbursement request.

(e) If a sponsor appeals an adverse reimbursement determination, the sponsor must submit the appeal in writing to the Secretary within 15 calendar days of receipt of the determination pursuant to guidance issued by the Secretary.

§ 149.510 Content of request for appeal.

The request for appeal must specify the findings or issues with which the sponsor disagrees and the reasons for the disagreements. The request for appeal may include supporting documentary evidence the sponsor wishes the Secretary to consider.

§ 149.520 Review of appeals.

(a) In conducting review of the appeal, the Secretary reviews the appeal, the evidence and findings upon which the adverse reimbursement determination was made, and any other written evidence submitted by the sponsor or the Secretary's designee and will provide a ruling on the appeal request.

(b) In conducting the review, the Secretary reviews the determination at issue, the evidence and findings upon which it was based, any written documents submitted to the Secretary by the sponsor and the Secretary's designee, and determines whether to uphold, reverse or modify the Secretary's initial reimbursement determination.

(c) A decision by the Secretary under this provision is final and binding.

(d) Regardless of the Secretary's decision, additional reimbursement is contingent upon the availability of funds at the time of the Secretary's determination.

(e) The Secretary informs the sponsor and the applicable Secretary's designee of the decision. The Secretary sends a written decision to the sponsor or the applicable Secretary's designee upon request.

Subpart G—Disclosure of Data Inaccuracies

§ 149.600 Sponsor's duty to report data inaccuracies.

A sponsor is required to disclose any data inaccuracies upon which a reimbursement determination is made, including inaccurate claims data and negotiated price concessions, in a manner and at a time specified by the Secretary in guidance.

§ 149.610 Secretary's authority to reopen and revise a reimbursement determination.

(a) The Secretary may reopen and revise a reimbursement determination upon the Secretary's own motion or upon the request of a sponsor:

(1) Within 1 year of the reimbursement determination for any reason.

(2) Within 4 years of a reimbursement determination for good cause.

(3) At any time, in instances of fraud or similar fault.

(b) For purposes of this section, the Secretary does not find good cause if the only reason for the revision is a change of legal interpretation or administrative ruling upon which the determination to reimburse was made.

(c) A decision by the Secretary not to revise a reimbursement determination is final and binding (unless fraud or similar fault is found) and cannot be appealed.

Subpart H—Change of Ownership Requirements

§ 149.700 Change of ownership requirements.

(a) *Change of ownership consists of:* (1) *Partnership.* The removal, addition, or

substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable state law.

(2) *Asset sale.* Transfer of all or substantially all of the assets of the sponsor to another party.

(3) *Corporation.* The merger of the sponsor's corporation into another corporation or the consolidation of the sponsor's organization with one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership; exception.* Transfer of corporate stock or the merger of another corporation into the sponsor's corporation, with the sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement.* A sponsor that has a sponsor agreement in effect under this part and is considering or negotiating a change in ownership must notify the Secretary at least 60 days before the anticipated effective date of the change.

(d) *Assignment of agreement.* When there is a change of ownership as specified in paragraph (a) of this section, and this results in a transfer of the liability for health benefits, the existing sponsor agreement is automatically assigned to the new owner.

(e) *Conditions that apply to assigned agreements.* The new owner to whom a sponsor agreement is assigned is subject to all applicable statutes and regulations and to the terms and conditions of the sponsor agreement.

(f) Failure to notify the Secretary at least 60 days before the anticipated effective date of the change may result in the Secretary recovering funds paid under this program.

PART 150—CMS ENFORCEMENT IN GROUP AND INDIVIDUAL INSURANCE MARKETS

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AUTHORITY: Secs. 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92).

SOURCE: 64 FR 45795, Aug. 20, 1999, unless otherwise noted.

Subpart A—General Provisions

§ 150.101 Basis and scope.

(a) *Basis*. CMS's enforcement authority under sections 2722 and 2761 of the PHS Act and its rulemaking authority under section 2792 of the PHS Act provide the basis for issuing regulations under this part 150.

(b) *Scope*—(1) *Enforcement with respect to group heath plans*. The provisions of title XXVII of the PHS Act that apply to group health plans that are non-Federal governmental plans are enforced by CMS using the procedures described in § 150.301 *et seq*.

(2) *Enforcement with respect to health insurance issuers*. The States have primary enforcement authority with respect to the requirements of title XXVII of the PHS Act that apply to health insurance issuers offering coverage in the group or individual health insurance market. If CMS determines under subpart B of this part that a State is not substantially enforcing title XXVII of the PHS Act, including the implementing regulations in part 146 and part 148 of this subchapter, CMS enforces them under subpart C of this part.

§ 150.103 Definitions.

The definitions that appear in part 144 of this subchapter apply to this part 150, unless stated otherwise. As used in this part:

Amendment, *endorsement*, or *rider* means a document that modifies or changes the terms or benefits of an individual policy, group policy, or certificate of insurance.

Application means a signed statement of facts by a potential insured that an issuer uses as a basis for its decision whether, and on what basis to insure an individual, or to issue a certificate of insurance, or that a non-Federal governmental health plan uses as a basis for a decision whether to enroll an individual under the plan.

Certificate of insurance means the document issued to a person or entity covered under an insurance policy issued to a group health plan or an association or trust that summarizes the benefits and principal provisions of the policy.

Complaint means any expression, written or oral, indicating a potential denial of any right or protection contained in HIPAA requirements (whether ultimately justified or not) by an individual, a personal representative or other entity acting on behalf of an individual, or any entity that believes such a right is being or has been denied an individual.

Group health insurance policy or group policy means the legal document or contract issued by an issuer to a plan sponsor with respect to a group health plan (including a plan that is a non-Federal governmental plan) that contains the conditions and terms of the insurance that covers the group.

HIPAA requirements means the requirements of title XXVII of the PHS Act and its implementing regulations in parts 146 and 148 of this subchapter.

Individual health insurance policy or individual policy means the legal document or contract issued by the issuer to an individual that contains the conditions and terms of the insurance. Any association or trust arrangement that is not a group health plan as defined in § 144.103 of this subchapter or does not provide coverage in connection with one or more group health plans is individual coverage subject to

the requirements of part 148 of this subchapter. The term ''individual health insurance policy'' includes a policy that is—

(1) Issued to an association that makes coverage available to individuals other than in connection with one or more group health plans; or

(2) Administered, or placed in a trust, and is not sold in connection with a group health plan subject to the provisions of part 146 of this subchapter.

Plan document means the legal document that provides the terms of the plan to individuals covered under a group health plan, such as a non-Federal governmental health plan.

State law means all laws, decisions, rules, regulations, or other State action having the effect of law, of any State as defined in § 144.103 of this subchapter. A law of the United States applicable to the District of Columbia is treated as a State law rather than a law of the United States.

Subpart B—CMS Enforcement Processes for Determining Whether States Are Failing To Substantially Enforce HIPAA Requirements

§ 150.201 State enforcement.

Except as provided in subpart C of this part, each State enforces HIPAA requirements with respect to health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State.

§ 150.203 Circumstances requiring CMS enforcement.

CMS enforces HIPAA requirements to the extent warranted (as determined by CMS) in any of the following circumstances:

(a) *Notification by State.* A State notifies CMS that it has not enacted legislation to enforce or that it is not otherwise enforcing HIPAA requirements.

(b) *Determination by CMS.* If CMS receives or obtains information that a State may not be substantially enforcing HIPAA requirements, it may initiate the process described in this subchapter to determine whether the State is failing to substantially enforce these requirements.

(c) *Special rule for guaranteed availability in the individual market.* If a State has notified CMS that it is implementing an acceptable alternative mechanism in accordance with § 148.128 of this subchapter instead of complying with the guaranteed availability requirements of § 148.120, CMS's determination focuses on the following:

(1) Whether the State's mechanism meets the requirements for an acceptable alternative mechanism.

(2) Whether the State is implementing the acceptable alternative mechanism.

(d) *Consequence of a State not implementing an alternative mechanism.* If a State is not implementing an acceptable alternative mechanism, CMS determines whether the State is substantially enforcing the requirements of §§ 148.101 through 148.126 and § 148.170 of this subchapter.

§ 150.205 Sources of information triggering an investigation of State enforcement.

Information that may trigger an investigation of State enforcement includes, but is not limited to, any of the following:

(a) A complaint received by CMS.

(b) Information learned during informal contact between CMS and State officials.

(c) A report in the news media.

(d) Information from the governors and commissioners of insurance of the various States regarding the status of their enforcement of HIPAA requirements.

(e) Information obtained during periodic review of State health care legislation. CMS may review State health care and insurance legislation and regulations to determine whether they are:

(1) Consistent with HIPAA requirements.

(2) Not pre-empted as provided in § 146.143 (relating to group market provisions) and § 148.120 (relating to individual market requirements) on the basis that they prevent the application of a HIPAA requirement.

(f) Any other information that indicates a possible failure to substantially enforce.

§ 150.207 Procedure for determining that a State fails to substantially enforce HIPAA requirements.

Sections 150.209 through 150.219 describe the procedures CMS follows to determine whether a State is substantially enforcing HIPAA requirements.

§ 150.209 Verification of exhaustion of remedies and contact with State officials.

If CMS receives a complaint or other information indicating that a State is failing to enforce HIPAA requirements, CMS assesses whether the affected individual or entity has made reasonable efforts to exhaust available State remedies. As part of its assessment, CMS may contact State officials regarding the questions raised.

§ 150.211 Notice to the State.

If CMS is satisfied that there is a reasonable question whether there has been a failure to substantially enforce HIPAA requirements, CMS sends, in writing, the notice described in § 150.213 of this part, to the following State officials:

(a) The governor or chief executive officer of the State.

(b) The insurance commissioner or chief insurance regulatory official.

(c) If the alleged failure involves HMOs, the official responsible for regulating HMOs if different from the official listed in paragraph (b) of this section.

§ 150.213 Form and content of notice.

The notice provided to the State is in writing and does the following:

(a) Identifies the HIPAA requirement or requirements that have allegedly not been substantially enforced.

(b) Describes the factual basis for the allegation of a failure or failures to enforce HIPAA requirements.

(c) Explains that the consequence of a State's failure to substantially enforce HIPAA requirements is that CMS enforces them.

(d) Advises the State that it has 30 days from the date of the notice to respond, unless the time for response is extended as described in § 150.215 of this subpart. The State's response should include any information that the State wishes CMS to consider in making the preliminary determination described in § 150.217.

§ 150.215 Extension for good cause.

CMS may extend, for good cause, the time the State has for responding to the notice described in § 150.213 of this subpart. Examples of good cause include an agreement between CMS and the State that there should be a public hearing on the State's enforcement, or evidence that the State is undertaking expedited enforcement activities.

§ 150.217 Preliminary determination.

If, at the end of the 30-day period (and any extension), the State has not established to CMS's satisfaction that it is substantially enforcing the HIPAA requirements described in the notice, CMS takes the following actions:

(a) Consults with the appropriate State officials identified in § 150.211 (or their designees).

(b) Notifies the State of CMS's preliminary determination that the State has failed to substantially enforce the requirements and that the failure is continuing.

(c) Permits the State a reasonable opportunity to show evidence of substantial enforcement.

§ 150.219 Final determination.

If, after providing notice and a reasonable opportunity for the State to show that it has corrected any failure to substantially enforce, CMS finds that the failure to substantially enforce has not been corrected, it will send the State a written notice of its final determination. The notice includes the following:

(a) Identification of the HIPAA requirements that CMS is enforcing.

(b) The effective date of CMS's enforcement.

§ 150.221 Transition to State enforcement.

(a) If CMS determines that a State for which it has assumed enforcement authority has enacted and implemented legislation to enforce HIPAA requirements and also determines that it is appropriate to return enforcement authority to the State, CMS will enter into discussions with State officials to

ensure that a transition is effected with respect to the following:

(1) Consumer complaints and inquiries.

(2) Instructions to issuers.

(3) Any other pertinent aspect of operations.

(b) CMS may also negotiate a process to ensure that, to the extent practicable, and as permitted by law, its records documenting issuer compliance and other relevant areas of CMS's enforcement operations are made available for incorporation into the records of the State regulatory authority that will assume enforcement responsibility.

Subpart C—CMS Enforcement With Respect to Issuers and Non-Federal Governmental Plans—Civil Money Penalties

§ 150.301 General rule regarding the imposition of civil money penalties.

If any health insurance issuer that is subject to CMS's enforcement authority under § 150.101(b)(2), or any non-Federal governmental plan (or employer that sponsors a non-Federal governmental plan) that is subject to CMS's enforcement authority under § 150.101(b)(1), fails to comply with HIPAA requirements, it may be subject to a civil money penalty as described in this subpart.

§ 150.303 Basis for initiating an investigation of a potential violation.

(a) *Information.* Any information that indicates that any issuer may be failing to meet the HIPAA requirements or that any non-Federal governmental plan that is a group health plan as defined in section 2791(a)(1) of the PHS Act and 45 CFR § 144.103 may be failing to meet an applicable HIPAA requirement, may warrant an investigation. CMS may consider, but is not limited to, the following sources or types of information:

(1) Complaints.

(2) Reports from State insurance departments, the National Association of Insurance Commissioners, and other Federal and State agencies.

(3) Any other information that indicates potential noncompliance with HIPAA requirements.

(b) *Who may file a complaint.* Any entity or individual, or any entity or personal representative acting on that individual's behalf, may file a complaint with CMS if he or she believes that a right to which the aggrieved person is entitled under HIPAA requirements is being, or has been, denied or abridged as a result of any action or failure to act on the part of an issuer or other responsible entity as defined in § 150.305.

(c) *Where a complaint should be directed.* A complaint may be directed to any CMS regional office.

§ 150.305 Determination of entity liable for civil money penalty.

If a failure to comply is established under this Part, the responsible entity, as determined under this section, is liable for any civil money penalty imposed.

(a) *Health insurance issuer is responsible entity*—(1) *Group health insurance policy.* To the extent a group health insurance policy issued, sold, renewed, or offered to a private plan sponsor or a non-Federal governmental plan sponsor is subject to applicable HIPAA requirements, a health insurance issuer is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraphs (b) or (c) of this section, if the policy itself or the manner in which the policy is marketed or administered fails to comply with an applicable HIPAA requirement.

(2) *Individual health insurance policy.* To the extent an individual health insurance policy is subject to an applicable HIPAA requirement, a health insurance issuer is subject to a civil money penalty if the policy itself, or the manner in which the policy is marketed or administered, violates any applicable HIPAA requirement.

(b) *Non-Federal governmental plan is responsible entity*—(1) *Basic rule.* If a non-Federal governmental plan is sponsored by two or more employers and fails to comply with an applicable HIPAA requirement, the plan is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraph (a) of this section. The plan is the responsible entity irrespective of whether the plan is administered by a health insurance

issuer, an employer sponsoring the plan, or a third-party administrator.

(2) *Exception*. In the case of a non-Federal governmental plan that is not provided through health insurance coverage, this paragraph (b) does not apply to the extent that the non-Federal governmental employers have elected under § 146.180 to exempt the plan from applicable HIPAA requirements.

(c) *Employer is responsible entity*—(1) *Basic rule*. If a non-Federal governmental plan is sponsored by a single employer and fails to comply with an applicable HIPAA requirement, the employer is subject to a civil money penalty, irrespective of whether a civil money penalty is imposed under paragraph (a) of this section. The employer is the responsible entity irrespective of whether the plan is administered by a health insurance issuer, the employer, or a third-party administrator.

(2) *Exception*. In the case of a non-Federal governmental plan that is not provided through health insurance coverage, this paragraph (c) does not apply to the extent the non-Federal governmental employer has elected under § 146.180 to exempt the plan from applicable HIPAA requirements.

(d) *Actions or inactions of agent*. A principal is liable for penalties assessed for the actions or inactions of its agent.

§ 150.307 Notice to responsible entities.

If an investigation under § 150.303 indicates a potential violation, CMS provides written notice to the responsible entity or entities identified under § 150.305. The notice does the following:

(a) Describes the substance of any complaint or other information.

(b) Provides 30 days from the date of the notice for the responsible entity or entities to respond with additional information, including documentation of compliance as described in § 150.311.

(c) States that a civil money penalty may be assessed.

[64 FR 45795, Aug. 20, 1999, as amended at 70 FR 71023, Nov. 25, 2005]

§ 150.309 Request for extension.

In circumstances in which an entity cannot prepare a response to CMS within the 30 days provided in the notice, the entity may make a written request for an extension from CMS detailing the reason for the extension request and showing good cause. If CMS grants the extension, the responsible entity must respond to the notice within the time frame specified in CMS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in CMS's imposition of a civil money penalty based upon the complaint or other information alleging or indicating a violation of HIPAA requirements.

§ 150.311 Responses to allegations of noncompliance.

In determining whether to impose a civil money penalty, CMS reviews and considers documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with HIPAA requirements. The following are examples of documentation that a potential responsible entity may submit for CMS's consideration in determining whether a civil money penalty should be assessed and the amount of any civil money penalty:

(a) Any individual policy, group policy, certificate of insurance, application, rider, amendment, endorsement, certificate of creditable coverage, advertising material, or any other documents if those documents form the basis of a complaint or allegation of noncompliance, or the basis for the responsible entity to refute the complaint or allegation.

(b) Any other evidence that refutes an alleged noncompliance.

(c) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(d) Documentation that the policies, certificates of insurance, or non-Federal governmental plan documents have been amended to comply with HIPAA requirements either by revision of the contracts or by the development of riders, amendments, or endorsements.

(e) Documentation of the entity's issuance of conforming policies, certificates of insurance, plan documents, or amendments to policyholders or certificate holders before the issuance of

the notice to the responsible entity or entities described in § 150.307.

(f) Evidence documenting the development and implementation of internal policies and procedures by an issuer, or non-Federal governmental health plan or employer, to ensure compliance with HIPAA requirements. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's, or non-Federal governmental health plan's or employer's, commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with HIPAA requirements and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(g) Evidence documenting the entity's record of previous compliance with HIPAA requirements.

[64 FR 45795, Aug. 20, 1999, as amended at 70 FR 71023, Nov. 25, 2005]

§ 150.313 Market conduct examinations.

(a) *Definition*. A market conduct examination means the examination of health insurance operations of an issuer, or the operation of a non-Federal governmental plan, involving the review of one or more (or a combination) of a responsible entity's business or operational affairs, or both, to verify compliance with HIPAA requirements.

(b) *General*. If, based on the information described in § 150.303, CMS finds evidence that a specific entity may be in violation of a HIPAA requirement, CMS may initiate a market conduct examination to determine whether the entity is out of compliance. CMS may conduct the examinations either at the site of the issuer or other responsible entity or a site CMS selects. When CMS selects a site, it may direct the issuer or other responsible entity to forward any documentation CMS considers relevant for purposes of the examination to that site.

(c) *Appointment of examiners*. When CMS identifies an issue that warrants investigation, CMS will appoint one or more examiners to perform the examination and instruct them as to the scope of the examination.

(d) *Appointment of professionals and specialists*. When conducting an examination under this part, CMS may retain attorneys, independent actuaries, independent market conduct examiners, or other professionals and specialists as examiners.

(e) *Report of market conduct examination*—(1) *CMS review*. When CMS receives a report, it will review the report, together with the examination work papers and any other relevant information, and prepare a final report. The final examination report will be provided to the issuer or other responsible entity.

(2) *Response from issuer or other responsible entity*. With respect to each examination issue identified in the report, the issuer or other responsible entity may:

(i) Concur with CMS's position(s) as outlined in the report, explaining the plan of correction to be implemented.

(ii) Dispute CMS's position(s), clearly outlining the basis for its dispute and submitting illustrative examples where appropriate.

(3) *CMS's reply to a response from an issuer or other responsible entity*. Upon receipt of a response from the issuer or other responsible entity, CMS will provide a letter containing its reply to each examination issue. CMS's reply will consist of one of the following:

(i) Concurrence with the issuer's or non-Federal governmental plan's position.

(ii) Approval of the issuer's or non-Federal governmental plan's proposed plan of correction.

(iii) Conditional approval of the issuer's or non-Federal governmental plan's proposed plan of correction, which will include any modifications CMS requires.

(iv) Notice to the issuer or non-Federal governmental plan that there exists a potential violation of HIPAA requirements.

§ 150.315 Amount of penalty—General.

A civil money penalty for each violation of 42 U.S.C. 300gg *et seq.* may not exceed $100 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this part are in addition to any other penalties prescribed or allowed by law.

§ 150.317 Factors CMS uses to determine the amount of penalty.

In determining the amount of any penalty, CMS takes into account the following:

(a) *The entity's previous record of compliance.* This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation or violations, CMS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of HIPAA requirements.

(2) Documentation that the responsible entity has submitted its policy forms to CMS for compliance review.

(3) Evidence that the responsible entity has never had a complaint for noncompliance with HIPAA requirements filed with a State or CMS.

(4) Such other factors as justice may require.

(b) *The gravity of the violation.* This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

§ 150.319 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil money penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by § 150.315 to reflect that fact. As guidelines for taking into account the factors listed in § 150.317, CMS considers the following:

(a) *Record of prior compliance.* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under § 150.307, implemented and followed a compliance plan as described in § 150.311(f).

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s).* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with HIPAA requirements so that the following occur:

(i) All employers, employees, individuals and non-Federal governmental entities are identified that are or were issued any policy, certificate of insurance or plan document, or any form used in connection therewith that failed to comply.

(ii) All employers, employees, individuals, and non-Federal governmental plans are identified that were denied coverage or were denied a right provided under HIPAA requirements.

(iii) Each employer, employee, individual, or non-Federal governmental plan adversely affected by the violation has been, for example, offered coverage or provided a certificate of creditable coverage in a manner that complies with HIPAA requirements that were violated so that, to the extent practicable, that employer, employee, individual, or non-Federal governmental entity is in the same position that he, she, or it would have been in had the violation not occurred.

(iv) The adjustments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from CMS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

§ 150.321 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil money penalty, if there are substantial or several aggravating circumstances, CMS sets the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by § 150.315 to reflect that fact. CMS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 150.323 Determining the amount of penalty—other matters as justice may require.

CMS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 150.325 Settlement authority.

Nothing in §§ 150.315 through 150.323 limits the authority of CMS to settle any issue or case described in the notice furnished in accordance with § 150.307 or to compromise on any penalty provided for in §§ 150.315 through 150.323.

§ 150.341 Limitations on penalties.

(a) *Circumstances under which a civil money penalty is not imposed.* CMS does not impose any civil money penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. CMS also does not impose a civil money penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to CMS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 150.343 Notice of proposed penalty.

If CMS proposes to assess a penalty in accordance with this part, it delivers to the responsible entity, or sends to that entity by certified mail, return receipt requested, written notice of its intent to assess a penalty. The notice includes the following:

(a) A description of the HIPAA requirements that CMS has determined that the responsible entity violated.

(b) A description of any complaint or other information upon which CMS based its determination, including the basis for determining the number of affected individuals and the number of days for which the violations occurred.

(c) The amount of the proposed penalty as of the date of the notice.

(d) Any circumstances described in §§ 150.317 through 150.323 that were considered when determining the amount of the proposed penalty.

(e) A specific statement of the responsible entity's right to a hearing.

(f) A statement that failure to request a hearing within 30 days permits the assessment of the proposed penalty without right of appeal in accordance with § 150.347.

§ 150.345 Appeal of proposed penalty.

Any entity against which CMS has assessed a penalty may appeal that penalty in accordance with § 150.401 *et seq*.

§ 150.347 Failure to request a hearing.

If the responsible entity does not request a hearing within 30 days of the issuance of the notice described in § 150.343, CMS may assess the proposed civil money penalty, a less severe penalty, or a more severe penalty. CMS notifies the responsible entity in writing of any penalty that has been assessed and of the means by which the responsible entity may satisfy the judgment. The responsible entity has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 unless the responsible entity can show good cause, as determined under § 150.405(b), for failing to timely exercise its right to a hearing.

Subpart D—Administrative Hearings

§ 150.401 Definitions.

In this subpart, unless the context indicates otherwise:

ALJ means administrative law judge of the Departmental Appeals Board of the Department of Health and Human Services.

Filing date means the date postmarked by the U.S. Postal Service, deposited with a carrier for commercial delivery, or hand delivered.

Hearing includes a hearing on a written record as well as an in-person or telephone hearing.

Party means CMS or the respondent.

Receipt date means five days after the date of a document, unless there is a showing that it was in fact received later.

Respondent means an entity that received a notice of proposed assessment of a civil money penalty issued pursuant to § 150.343.

§ 150.403 Scope of ALJ's authority.

(a) The ALJ has the authority, including all of the authority conferred by the Administrative Procedure Act, to adopt whatever procedures may be necessary or proper to carry out in an efficient and effective manner the ALJ's duty to provide a fair and impartial hearing on the record and to issue an initial decision concerning the imposition of a civil money penalty.

(b) The ALJ's authority includes the authority to modify, consistent with the Administrative Procedure Act (5 U.S.C. 552a), any hearing procedures set out in this subpart.

(c) The ALJ does not have the authority to find invalid or refuse to follow Federal statutes or regulations.

§ 150.405 Filing of request for hearing.

(a) A respondent has a right to a hearing before an ALJ if it files a request for hearing that complies with § 150.407(a), within 30 days after the date of issuance of either CMS's notice of proposed assessment under § 150.343 or notice that an alternative dispute resolution process has terminated. The request for hearing should be addressed as instructed in the notice of proposed determination. ''Date of issuance'' is five (5) days after the filing date, unless there is a showing that the document was received earlier.

(b) The ALJ may extend the time for filing a request for hearing only if the ALJ finds that the respondent was prevented by events or circumstances beyond its control from filing its request within the time specified above. Any request for an extension of time must be made promptly by written motion.

§ 150.407 Form and content of request for hearing.

(a) The request for hearing must do the following:

(1) Identify any factual or legal bases for the assessment with which the respondent disagrees.

(2) Describe with reasonable specificity the basis for the disagreement, including any affirmative facts or legal arguments on which the respondent is relying.

(b) The request for hearing must identify the relevant notice of assessment by date and attach a copy of the notice.

§ 150.409 Amendment of notice of assessment or request for hearing.

The ALJ may permit CMS to amend its notice of assessment, or permit the respondent to amend a request for hearing that complies with § 150.407(a), if the ALJ finds that no undue prejudice to either party will result.

§ 150.411 Dismissal of request for hearing.

An ALJ will order a request for hearing dismissed if the ALJ determines that:

(a) The request for hearing was not filed within 30 days as specified by § 150.405(a) or any extension of time granted by the ALJ pursuant to § 150.405(b).

(b) The request for hearing fails to meet the requirements of § 150.407.

(c) The entity that filed the request for hearing is not a respondent under § 150.401.

(d) The respondent has abandoned its request.

(e) The respondent withdraws its request for hearing.

§ 150.413 Settlement.

CMS has exclusive authority to settle any issue or any case, without the consent of the administrative law judge at any time before or after the administrative law judge's decision.

§ 150.415 Intervention.

(a) The ALJ may grant the request of an entity, other than the respondent, to intervene if all of the following occur:

(1) The entity has a significant interest relating to the subject matter of the case.

(2) Disposition of the case will, as a practical matter, likely impair or impede the entity's ability to protect that interest.

(3) The entity's interest is not adequately represented by the existing parties.

(4) The intervention will not unduly delay or prejudice the adjudication of the rights of the existing parties.

(b) A request for intervention must specify the grounds for intervention and the manner in which the entity seeks to participate in the proceedings. Any participation by an intervenor must be in the manner and by any deadline set by the ALJ.

(c) The Department of Labor or the IRS may intervene without regard to paragraphs (a)(1) through (a)(3) of this section.

§ 150.417 Issues to be heard and decided by ALJ.

(a) The ALJ has the authority to hear and decide the following issues:

(1) Whether a basis exists to assess a civil money penalty against the respondent.

(2) Whether the amount of the assessed civil money penalty is reasonable.

(b) In deciding whether the amount of a civil money penalty is reasonable, the ALJ—

(1) Applies the factors that are identified in § 150.317.

(2) May consider evidence of record relating to any factor that CMS did not apply in making its initial determination, so long as that factor is identified in this subpart.

(c) If the ALJ finds that a basis exists to assess a civil money penalty, the ALJ may sustain, reduce, or increase the penalty that CMS assessed.

§ 150.419 Forms of hearing.

(a) All hearings before an ALJ are on the record. The ALJ may receive argument or testimony in writing, in person, or by telephone. The ALJ may receive testimony by telephone only if the ALJ determines that doing so is in the interest of justice and economy and that no party will be unduly prejudiced. The ALJ may require submission of a witness' direct testimony in writing only if the witness is available for cross-examination.

(b) The ALJ may decide a case based solely on the written record where there is no disputed issue of material fact the resolution of which requires the receipt of oral testimony.

§ 150.421 Appearance of counsel.

Any attorney who is to appear on behalf of a party must promptly file, with the ALJ, a notice of appearance.

§ 150.423 Communications with the ALJ.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 150.425 Motions.

(a) Any request to the ALJ for an order or ruling must be by motion, stating the relief sought, the authority relied upon, and the facts alleged. All motions must be in writing, with a copy served on the opposing party, except in either of the following situations:

(1) The motion is presented during an oral proceeding before an ALJ at which both parties have the opportunity to be present.

(2) An extension of time is being requested by agreement of the parties or with waiver of objections by the opposing party.

(b) Unless otherwise specified in this subpart, any response or opposition to a motion must be filed within 20 days of the party's receipt of the motion. The ALJ does not rule on a motion before the time for filing a response to the motion has expired except where the response is filed at an earlier date, where the opposing party consents to the motion being granted, or where the ALJ determines that the motion should be denied.

§ 150.427 Form and service of submissions.

(a) Every submission filed with the ALJ must be filed in triplicate, including one original of any signed documents, and include:

(1) A caption on the first page, setting forth the title of the case, the docket number (if known), and a description of the submission (such as ''Motion for Discovery'').

(2) The signatory's name, address, and telephone number.

(3) A signed certificate of service, specifying each address to which a copy of the submission is sent, the date on which it is sent, and the method of service.

(b) A party filing a submission with the ALJ must, at the time of filing, serve a copy of such submission on the opposing party. An intervenor filing a submission with the ALJ must, at the time of filing, serve a copy of the submission on all parties. Service must be made by mailing or hand delivering a copy of the submission to the opposing party. If a party is represented by an attorney, service must be made on the attorney.

§ 150.429 Computation of time and extensions of time.

(a) For purposes of this subpart, in computing any period of time, 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. When the period of time allowed is less than seven days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal government are excluded from the computation.

(b) The period of time for filing any responsive pleading or papers is determined by the date of receipt (as defined in § 150.401) of the submission to which a response is being made.

(c) The ALJ may grant extensions of the filing deadlines specified in these regulations or set by the ALJ for good cause shown (except that requests for extensions of time to file a request for hearing may be granted only on the grounds specified in section § 150.405(b)).

§ 150.431 Acknowledgment of request for hearing.

After receipt of the request for hearing, the ALJ assigned to the case or someone acting on behalf of the ALJ will send a letter to the parties that acknowledges receipt of the request for hearing, identifies the docket number assigned to the case, provides instructions for filing submissions and other general information concerning procedures, and sets out the next steps in the case.

§ 150.435 Discovery.

(a) The parties must identify any need for discovery from the opposing party as soon as possible, but no later than the time for the reply specified in § 150.437(c). Upon request of a party, the ALJ may stay proceedings for a reasonable period pending completion of discovery if the ALJ determines that a party would not be able to make the submissions required by § 150.437 without discovery. The parties should attempt to resolve any discovery issues informally before seeking an order from the ALJ.

(b) Discovery devices may include requests for production of documents, requests for admission, interrogatories, depositions, and stipulations. The ALJ orders interrogatories or depositions only if these are the only means to develop the record adequately on an issue that the ALJ must resolve to decide the case.

(c) Each discovery request must be responded to within 30 days of receipt, unless that period of time is extended for good cause by the ALJ.

(d) A party to whom a discovery request is directed may object in writing for any of the following reasons:

(1) Compliance with the request is unduly burdensome or expensive.

(2) Compliance with the request will unduly delay the proceedings.

(3) The request seeks information that is wholly outside of any matter in dispute.

(4) The request seeks privileged information. Any party asserting a claim of privilege must sufficiently describe the information or document being withheld to show that the privilege applies. If an asserted privilege applies to only part of a document, a party withholding the entire document must state why the nonprivileged part is not segregable.

(e) Any motion to compel discovery must be filed within 10 days after receipt of objections to the party's discovery request, within 10 days after the time for response to the discovery request has elapsed if no response is received, or within 10 days after receipt of an incomplete response to the discovery request. The motion must be reasonably specific as to the information or document sought and must state its relevance to the issues in the case.

§ 150.437 Submission of briefs and proposed hearing exhibits.

(a) Within 60 days of its receipt of the acknowledgment provided for in § 150.431, the respondent must file the following with the ALJ:

(1) A statement of its arguments concerning CMS's notice of assessment (respondent's brief), including citations to the respondent's hearing exhibits provided in accordance with paragraph (a)(2) of this section. The brief may not address factual or legal bases for the assessment that the respondent did not identify as disputed in its request for hearing or in an amendment to that request permitted by the ALJ.

(2) All documents (including any affidavits) supporting its arguments, tabbed and organized chronologically and accompanied by an indexed list identifying each document (respondent's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any stipulations or admissions.

(b) Within 30 days of its receipt of the respondent's submission required by paragraph (a) of this section, CMS will file the following with the ALJ:

(1) A statement responding to the respondent's brief, including the respondent's proposed hearing exhibits, if appropriate. The statement may include citations to CMS's proposed hearing exhibits submitted in accordance with paragraph (b)(2) of this section.

(2) Any documents supporting CMS's response not already submitted as part of the respondent's proposed hearing exhibits, organized and indexed as indicated in paragraph (a)(2) of this section (CMS's proposed hearing exhibits).

(3) A statement regarding whether there is a need for an in-person hearing and, if so, a list of proposed witnesses and a summary of their expected testimony that refers to any factual dispute to which the testimony will relate.

(4) Any admissions or stipulations.

(c) Within 15 days of its receipt of CMS's submission required by paragraph (b) of this section, the respondent may file with the ALJ a reply to CMS's submission.

§ 150.439 Effect of submission of proposed hearing exhibits.

(a) Any proposed hearing exhibit submitted by a party in accordance with § 150.437 is deemed part of the record unless the opposing party raises an objection to that exhibit and the ALJ rules to exclude it from the record. An objection must be raised either in writing prior to the prehearing conference provided for in § 150.441 or at the prehearing conference. The ALJ may require a party to submit the original hearing exhibit on his or her own motion or in response to a challenge to the authenticity of a proposed hearing exhibit.

(b) A party may introduce a proposed hearing exhibit following the times for submission specified in § 150.437 only if the party establishes to the satisfaction of the ALJ that it could not have produced the exhibit earlier and that the opposing party will not be prejudiced.

§ 150.441 Prehearing conferences.

An ALJ may schedule one or more prehearing conferences (generally conducted by telephone) on the ALJ's own motion or at the request of either party for the purpose of any of the following:

(a) Hearing argument on any outstanding discovery request.

(b) Establishing a schedule for any supplements to the submissions required by § 150.437 because of information obtained through discovery.

(c) Hearing argument on a motion.

(d) Discussing whether the parties can agree to submission of the case on a stipulated record.

(e) Establishing a schedule for an in-person hearing, including setting deadlines for the submission of written direct testimony or for the written reports of experts.

(f) Discussing whether the issues for a hearing can be simplified or narrowed.

(g) Discussing potential settlement of the case.

(h) Discussing any other procedural or substantive issues.

§ 150.443 Standard of proof.

(a) In all cases before an ALJ—

(1) CMS has the burden of coming forward with evidence sufficient to establish a prima facie case;

(2) The respondent has the burden of coming forward with evidence in response, once CMS has established a prima facie case; and

(3) CMS has the burden of persuasion regarding facts material to the assessment; and

(4) The respondent has the burden of persuasion regarding facts relating to an affirmative defense.

(b) The preponderance of the evidence standard applies to all cases before the ALJ.

§ 150.445 Evidence.

(a) The ALJ will determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ will not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate; for example, to exclude unreliable evidence.

(c) The ALJ excludes irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence is excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement made in this action will be inadmissible to the extent provided in the Federal Rules of Evidence.

(g) Evidence of acts other than those at issue in the instant case is admissible in determining the amount of any civil money penalty if those acts are used under §§ 150.317 and 150.323 of this part to consider the entity's prior record of compliance, or to show motive, opportunity, intent, knowledge, preparation, identity, or lack of mistake. This evidence is admissible regardless of whether the acts occurred

during the statute of limitations period applicable to the acts that constitute the basis for liability in the case and regardless of whether CMS's notice sent in accordance with §§ 150.307 and 150.343 referred to them.

(h) The ALJ will permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record will be open to examination by all parties, unless the ALJ orders otherwise for good cause shown.

(j) The ALJ may not consider evidence regarding the willingness and ability to enter into and successfully complete a corrective action plan when that evidence pertains to matters occurring after CMS's notice under § 150.307.

§ 150.447 The record.

(a) Any testimony that is taken in-person or by telephone is recorded and transcribed. The ALJ may order that other proceedings in a case, such as a prehearing conference or oral argument of a motion, be recorded and transcribed.

(b) The transcript of any testimony, exhibits and other evidence that is admitted, and all pleadings and other documents that are filed in the case constitute the record for purposes of an ALJ decision.

(c) For good cause, the ALJ may order appropriate redactions made to the record.

§ 150.449 Cost of transcripts.

Generally, each party is responsible for 50 percent of the transcript cost. Where there is an intervenor, the ALJ determines what percentage of the transcript cost is to be paid for by the intervenor.

§ 150.451 Posthearing briefs.

Each party is entitled to file proposed findings and conclusions, and supporting reasons, in a posthearing brief. The ALJ will establish the schedule by which such briefs must be filed. The ALJ may direct the parties to brief specific questions in a case and may impose page limits on posthearing briefs. Additionally, the ALJ may allow the parties to file posthearing reply briefs.

§ 150.453 ALJ decision.

The ALJ will issue an initial agency decision based only on the record and on applicable law; the decision will contain findings of fact and conclusions of law. The ALJ's decision is final and appealable after 30 days unless it is modified or vacated under § 150.457.

§ 150.455 Sanctions.

(a) The ALJ may sanction a party or an attorney for failing to comply with an order or other directive or with a requirement of a regulation, for abandonment of a case, or for other actions that interfere with the speedy, orderly or fair conduct of the hearing. Any sanction that is imposed will relate reasonably to the severity and nature of the failure or action.

(b) A sanction may include any of the following actions:

(1) In the case of failure or refusal to provide or permit discovery, drawing negative fact inferences or treating such failure or refusal as an admission by deeming the matter, or certain facts, to be established.

(2) Prohibiting a party from introducing certain evidence or otherwise advocating a particular claim or defense.

(3) Striking pleadings, in whole or in part.

(4) Staying the case.

(5) Dismissing the case.

(6) Entering a decision by default.

(7) Refusing to consider any motion or other document that is not filed in a timely manner.

(8) Taking other appropriate action.

§ 150.457 Review by Administrator.

(a) The Administrator of CMS (which for purposes of this subsection may include his or her delegate), at his or her discretion, may review in whole or in part any initial agency decision issued under § 150.453.

(b) The Administrator may decide to review an initial agency decision if it appears from a preliminary review of the decision (or from a preliminary review of the record on which the initial agency decision was based, if available at the time) that:

(1) The ALJ made an erroneous interpretation of law or regulation.

(2) The initial agency decision is not supported by substantial evidence.

(3) The ALJ has incorrectly assumed or denied jurisdiction or extended his or her authority to a degree not provided for by statute or regulation.

(4) The ALJ decision requires clarification, amplification, or an alternative legal basis for the decision.

(5) The ALJ decision otherwise requires modification, reversal, or remand.

(c) Within 30 days of the date of the initial agency decision, the Administrator will mail a notice advising the respondent of any intent to review the decision in whole or in part.

(d) Within 30 days of receipt of a notice that the Administrator intends to review an initial agency decision, the respondent may submit, in writing, to the Administrator any arguments in support of, or exceptions to, the initial agency decision.

(e) This submission of the information indicated in paragraph (d) of this section must be limited to issues the Administrator has identified in his or her notice of intent to review, if the Administrator has given notice of an intent to review the initial agency decision only in part. A copy of this submission must be sent to the other party.

(f) After receipt of any submissions made pursuant to paragraph (d) of this section and any additional submissions for which the Administrator may provide, the Administrator will affirm, reverse, modify, or remand the initial agency decision. The Administrator will mail a copy of his or her decision to the respondent.

(g) The Administrator's decision will be based on the record on which the initial agency decision was based (as forwarded by the ALJ to the Administrator) and any materials submitted pursuant to paragraphs (b), (d), and (f) of this section.

(h) The Administrator's decision may rely on decisions of any courts and other applicable law, whether or not cited in the initial agency decision.

§ 150.459 Judicial review.

(a) *Filing of an action for review*. Any responsible entity against whom a final order imposing a civil money penalty is entered may obtain review in the United States District Court for any district in which the entity is located or in the United States District Court for the District of Columbia by doing the following:

(1) Filing a notice of appeal in that court within 30 days from the date of a final order.

(2) Simultaneously sending a copy of the notice of appeal by registered mail to CMS.

(b) *Certification of administrative record*. CMS promptly certifies and files with the court the record upon which the penalty was assessed.

(c) *Standard of review*. The findings of CMS and the ALJ may not be set aside unless they are found to be unsupported by substantial evidence, as provided by 5 U.S.C. 706(2)(E).

§ 150.461 Failure to pay assessment.

If any entity fails to pay an assessment after it becomes a final order, or after the court has entered final judgment in favor of CMS, CMS refers the matter to the Attorney General, who brings an action against the entity in the appropriate United States district court to recover the amount assessed.

§ 150.463 Final order not subject to review.

In an action brought under § 150.461, the validity and appropriateness of the final order described in § 150.459 is not subject to review.

§ 150.465 Collection and use of penalty funds.

(a) Any funds collected under § 150.461 are paid to CMS.

(b) The funds are available without appropriation until expended.

(c) The funds may be used only for the purpose of enforcing the HIPAA requirements for which the penalty was assessed.

PART 151 [RESERVED]

PART 152—PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM

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AUTHORITY: Sec. 1101 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 45029, July 30, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 152.1 Statutory basis.

(a) *Basis*. This part establishes provisions needed to implement section 1101 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), which requires the Secretary of the Department of Health and Human Services to establish a temporary high risk health insurance pool program to provide health insurance coverage for individuals described in § 152.14 of this part.

(b) *Scope*. This part establishes standards and sets forth the requirements, limitations, and procedures for the temporary high risk health insurance pool program, hereafter referred to as the ''Pre-Existing Condition Insurance Plan'' (PCIP) program.

§ 152.2 Definitions.

For purposes of this part the following definitions apply:

Creditable coverage means coverage of an individual as defined in section 2701(c)(1) of the Public Health Service Act as of March 23, 2010 and 45 CFR 146.113(a)(1).

Enrollee means an individual receiving coverage from a PCIP established under this section.

Lawfully present means

(1) A qualified alien as defined in section 431 of the Personal Responsibility and Work Opportunity Act (PRWORA) (8 U.S.C. 1641);

(2) An alien in nonimmigrant status who has not violated the terms of the status under which he or she was admitted or to which he or she has changed after admission;

(3) An alien who has been paroled into the United States pursuant to section 212(d)(5) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(d)(5)) for less than 1 year, except for an alien paroled for prosecution, for deferred inspection or pending removal proceedings;

(4) An alien who belongs to one of the following classes:

(i) Aliens currently in temporary resident status pursuant to section 210 or 245A of the INA (8 U.S.C. 1160 or 1255a, respectively);

(ii) Aliens currently under Temporary Protected Status (TPS) pursuant to section 244 of the INA (8 U.S.C. 1254a), and pending applicants for TPS who have been granted employment authorization;

(iii) Aliens who have been granted employment authorization under 8

CFR 274a.12(c)(9), (10), (16), (18), (20), (22), or (24);

(iv) Family Unity beneficiaries pursuant to section 301 of Public Law 101–649 as amended;

(v) Aliens currently under Deferred Enforced Departure (DED) pursuant to a decision made by the President;

(vi) Aliens currently in deferred action status;

(vii) Aliens whose visa petitions have been approved and who have a pending application for adjustment of status;

(5) A pending applicant for asylum under section 208(a) of the INA (8 U.S.C. 1158) or for withholding of removal under section 241(b)(3) of the INA (8 U.S.C. 1231) or under the Convention Against Torture who has been granted employment authorization, and such an applicant under the age of 14 who has had an application pending for at least 180 days;

(6) An alien who has been granted withholding of removal under the Convention Against Torture; or

(7) A child who has a pending application for Special Immigrant Juvenile status as described in section 101(a)(27)(J) of the INA (8 U.S.C. 1101(a)(27)(J)).

Out-of-pocket costs means the sum of the annual deductible and the other annual out-of-pocket expenses, other than for premiums, required to be paid under the program.

Pre-Existing condition exclusion has the meaning given such term in 45 CFR 144.103.

Pre-Existing Condition Insurance Plan (PCIP) means the temporary high risk health insurance pool plan (sometimes referred to as a ''qualified high risk pool'') that provides coverage in a State, or combination of States, in accordance with the requirements of section 1101 of the Affordable Care Act and this part. The term ''PCIP program'' is generally used to describe the national program the Secretary is charged with carrying out, under which States or non-profit entities operate individual PCIPs.

Resident means an individual who has been legally domiciled in a State.

Service Area refers to the geographic area encompassing an entire State or States in which PCIP furnishes benefits.

State refers each of the 50 States and the District of Columbia.

(8) *Exception*. An individual with deferred action under the Department of Homeland Security's deferred action for childhood arrivals process, as described in the Secretary of Homeland Security's June 15, 2012, memorandum, shall not be considered to be lawfully present with respect to any of the above categories in paragraphs (1) through (7) of this definition.

[75 FR 45029, July 30, 2010, as amended at 77 FR 52616, Aug. 30, 2012]

Subpart B—PCIP Program Administration

§ 152.6 Program administration.

(a) *General rule*. Section 1101(b)(1) of the Affordable Care Act requires that HHS carry out the Pre-Existing Condition Insurance Plan program directly or through contracts with eligible entities, which are States or nonprofit private entities.

(b) *Administration by State*. A State (or its designated non-profit private entity) may submit a proposal to enter into a contract with HHS to establish and administer a PCIP in accordance with section 1101 of the Affordable Care Act and this part.

(1) At the Secretary's discretion, a State may designate a nonprofit entity or entities to contract with HHS to administer a PCIP.

(2) As part of its administrative approach, a State or designated entity may subcontract with either a for-profit or nonprofit entity.

(c) *Administration by HHS*. If a State or its designated entity notifies HHS that it will not establish or continue to administer a PCIP, or does not submit an acceptable or timely proposal to do so, HHS will contract with a nonprofit private entity or entities to administer a PCIP in that State.

(d) *Transition in administration*. The Secretary may consider a request from a State to transition from administration by HHS to administration by a State or from administration by a State to administration by HHS. Such transitions shall be approved only if the Secretary determines that the transition is in the best interests of the

PCIP enrollees and potential PCIP enrollees in that state, consistent with § 152.7(b) of this part.

§ 152.7 PCIP proposal process.

(a) *General.* A proposal from a State or nonprofit private entity to contract with HHS shall demonstrate that the eligible entity has the capacity and technical capability to perform all functions necessary for the design and operation of a PCIP, and that its proposed PCIP is in full compliance with all of the requirements of this part.

(b) *Special rules for transitions in administration.* (1) Transitions from HHS administration of a PCIP to State administration must take effect on January 1 of a given year.

(2) A State's proposal to administer a PCIP must meet all the requirements of this section.

(3) Transitions from State administration to HHS administration must comply with the termination procedures of the PCIP contract in effect with the State or its designated entity.

(4) The Secretary may establish other requirements needed to ensure a seamless transition of coverage for all existing enrollees.

Subpart C—Eligibility and Enrollment

§ 152.14 Eligibility.

(a) *General rule.* An individual is eligible to enroll in a PCIP if he or she:

(1) Is a citizen or national of the United States or lawfully present in the United States;

(2) Subject to paragraph (b) of this section, has not been covered under creditable coverage for a continuous 6-month period of time prior to the date on which such individual is applying for PCIP;

(3) Has a pre-existing condition as established under paragraph (c) of this section; and

(4) Is a resident of one of the 50 States or the District of Columbia which constitutes or is within the service area of the PCIP. A PCIP may not establish any standards with regard to the duration of residency in the PCIP service area.

(b) *Satisfaction of 6-month creditable coverage requirement when an enrollee leaves the PCIP service area.* An individual who becomes ineligible for a PCIP on the basis of no longer residing in the PCIP's service area as described in paragraph (a)(4) of this section is deemed to have satisfied the requirement in paragraph (a)(2) of this section for purposes of applying to enroll in a PCIP in the new service area.

(c) *Pre-existing condition requirement.* For purposes of establishing a process for determining eligibility, and subject to HHS approval, a PCIP may elect to apply any one or more of the following criteria in determining whether an individual has a pre-existing condition for purposes of this section:

(1) *Refusal of coverage.* Documented evidence that an insurer has refused, or a clear indication that the insurer would refuse, to issue coverage to an individual on grounds related to the individual's health.

(2) *Exclusion of coverage.* Documented evidence that such individual has been offered coverage but only with a rider that excludes coverage of benefits associated with an individuals' identified pre-existing condition.

(3) *Medical or health condition.* Documented evidence of the existence or history of certain medical or health condition, as approved or specified by the Secretary.

(4) Other. Other criteria, as defined by a PCIP and approved by HHS.

§ 152.15 Enrollment and disenrollment process.

(a) *Enrollment process.* (1) A PCIP must establish a process for verifying eligibility and enrolling an individual that is approved by HHS.

(2) A PCIP must allow an individual to remain enrolled in the PCIP unless:

(i) The individual is disenrolled under paragraph (b) of this section;

(ii) The individual obtains other creditable coverage;

(iii) The PCIP program terminates, or is terminated; or

(iv) As specified by the PCIP program and approved by HHS.

(3) A PCIP must verify that an individual is a United States citizen or national or lawfully present in the United States by:

(i) Verifying the individual's citizenship, nationality, or lawful presence

with the Commissioner of Security or Secretary of Homeland Security as applicable; or

(ii) By requiring the individual to provide documentation which establishes the individual's citizenship, nationality, or lawful presence.

(iii) The PCIP must provide an individual who is applying to enroll in the PCIP with a disclosure specifying if the information will be shared with the Department of Health and Human Services, Social Security Administration, and if necessary, Department of Homeland Security for purposes of establishing eligibility.

(b) *Disenrollment process.* (1) A PCIP must establish a disenrollment process that is approved by HHS.

(2) A PCIP may disenroll an individual if the monthly premium is not paid on a timely basis, following notice and a reasonable grace period, not to exceed 61 days from when payment is due, as defined by the PCIP and approved by HHS.

(3) A PCIP must disenroll an individual in any of the following circumstances:

(i) The individual no longer resides in the PCIP service area.

(ii) The individual obtains other creditable coverage.

(iii) Death of the individual.

(iv) Other exceptional circumstances established by HHS.

(c) *Effective dates.* A PCIP must establish rules governing the effective date of enrollment and disenrollment that are approved by HHS. A complete enrollment request submitted by an eligible individual by the 15th day of a month, where the individual is determined to be eligible for enrollment, must take effect by the 1st day of the following month, except in exceptional circumstances that are subject to HHS approval.

(d) *Funding limitation.* A PCIP may stop taking applications for enrollment to comply with funding limitations established by the HHS under section 1101(g) of Public Law 111–148 and § 152.35 of this part. Accordingly, a PCIP may employ strategies to manage enrollment over the course of the program that may include enrollment capacity limits, phased-in (delayed) enrollment, and other measures, as defined by the PCIP and approved by HHS, including measures specified under § 152.35(b).

Subpart D—Benefits

§ 152.19 Covered benefits.

(a) *Required benefits.* Each benefit plan offered by a PCIP shall cover at least the following categories and the items and services:

(1) Hospital inpatient services

(2) Hospital outpatient services

(3) Mental health and substance abuse services

(4) Professional services for the diagnosis or treatment of injury, illness, or condition

(5) Non-custodial skilled nursing services

(6) Home health services

(7) Durable medical equipment and supplies

(8) Diagnostic x-rays and laboratory tests

(9) Physical therapy services (occupational therapy, physical therapy, speech therapy)

(10) Hospice

(11) Emergency services, consistent with § 152.22(b), and ambulance services

(12) Prescription drugs

(13) Preventive care

(14) Maternity care

(b) *Excluded services.* Benefit plans offered by a PCIP shall not cover the following services:

(1) Cosmetic surgery or other treatment for cosmetic purposes except to restore bodily function or correct deformity resulting from disease.

(2) Custodial care except for hospice care associated with the palliation of terminal illness.

(3) In vitro fertilization, artificial insemination or any other artificial means used to cause pregnancy.

(4) Abortion services except when the life of the woman would be endangered or when the pregnancy is the result of an act of rape or incest.

(5) Experimental care except as part of an FDA-approved clinical trial.

§ 152.20 Prohibitions on pre-existing condition exclusions and waiting periods.

(a) *Pre-existing condition exclusions.* A PCIP must provide all enrollees with health coverage that does not impose

any pre-existing condition exclusions (as defined in § 152.2) with respect to such coverage.

(b) *Waiting periods.* A PCIP may not impose a waiting period with respect to the coverage of services after the effective date of enrollment.

§ 152.21 Premiums and cost-sharing.

(a) *Limitation on enrollee premiums.* (1) The premiums charged under the PCIP may not exceed 100 percent of the premium for the applicable standard risk rate that would apply to the coverage offered in the State or States. The PCIP shall determine a standard risk rate by considering the premium rates charged for similar benefits and cost-sharing by other insurers offering health insurance coverage to individuals in the applicable State or States. The standard risk rate shall be established using reasonable actuarial techniques, that are approved by the Secretary, and that reflect anticipated experience and expenses. A PCIP may not use other methods of determining the standard rate, except with the approval of the Secretary.

(2) Premiums charged to enrollees in the PCIP may vary on the basis of age by a factor not greater than 4 to 1.

(b) *Limitation on enrollee costs.* (1) The PCIP's average share of the total allowed costs of the PCIP benefits must be at least 65 percent of such costs.

(2) The out-of-pocket limit of coverage for cost-sharing for covered services under the PCIP may not be greater than the applicable amount described in section 223(c)(2) of the Internal Revenue code of 1986 for the year involved. If the plan uses a network of providers, this limit may be applied only for in-network providers, consistent with the terms of PCIP benefit package.

§ 152.22 Access to services.

(a) *General rule.* A PCIP may specify the networks of providers from whom enrollees may obtain plan services. The PCIP must demonstrate to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees.

(b) *Emergency services.* In the case of emergency services, such services must be covered out of network if:

(1) The enrollee had a reasonable concern that failure to obtain immediate treatment could present a serious risk to his or her life or health; and

(2) The services were required to assess whether a condition requiring immediate treatment exists, or to provide such immediate treatment where warranted.

Subpart E—Oversight

§ 152.26 Appeals procedures.

(a) *General.* A PCIP shall establish and maintain procedures for individuals to appeal eligibility and coverage determinations.

(b) *Minimum requirements.* The appeals procedure must, at a minimum, provide:

(1) A potential enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding PCIP eligibility, including a determination of whether the individual is a citizen or national of the United States, or is lawfully present in the United States.

(2) An enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding the coverage of a service or the amount paid by the PCIP for a service.

(3) An enrollee with the right to a timely reconsideration of a redetermination made under paragraph (b)(2) of this section by an entity independent of the PCIP.

§ 152.27 Fraud, waste, and abuse.

(a) *Procedures.* The PCIP shall develop, implement, and execute operating procedures to prevent, detect, recover (when applicable or allowable), and promptly report to HHS incidences of waste, fraud, and abuse, and to appropriate law enforcement authorities instances of fraud. Such procedures shall include identifying situations in which enrollees or potential enrollees (or their family members) are employed, and may have, or have had, access to other coverage such as group health coverage, but were discouraged from enrolling.

(b) *Cooperation.* The PCIP shall cooperate with Federal law enforcement and oversight authorities in cases involving waste, fraud and abuse, and

shall report to appropriate authorities situations in which enrollment in other coverage may have been discouraged.

§ 152.28 Preventing insurer dumping.

(a) *General rule*. If it is determined based on the procedures and criteria set forth in paragraph (b) of this section that a health insurance issuer or group health plan has discouraged an individual from remaining enrolled in coverage offered by such issuer or health plan based on the individual's health status, if the individual subsequently enrolls in a PCIP under this part, the issuer or health plan will be responsible for any medical expenses incurred by the PCIP with respect to the individual.

(b) *Procedures and criteria for a determination of dumping*. A PCIP shall establish procedures to identify and report to HHS instances in which health insurance issuers or employer-based group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage in instances in which such individuals subsequently are eligible to enroll in the qualified high risk pool. Such procedures shall include methods to identify the following circumstances, either through the PCIP enrollment application form or other vehicles:

(1) Situations where an enrollee or potential enrollee had prior coverage obtained through a group health plan or issuer, and the individual was provided financial consideration or other rewards for disenrolling from their coverage, or disincentives for remaining enrolled.

(2) Situations where enrollees or potential enrollees had prior coverage obtained directly from an issuer or a group health plan and either of the following occurred:

(i) The premium for the prior coverage was increased to an amount that exceeded the premium required by the PCIP (adjusted based on the age factors applied to the prior coverage), and this increase was not otherwise explained;

(ii) The health plan, issuer or employer otherwise provided money or other financial consideration to disenroll from coverage, or disincentive to remain enrolled in such coverage. Such considerations include payment of the PCIP premium for an enrollee or potential enrollee.

(c) *Remedies*. If the Secretary determines, based on the criteria in paragraph (b) of this section, that the rule in paragraph (a) of this section applies, an issuer or a group health plan will be billed for the medical expenses incurred by the PCIP. The issuer or group health plan also will be referred to appropriate Federal and State authorities for other enforcement actions that may be warranted based on the behavior at issue.

(d) *Other*. Nothing in this section may be construed as constituting exclusive remedies for violations of this section or as preventing States from applying or enforcing this section or other provisions of law with respect to health insurance issuers.

Subpart F—Funding

§ 152.32 Use of funds.

(a) *Limitation on use of funding*. All funds awarded through the contracts established under this program must be used exclusively to pay allowable claims and administrative costs incurred in the development and operation of the PCIP that are in excess of the amounts of premiums collected from individuals enrolled in the program.

(b) *Limitation on administrative expenses*. No more than 10 percent of available funds shall be used for administrative expenses over the life of the contract with the PCIP, absent approval from HHS.

§ 152.33 Initial allocation of funds.

HHS will establish an initial ceiling for the amount of the $5 billion in Federal funds allocated for PCIPs in each State using a methodology consistent with that used to established allocations under the Children's Health Insurance Program, as set forth under 42 CFR Part 457, Subpart F, Payment to States.

§ 152.34 Reallocation of funds.

If HHS determines, based on actual and projected enrollment and claims experience, that the PCIP in a given State will not make use of the total estimated funding allocated to that

State, HHS may reallocate unused funds to other States, as needed.

§ 152.35 Insufficient funds.

(a) *Adjustments by a PCIP to eliminate a deficit*. In the event that a PCIP determines, based on actual and projected enrollment and claims data, that its allocated funds are insufficient to cover projected PCIP expenses, the PCIP shall report such insufficiency to HHS, and identify and implement necessary adjustments to eliminate such deficit, subject to HHS approval.

(b) *Adjustment by the Secretary*. If the Secretary estimates that aggregate amounts available for PCIP expenses will be less than the actual amount of expenses, HHS reserves the right to make such adjustments as are necessary to eliminate such deficit.

Subpart G—Relationship to Existing Laws and Programs

§ 152.39 Maintenance of effort.

(a) *General*. A State that enters into a contract with HHS under this part must demonstrate, subject to approval by HHS, that it will continue to provide funding of any existing high risk pool in the State at a level that is not reduced from the amount provided for in the year prior to the year in which the contract is entered.

(b) *Failure to maintain efforts*. In situations where a State enters into a contract with HHS under this part, HHS shall take appropriate action, such as terminating the PCIP contract, against any State that fails to maintain funding levels for existing State high risk pools as required, and approved by HHS, under paragraph (a) of this section.

§ 152.40 Relation to State laws.

The standards established under this section shall supersede any State law or regulation, other than State licensing laws or State laws relating to plan solvency, with respect to PCIPs which are established in accordance with this section.

Subpart H—Transition to Exchanges

§ 152.44 End of PCIP program coverage.

Effective January 1, 2014, coverage under the PCIP program (45 CFR part 152) will end.

§ 152.45 Transition to the exchanges.

Prior to termination of the PCIP program, HHS will develop procedures to transition PCIP enrollees to the Exchanges, established under sections 1311 or 1321 of the Affordable Care Act, to ensure that there are no lapses in health coverage for those individuals.

PART 153—STANDARDS RELATED TO REINSURANCE, RISK CORRIDORS, AND RISK ADJUSTMENT UNDER THE AFFORDABLE CARE ACT

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153.600 [Reserved]
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153.620 Compliance with risk adjustment standards.

AUTHORITY: Secs. 1321, 1341–1343, Pub. L. 111–148, 24 Stat. 119.

SOURCE: 77 FR 17245, Mar. 23, 2012, unless otherwise noted.

Subpart A—General Provisions

§ 153.10 Basis and scope.

(a) *Basis*. This part is based on the following sections of title I of the Affordable Care Act (Pub. L. 111–148, 24 Stat. 119):

(1) Section 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(2) Section 1341. Transitional reinsurance program for individual market in each State.

(3) Section 1342. Establishment of risk corridors for plans in individual and small group markets.

(4) Section 1343. Risk adjustment.

(b) *Scope*. This part establishes standards for the establishment and operation of a transitional reinsurance program, temporary risk corridors program, and a permanent risk adjustment program.

§ 153.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Alternate risk adjustment methodology means a risk adjustment methodology proposed by a State for use instead of a Federally certified risk adjustment methodology that has not yet been certified by HHS.

Applicable reinsurance entity means a not-for-profit organization that is exempt from taxation under Chapter 1 of the Internal Revenue Code of 1986 that carries out reinsurance functions under this part on behalf of the State. An entity is not an applicable reinsurance entity to the extent it is carrying out reinsurance functions under subpart C of this part on behalf of HHS.

Attachment point means the threshold dollar amount for claims costs incurred by a health insurance issuer for an enrolled individual's covered benefits in a benefit year, after which threshold the claims costs for such benefits are eligible for reinsurance payments.

Benefit year has the meaning given to the term in § 155.20 of this subchapter.

Calculation of payments and charges means the methodology applied to plan average actuarial risk to determine risk adjustment payments and charges for a risk adjustment covered plan.

Calculation of plan average actuarial risk means the specific procedures used to determine plan average actuarial risk from individual risk scores for a risk adjustment covered plan, including adjustments for variable rating and the specification of the risk pool from which average actuarial risk is to be calculated.

Coinsurance rate means the rate at which the applicable reinsurance entity will reimburse the health insurance issuer for claims costs incurred for an enrolled individual's covered benefits in a benefit year after the attachment point and before the reinsurance cap.

Contributing entity means a health insurance issuer or a third party administrator on behalf a self-insured group health plan.

Contribution rate means, with respect to a benefit year, the per capita amount each contributing entity must pay for a reinsurance program established under this part with respect to

each reinsurance contribution enrollee who resides in that State.

Exchange has the meaning given to the term in § 155.20 of this subchapter.

Federally certified risk adjustment methodology means a risk adjustment methodology that either has been developed and promulgated by HHS, or has been certified by HHS.

Grandfathered health plan has the meaning given to the term in § 147.140(a) of this subchapter.

Group health plan has the meaning given to the term in § 144.103 of this subchapter.

Health insurance coverage has the meaning given to the term in § 144.103 of this subchapter.

Health insurance issuer or *issuer* has the meaning given to the term in § 144.103 of this subchapter.

Health plan has the meaning given to the term in section 1301(b)(1) of the Affordable Care Act.

Individual market has the meaning given to the term in § 144.103 of this subchapter.

Individual risk score means a relative measure of predicted health care costs for a particular enrollee that is the result of a risk adjustment model.

Large employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan or *QHP* has the meaning given to the term in § 155.20 of this subchapter.

Qualified individual has the meaning given to the term in § 155.20 of this subchapter.

Reinsurance cap means the threshold dollar amount for claims costs incurred by a health insurance issuer for an enrolled individual's covered benefits, after which threshold, the claims costs for such benefits are no longer eligible for reinsurance payments.

Reinsurance contribution enrollee means an individual covered by a plan for which reinsurance contributions must be made pursuant to § 153.400.

Reinsurance-eligible plan means, for the purpose of the reinsurance program, any health insurance coverage offered in the individual market, except for grandfathered plans and health insurance coverage not required to submit reinsurance contributions under § 153.400(a).

Risk adjustment covered plan means, for the purpose of the risk adjustment program, any health insurance coverage offered in the individual or small group market with the exception of grandfathered health plans, group health insurance coverage described in § 146.145(c) of this subchapter, individual health insurance coverage described in § 148.220 of this subchapter, and any other plan determined not to be a risk adjustment covered plan in the annual HHS notice of benefit and payment parameters.

Risk adjustment data means all data that are used in a risk adjustment model, the calculation of plan average actuarial risk, or the calculation of payments and charges, or that are used for validation or audit of such data.

Risk adjustment data collection approach means the specific procedures by which risk adjustment data is to be stored, collected, accessed, transmitted, validated and audited and the applicable timeframes, data formats, and privacy and security standards.

Risk adjustment methodology means the risk adjustment model, the calculation of plan average actuarial risk, the calculation of payments and charges, the risk adjustment data collection approach, and the schedule for the risk adjustment program.

Risk adjustment model means an actuarial tool used to predict health care costs based on the relative actuarial risk of enrollees in risk adjustment covered plans.

Risk pool means the State-wide population across which risk is distributed.

Small group market has the meaning given to the term in section 1304(a)(3) of the Affordable Care Act.

State has the meaning given to the term in § 155.20 of this subchapter.

Subpart B—State Notice of Benefit and Payment Parameters

§ 153.100 State notice of benefit and payment parameters.

(a) *General requirement for reinsurance.* A State establishing a reinsurance program must issue an annual notice of

benefit and payment parameters specific to that State if that State elects to:

(1) Modify the data requirements or data collection frequency for health insurance issuers to receive reinsurance payment from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Collect reinsurance contributions pursuant to § 153.220(a)(1);

(3) Collect additional reinsurance contributions pursuant to § 153.220(g);

(4) Use more than one applicable reinsurance entity; or

(5) Modify any reinsurance payment parameters from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

(b) *Risk adjustment requirements.* A State operating a risk adjustment program must issue an annual notice of benefit and payment parameters specific to that State setting forth the risk adjustment methodology and data validation standards it will use.

(c) *State notice deadlines.* If a State is required to publish an annual State notice of benefit and payment parameters, it must do so by March 1 of the calendar year prior to the benefit year for which the notice applies.

(d) *State failure to publish notice.* Any State establishing a reinsurance program or operating a risk adjustment program that fails to publish a State notice of benefit and payment parameters within the period specified in paragraph (c) of this section must—

(1) Adhere to the data requirements and data collection frequency for health insurance issuers to receive reinsurance payments that are specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year;

(2) Forgo the collection of reinsurance contributions pursuant to § 153.220(a);

(3) Forgo the collection of additional reinsurance contributions pursuant to § 153.220(g);

(4) Forgo the use of more than one applicable reinsurance entity;

(5) Adhere to the reinsurance parameters specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year; and

(6) Adhere to the risk adjustment methodology and data validation standards published in the annual HHS notice of benefit and payment parameters for use by HHS when operating risk adjustment on behalf of a State.

§ 153.110 Standards for the State notice of benefit and payment parameters.

(a) *Data requirements.* If a State that establishes a reinsurance program elects to modify the data requirements or data collection frequency for health insurance issuers to receive reinsurance payment from those specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, the State notice of benefit and payment parameters must specify those modifications.

(b) *Reinsurance collection.* If a State that establishes a reinsurance program elects to collect reinsurance contributions pursuant to § 153.220(a), then the State must announce its intention to do so in the State notice of benefit and payment parameters.

(c) *Additional collections.* If a State that establishes a reinsurance program elects to collect additional funds pursuant to § 153.220(g), the State must publish the following:

(1) A description of the purpose of the additional collection, including whether it will be used to cover reinsurance payments, administrative costs, or both; and

(2) The additional contribution rate at which the funds will be collected.

(d) *Multiple reinsurance entities.* If a State plans to use more than one applicable reinsurance entity, the State must publish in the State notice of benefit and payment parameters, for each applicable reinsurance entity—

(1) The geographic boundaries for that entity;

(2) An estimate of the number of enrollees in fully insured plans within those boundaries;

(3) An estimate of the number of enrollees in the individual market within those boundaries;

(4) An estimate of the reinsurance contributions that will be collected by the applicable reinsurance entity;

(5) The percentage of reinsurance contributions received from HHS for the State to be allocated to the applicable reinsurance entity; and

(6) An estimate of the amount of reinsurance payments that will be made to issuers with respect to enrollees within those boundaries.

(e) *Reinsurance payment.* If a State that establishes a reinsurance program intends to modify the attachment point, reinsurance cap, or coinsurance rate from the corresponding parameters specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, the State must—

(1) Describe those modified parameters in the State notice of benefit and payment parameters; and

(2) Apply the modified parameters uniformly throughout the State.

(f) *Risk adjustment content.* A State operating a risk adjustment program must provide the information set forth in §153.330(a) and the data validation standards set forth pursuant to §153.350 in the State notice of benefit and payment parameters.

Subpart C—State Standards Related to the Reinsurance Program

§153.200 [Reserved]

§153.210 State establishment of a reinsurance program.

(a) *General requirement.* Each State is eligible to establish a reinsurance program for the years 2014 through 2016.

(1) If a State establishes a reinsurance program, the State must enter into a contract with one or more applicable reinsurance entities to carry out the provisions of this subpart.

(2) If a State contracts with more than one applicable reinsurance entity, the State must:

(i) Ensure that each applicable reinsurance entity operates in a distinct geographic area with no overlap of jurisdiction with any other applicable reinsurance entity;

(ii) Use the same payment parameters with respect to each applicable reinsurance entity; and

(iii) Notify HHS in the manner and timeframe specified by HHS of the percentage of reinsurance contributions received from HHS for the State to be allocated to each applicable reinsurance entity.

(3) A State may permit an applicable reinsurance entity to subcontract specific administrative functions required under this subpart and subpart E of this part.

(4) A State must review and approve subcontracting arrangements to ensure efficient and appropriate expenditures of administrative funds collected under this subpart.

(5) A State must ensure that the applicable reinsurance entity completes all reinsurance-related activities for benefit years 2014 through 2016 and any activities required to be undertaken in subsequent periods.

(b) *Multi-State reinsurance arrangements.* Multiple States may contract with a single entity to serve as an applicable reinsurance entity for each State. In such a case, the reinsurance programs for those States must be operated as separate programs.

(c) *Non-electing States.* HHS will establish a reinsurance program for each State that does not elect to establish its own reinsurance program.

(d) *Oversight.* Each State that establishes a reinsurance program must ensure that the applicable reinsurance entity complies with all provisions of this subpart and subpart E of this part throughout the duration of its contract.

§153.220 Collection of reinsurance contribution funds.

(a) *Collections.* If a State establishes a reinsurance program, then—

(1) The State may elect to—

(i) Have the applicable reinsurance entity collect contributions for reinsurance contribution enrollees who reside in that State directly from issuers of health plans; or

(ii) Ensure that the applicable reinsurance entity accepts contributions for reinsurance contribution enrollees who reside in that State with respect to issuers of health plans from HHS.

(2) The State must ensure that the applicable reinsurance entity accepts contributions for reinsurance contribution enrollees who reside in that State

with respect to all contributing entities other than issuers of health plans from HHS.

(b) *Notification of election to collect.* If a State establishes a reinsurance program, then that State must notify HHS by December 1, 2012, if the State elects to collect reinsurance contributions from fully insured plans for the 2014 benefit year, and by September 1 of the calendar year that is two years prior to the applicable benefit year if the State elects to collect reinsurance contributions from fully insured plans for any benefit year after 2014, in each case pursuant to paragraph (a)(1)(i) of this section. The State's notification will be effective for the applicable benefit year and each subsequent benefit year during which activities related to the transitional reinsurance program continue.

(c) *Contribution funding.* Reinsurance contributions collected must fund the following:

(1) Reinsurance payments that will total, on a national basis, $10 billion in 2014, $6 billion in 2015, and $4 billion in 2016;

(2) U.S. Treasury contributions that will total, on a national basis, $2 billion in 2014, $2 billion in 2015, and $1 billion in 2016; and

(3) Administrative expenses of the applicable reinsurance entity or HHS when performing reinsurance functions under this subpart.

(d) *Distribution of reinsurance contributions.* If a State establishes a reinsurance program, HHS will distribute funds collected for reinsurance contribution enrollees who reside in a State to the applicable reinsurance entity for that State (or the applicable reinsurance entities, if more than one, in accordance with the allocation specified by the State pursuant to § 153.210(a)(2)(iii)), less:

(1) The State's pro rata share of the U.S. Treasury contribution described in paragraph (c)(2) of this section; and

(2) The State's pro rata share of administrative expenses incurred by HHS when performing reinsurance functions under this subpart.

(e) *National contribution rate.* HHS will set in the annual HHS notice of benefit and payment parameters for the applicable benefit year the national contribution rate and the proportion of contributions collected under the national contribution rate to be allocated to:

(1) Reinsurance payments;

(2) Payments to the U.S. Treasury as described in paragraph (c)(2) of this section; and

(3) Administrative expenses of the applicable reinsurance entity or HHS when performing reinsurance functions under this subpart.

(f) *State collections.* If a State elects to have the applicable reinsurance entity collect contributions pursuant to paragraph (a)(1)(i) of this section, the State must ensure that:

(1) The applicable reinsurance entity for the State collects contributions for reinsurance contribution enrollees who reside in that State directly from issuers of health plans in the amounts required under the national contribution rate.

(2) Reinsurance contributions are allocated as required in the annual HHS notice of benefit and payment parameters for the applicable benefit year, such that:

(i) Contributions allocated for reinsurance payments are only used for reinsurance payments; and

(ii) Contributions allocated for payments to the U.S. Treasury are paid to the U.S. Treasury in a timeframe to be established by HHS.

(g) *Additional State collections.* If a State establishes a reinsurance program, it may elect to collect more than the amounts that would be collected based on the national contribution rate set forth in the annual HHS notice of benefit and payment parameters for the applicable benefit year to provide:

(1) Funding for administrative expenses of the applicable reinsurance entity; or

(2) Additional funding for reinsurance payments.

(h) *Administration of additional State collections.* If a State elects to collect additional amounts pursuant to paragraph (g) of this section for administrative expenses or reinsurance payments, then:

(1) The State must notify HHS within 30 days after publication of the draft annual HHS notice of benefit and payment parameters for the applicable

benefit year of the additional contribution rate that it elects to collect for additional administrative expenses. The State must ensure that the State's applicable reinsurance entity—

(i) Collects these additional amounts for additional administrative expenses from issuers of health plans when the State elects to collect contributions from such issuers under paragraph (a)(1) of this section; and

(ii) Accepts additional amounts for additional administrative expenses from HHS from all contributing entities from which HHS collects in accordance with the State's election under paragraph (a)(1) of this section.

(2) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, the State must ensure that the applicable reinsurance entity collects all additional reinsurance contributions for the purpose of reinsurance payments from all contributing entities.

[77 FR 17245, Mar. 23, 2012, as amended at 77 FR 29236, May, 17, 2012]

§ 153.230 Calculation of reinsurance payments.

(a) *General requirement.* A health insurance issuer of a non-grandfathered individual market plan becomes eligible for reinsurance payments when its claims costs for an individual enrollee's covered benefits in a benefit year exceed the attachment point.

(b) *Reinsurance payment parameters.* If a State establishes a reinsurance program, the State must use, subject to any modifications made pursuant to paragraph (d) of this section, the payment formula and values for the attachment point, reinsurance cap, and coinsurance rate for each year commencing in 2014 and ending in 2016 established in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

(c) *Reinsurance payments.* If a State establishes a reinsurance program, the State must ensure, subject to § 153.240(b)(1), that the reinsurance payment represents the product of the coinsurance rate multiplied by the health insurance issuer's claims costs for an individual enrollee's covered benefits that the health insurance issuer incurs between the attachment point and the reinsurance cap.

(d) *State modification of reinsurance payment formula.* If a State establishes a reinsurance program, the State may modify the reinsurance payment formula in accordance with the following:

(1) The State may only use one or more of the following methods to modify the reinsurance payment formula:

(i) Increasing or decreasing the attachment point;

(ii) Increasing, decreasing, or eliminating the reinsurance cap; or

(iii) Increasing or decreasing the coinsurance rate.

(2) The State must publish any such modification to the reinsurance payment formula and parameters in a State notice of benefit and payment parameters as described in subpart B of this part.

(3) Any State modification to the reinsurance payment formula pursuant to paragraph (d)(1) of this section must be reasonably calculated to ensure that reinsurance contributions received toward reinsurance are sufficient to cover payments that the applicable reinsurance entity is obligated to make under that State formula for the given benefit year for the reinsurance program.

(4) The State must use a uniform attachment point, coinsurance rate, and reinsurance cap throughout the State.

§ 153.240 Disbursement of reinsurance payments.

(a) *Data collection.* If a State establishes a reinsurance program, the State must ensure that the applicable reinsurance entity collects from health insurance issuers of reinsurance-eligible plans data required to calculate payments described in § 153.230, according to the data requirements and data collection frequency specified by the State in the notice of benefit and payment parameters described in subpart B of this part.

(b) *Reinsurance entity payments.* If a State establishes a reinsurance program, the State must ensure that each applicable reinsurance entity does not make payments to health insurance issuers that exceed contributions received to date by the applicable reinsurance entity.

(1) If a State, or HHS on behalf of the State, determines that reinsurance

payments requested for a benefit year will likely exceed the reinsurance contributions that will be received for the year, the State may require that the applicable reinsurance entity reduce (or HHS on behalf of the State may reduce) reinsurance payments, so long as the manner in which payments are reduced is fair and equitable for all health insurance issuers in the individual market.

(2) The State must ensure that an applicable reinsurance entity makes payment to the health insurance issuer of a reinsurance-eligible plan after receiving a valid claim for payment from that health insurance issuer in accordance with the requirements of § 153.410.

(c) *Maintenance of records.* If a State establishes a reinsurance program, the State must maintain books, records, documents, and other evidence of accounting procedures and practices of the reinsurance program for each benefit year for at least 10 years.

§ 153.250 Coordination with high-risk pools.

(a) *General requirement.* The State must eliminate or modify any State high-risk pool to the extent necessary to carry out the reinsurance program established under this subpart.

(b) *Coordination with high-risk pools.* The State may coordinate the State high-risk pool with the reinsurance program to the extent that the State high-risk pool conforms to the provisions of this subpart.

Subpart D—State Standards Related to the Risk Adjustment Program

§ 153.300 [Reserved]

§ 153.310 Risk adjustment administration.

(a) *State eligibility to establish a risk adjustment program.* (1) A State that elects to operate an Exchange is eligible to establish a risk adjustment program.

(2) Any State that does not elect to operate an Exchange, or that HHS has not approved to operate an Exchange, will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(3) Any State that elects to operate an Exchange but does not elect to administer risk adjustment will forgo implementation of all State functions in this subpart, and HHS will carry out all of the provisions of this subpart on behalf of the State.

(b) *Entities eligible to carry out risk adjustment activities.* If a State is operating a risk adjustment program, the State may elect to have an entity other than the Exchange perform the State functions of this subpart, provided that the entity meets the standards promulgated by HHS to be an entity eligible to carry out Exchange functions.

(c) *Timeframes.* A State, or HHS on behalf of the State, must implement risk adjustment for the 2014 benefit year and every benefit year thereafter. For each benefit year, a State, or HHS on behalf of the State, must notify issuers of risk adjustment payments due or charges owed annually by June 30 of the year following the benefit year.

(d) *State summary reports.* Each State operating a risk adjustment program must submit to HHS an annual summary of risk adjustment program operations in the manner and timeframe specified by HHS.

§ 153.320 Federally certified risk adjustment methodology.

(a) *General requirement.* Any risk adjustment methodology used by a State, or HHS on behalf of the State, must be a Federally certified risk adjustment methodology. A risk adjustment methodology may become Federally certified by one of the following processes:

(1) The risk adjustment methodology is developed by HHS and published in an annual HHS notice of benefit and payment parameters; or

(2) An alternate risk adjustment methodology is submitted by a State in accordance with § 153.330, reviewed and certified by HHS, and published in an annual HHS notice of benefit and payment parameters.

(b) *Publication of methodology in notices.* The publication of a risk adjustment methodology by HHS in an annual HHS notice of benefit and payment parameters or by a State in an annual State notice of benefit and payment parameters described in subpart B of this part must include:

(1) A complete description of the risk adjustment model, including—

(i) Factors to be employed in the model, including but not limited to demographic factors, diagnostic factors, and utilization factors, if any;

(ii) The qualifying criteria for establishing that an individual is eligible for a specific factor;

(iii) Weights assigned to each factor; and

(iv) The schedule for the calculation of individual risk scores.

(2) A complete description of the calculation of plan average actuarial risk.

(3) A complete description of the calculation of payments and charges.

(4) A complete description of the risk adjustment data collection approach.

(5) The schedule for the risk adjustment program.

(c) *Use of methodology for States that do not operate a risk adjustment program.* HHS will specify in the annual HHS notice of benefit and payment parameters for the applicable year the Federally certified risk adjustment methodology that will apply in States that do not operate a risk adjustment program.

§ 153.330 State alternate risk adjustment methodology.

(a) *State request for alternate methodology certification.* (1) A State request to HHS for the certification of an alternate risk adjustment methodology must include:

(i) The elements specified in § 153.320(b);

(ii) The calibration methodology and frequency of calibration; and

(iii) The statistical performance metrics specified by HHS.

(2) The request must include the extent to which the methodology:

(i) Accurately explains the variation in health care costs of a given population;

(ii) Links risk factors to daily clinical practice and is clinically meaningful to providers;

(iii) Encourages favorable behavior among providers and health plans and discourages unfavorable behavior;

(iv) Uses data that is complete, high in quality, and available in a timely fashion;

(v) Is easy for stakeholders to understand and implement;

(vi) Provides stable risk scores over time and across plans; and

(vii) Minimizes administrative costs.

(b) *State renewal of alternate methodology.* If a State is operating a risk adjustment program, the State may not implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology without first obtaining HHS certification.

(1) Recalibration of the risk adjustment model must be performed at least as frequently as described in paragraph (a)(1)(ii) of this section;

(2) A State request to implement a recalibrated risk adjustment model or otherwise alter its risk adjustment methodology must include any changes to the parameters described in paragraph (a)(1) of this section.

§ 153.340 Data collection under risk adjustment.

(a) *Data collection requirements.* If a State is operating a risk adjustment program, the State must collect risk adjustment data.

(b) *Minimum standards.* (1) If a State is operating a risk adjustment program, the State may vary the amount and type of data collected, but the State must collect or calculate individual risk scores generated by the risk adjustment model in the applicable Federally certified risk adjustment methodology;

(2) If a State is operating a risk adjustment program, the State must require that issuers offering risk adjustment covered plans in the State comply with data privacy and security standards set forth in the applicable risk adjustment data collection approach; and

(3) If a State is operating a risk adjustment program, the State must ensure that any collection of personally identifiable information is limited to information reasonably necessary for use in the applicable risk adjustment

model, calculation of plan average actuarial risk, or calculation of payments and charges. Except for purposes of data validation, the State may not collect or store any personally identifiable information for use as a unique identifier for an enrollee's data, unless such information is masked or encrypted by the issuer, with the key to that masking or encryption withheld from the State.

(4) If a State is operating a risk adjustment program, the State must implement security standards that provide administrative, physical, and technical safeguards for the individually identifiable information consistent with the security standards described at 45 CFR 164.308, 164.310, and 164.312.

§ 153.350 Risk adjustment data validation standards.

(a) *General requirement*. The State, or HHS on behalf of the State, must ensure proper implementation of any risk adjustment software and ensure proper validation of a statistically valid sample of risk adjustment data from each issuer that offers at least one risk adjustment covered plan in that State.

(b) *Adjustment to plan average actuarial risk*. The State, or HHS on behalf of the State, may adjust the plan average actuarial risk for a risk adjustment covered plan based on errors discovered with respect to implementation of risk adjustment software or as a result of data validation conducted pursuant to paragraph (a) of this section.

(c) *Adjustment to charges and payments*. The State, or HHS on behalf of the State, may adjust charges and payments to all risk adjustment covered plan issuers based on the adjustments calculated in paragraph (b) of this section.

(d) *Appeals*. The State, or HHS on behalf of the State, must provide an administrative process to appeal findings with respect to the implementation of risk adjustment software or data validation.

Subpart E—Health Insurance Issuer and Group Health Plan Standards Related to the Reinsurance Program

§ 153.400 Reinsurance contribution funds.

(a) *General requirement*. Each contributing entity must make reinsurance contributions at the national contribution rate (and any additional contribution rate if the State has elected to collect additional contributions pursuant to §153.220(g)) for the reinsurance program for all reinsurance contribution enrollees who reside in a State, in a frequency and manner determined by HHS or the State, to HHS or the applicable reinsurance entity, as applicable.

(1) A contributing entity must make reinsurance contributions on behalf of its group health plans and health insurance coverage, except as set forth in paragraph (a)(2) of this section.

(2) A contributing entity is not required to make contributions on behalf of plans or health insurance coverage that consist solely of excepted benefits as defined by section 2791(c) of the PHS Act.

(b) *Multiple reinsurance entities*. If the State establishes or contracts with more than one applicable reinsurance entity, the contributing entity must make reinsurance contributions to each applicable reinsurance entity for the reinsurance contribution enrollees who reside in the applicable geographic area.

(c) *Timeframe for Federal collections*. Each contributing entity must submit contributions to HHS on a quarterly basis beginning January 15, 2014.

(d) *Data requirements*. Each contributing entity must submit to HHS and each applicable reinsurance entity, if the State elects to collect reinsurance contributions, data required to substantiate the contribution amounts for the contributing entity, in the manner and timeframe specified by the State or HHS.

§ 153.410 Requests for reinsurance payment.

(a) *General requirement*. An issuer of a reinsurance-eligible plan may make a request for payment when an enrollee of that reinsurance-eligible plan has

met the criteria for reinsurance payment set forth in the annual HHS notice of benefit and payment parameters for the applicable year or the State notice of benefit and payment parameters described in subpart B of this part, as applicable.

(b) *Manner of request.* An issuer of a reinsurance-eligible plan must make requests for payment in accordance with the requirements of the annual HHS notice of benefit and payment parameters for the applicable benefit year or the State notice of benefit and payment parameters described in subpart B of this part, as applicable.

Subpart F—Health Insurance Issuer Standards Related to the Risk Corridors Program

§ 153.500 Definitions.

The following definitions apply to this subpart:

Administrative costs mean, with respect to a QHP, total non-claims costs incurred by the QHP issuer for the QHP, as described in § 158.160(b) of this subchapter.

Allowable administrative costs mean, with respect to a QHP, administrative costs of the QHP, up to 20 percent of the premiums earned with respect to the QHP (including any premium tax credit under any governmental program).

Allowable costs mean, with respect to a QHP, an amount equal to the sum of incurred claims of the QHP issuer for the QHP, within the meaning of § 158.140 of this subchapter (including adjustments for any direct and indirect remuneration); expenditures by the QHP issuer for the QHP for activities that improve health care quality as set forth in § 158.150 of this subchapter; expenditures by the QHP issuer for the QHP related to health information technology and meaningful use requirements as set forth in § 158.151 of this subchapter; and the adjustments set forth in § 153.530(b).

Charge means the flow of funds from QHP issuers to HHS.

Direct and indirect remuneration means prescription drug rebates received by a QHP issuer within the meaning of § 158.140(b)(1)(i) of this subchapter.

Payment means the flow of funds from HHS to QHP issuers.

Premiums earned mean, with respect to a QHP, all monies paid by or for enrollees with respect to that plan as a condition of receiving coverage, including any fees or other contributions paid by or for enrollees, within the meaning of § 158.130 of this subchapter.

Risk corridors means any payment adjustment system based on the ratio of allowable costs of a plan to the plan's target amount.

Target amount means, with respect to a QHP, an amount equal to the total premiums earned with respect to a QHP, including any premium tax credit under any governmental program, reduced by the allowable administrative costs of the plan.

§ 153.510 Risk corridors establishment and payment methodology.

(a) *General requirement.* A QHP issuer must adhere to the requirements set by HHS in this subpart and in the annual HHS notice of benefit and payment parameters for the establishment and administration of a program of risk corridors for calendar years 2014, 2015, and 2016.

(b) *HHS payments to health insurance issuers.* QHP issuers will receive payment from HHS in the following amounts, under the following circumstances:

(1) When a QHP's allowable costs for any benefit year are more than 103 percent but not more than 108 percent of the target amount, HHS will pay the QHP issuer an amount equal to 50 percent of the allowable costs in excess of 103 percent of the target amount; and

(2) When a QHP's allowable costs for any benefit year are more than 108 percent of the target amount, HHS will pay to the QHP issuer an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of allowable costs in excess of 108 percent of the target amount.

(c) *Health insurance issuers' remittance of charges.* QHP issuers must remit charges to HHS in the following amounts, under the following circumstances:

(1) If a QHP's allowable costs for any benefit year are less than 97 percent

but not less than 92 percent of the target amount, the QHP issuer must remit charges to HHS in an amount equal to 50 percent of the difference between 97 percent of the target amount and the allowable costs; and

(2) When a QHP's allowable costs for any benefit year are less than 92 percent of the target amount, the QHP issuer must remit charges to HHS in an amount equal to the sum of 2.5 percent of the target amount plus 80 percent of the difference between 92 percent of the target amount and the allowable costs.

§ 153.520 Attribution and allocation of revenue and expense items.

(a) *Attribution to QHP.* Each item of revenue or expense in allowable costs or the target amount with respect to a QHP must be reasonably attributable to the operation of the QHP, with the attribution based on a generally accepted accounting method, consistently applied. To the extent that an issuer utilizes a specific method for allocating expenses for purposes of § 158.170 of this subchapter, the method used for purposes of this paragraph must be consistent.

(b) *Allocation across plans.* Each item of revenue or expense in allowable costs or the target amount must be reasonably allocated across a QHP issuer's plans, with the allocation based on a generally accepted accounting method, consistently applied. To the extent that an issuer utilizes a specific method for allocating expenses for purposes of § 158.170 of this subchapter, the method used for purposes of this paragraph must be consistent.

(c) *Disclosure of attribution and allocation methods.* A QHP issuer must submit to HHS a report, in the manner and timeframe specified in the annual HHS notice of benefit and payment parameters, with a detailed description of the methods and specific bases used to perform the attributions and allocations set forth in paragraphs (a) and (b) of this section.

(d) *Attribution of reinsurance and risk adjustment to benefit year.* A QHP issuer must attribute reinsurance payments and contributions and risk adjustment payments and charges to allowable costs for the benefit year with respect to which the reinsurance payments or contributions or risk adjustment calculations apply.

(e) *Maintenance of records.* A QHP issuer must maintain for 10 years and make available to HHS upon request the data used to make the attributions and allocations set forth in paragraphs (a) and (b) of this section, together with all supporting information required to determine that these methods and bases were accurately implemented.

§ 153.530 Risk corridors data requirements.

(a) *Premium data.* A QHP issuer must submit to HHS data on the premiums earned with respect to each QHP that the issuer offers in the manner and timeframe set forth in the annual HHS notice of benefit and payment parameters.

(b) *Allowable costs.* A QHP issuer must submit to HHS data on the allowable costs incurred with respect to each QHP that the QHP issuer offers in the manner and timeframe set forth in the annual HHS notice of benefit and payment parameters. For purposes of this subpart, allowable costs must be—

(1) Increased by—

(i) Any risk adjustment charges paid by the issuer for the QHP under the risk adjustment program established pursuant to subpart D of this part; and

(ii) Any reinsurance contributions made by the issuer for the QHP under the transitional reinsurance program established pursuant to subpart C of this part.

(2) Reduced by—

(i) Any risk adjustment payments received by the issuer for the QHP under the risk adjustment program established pursuant to subpart D of this part;

(ii) Any reinsurance payments received by the issuer for the QHP under the transitional reinsurance program established pursuant to subpart C of this part; and

(iii) Any cost-sharing reduction payments received by the issuer for the QHP.

(c) *Allowable administrative costs.* A QHP issuer must submit to HHS data on the allowable administrative costs incurred with respect to each QHP that the QHP issuer offers in the manner

and timeframe set forth in the annual HHS notice of benefit and payment parameters.

Subpart G—Health Insurance Issuer Standards Related to the Risk Adjustment Program

§ 153.600 [Reserved]

§ 153.610 Risk adjustment issuer requirements.

(a) *Data requirements.* An issuer that offers risk adjustment covered plans must submit or make accessible all required risk adjustment data for those risk adjustment covered plans in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(b) *Risk adjustment data storage.* An issuer that offers risk adjustment covered plans must store all required risk adjustment data in accordance with the risk adjustment data collection approach established by the State, or by HHS on behalf of the State.

(c) *Issuer contracts.* An issuer that offers risk adjustment covered plans may include in its contract with a provider, supplier, physician, or other practitioner, provisions that require such contractor's submission of complete and accurate risk adjustment data in the manner and timeframe established by the State, or HHS on behalf of the State. These provisions may include financial penalties for failure to submit complete, timely, or accurate data.

(d) *Assessment of charges.* An issuer that offers risk adjustment covered plans that has a net balance of risk adjustment charges payable, including adjustments made pursuant to § 153.350(c), will be notified by the State, or by HHS on behalf of the State, of those net charges, and must remit those risk adjustment charges to the State, or to HHS on behalf of the State, as applicable.

(e) *Charge submission deadline.* An issuer must remit net charges to the State, or HHS on behalf of the State, within 30 days of notification of net charges payable by the State, or HHS on behalf of the State.

§ 153.620 Compliance with risk adjustment standards.

(a) *Issuer support of data validation.* An issuer that offers risk adjustment covered plans must comply with any data validation requests by the State or HHS on behalf of the State.

(b) *Issuer records maintenance requirements.* An issuer that offers risk adjustment covered plans must retain any information requested to support risk adjustment data validation for a period of at least ten years after the date of the report.

PART 154—HEALTH INSURANCE ISSUER RATE INCREASES: DISCLOSURE AND REVIEW REQUIREMENTS

Subpart A—General Provisions

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Subpart B—Disclosure and Review Provisions

154.200 Rate increases subject to review.
154.205 Unreasonable rate increases.
154.210 Review of rate increases subject to review by CMS or by a State.
154.215 Submission of disclosure to CMS for rate increases subject to review.
154.220 Timing of providing the Preliminary Justification.
154.225 Determination by CMS or a State of an unreasonable rate increase.
154.230 Submission and posting of Final Justifications for unreasonable rate increases.

Subpart C—Effective Rate Review Programs

154.301 CMS's determinations of Effective Rate Review Programs.

AUTHORITY: Section 2794 of the Public Health Service Act (42 USC 300gg–94).

SOURCE: 76 FR 29985, May 23, 2011, unless otherwise noted.

Subpart A—General Provisions

§ 154.101 Basis and scope.

(a) *Basis.* This part implements section 2794 of the Public Health Service (PHS) Act.

(b) *Scope*. This part establishes the requirements for health insurance issuers offering health insurance coverage in the small group or individual markets to report information concerning unreasonable rate increases to the Centers for Medicare & Medicaid Services (CMS). This part further establishes the process by which it will be determined whether the rate increases are unreasonable rate increases as defined in this part.

§ 154.102 Definitions.

As used in this part:

CMS means the Centers for Medicare & Medicaid Services.

Effective Rate Review Program means a State program that CMS has determined meets the requirements set forth in § 154.301(a) and (b) for the relevant market segment in the State.

Federal medical loss ratio standard means the applicable medical loss ratio standard for the State and market segment involved, determined under subpart B of 45 CFR part 158.

Health insurance coverage has the meaning given the term in section 2791(b)(1) of the PHS Act.

Health insurance issuer has the meaning given the term in section 2791(b)(2) of the PHS Act.

Individual market has the meaning given the term under the applicable State's rate filing laws, except that:

(1) Where State law does not define the term, it has the meaning given in section 2791(e)(1)(A) of the PHS Act; and

(2) Coverage that would be regulated as individual market coverage (as defined in section 2791(e)(1)(A)) if it were not sold through an association is subject to rate review as individual market coverage.

Product means a package of health insurance coverage benefits with a discrete set of rating and pricing methodologies that a health insurance issuer offers in a State.

Rate increase means any increase of the rates for a specific product offered in the individual or small group market.

Rate increase subject to review means a rate increase that meets the criteria set forth in § 154.200.

Secretary means the Secretary of the Department of Health and Human Services.

Small group market has the meaning given under the applicable State's rate filing laws, except that:

(1) Where State law does not define the term, it has the meaning given in section 2791(e)(5) of the PHS Act; provided, however, that for the purpose of this definition, ''50'' employees applies in place of ''100'' employees in the definition of ''small employer'' under section 2791(e)(4); and

(2) Coverage that would be regulated as small group market coverage (as defined in section 2791(e)(5)) if it were not sold through an association is subject to rate review as small group market coverage.

State has the meaning given the term in section 2791(d)(14) of the PHS Act.

Unreasonable rate increase means:

(1) When CMS is conducting the review required by this part, a rate increase that CMS determines under § 154.205 is:

(i) An excessive rate increase;

(ii) An unjustified rate increase; or

(iii) An unfairly discriminatory rate increase.

(2) When CMS adopts the determination of a State that has an Effective Rate Review Program, a rate increase that the State determines is excessive, unjustified, unfairly discriminatory, or otherwise unreasonable as provided under applicable State law.

[76 FR 29985, May 23, 2011, as amended at 76 FR 54976, Sept. 6, 2011]

§ 154.103 Applicability.

(a) *In general*. The requirements of this part apply to health insurance issuers offering health insurance coverage in the individual market and small group market.

(b) *Exceptions*. The requirements of this part do not apply to grandfathered health plan coverage as defined in 45 CFR § 147.140, or to excepted benefits as described in section 2791(c) of the PHS Act.

Subpart B—Disclosure and Review Provisions

§ 154.200 Rate increases subject to review.

(a) A rate increase filed in a State on or after September 1, 2011, or effective on or after September 1, 2011, in a State that does not require a rate increase to be filed, is subject to review if:

(1) The rate increase is 10 percent or more, applicable to a 12-month period that begins on September 1, as calculated under paragraph (c) of this section; or

(2) The rate increase meets or exceeds a State-specific threshold applicable to a 12-month period that begins on September 1, as calculated under paragraph (c) of this section, determined by the Secretary. In establishing a State-specific threshold, the Secretary shall consult with the State and may consider relevant information provided by other interested parties. A State-specific threshold shall be based on factors impacting rate increases in a State to the extent that data relating to such State-specific factors is available.

(b) The Secretary will publish a notice no later than June 1 of each year concerning whether a threshold under paragraph (a)(1) or (2) of this section applies to a State; except that, with respect to the 12-month period that begins on September 1, 2011, the threshold under paragraph (a)(1) of this section applies.

(c) A rate increase meets or exceeds the applicable threshold set forth in paragraph (a) of this section if the average increase for all enrollees weighted by premium volume meets or exceeds the applicable threshold.

(d) If a rate increase that does not otherwise meet or exceed the threshold under paragraph (c) of this section meets or exceeds the threshold when combined with a previous increase or increases during the 12-month period preceding the date on which the rate increase would become effective, then the rate increase must be considered to meet or exceed the threshold and is subject to review under § 154.210, and such review shall include a review of the aggregate rate increases during the applicable 12-month period.

§ 154.205 Unreasonable rate increases.

(a) When CMS reviews a rate increase subject to review under § 154.210(a), CMS will determine that the rate increase is an unreasonable rate increase if the increase is an excessive rate increase, an unjustified rate increase, or an unfairly discriminatory rate increase.

(b) The rate increase is an excessive rate increase if the increase causes the premium charged for the health insurance coverage to be unreasonably high in relation to the benefits provided under the coverage. In determining whether the rate increase causes the premium charged to be unreasonably high in relationship to the benefits provided, CMS will consider:

(1) Whether the rate increase results in a projected medical loss ratio below the Federal medical loss ratio standard in the applicable market to which the rate increase applies, after accounting for any adjustments allowable under Federal law;

(2) Whether one or more of the assumptions on which the rate increase is based is not supported by substantial evidence; and

(3) Whether the choice of assumptions or combination of assumptions on which the rate increase is based is unreasonable.

(c) The rate increase is an unjustified rate increase if the health insurance issuer provides data or documentation to CMS in connection with the increase that is incomplete, inadequate or otherwise does not provide a basis upon which the reasonableness of an increase may be determined.

(d) The rate increase is an unfairly discriminatory rate increase if the increase results in premium differences between insureds within similar risk categories that:

(1) Are not permissible under applicable State law; or

(2) In the absence of an applicable State law, do not reasonably correspond to differences in expected costs.

§ 154.210 Review of rate increases subject to review by CMS or by a State.

(a) Except as provided in paragraph (b) of this section, CMS will review a rate increase subject to review to determine whether it is unreasonable, as required by this part.

(b) CMS will adopt a State's determination of whether a rate increase is an unreasonable rate increase, if the State:

(1) Has an Effective Rate Review Program as described in § 154.301; and

(2) The State provides to CMS, on a form and in a manner prescribed by the Secretary, its final determination of whether a rate increase is unreasonable, which must include a brief explanation of how its analysis of the relevant factors set forth in § 154.301(a)(3) caused it to arrive at that determination, within five business days following the State's final determination.

(c) CMS will post and maintain on its Web site a list of the States with market segments that meet the requirements of paragraph (b) of this section.

§ 154.215 Submission of disclosure to CMS for rate increases subject to review.

(a) For each rate increase subject to review, a health insurance issuer must submit a Preliminary Justification for each product affected by the increase on a form and in the manner prescribed by the Secretary.

(b) The Preliminary Justification must consist of the following Parts:

(1) Rate increase summary (Part I), as described by paragraph (e) of this section;

(2) Written description justifying the rate increase (Part II), as described by paragraph (f) of this section; and

(3) When CMS is reviewing the rate increase under § 154.210(a), rate filing documentation (Part III), as described by paragraph (g) of this section.

(c) A health insurance issuer must complete and submit Parts I and II of the Preliminary Justification described in paragraphs (b)(1) and (2) of this section to CMS and, as long as the applicable State accepts such submissions, to the applicable State for any rate increase subject to review. If a rate increase subject to review is for a product offered in the individual market or small group market and CMS is reviewing the rate increase under § 154.210(a), then the health insurance issuer must also complete and submit Part III of the Preliminary Justification described in paragraph (b)(3) of this section to CMS only.

(d) The health insurance issuer may submit a single, combined Preliminary Justification for rate increases subject to review affecting multiple products, if the claims experience of all products has been aggregated to calculate the rate increases and the rate increases are the same across all products.

(e) Content of rate increase summary (Part I): The rate increase summary must include the following as determined appropriate by the Secretary:

(1) Historical and projected claims experience;

(2) Trend projections related to utilization, and service or unit cost:

(3) Any claims assumptions related to benefit changes;

(4) Allocation of the overall rate increase to claims and non-claims costs;

(5) Per enrollee per month allocation of current and projected premium; and

(6) Three year history of rate increases for the product associated with the rate increase.

(f) Content of written description justifying the rate increase (Part II): The written description of the rate increase must include a simple and brief narrative describing the data and assumptions that were used to develop the rate increase and include the following:

(1) Explanation of the most significant factors causing the rate increase, including a brief description of the relevant claims and non-claims expense increases reported in the rate increase summary; and

(2) Brief description of the overall experience of the policy, including historical and projected expenses, and loss ratios.

(g) Content of rate filing documentation (Part III): (1) The rate filing documentation must be sufficient for CMS to conduct an examination satisfying the requirements of § 154.301(a)(3) and (4) and determine whether the rate increase is an unreasonable increase. Instructions concerning the requirements for the rate filing documentation will be provided in guidance issued by CMS.

(2) If the health insurance issuer is also required to submit a rate filing to a State in connection with the rate increase under State law, CMS will accept a copy of the filing provided that the filing includes all of the information described in paragraph (g)(1) of this section.

(h) If the level of detail provided by the issuer for the information under paragraph (g) of this section does not provide sufficient basis for CMS to determine whether the rate increase is an unreasonable rate increase, CMS will request the additional information necessary to make its determination. The health insurance issuer must provide the requested information to CMS within 10 business days following its receipt of the request.

(i) Posting of the disclosure on the CMS Web site: (1) CMS promptly will make available to the public on its Web site the information contained in Parts I and II of each Preliminary Justification.

(2) CMS will make available to the public on its Web site the information contained in Part III of each Preliminary Justification that is not a trade secret or confidential commercial or financial information as defined in CMS's Freedom of Information Act regulations, 45 CFR 5.65.

(3) CMS will include a disclaimer on its Web site with the information made available to the public that explains the purpose and role of the Preliminary Justification.

(j) CMS will include information on its Web site concerning how the public can submit comments on the proposed rate increases that CMS reviews.

§ 154.220 Timing of providing the Preliminary Justification.

A health insurance issuer must submit a Preliminary Justification for all rate increases subject to review that are filed in a State on or after September 1, 2011, or effective on or after September 1, 2011 in a State that does not require the rate increase subject to review to be filed, as follows:

(a) If a State requires that a proposed rate increase be filed with the State prior to the implementation of the rate, the health insurance issuer must submit to CMS and the applicable State the Preliminary Justification on the date on which the health insurance issuer submits the proposed rate increase to the State.

(b) For all other States, the health insurance issuer must submit to CMS and the State the Preliminary Justification prior to the implementation of the rate increase.

§ 154.225 Determination by CMS or a State of an unreasonable rate increase.

(a) When CMS receives a Preliminary Justification for a rate increase subject to review and CMS reviews the rate increase under § 154.210(a), CMS will make a timely determination whether the rate increase is an unreasonable rate increase.

(1) CMS will post on its Web site its final determination and a brief explanation of its analysis, consistent with the form and manner prescribed by the Secretary under § 154.210(b)(2), within five business days following its final determination.

(2) If CMS determines that the rate increase is an unreasonable rate increase, CMS will also provide its final determination and brief explanation to the health insurance issuer within five business days following its final determination.

(b) If a State conducts a review under § 154.210(b), CMS will adopt the State's determination of whether a rate increase is unreasonable and post on the CMS Web site the State's final determination described in § 154.210(b)(2).

(c) If a State determines that the rate increase is an unreasonable rate increase and the health insurance issuer is legally permitted to implement the unreasonable rate increase under applicable State law, CMS will provide the State's final determination and brief explanation to the health insurance issuer within five business days following CMS's receipt thereof.

§ 154.230 Submission and posting of Final Justifications for unreasonable rate increases.

(a) If a health insurance issuer receives from CMS a final determination by CMS or a State that a rate increase is an unreasonable rate increase, and the health insurance issuer declines to

implement the rate increase or chooses to implement a lower increase, the health insurance issuer must submit to CMS timely notice that it will not implement the rate increase or that it will implement a lower increase on a form and in the manner prescribed by the Secretary.

(b) If a health insurance issuer implements a lower increase as described in paragraph (a) of this section and the lower increase does not meet or exceed the applicable threshold under § 154.200, such lower increase is not subject to this part. If the lower increase meets or exceeds the applicable threshold, the health insurance issuer must submit a new Preliminary Justification under this part.

(c) If a health insurance issuer implements a rate increase determined by CMS or a State to be unreasonable, within the later of 10 business days after the implementation of such increase or the health insurance issuer's receipt of CMS's final determination that a rate increase is an unreasonable rate increase, the health insurance issuer must:

(1) Submit to CMS a Final Justification in response to CMS's or the State's final determination, as applicable. The information in the Final Justification must be consistent with the information submitted in the Preliminary Justification supporting the rate increase; and

(2) Prominently post on its Web site the following information on a form and in the manner prescribed by the Secretary:

(i) The information made available to the public by CMS and described in § 154.215(i);

(ii) CMS's or the State's final determination and brief explanation described in § 154.225(a) and § 154.210(b)(2), as applicable; and

(iii) The health insurance issuer's Final Justification for implementing an increase that has been determined to be unreasonable by CMS or the State, as applicable.

(3) The health insurance issuer must continue to make this information available to the public on its Web site for at least three years.

(d) CMS will post all Final Justifications on the CMS Web site. This information will remain available to the public on the CMS Web site for three years.

Subpart C—Effective Rate Review Programs

§ 154.301 CMS's determinations of Effective Rate Review Programs.

(a) *Effective Rate Review Program.* In evaluating whether a State has an Effective Rate Review Program, CMS will apply the following criteria for the review of rates for the small group market and the individual market, and also, as applicable depending on State law, the review of rates for different types of products within those markets:

(1) The State receives from issuers data and documentation in connection with rate increases that are sufficient to conduct the examination described in paragraph (a)(3) of this section.

(2) The State conducts an effective and timely review of the data and documentation submitted by a health insurance issuer in support of a proposed rate increase.

(3) The State's rate review process includes an examination of:

(i) The reasonableness of the assumptions used by the health insurance issuer to develop the proposed rate increase and the validity of the historical data underlying the assumptions; and

(ii) The health insurance issuer's data related to past projections and actual experience.

(4) The examination must take into consideration the following factors to the extent applicable to the filing under review:

(i) The impact of medical trend changes by major service categories;

(ii) The impact of utilization changes by major service categories;

(iii) The impact of cost-sharing changes by major service categories;

(iv) The impact of benefit changes;

(v) The impact of changes in enrollee risk profile;

(vi) The impact of any overestimate or underestimate of medical trend for prior year periods related to the rate increase;

(vii) The impact of changes in reserve needs;

(viii) The impact of changes in administrative costs related to programs that improve health care quality;

(ix) The impact of changes in other administrative costs;

(x) The impact of changes in applicable taxes, licensing or regulatory fees;

(xi) Medical loss ratio; and

(xii) The health insurance issuer's capital and surplus.

(5) The State's determination of whether a rate increase is unreasonable is made under a standard that is set forth in State statute or regulation.

(b) *Public disclosure and input.* In addition to satisfying the provisions in paragraph (a) of this section, a State with an Effective Rate Review Program must provide access from its Web site to the Parts I and II of the Preliminary Justifications of the proposed rate increases that it reviews and have a mechanism for receiving public comments on those proposed rate increases.

(c) CMS will determine whether a State has an Effective Rate Review Program for each market based on information available to CMS that a rate review program meets the criteria described in paragraphs (a) and (b) of this section.

(d) CMS reserves the right to evaluate from time to time whether, and to what extent, a State's circumstances have changed such that it has begun to or has ceased to satisfy the criteria set forth in paragraphs (a) and (b) of this section.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

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AUTHORITY: Title I of the Affordable Care Act, sections 1301, 1302, 1303, 1304, 1311, 1312, 1313, 1321, 1322, 1331, 1334, 1402, 1411, 1412, 1413.

SOURCE: 77 FR 11718, Feb. 27, 2012, unless otherwise noted.

Subpart A—General Provisions.

SOURCE: 77 FR 18444, Mar. 27, 2012, unless otherwise noted.

§ 155.10 Basis and scope.

(a) *Basis*. This part is based on the following sections of title I of the Affordable Care Act:

(1) 1301. Qualified health plan defined

(2) 1302. Essential health benefits requirements

(3) 1303. Special rules

(4) 1304. Related definitions

(5) 1311. Affordable choices of health benefit plans.

(6) 1312. Consumer choice

(7) 1313. Financial integrity.

(8) 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(9) 1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers.

(10) 1331. State flexibility to establish Basic Health Programs for low-income individuals not eligible for Medicaid.

(11) 1334. Multi-State plans.

(12) 1402. Reduced cost-sharing for individuals enrolling in QHPs.

(13) 1411. Procedures for determining eligibility for Exchange participation, advance premium tax credits and reduced cost sharing, and individual responsibility exemptions.

(14) 1412. Advance determination and payment of premium tax credits and cost-sharing reductions.

(15) 1413. Streamlining of procedures for enrollment through an exchange and State Medicaid, CHIP, and health subsidy programs.

(b) *Scope*. This part establishes minimum standards for the establishment of an Exchange, minimum Exchange functions, eligibility determinations, enrollment periods, minimum SHOP functions, certification of QHPs, and health plan quality improvement.

§ 155.20 Definitions.

The following definitions apply to this part:

Advance payments of the premium tax credit means payment of the tax credits specified in section 36B of the Code (as added by section 1401 of the Affordable Care Act) which are provided on an advance basis to an eligible individual enrolled in a QHP through an Exchange in accordance with sections 1402 and 1412 of the Affordable Care Act.

Affordable Care Act means the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152).

Agent or broker means a person or entity licensed by the State as an agent, broker or insurance producer.

Annual open enrollment period means the period each year during which a qualified individual may enroll or change coverage in a QHP through the Exchange.

Applicant means:

(1) An individual who is seeking eligibility for him or herself through an application submitted to the Exchange or transmitted to the Exchange by an agency administering an insurance affordability program for at least one of the following:

(i) Enrollment in a QHP through the Exchange; or

(ii) Medicaid, CHIP, and the BHP, if applicable.

(2) An employer or employee seeking eligibility for enrollment in a QHP through the SHOP, where applicable.

Application filer means an applicant, an adult who is in the applicant's household, as defined in 42 CFR 435.603(f), or family, as defined in section 36B(d)(1) of the Code, an authorized representative, or if the applicant is a minor or incapacitated, someone acting responsibly for an applicant.

Benefit year means a calendar year for which a health plan provides coverage for health benefits.

Code means the Internal Revenue Code of 1986.

Cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services.

Cost-sharing reductions means reductions in cost sharing for an eligible individual enrolled in a silver level plan in the Exchange or for an individual who is an Indian enrolled in a QHP in the Exchange.

Educated health care consumer has the meaning given the term in section 1304(e) of the Affordable Care Act.

Eligible employer-sponsored plan has the meaning given the term in section 5000A(f)(2) of the Code.

Employee has the meaning given to the term in section 2791 of the PHS Act.

Employer has the meaning given to the term in section 2791 of the PHS Act, except that such term includes employers with one or more employees. All persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Code are treated as one employer.

Employer contributions means any financial contributions towards an employer sponsored health plan, or other eligible employer-sponsored benefit made by the employer including those made by salary reduction agreement that is excluded from gross income.

Enrollee means a qualified individual or qualified employee enrolled in a QHP.

Exchange means a governmental agency or non-profit entity that meets the applicable standards of this part and makes QHPs available to qualified individuals and qualified employers. Unless otherwise identified, this term refers to State Exchanges, regional Exchanges, subsidiary Exchanges, and a Federally-facilitated Exchange.

Exchange Blueprint means information submitted by a State, an Exchange, or a regional Exchange that sets forth how an Exchange established by a State or a regional Exchange meets the Exchange approval standards established in §155.105(b) and demonstrates operational readiness of an Exchange as described in §155.105(c)(2).

Exchange service area means the area in which the Exchange is certified to operate, in accordance with the standards specified in subpart B of this part.

Grandfathered health plan has the meaning given the term in §147.140.

Group health plan has the meaning given to the term in §144.103.

Health insurance issuer or *issuer* has the meaning given to the term in §144.103.

Health insurance coverage has the meaning given to the term in §144.103.

Health plan has the meaning given to the term in section 1301(b)(1) of the Affordable Care Act.

Individual market has the meaning given the term in section 1304(a)(2) of the Affordable Care Act.

Initial open enrollment period means the period during which a qualified individual may enroll in coverage through the Exchange for coverage during the 2014 benefit year.

Large employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 101 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define large employer by substituting ''51 employees'' for ''101 employees.''

Lawfully present has the meaning given the term in § 152.2.

Minimum essential coverage has the meaning given in section 5000A(f) of the Code.

Navigator means a private or public entity or individual that is qualified, and licensed, if appropriate, to engage in the activities and meet the standards described in § 155.210.

Plan year means a consecutive 12 month period during which a health plan provides coverage for health benefits. A plan year may be a calendar year or otherwise.

Plain language has the meaning given to the term in section 1311(e)(3)(B) of the Affordable Care Act.

Qualified employee means an individual employed by a qualified employer who has been offered health insurance coverage by such qualified employer through the SHOP.

Qualified employer means a small employer that elects to make, at a minimum, all full-time employees of such employer eligible for one or more QHPs in the small group market offered through a SHOP. Beginning in 2017, if a State allows large employers to purchase coverage through the SHOP, the term ''qualified employer'' shall include a large employer that elects to make all full-time employees of such employer eligible for one or more QHPs in the large group market offered through the SHOP.

Qualified health plan or *QHP* means a health plan that has in effect a certification that it meets the standards described in subpart C of part 156 issued or recognized by each Exchange through which such plan is offered in accordance with the process described in subpart K of part 155.

Qualified health plan issuer or *QHP issuer* means a health insurance issuer that offers a QHP in accordance with a certification from an Exchange.

Qualified individual means, with respect to an Exchange, an individual who has been determined eligible to enroll through the Exchange in a QHP in the individual market.

SHOP means a Small Business Health Options Program operated by an Exchange through which a qualified employer can provide its employees and their dependents with access to one or more QHPs.

Small employer means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. In the case of plan years beginning before January 1, 2016, a State may elect to define small employer by substituting ''50 employees'' for ''100 employees.''

Small group market has the meaning given to the term in section 1304(a)(3) of the Affordable Care Act.

Special enrollment period means a period during which a qualified individual or enrollee who experiences certain qualifying events may enroll in, or change enrollment in, a QHP through the Exchange outside of the initial and annual open enrollment periods.

State means each of the 50 States and the District of Columbia.

Subpart B—General Standards Related to the Establishment of an Exchange

§ 155.100 Establishment of a State Exchange.

(a) *General requirements.* Each State may elect to establish an Exchange that facilitates the purchase of health insurance coverage in QHPs and provides for the establishment of a SHOP.

(b) *Eligible Exchange entities.* The Exchange must be a governmental agency or non-profit entity established by a State, consistent with § 155.110.

§ 155.105 Approval of a State Exchange.

(a) *State Exchange approval requirement.* Each State Exchange must be approved by HHS by no later than January 1, 2013 to offer QHPs on January 1, 2014, and thereafter required in accordance with § 155.106. HHS may consult with other Federal Government agencies in determining whether to approve an Exchange.

(b) *State Exchange approval standards.* HHS will approve the operation of an Exchange established by a State provided that it meets the following standards:

(1) The Exchange is able to carry out the required functions of an Exchange consistent with subparts C, D, E, H, and K of this part;

(2) The Exchange is capable of carrying out the information reporting requirements in accordance with section 36B of the Code;

(3) The entire geographic area of the State is in the service area of an Exchange, or multiple Exchanges consistent with § 155.140(b).

(c) *State Exchange approval process.* In order to have its Exchange approved, a State must:

(1) Elect to establish an Exchange by submitting, in a form and manner specified by HHS, an Exchange Blueprint that sets forth how the Exchange meets the standards outlined in paragraph (b) of this section; and

(2) Demonstrate operational readiness to execute its Exchange Blueprint through a readiness assessment conducted by HHS.

(d) *State Exchange approval.* Each Exchange must receive written approval or conditional approval of its Exchange Blueprint and its performance under the operational readiness assessment consistent with paragraph (c) of this section in order to be considered an approved Exchange.

(e) *Significant changes to Exchange Blueprint.* The State must notify HHS in writing before making a significant change to its Exchange Blueprint; no significant change to an Exchange Blueprint may be effective until it is approved by HHS in writing or 60 days after HHS receipt of a completed request. For good cause, HHS may extend the review period by an additional 30 days to a total of 90 days. HHS may deny a request for a significant change to an Exchange Blueprint within the review period.

(f) *HHS operation of an Exchange.* If a State is not an electing State under § 155.100(a) or an electing State does not have an approved or conditionally approved Exchange by January 1, 2013, HHS must (directly or through agreement with a not-for-profit entity) establish and operate such Exchange within the State. In the case of a Federally-facilitated Exchange, the requirements in § 155.130 and subparts C, D, E, H, and K of this part will apply.

§ 155.106 Election to operate an Exchange after 2014.

(a) *Election to operate an Exchange after 2014.* A State electing to seek approval of its Exchange later than January 1, 2013 must:

(1) Comply with the State Exchange approval requirements and process set forth in § 155.105;

(2) Have in effect an approved, or conditionally approved, Exchange Blueprint and operational readiness assessment at least 12 months prior to the Exchange's first effective date of coverage; and

(3) Develop a plan jointly with HHS to facilitate the transition from a Federally-facilitated Exchange to a State Exchange.

(b) *Transition process for State Exchanges that cease operations.* A State that ceases operations of its Exchange after January 1, 2014 must:

(1) Notify HHS that it will no longer operate an Exchange at least 12 months prior to ceasing operations; and

(2) Coordinate with HHS on a transition plan to be developed jointly between HHS and the State.

§ 155.110 Entities eligible to carry out Exchange functions.

(a) *Eligible contracting entities.* The State may elect to authorize an Exchange established by the State to

enter into an agreement with an eligible entity to carry out one or more responsibilities of the Exchange. Eligible entities are:

(1) An entity:

(i) Incorporated under, and subject to the laws of, one or more States;

(ii) That has demonstrated experience on a State or regional basis in the individual and small group health insurance markets and in benefits coverage; and

(iii) Is not a health insurance issuer or treated as a health insurance issuer under subsection (a) or (b) of section 52 of the Code of 1986 as a member of the same controlled group of corporations (or under common control with) as a health insurance issuer; or

(2) The State Medicaid agency, or any other State agency that meets the qualifications of paragraph (a)(1) of this section.

(b) *Responsibility*. To the extent that an Exchange establishes such agreements, the Exchange remains responsible for ensuring that all Federal requirements related to contracted functions are met.

(c) *Governing board structure*. If the Exchange is an independent State agency or a non-profit entity established by the State, the State must ensure that the Exchange has in place a clearly-defined governing board that:

(1) Is administered under a formal, publicly-adopted operating charter or by-laws;

(2) Holds regular public governing board meetings that are announced in advance;

(3) Represents consumer interests by ensuring that overall governing board membership:

(i) Includes at least one voting member who is a consumer representative;

(ii) Is not made up of a majority of voting representatives with a conflict of interest, including representatives of health insurance issuers or agents or brokers, or any other individual licensed to sell health insurance; and

(4) Ensures that a majority of the voting members on its governing board have relevant experience in health benefits administration, health care finance, health plan purchasing, health care delivery system administration, public health, or health policy issues related to the small group and individual markets and the uninsured.

(d) *Governance principles*. (1) The Exchange must have in place and make publicly available a set of guiding governance principles that include ethics, conflict of interest standards, accountability and transparency standards, and disclosure of financial interest.

(2) The Exchange must implement procedures for disclosure of financial interests by members of the Exchange board or governance structure.

(e) *SHOP independent governance*. (1) A State may elect to create an independent governance and administrative structure for the SHOP, consistent with this section, if the State ensures that the SHOP coordinates and shares relevant information with the Exchange operating in the same service area.

(2) If a State chooses to operate its Exchange and SHOP under a single governance or administrative structure, it must ensure that the Exchange has adequate resources to assist individuals and small employers in the Exchange.

(f) *HHS review*. HHS may periodically review the accountability structure and governance principles of a State Exchange.

§ 155.120 Non-interference with Federal law and non-discrimination standards.

(a) *Non-interference with Federal law*. An Exchange must not establish rules that conflict with or prevent the application of regulations promulgated by HHS under subtitle D of title I of the Affordable Care Act.

(b) *Non-interference with State law*. Nothing in parts 155, 156, or 157 of this subchapter shall be construed to preempt any State law that does not prevent the application of the provisions of title I of the Affordable Care Act.

(c) *Non-discrimination*. In carrying out the requirements of this part, the State and the Exchange must:

(1) Comply with applicable non-discrimination statutes; and

(2) Not discriminate based on race, color, national origin, disability, age, sex, gender identity or sexual orientation.

§ 155.130 Stakeholder consultation.

The Exchange must regularly consult on an ongoing basis with the following stakeholders:

(a) Educated health care consumers who are enrollees in QHPs;

(b) Individuals and entities with experience in facilitating enrollment in health coverage;

(c) Advocates for enrolling hard to reach populations, which include individuals with mental health or substance abuse disorders;

(d) Small businesses and self-employed individuals;

(e) State Medicaid and CHIP agencies;

(f) Federally-recognized Tribes, as defined in the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a, that are located within such Exchange's geographic area;

(g) Public health experts;

(h) Health care providers;

(i) Large employers;

(j) Health insurance issuers; and

(k) Agents and brokers.

§ 155.140 Establishment of a regional Exchange or subsidiary Exchange.

(a) *Regional Exchange.* A State may participate in a regional Exchange if:

(1) The Exchange spans two or more States, regardless of whether the States are contiguous; and

(2) The regional Exchange submits a single Exchange Blueprint and is approved to operate consistent with § 155.105(c).

(b) *Subsidiary Exchange.* A State may establish one or more subsidiary Exchanges within the State if:

(1) Each such Exchange serves a geographically distinct area; and

(2) The area served by each subsidiary Exchange is at least as large as a rating area described in section 2701(a) of the PHS Act.

(c) *Exchange standards.* Each regional or subsidiary Exchange must:

(1) Otherwise meet the requirements of an Exchange consistent with this part; and

(2) Meet the following standards for SHOP:

(i) Perform the functions of a SHOP for its service area in accordance with subpart H of this part; and

(ii) If a State elects to operate its individual market Exchange and SHOP under two governance or administrative structures as described in § 155.110(e), the SHOP must encompass a geographic area that matches the geographic area of the regional or subsidiary Exchange.

§ 155.150 Transition process for existing State health insurance exchanges.

(a) *Presumption.* Unless an exchange is determined to be non-compliant through the process in paragraph (b) of this section, HHS will otherwise presume that an existing State exchange meets the standards under this part if:

(1) The exchange was in operation prior to January 1, 2010; and

(2) The State has insured a percentage of its population not less than the percentage of the population projected to be covered nationally after the implementation of the Affordable Care Act, according to the Congressional Budget Office estimates for projected coverage in 2016 that were published on March 30, 2011.

(b) *Process for determining non-compliance.* Any State described in paragraph (a) of this section must work with HHS to identify areas of non-compliance with the standards under this part.

§ 155.160 Financial support for continued operations.

(a) *Definition.* For purposes of this section, participating issuers has the meaning provided in § 156.50.

(b) *Funding for ongoing operations.* A State must ensure that its Exchange has sufficient funding in order to support its ongoing operations beginning January 1, 2015, as follows:

(1) States may generate funding, such as through user fees on participating issuers, for Exchange operations; and

(2) No Federal grants under section 1311 of the Affordable Care Act will be awarded for State Exchange establishment after January 1, 2015.

Subpart C—General Functions of an Exchange

§ 155.200 Functions of an Exchange.

(a) *General requirements.* The Exchange must perform the minimum

functions described in this subpart and in subparts D, E, H, and K of this part.

(b) *Certificates of exemption*. The Exchange must issue certificates of exemption consistent with sections 1311(d)(4)(H) and 1411 of the Affordable Care Act.

(c) *Oversight and financial integrity*. The Exchange must perform required functions related to oversight and financial integrity requirements in accordance with section 1313 of the Affordable Care Act.

(d) *Quality activities*. The Exchange must evaluate quality improvement strategies and oversee implementation of enrollee satisfaction surveys, assessment and ratings of health care quality and outcomes, information disclosures, and data reporting in accordance with sections 1311(c)(1), 1311(c)(3), and 1311(c)(4) of the Affordable Care Act.

(e) *Clarification*. In carrying out its responsibilities under this subpart, an Exchange is not operating on behalf of a QHP.

§ 155.205 Consumer assistance tools and programs of an Exchange.

(a) *Call center*. The Exchange must provide for operation of a toll-free call center that addresses the needs of consumers requesting assistance and meets the requirements outlined in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section.

(b) *Internet Web site*. The Exchange must maintain an up-to-date Internet Web site that meets the requirements outlined in paragraph (c) of this section and:

(1) Provides standardized comparative information on each available QHP, including at a minimum:

(i) Premium and cost-sharing information;

(ii) The summary of benefits and coverage established under section 2715 of the PHS Act;

(iii) Identification of whether the QHP is a bronze, silver, gold, or platinum level plan as defined by section 1302(d) of the Affordable Care Act, or a catastrophic plan as defined by section 1302(e) of the Affordable Care Act;

(iv) The results of the enrollee satisfaction survey, as described in section 1311(c)(4) of the Affordable Care Act;

(v) Quality ratings assigned in accordance with section 1311(c)(3) of the Affordable Care Act;

(vi) Medical loss ratio information as reported to HHS in accordance with 45 CFR part 158;

(vii) Transparency of coverage measures reported to the Exchange during certification in accordance with § 155.1040; and

(viii) The provider directory made available to the Exchange in accordance with § 156.230.

(2) Publishes the following financial information:

(i) The average costs of licensing required by the Exchange;

(ii) Any regulatory fees required by the Exchange;

(iii) Any payments required by the Exchange in addition to fees under paragraphs (b)(2)(i) and (ii) of this section;

(iv) Administrative costs of such Exchange; and

(v) Monies lost to waste, fraud, and abuse.

(3) Provides applicants with information about Navigators as described in § 155.210 and other consumer assistance services, including the toll-free telephone number of the Exchange call center required in paragraph (a) of this section.

(4) Allows for an eligibility determination to be made in accordance with subpart D of this part.

(5) Allows a qualified individual to select a QHP in accordance with subpart E of this part.

(6) Makes available by electronic means a calculator to facilitate the comparison of available QHPs after the application of any advance payments of the premium tax credit and any cost-sharing reductions.

(c) *Accessibility*. Information must be provided to applicants and enrollees in plain language and in a manner that is accessible and timely to—

(1) Individuals living with disabilities including accessible Web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

(2) Individuals who are limited English proficient through the provision of language services at no cost to the individual, including

(i) Oral interpretation;

(ii) Written translations; and

(iii) Taglines in non-English languages indicating the availability of language services.

(3) Inform individuals of the availability of the services described in paragraphs (c)(1) and (2) of this section and how to access such services.

(d) *Consumer assistance*. The Exchange must have a consumer assistance function that meets the standards in paragraph (c) of this section, including the Navigator program described in § 155.210, and must refer consumers to consumer assistance programs in the State when available and appropriate.

(e) *Outreach and education*. The Exchange must conduct outreach and education activities that meet the standards in paragraph (c) of this section to educate consumers about the Exchange and insurance affordability programs to encourage participation.

§ 155.210 Navigator program standards.

(a) *General Requirements*. The Exchange must establish a Navigator program consistent with this section through which it awards grants to eligible public or private entities or individuals described in paragraph (c) of this section.

(b) *Standards*. The Exchange must develop and publicly disseminate—

(1) A set of standards, to be met by all entities and individuals to be awarded Navigator grants, designed to prevent, minimize and mitigate any conflicts of interest, financial or otherwise, that may exist for an entity or individuals to be awarded a Navigator grant and to ensure that all entities and individuals carrying out Navigator functions have appropriate integrity; and

(2) A set of training standards, to be met by all entities and individuals carrying out Navigator functions under the terms of a Navigator grant, to ensure expertise in:

(i) The needs of underserved and vulnerable populations;

(ii) Eligibility and enrollment rules and procedures;

(iii) The range of QHP options and insurance affordability programs; and,

(iv) The privacy and security standards applicable under § 155.260.

(c) *Entities and individuals eligible to be a Navigator*. (1) To receive a Navigator grant, an entity or individual must—

(i) Be capable of carrying out at least those duties described in paragraph (e) of this section;

(ii) Demonstrate to the Exchange that the entity has existing relationships, or could readily establish relationships, with employers and employees, consumers (including uninsured and underinsured consumers), or self-employed individuals likely to be eligible for enrollment in a QHP;

(iii) Meet any licensing, certification or other standards prescribed by the State or Exchange, if applicable;

(iv) Not have a conflict of interest during the term as Navigator; and,

(v) Comply with the privacy and security standards adopted by the Exchange as required in accordance with § 155.260.

(2) The Exchange must include an entity as described in paragraph (c)(2)(i) of this section and an entity from at least one of the other following categories for receipt of a Navigator grant:

(i) Community and consumer-focused nonprofit groups;

(ii) Trade, industry, and professional associations;

(iii) Commercial fishing industry organizations, ranching and farming organizations;

(iv) Chambers of commerce;

(v) Unions;

(vi) Resource partners of the Small Business Administration;

(vii) Licensed agents and brokers; and

(viii) Other public or private entities or individuals that meet the requirements of this section. Other entities may include but are not limited to Indian tribes, tribal organizations, urban Indian organizations, and State or local human service agencies.

(d) *Prohibition on Navigator conduct*. The Exchange must ensure that a Navigator must not—

(1) Be a health insurance issuer;

(2) Be a subsidiary of a health insurance issuer;

(3) Be an association that includes members of, or lobbies on behalf of, the insurance industry; or,

(4) Receive any consideration directly or indirectly from any health insurance issuer in connection with the enrollment of any individuals or employees in a QHP or a non-QHP.

(e) *Duties of a Navigator.* An entity that serves as a Navigator must carry out at least the following duties:

(1) Maintain expertise in eligibility, enrollment, and program specifications and conduct public education activities to raise awareness about the Exchange;

(2) Provide information and services in a fair, accurate and impartial manner. Such information must acknowledge other health programs;

(3) Facilitate selection of a QHP;

(4) Provide referrals to any applicable office of health insurance consumer assistance or health insurance ombudsman established under section 2793 of the PHS Act, or any other appropriate State agency or agencies, for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and

(5) Provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the Exchange, including individuals with limited English proficiency, and ensure accessibility and usability of Navigator tools and functions for individuals with disabilities in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

(f) *Funding for Navigator grants.* Funding for Navigator grants may not be from Federal funds received by the State to establish the Exchange.

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

(a) *General rule.* A State may permit agents and brokers to—

(1) Enroll individuals, employers or employees in any QHP in the individual or small group market as soon as the QHP is offered through an Exchange in the State;

(2) Subject to paragraphs (c), (d), and (e) of this section, enroll qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange; and

(3) Subject to paragraphs (d) and (e) of this section, assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs.

(b) *Web site disclosure.* The Exchange may elect to provide information regarding licensed agents and brokers on its Web site for the convenience of consumers seeking insurance through that Exchange.

(c) *Enrollment through the Exchange.* A qualified individual may be enrolled in a QHP through the Exchange with the assistance of an agent or broker if—

(1) The agent or broker ensures the applicant's completion of an eligibility verification and enrollment application through the Exchange Web site as described in § 155.405;

(2) The Exchange transmits enrollment information to the QHP issuer as provided in § 155.400(a) to allow the issuer to effectuate enrollment of qualified individuals in the QHP.

(3) When an Internet Web site of the agent or broker is used to complete the QHP selection, at a minimum the Internet Web site must:

(i) Meet all standards for disclosure and display of QHP information contained in § 155.205(b)(1) and (c);

(ii) Provide consumers the ability to view all QHPs offered through the Exchange;

(iii) Not provide financial incentives, such as rebates or giveaways;

(iv) Display all QHP data provided by the Exchange;

(v) Maintain audit trails and records in an electronic format for a minimum of ten years; and

(vi) Provide consumers with the ability to withdraw from the process and use the Exchange Web site described in § 155.205(b) instead at any time.

(d) *Agreement.* An agent or broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax

credit and cost-sharing reductions for QHPs must comply with the terms of an agreement between the agent or broker and the Exchange under which the agent or broker at least:

(1) Registers with the Exchange in advance of assisting qualified individuals enrolling in QHPs through the Exchange;

(2) Receives training in the range of QHP options and insurance affordability programs; and

(3) Complies with the Exchange's privacy and security standards adopted consistent with § 155.260.

(e) *Compliance with State law.* An agent or broker that enrolls qualified individuals in a QHP in a manner that constitutes enrollment through the Exchange or assists individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs must comply with applicable State law related to agents and brokers, including applicable State law related to confidentiality and conflicts of interest.

§ 155.230 General standards for Exchange notices.

(a) *General requirement.* Any notice required to be sent by an Exchange to applicants, qualified individuals, qualified employees, qualified employers, and enrollees must be written and include:

(1) Contact information for available customer service resources;

(2) An explanation of appeal rights, if applicable; and

(3) A citation to or identification of the specific regulation supporting the action, including the reason for the intended action.

(b) *Accessibility and readability requirements.* All applications, forms, and notices, including the single, streamlined application described in § 155.405 and notice of annual redetermination described in § 155.335(c), must conform to the standards outlined in § 155.205(c).

(c) *Re-evaluation of appropriateness and usability.* The Exchange must re-evaluate the appropriateness and usability of applications, forms, and notices.

§ 155.240 Payment of premiums.

(a) *Payment by individuals.* The Exchange must allow a qualified individual to pay any applicable premium owed by such individual directly to the QHP issuer.

(b) *Payment by tribes, tribal organizations, and urban Indian organizations.* The Exchange may permit Indian tribes, tribal organizations and urban Indian organizations to pay aggregated QHP premiums on behalf of qualified individuals, including aggregated payment, subject to terms and conditions determined by the Exchange.

(c) *Payment facilitation.* The Exchange may establish a process to facilitate through electronic means the collection and payment of premiums to QHP issuers.

(d) *Required standards.* In conducting an electronic transaction with a QHP issuer that involves the payment of premiums or an electronic funds transfer, the Exchange must comply with the privacy and security standards adopted in accordance with § 155.260 and use the standards and operating rules referenced in § 155.270.

§ 155.260 Privacy and security of personally identifiable information.

(a) *Creation, collection, use and disclosure.* (1) Where the Exchange creates or collects personally identifiable information for the purposes of determining eligibility for enrollment in a qualified health plan; determining eligibility for other insurance affordability programs, as defined in 155.20; or determining eligibility for exemptions from the individual responsibility provisions in section 5000A of the Code, the Exchange may only use or disclose such personally identifiable information to the extent such information is necessary to carry out the functions described in § 155.200 of this subpart.

(2) The Exchange may not create, collect, use, or disclose personally identifiable information while the Exchange is fulfilling its responsibilities in accordance with § 155.200 of this subpart unless the creation, collection, use, or disclosure is consistent with this section.

(3) The Exchange must establish and implement privacy and security standards that are consistent with the following principles:

(i) *Individual access.* Individuals should be provided with a simple and timely means to access and obtain their personally identifiable information in a readable form and format;

(ii) *Correction.* Individuals should be provided with a timely means to dispute the accuracy or integrity of their personally identifiable information and to have erroneous information corrected or to have a dispute documented if their requests are denied;

(iii) *Openness and transparency.* There should be openness and transparency about policies, procedures, and technologies that directly affect individuals and/or their personally identifiable information;

(iv) *Individual choice.* Individuals should be provided a reasonable opportunity and capability to make informed decisions about the collection, use, and disclosure of their personally identifiable information;

(v) *Collection, use, and disclosure limitations.* Personally identifiable information should be created, collected, used, and/or disclosed only to the extent necessary to accomplish a specified purpose(s) and never to discriminate inappropriately;

(vi) *Data quality and integrity.* Persons and entities should take reasonable steps to ensure that personally identifiable information is complete, accurate, and up-to-date to the extent necessary for the person's or entity's intended purposes and has not been altered or destroyed in an unauthorized manner;

(vii) *Safeguards.* Personally identifiable information should be protected with reasonable operational, administrative, technical, and physical safeguards to ensure its confidentiality, integrity, and availability and to prevent unauthorized or inappropriate access, use, or disclosure; and,

(viii) *Accountability.* These principles should be implemented, and adherence assured, through appropriate monitoring and other means and methods should be in place to report and mitigate non-adherence and breaches.

(4) For the purposes of implementing the principle described in paragraph (a)(3)(vii) of this section, the Exchange must establish and implement operational, technical, administrative and physical safeguards that are consistent with any applicable laws (including this section) to ensure—

(i) The confidentiality, integrity, and availability of personally identifiable information created, collected, used, and/or disclosed by the Exchange;

(ii) Personally identifiable information is only used by or disclosed to those authorized to receive or view it;

(iii) Return information, as such term is defined by section 6103(b)(2) of the Code, is kept confidential under section 6103 of the Code;

(iv) Personally identifiable information is protected against any reasonably anticipated threats or hazards to the confidentiality, integrity, and availability of such information;

(v) Personally identifiable information is protected against any reasonably anticipated uses or disclosures of such information that are not permitted or required by law; and

(vi) Personally identifiable information is securely destroyed or disposed of in an appropriate and reasonable manner and in accordance with retention schedules;

(5) The Exchange must monitor, periodically assess, and update the security controls and related system risks to ensure the continued effectiveness of those controls.

(6) The Exchange must develop and utilize secure electronic interfaces when sharing personally identifiable information electronically.

(b) *Application to non-Exchange entities.* Except for tax return information, which is governed by section 6103 of the Code, when collection, use or disclosure is not otherwise required by law, an Exchange must require the same or more stringent privacy and security standards (as §155.260(a)) as a condition of contract or agreement with individuals or entities, such as Navigators, agents, and brokers, that:

(1) Gain access to personally identifiable information submitted to an Exchange; or

(2) Collect, use or disclose personally identifiable information gathered directly from applicants, qualified individuals, or enrollees while that individual or entity is performing the functions outlined in the agreement with the Exchange.

(c) *Workforce compliance.* The Exchange must ensure its workforce complies with the policies and procedures developed and implemented by the Exchange to comply with this section.

(d) *Written policies and procedures.* Policies and procedures regarding the creation collection, use, and disclosure of personally identifiable information must, at minimum:

(1) Be in writing, and available to the Secretary of HHS upon request; and

(2) Identify applicable law governing collection, use, and disclosure of personally identifiable information.

(e) *Data sharing.* Data matching and sharing arrangements that facilitate the sharing of personally identifiable information between the Exchange and agencies administering Medicaid, CHIP or the BHP for the exchange of eligibility information must:

(1) Meet any applicable requirements described in this section;

(2) Meet any applicable requirements described in section 1413(c)(1) and (c)(2) of the Affordable Care Act;

(3) Be equal to or more stringent than the requirements for Medicaid programs under section 1942 of the Act; and

(4) For those matching agreements that meet the definition of ''matching program'' under 5 U.S.C. 552a(a)(8), comply with 5 U.S.C. 552a(o).

(f) *Compliance with the Code.* Return information, as defined in section 6103(b)(2) of the Code, must be kept confidential and disclosed, used, and maintained only in accordance with section 6103 of the Code.

(g) *Improper use and disclosure of information.* Any person who knowingly and willfully uses or discloses information in violation of section 1411(g) of the Affordable Care Act will be subject to a civil penalty of not more than $25,000 per person or entity, per use or disclosure, in addition to other penalties that may be prescribed by law.

[77 FR 18444, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

§ 155.270 Use of standards and protocols for electronic transactions.

(a) *HIPAA administrative simplification.* To the extent that the Exchange performs electronic transactions with a covered entity, the Exchange must use standards, implementation specifications, operating rules, and code sets adopted by the Secretary in 45 CFR parts 160 and 162.

(b) *HIT enrollment standards and protocols.* The Exchange must incorporate interoperable and secure standards and protocols developed by the Secretary in accordance with section 3021 of the PHS Act. Such standards and protocols must be incorporated within Exchange information technology systems.

Subpart D—Exchange Functions in the Individual Market: Eligibility Determinations for Exchange Participation and Insurance Affordability Programs

§ 155.300 Definitions and general standards for eligibility determinations.

(a) *Definitions.* In addition to those definitions in § 155.20, for purposes of this subpart, the following terms have the following meaning:

Adoption taxpayer identification number has the same meaning as it does in 26 CFR 301.6109–3(a).

Applicable Children's Health Insurance Program (CHIP) MAGI-based income standard means the applicable income standard as defined at 42 CFR 457.310(b)(1), as applied under the State plan adopted in accordance with title XXI of the Act, or waiver of such plan and as certified by the State CHIP Agency in accordance with 42 CFR 457.348(d), for determining eligibility for child health assistance and enrollment in a separate child health program.

Applicable Medicaid modified adjusted gross income (MAGI)-based income standard has the same meaning as ''applicable modified adjusted gross income standard,'' as defined at 42 CFR 435.911(b), as applied under the State plan adopted in accordance with title XIX of the Act, or waiver of such plan, and as certified by the State Medicaid

agency in accordance with 42 CFR 435.1200(b)(2) for determining eligibility for Medicaid.

Federal poverty level or *FPL* means the most recently published Federal poverty level, updated periodically in the FEDERAL REGISTER by the Secretary of Health and Human Services under the authority of 42 U.S.C. 9902(2), as of the first day of the annual open enrollment period for coverage in a QHP through the Exchange, as specified in § 155.410.

Indian means any individual as defined in section 4(d) of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

Insurance affordability program has the same meaning as ''insurance affordability program,'' as specified in 42 CFR 435.4.

MAGI-based income has the same meaning as it does in 42 CFR 435.603(e).

Minimum value, when used to describe coverage in an eligible employer-sponsored plan, means that the plan meets the requirements with respect to coverage of the total allowed costs of benefits set forth in section 36B(c)(2)(C)(ii) of the Code.

Modified Adjusted Gross Income (MAGI) has the same meaning as it does in section 36B(d)(2)(B) of the Code.

Non-citizen means an individual who is not a citizen or national of the United States, in accordance with section 101(a)(3) of the Immigration and Nationality Act.

Qualifying coverage in an eligible employer-sponsored plan means coverage in an eligible employer-sponsored plan that meets the affordability and minimum value standards specified in section 36B(c)(2)(C) of the Code.

State CHIP Agency means the agency that administers a separate child health program established by the State under title XXI of the Act in accordance with implementing regulations at 42 CFR 457.

State Medicaid Agency means the agency established or designated by the State under title XIX of the Act that administers the Medicaid program in accordance with implementing regulations at 42 CFR parts 430 through 456.

Tax dependent has the same meaning as the term dependent under section 152 of the Code.

Tax filer means an individual, or a married couple, who indicates that he, she or they expects—

(1) To file an income tax return for the benefit year, in accordance with 26 U.S.C. 6011, 6012, and implementing regulations;

(2) If married (within the meaning of 26 CFR 1.7703–1), to file a joint tax return for the benefit year;

(3) That no other taxpayer will be able to claim him, her or them as a tax dependent for the benefit year; and

(4) That he, she, or they expects to claim a personal exemption deduction under section 151 of the Code on his or her tax return for one or more applicants, who may or may not include himself or herself and his or her spouse.

(b) *Medicaid and CHIP*. In general, references to Medicaid and CHIP regulations in this subpart refer to those regulations as implemented in accordance with rules and procedures which are the same as those applied by the State Medicaid or State CHIP agency or approved by such agency in the agreement described in § 155.345(a).

(c) *Attestation*. (1) Except as specified in paragraph (c)(2) of this section, for the purposes of this subpart, an attestation may be made by the application filer.

(2) The attestations specified in § 155.310(d)(2)(ii) and § 155.315(f)(4)(ii) must be provided by the tax filer.

(d) *Reasonably compatible*. For purposes of this subpart, the Exchange must consider information obtained through electronic data sources, other information provided by the applicant, or other information in the records of the Exchange to be reasonably compatible with an applicant's attestation if the difference or discrepancy does not impact the eligibility of the applicant, including the amount of advance payments of the premium tax credit or category of cost-sharing reductions.

§ 155.302 Options for conducting eligibility determinations.

(a) *Options for conducting eligibility determinations*. The Exchange may satisfy the requirements of this subpart—

(1) Directly or through contracting arrangements in accordance with § 155.110(a); or

(2) Through a combination of the approach described in paragraph (a)(1) of this section and one or both of the options described in paragraph (b) or (c) of this section, subject to the standards in paragraph (d) of this section.

(b) *Medicaid and CHIP*. Notwithstanding the requirements of this subpart, the Exchange may conduct an assessment of eligibility for Medicaid and CHIP, rather than an eligibility determination for Medicaid and CHIP, provided that—

(1) The Exchange makes such an assessment based on the applicable Medicaid and CHIP MAGI-based income standards and citizenship and immigration status, using verification rules and procedures consistent with 42 CFR parts 435 and 457, without regard to how such standards are implemented by the State Medicaid and CHIP agencies.

(2) Notices and other activities required in connection with an eligibility determination for Medicaid or CHIP are performed by the Exchange consistent with the standards identified in this subpart or the State Medicaid or CHIP agency consistent with applicable law.

(3) *Applicants found potentially eligible for Medicaid or CHIP*. When the Exchange assesses an applicant as potentially eligible for Medicaid or CHIP consistent with the standards in subparagraph (b)(1) of this section, the Exchange transmits all information provided as a part of the application, update, or renewal that initiated the assessment, and any information obtained or verified by the Exchange to the State Medicaid agency or CHIP agency via secure electronic interface, promptly and without undue delay.

(4) *Applicants not found potentially eligible for Medicaid and CHIP*. (i) If the Exchange conducts an assessment in accordance with paragraph (b) of this section and finds that an applicant is not potentially eligible for Medicaid or CHIP based on the applicable Medicaid and CHIP MAGI-based income standards, the Exchange must consider the applicant as ineligible for Medicaid and CHIP for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions and must notify such applicant, and provide him or her with the opportunity to—

(A) Withdraw his or her application for Medicaid and CHIP; or

(B) Request a full determination of eligibility for Medicaid and CHIP by the applicable State Medicaid and CHIP agencies.

(ii) To the extent that an applicant described in paragraph (b)(4)(i) of this section requests a full determination of eligibility for Medicaid and CHIP, the Exchange must—

(A) Transmit all information provided as a part of the application, update, or renewal that initiated the assessment, and any information obtained or verified by the Exchange to the State Medicaid agency and CHIP agency via secure electronic interface, promptly and without undue delay; and

(B) Consider such an applicant as ineligible for Medicaid and CHIP for purposes of determining eligibility for advance payments of the premium tax credit and cost-sharing reductions until the State Medicaid or CHIP agency notifies the Exchange that the applicant is eligible for Medicaid or CHIP.

(5) The Exchange adheres to the eligibility determination for Medicaid or CHIP made by the State Medicaid or CHIP agency;

(6) The Exchange and the State Medicaid and CHIP agencies enter into an agreement specifying their respective responsibilities in connection with eligibility determinations for Medicaid and CHIP.

(c) *Advance payments of the premium tax credit and cost-sharing reductions*. Notwithstanding the requirements of this subpart, the Exchange may implement a determination of eligibility for advance payments of the premium tax credit and cost-sharing reductions made by HHS, provided that—

(1) Verifications, notices, and other activities required in connection with an eligibility determination for advance payments of the premium tax credit and cost-sharing reductions are performed by the Exchange in accordance with the standards identified in this subpart or by HHS in accordance with the agreement described in paragraph (c)(4) of this section;

(2) The Exchange transmits all information provided as a part of the application, update, or renewal that initiated the eligibility determination, and any information obtained or verified by the Exchange, to HHS via secure electronic interface, promptly and without undue delay;

(3) The Exchange adheres to the eligibility determination for advance payments of the premium tax credit and cost-sharing reductions made by HHS; and

(4) The Exchange and HHS enter into an agreement specifying their respective responsibilities in connection with eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions.

(d) *Standards*. To the extent that assessments of eligibility for Medicaid and CHIP based on MAGI or eligibility determinations for advance payments of the premium tax credit and cost-sharing reductions are made in accordance with paragraphs (b) or (c) of this section, the Exchange must ensure that—

(1) Eligibility processes for all insurance affordability programs are streamlined and coordinated across HHS, the Exchange, the State Medicaid agency, and the State CHIP agency, as applicable;

(2) Such arrangement does not increase administrative costs and burdens on applicants, enrollees, beneficiaries, or application filers, or increase delay; and

(3) Applicable requirements under 45 CFR 155.260, 155.270, and 155.315(i), and section 6103 of the Code with respect to the confidentiality, disclosure, maintenance, and use of information are met.

§ 155.305 Eligibility standards.

(a) *Eligibility for enrollment in a QHP through the Exchange*. The Exchange must determine an applicant eligible for enrollment in a QHP through the Exchange if he or she meets the following requirements:

(1) *Citizenship, status as a national, or lawful presence*. Is a citizen or national of the United States, or is a non-citizen who is lawfully present in the United States, and is reasonably expected to be a citizen, national, or a non-citizen who is lawfully present for the entire period for which enrollment is sought;

(2) *Incarceration*. Is not incarcerated, other than incarceration pending the disposition of charges; and

(3) *Residency*. Meets the applicable residency standard identified in this paragraph (a)(3).

(i) For an individual who is age 21 and over, is not living in an institution as defined in 42 CFR 435.403(b), is capable of indicating intent, and is not receiving an optional State supplementary payment as addressed in 42 CFR 435.403(f), the service area of the Exchange of the individual is the service areas of the Exchange in which he or she is living and—

(A) Intends to reside, including without a fixed address; or

(B) Has entered with a job commitment or is seeking employment (whether or not currently employed).

(ii) For an individual who is under the age of 21, is not living in an institution as defined in 42 CFR 435.403(b), is not eligible for Medicaid based on receipt of assistance under title IV–E of the Social Security Act as addressed in 42 CFR 435.403(g), is not emancipated, is not receiving an optional State supplementary payment as addressed in 42 CFR 435.403(f), the Exchange service area of the individual—

(A) Is the service area of the Exchange in which he or she resides, including without a fixed address; or

(B) Is the service area of the Exchange of a parent or caretaker, established in accordance with paragraph (a)(3)(i) of this section, with whom the individual resides.

(iii) *Other special circumstances*. In the case of an individual who is not described in paragraphs (a)(3)(i) or (ii) of this section, the Exchange must apply the residency requirements described in 42 CFR 435.403 with respect to the service area of the Exchange.

(iv) *Special rule for tax households with members in multiple Exchange service areas*. (A) Except as specified in paragraph (a)(3)(iv)(B) of this section if all of the members of a tax household are not within the same Exchange service area, in accordance with the applicable standards in paragraphs (a)(3)(i), (ii), and (iii) of this section, any member of the tax household may enroll in a QHP

through any of the Exchanges for which one of the tax filers meets the residency standard.

(B) If both spouses in a tax household enroll in a QHP through the same Exchange, a tax dependent may only enroll in a QHP through that Exchange, or through the Exchange that services the area in which the dependent meets a residency standard described in paragraphs (a)(3)(i), (ii), or (iii) of this section.

(b) *Eligibility for QHP enrollment periods*. The Exchange must determine an applicant eligible for an enrollment period if he or she meets the criteria for an enrollment period, as specified in §§ 155.410 and 155.420.

(c) *Eligibility for Medicaid*. The Exchange must determine an applicant eligible for Medicaid if he or she meets the non-financial eligibility criteria for Medicaid for populations whose eligibility is based on MAGI-based income, as certified by the Medicaid agency in accordance with 42 CFR 435.1200(b)(2), has a household income, as defined in 42 CFR 435.603(d), that is at or below the applicable Medicaid MAGI-based income standard as defined in 42 CFR 435.911(b)(1) and—

(1) Is a pregnant woman, as defined in the Medicaid State Plan in accordance with 42 CFR 435.4;

(2) Is under age 19;

(3) Is a parent or caretaker relative of a dependent child, as defined in the Medicaid State plan in accordance with 42 CFR 435.4; or

(4) Is not described in paragraph (c)(1), (2), or (3) of this section, is under age 65 and is not entitled to or enrolled for benefits under part A of title XVIII of the Social Security Act, or enrolled for benefits under part B of title XVIII of the Social Security Act.

(d) *Eligibility for CHIP*. The Exchange must determine an applicant eligible for CHIP if he or she meets the requirements of 42 CFR 457.310 through 457.320 and has a household income, as defined in 42 CFR 435.603(d), at or below the applicable CHIP MAGI-based income standard.

(e) *Eligibility for BHP*. If a BHP is operating in the service area of the Exchange, the Exchange must determine an applicant eligible for the BHP if he or she meets the requirements specified in section 1331(e) of the Affordable Care Act and regulations implementing that section.

(f) *Eligibility for advance payments of the premium tax credit*. (1) *In general*. The Exchange must determine a tax filer eligible for advance payments of the premium tax credit if the Exchange determines that—

(i) He or she is expected to have a household income, as defined in section 36B(d)(2) of the Code, of greater than or equal to 100 percent but not more than 400 percent of the FPL for the benefit year for which coverage is requested; and

(ii) One or more applicants for whom the tax filer expects to claim a personal exemption deduction on his or her tax return for the benefit year, including the tax filer and his or her spouse—

(A) Meets the requirements for eligibility for enrollment in a QHP through the Exchange, as specified in paragraph (a) of this section; and

(B) Is not eligible for minimum essential coverage, with the exception of coverage in the individual market, in accordance with section 36B(c)(2)(B) and (C) of the Code.

(2) *Special rule for non-citizens who are lawfully present and who are ineligible for Medicaid by reason of immigration status*. The Exchange must determine a tax filer eligible for advance payments of the premium tax credit if the Exchange determines that—

(i) He or she meets the requirements specified in paragraph (f)(1) of this section, except for paragraph (f)(1)(i);

(ii) He or she is expected to have a household income, as defined in section 36B(d)(2) of the Code, of less than 100 percent of the FPL for the benefit year for which coverage is requested; and

(iii) One or more applicants for whom the tax filer expects to claim a personal exemption deduction on his or her tax return for the benefit year, including the tax filer and his or her spouse, is a non-citizen who is lawfully present and ineligible for Medicaid by reason of immigration status, in accordance with section 36B(c)(1)(B) of the Code.

(3) *Enrollment required*. The Exchange may provide advance payments of the premium tax credit on behalf of a tax

filer only if one or more applicants for whom the tax filer attests that he or she expects to claim a personal exemption deduction for the benefit year, including the tax filer and his or her spouse, is enrolled in a QHP through the Exchange.

(4) *Compliance with filing requirement.* The Exchange may not determine a tax filer eligible for advance payments of the premium tax credit if HHS notifies the Exchange as part of the process described in §155.320(c)(3) that advance payments of the premium tax credit were made on behalf of the tax filer or either spouse if the tax filer is a married couple for a year for which tax data would be utilized for verification of household income and family size in accordance with §155.320(c)(1)(i), and the tax filer or his or her spouse did not comply with the requirement to file an income tax return for that year as required by 26 U.S.C. 6011, 6012, and implementing regulations and reconcile the advance payments of the premium tax credit for that period.

(5) *Calculation of advance payments of the premium tax credit.* The Exchange must calculate advance payments of the premium tax credit in accordance with section 36B of the Code.

(6) *Collection of Social Security numbers.* The Exchange must require an application filer to provide the Social Security number of a tax filer who is not an applicant only if an applicant attests that the tax filer has a Social Security number and filed a tax return for the year for which tax data would be utilized for verification of household income and family size.

(g) *Eligibility for cost-sharing reductions.* (1) *Eligibility criteria.* (i) The Exchange must determine an applicant eligible for cost-sharing reductions if he or she—

(A) Meets the requirements for eligibility for enrollment in a QHP through the Exchange, as specified in paragraph (a) of this section;

(B) Meets the requirements for advance payments of the premium tax credit, as specified in paragraph (f) of this section; and

(C) Is expected to have a household income that does not exceed 250 percent of the FPL, for the benefit year for which coverage is requested.

(ii) The Exchange may only provide cost-sharing reductions to an enrollee who is not an Indian if he or she is enrolled through the Exchange in a silver-level QHP, as defined by section 1302(d)(1)(B) of the Affordable Care Act.

(2) *Eligibility categories.* The Exchange must use the following eligibility categories for cost-sharing reductions when making eligibility determinations under this section—

(i) An individual who is expected to have a household income greater than or equal to 100 percent of the FPL and less than or equal to 150 percent of the FPL for the benefit year for which coverage is requested, or for an individual who is eligible for advance payments of the premium tax credit under paragraph (f)(2) of this section, a household income less than 100 percent of the FPL for the benefit year for which coverage is requested;

(ii) An individual is expected to have a household income greater than 150 percent of the FPL and less than or equal to 200 percent of the FPL for the benefit year for which coverage is requested; and

(iii) An individual who is expected to have a household income greater than 200 percent of the FPL and less than or equal to 250 percent of the FPL for the benefit year for which coverage is requested.

(3) *Special rule for multiple tax households.* To the extent that an enrollment in a QHP under a single policy covers individuals who are expected to be in different tax households for the benefit year for which coverage is requested, the Exchange must apply only the first category of cost-sharing reductions listed below for which the Exchange has determined that one of the applicants in the tax households is eligible.

(i) §155.350(b);

(ii) Paragraph (g)(2)(iii) of this section;

(iii) Paragraph (g)(2)(ii) of this section;

(iv) Paragraph (g)(3)(i) of this section;

(v) §155.350(a).

(4) For the purposes of paragraph (g) of this section, ''household income'' means household income as defined in section 36B(d)(2) of the Code.

§ 155.310 Eligibility process.

(a) *Application*. (1) *Accepting applications*. The Exchange must accept applications from individuals in the form and manner specified in § 155.405.

(2) *Information collection from non-applicants*. The Exchange may not request information regarding citizenship, status as a national, or immigration status for an individual who is not seeking coverage for himself or herself on any application or supplemental form.

(3) *Collection of Social Security numbers*. (i) The Exchange must require an applicant who has a Social Security number to provide such number to the Exchange.

(ii) The Exchange may not require an individual who is not seeking coverage for himself or herself to provide a Social Security number, except as specified in § 155.305(f)(6).

(b) *Applicant choice for Exchange to determine eligibility for insurance affordability programs*. The Exchange must permit an applicant to request only an eligibility determination for enrollment in a QHP through the Exchange; however, the Exchange may not permit an applicant to request an eligibility determination for less than all insurance affordability programs.

(c) *Timing*. The Exchange must accept an application and make an eligibility determination for an applicant seeking an eligibility determination at any point in time during the year.

(d) *Determination of eligibility*. (1) The Exchange must determine an applicant's eligibility, in accordance with the standards specified in § 155.305.

(2) *Special rules relating to advance payments of the premium tax credit*. (i) The Exchange must permit an enrollee to accept less than the full amount of advance payments of the premium tax credit for which he or she is determined eligible.

(ii) The Exchange may authorize advance payments of the premium tax credit on behalf of a tax filer only if the Exchange first obtains necessary attestations from the tax filer regarding advance payments of the premium tax credit, including, but not limited to attestations that—

(A) He or she will file an income tax return for the benefit year, in accordance with 26 U.S.C. 6011, 6012, and implementing regulations;

(B) If married (within the meaning of 26 CFR 1.7703–1), he or she will file a joint tax return for the benefit year;

(C) No other taxpayer will be able to claim him or her as a tax dependent for the benefit year; and

(D) He or she will claim a personal exemption deduction on his or her tax return for the applicants identified as members of his or her family, including the tax filer and his or her spouse, in accordance with § 155.320(c)(3)(i).

(3) *Special rule relating to Medicaid and CHIP*. To the extent that the Exchange determines an applicant eligible for Medicaid or CHIP, the Exchange must notify the State Medicaid or CHIP agency and transmit all information from the records of the Exchange to the State Medicaid or CHIP agency, promptly and without undue delay, that is necessary for such agency to provide the applicant with coverage.

(e) *Timeliness standards*. (1) The Exchange must determine eligibility promptly and without undue delay.

(2) The Exchange must assess the timeliness of eligibility determinations based on the period from the date of application or transfer from an agency administering an insurance affordability program to the date the Exchange notifies the applicant of its decision or the date the Exchange transfers the application to another agency administering an insurance affordability program, when applicable.

(f) *Effective dates for eligibility*. Upon making an eligibility determination, the Exchange must implement the eligibility determination under this section for enrollment in a QHP through the Exchange, advance payments of the premium tax credit, and cost-sharing reductions as follows—

(1) For an initial eligibility determination, in accordance with the dates specified in § 155.410(c) and (f) and § 155.420(b), as applicable,

(2) For a redetermination, in accordance with the dates specified in § 155.330(f) and § 155.335(i), as applicable.

(g) *Notification of eligibility determination*. The Exchange must provide timely written notice to an applicant of any eligibility determination made in accordance with this subpart.

(h) *Notice of an employee's eligibility for advance payments of the premium tax credit and cost-sharing reductions to an employer*. The Exchange must notify an employer that an employee has been determined eligible for advance payments of the premium tax credit or cost-sharing reductions upon determination that an employee is eligible for advance payments of the premium tax credit or cost-sharing reductions. Such notice must:

(1) Identify the employee;

(2) Indicate that the employee has been determined eligible for advance payments of the premium tax credit;

(3) Indicate that, if the employer has 50 or more full-time employees, the employer may be liable for the payment assessed under section 4980H of the Code; and

(4) Notify the employer of the right to appeal the determination.

(i) *Duration of eligibility determinations without enrollment*. To the extent that an applicant who is determined eligible for enrollment in a QHP does not select a QHP within his or her enrollment period in accordance with subpart E, and seeks a new enrollment period—

(1) Prior to the date on which his or her eligibility would have been redetermined in accordance with § 155.335 had he or she enrolled in a QHP, the Exchange must require the applicant to attest as to whether information affecting his or her eligibility has changed since his or her most recent eligibility determination before determining his or her eligibility for an enrollment period, and must process any changes reported in accordance with the procedures specified in § 155.330.

(2) On or after the date on which his or her eligibility would have been redetermined in accordance with § 155.335 had he or she enrolled in a QHP, the Exchange must apply the procedures specified in § 155.335 before determining his or her eligibility for an enrollment period.

§ 155.315 Verification process related to eligibility for enrollment in a QHP through the Exchange.

(a) *General requirement*. Unless a request for modification is granted in accordance with paragraph (h) of this section, the Exchange must verify or obtain information as provided in this section in order to determine that an applicant is eligible for enrollment in a QHP through the Exchange.

(b) *Validation of Social Security number*. (1) For any individual who provides his or her Social Security number to the Exchange, the Exchange must transmit the Social Security number and other identifying information to HHS, which will submit it to the Social Security Administration.

(2) To the extent that the Exchange is unable to validate an individual's Social Security number through the Social Security Administration, the Exchange must follow the procedures specified in paragraph (f) of this section, except that the Exchange must provide the individual with a period of 90 days from the date on which the notice described in paragraph (f)(2)(i) of this section is received for the applicant to provide satisfactory documentary evidence or resolve the inconsistency with the Social Security Administration. The date on which the notice is received means 5 days after the date on the notice, unless the individual demonstrates that he or she did not receive the notice within the 5 day period.

(c) *Verification of citizenship, status as a national, or lawful presence*. (1) *Verification with records from the Social Security Administration*. For an applicant who attests to citizenship and has a Social Security number, the Exchange must transmit the applicant's Social Security number and other identifying information to HHS, which will submit it to the Social Security Administration.

(2) *Verification with the records of the Department of Homeland Security*. For an applicant who has documentation that can be verified through the Department of Homeland Security and who attests to lawful presence, or who attests to citizenship and for whom the Exchange cannot substantiate a claim of citizenship through the Social Security Administration, the Exchange must transmit information from the applicant's documentation and other identifying information to HHS, which will submit necessary information to the Department of Homeland Security for verification.

(3) *Inconsistencies and inability to verify information.* For an applicant who attests to citizenship, status as a national, or lawful presence, and for whom the Exchange cannot verify such attestation through the Social Security Administration or the Department of Homeland Security, the Exchange must follow the procedures specified in paragraph (f) of this section, except that the Exchange must provide the applicant with a period of 90 days from the date on which the notice described in paragraph (f)(2)(i) of this section is received for the applicant to provide satisfactory documentary evidence or resolve the inconsistency with the Social Security Administration or the Department of Homeland Security, as applicable. The date on which the notice is received means 5 days after the date on the notice, unless the applicant demonstrates that he or she did not receive the notice within the 5 day period.

(d) *Verification of residency.* The Exchange must verify an applicant's attestation that he or she meets the standards of §155.305(a)(3) as follows—

(1) Except as provided in paragraphs (d)(3) and (4) of this section, accept his or her attestation without further verification; or

(2) Examine electronic data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently current and accurate, and minimize administrative costs and burdens.

(3) If information provided by an applicant regarding residency is not reasonably compatible with other information provided by the individual or in the records of the Exchange the Exchange must examine information in data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently current and accurate.

(4) If the information in such data sources is not reasonably compatible with the information provided by the applicant, the Exchange must follow the procedures specified in paragraph (f) of this section. Evidence of immigration status may not be used to determine that an applicant is not a resident of the Exchange service area.

(e) *Verification of incarceration status.* The Exchange must verify an applicant's attestation that he or she meets the requirements of §155.305(a)(2) by—

(1) Relying on any electronic data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently current, accurate, and offer less administrative complexity than paper verification; or

(2) Except as provided in paragraph (e)(3) of this section, if an approved data source is unavailable, accepting his or her attestation without further verification.

(3) To the extent that an applicant's attestation is not reasonably compatible with information from approved data sources described in paragraph (e)(1) of this section or other information provided by the applicant or in the records of the Exchange, the Exchange must follow the procedures specified in §155.315(f).

(f) *Inconsistencies.* Except as otherwise specified in this subpart, for an applicant for whom the Exchange cannot verify information required to determine eligibility for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions, including when electronic data is required in accordance with this subpart but not available, the Exchange:

(1) Must make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors, by contacting the application filer to confirm the accuracy of the information submitted by the application filer;

(2) If unable to resolve the inconsistency through the process described in paragraph (f)(1) of this section, must—

(i) Provide notice to the applicant regarding the inconsistency; and

(ii) Provide the applicant with a period of 90 days from the date on which the notice described in paragraph (f)(2)(i) of this section is sent to the applicant to either present satisfactory documentary evidence via the channels available for the submission of an application, as described in §155.405(c),

except for by telephone through a call center, or otherwise resolve the inconsistency.

(3) May extend the period described in paragraph (f)(2)(ii) of this section for an applicant if the applicant demonstrates that a good faith effort has been made to obtain the required documentation during the period.

(4) During the period described in paragraph (f)(2)(ii) of this section, must:

(i) Proceed with all other elements of eligibility determination using the applicant's attestation, and provide eligibility for enrollment in a QHP to the extent that an applicant is otherwise qualified; and

(ii) Ensure that advance payments of the premium tax credit and cost-sharing reductions are provided on behalf of an applicant within this period who is otherwise qualified for such payments and reductions, as described in § 155.305, if the tax filer attests to the Exchange that he or she understands that any advance payments of the premium tax credit paid on his or her behalf are subject to reconciliation.

(5) If, after the period described in paragraph (f)(2)(ii) of this section, the Exchange remains unable to verify the attestation, must—

(i) Determine the applicant's eligibility based on the information available from the data sources specified in this subpart, unless such applicant qualifies for the exception provided under paragraph (g) of this section, and notify the applicant of such determination in accordance with the notice requirements specified in § 155.310(g), including notice that the Exchange is unable to verify the attestation; and

(ii) Effectuate the determination specified in paragraph (f)(5)(i) of this section no earlier than 10 days after and no later than 30 days after the date on which the notice in paragraph (f)(5)(i) of this section is sent.

(g) *Exception for special circumstances.* For an applicant who does not have documentation with which to resolve the inconsistency through the process described in paragraph (f)(2) of this section because such documentation does not exist or is not reasonably available and for whom the Exchange is unable to otherwise resolve the inconsistency, with the exception of an inconsistency related to citizenship or immigration status, the Exchange must provide an exception, on a case-by-case basis, to accept an applicant's attestation as to the information which cannot otherwise be verified along with an explanation of circumstances as to why the applicant does not have documentation.

(h) *Flexibility in information collection and verification.* HHS may approve an Exchange Blueprint in accordance with § 155.105(d) or a significant change to the Exchange Blueprint in accordance with § 155.105(e) to modify the methods to be used for collection of information and verification of information as set forth in this subpart, as well as the specific information required to be collected, provided that HHS finds that such modification would reduce the administrative costs and burdens on individuals while maintaining accuracy and minimizing delay, that it would not undermine coordination with Medicaid and CHIP, and that applicable requirements under § 155.260, § 155.270, paragraph (i) of this section, and section 6103 of the Code with respect to the confidentiality, disclosure, maintenance, or use of such information will be met.

(i) *Applicant information.* The Exchange must not require an applicant to provide information beyond the minimum necessary to support the eligibility and enrollment processes of the Exchange, Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, described in this subpart.

[77 FR 18444, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

§ 155.320 Verification process related to eligibility for insurance affordability programs.

(a) *General requirements.* (1) The Exchange must verify information in accordance with this section only for an applicant or tax filer who requested an eligibility determination for insurance affordability programs in accordance with § 155.310(b).

(2) Unless a request for modification is granted in accordance with § 155.315(h), the Exchange must verify or obtain information in accordance

with this section before making an eligibility determination for insurance affordability programs, and must use such information in such determination.

(b) *Verification of eligibility for minimum essential coverage other than through an eligible employer-sponsored plan.* (1) The Exchange must verify whether an applicant is eligible for minimum essential coverage other than through an eligible employer-sponsored plan, Medicaid, CHIP, or the BHP, using information obtained by transmitting identifying information specified by HHS to HHS.

(2) The Exchange must verify whether an applicant has already been determined eligible for coverage through Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, within the State or States in which the Exchange operates using information obtained from the agencies administering such programs.

(c) *Verification of household income and family/household size.* (1) *Data.* (i) *Tax return data.* (A) For all individuals whose income is counted in calculating a tax filer's household income, in accordance with section 36B(d)(2) of the Code, or an applicant's household income, in accordance with 42 CFR 435.603(d), and for whom the Exchange has a Social Security number or an adoption taxpayer identification number, the Exchange must request tax return data regarding MAGI and family size from the Secretary of the Treasury by transmitting identifying information specified by HHS to HHS.

(B) If the identifying information for one or more individuals does not match a tax record on file with the Secretary of the Treasury that may be disclosed in accordance with section 6103(l)(21) of the Code and its accompanying regulations, the Exchange must proceed in accordance with § 155.315(f)(1).

(ii) *Data regarding MAGI-based income.* For all individuals whose income is counted in calculating a tax filer's household income, in accordance with section 36B(d)(2) of the Code, or an applicant's household income, in accordance with 42 CFR 435.603(d), the Exchange must request data regarding MAGI-based income in accordance with 42 CFR 435.948(a).

(2) *Verification process for Medicaid and CHIP.* (i) *Household size.* (A) The Exchange must verify household size in accordance with 42 CFR 435.945(a) or through other reasonable verification procedures consistent with the requirements in 42 CFR 435.952.

(B) The Exchange must verify the information in paragraph (c)(2)(i)(A) of this section by accepting an applicant's attestation without further verification, unless the Exchange finds that an applicant's attestation to the individuals that comprise his or her household for Medicaid and CHIP is not reasonably compatible with other information provided by the application filer for the applicant or in the records of the Exchange, in which case the Exchange must utilize data obtained through electronic data sources to verify the attestation. If such data sources are unavailable or information in such data sources is not reasonably compatible with the applicant's attestation, the Exchange must request additional documentation to support the attestation within the procedures specified in 42 CFR 435.952.

(ii) *Verification process for MAGI-based household income.* The Exchange must verify MAGI-based income, within the meaning of 42 CFR 435.603(d), for the household described in paragraph (c)(2)(i) in accordance with the procedures specified in Medicaid regulations 42 CFR 435.945, 42 CFR 435.948, and 42 CFR 435.952 and CHIP regulations at 42 CFR 457.380.

(3) *Verification process for advance payments of the premium tax credit and cost-sharing reductions.* (i) *Family size.* (A) The Exchange must require an applicant to attest to the individuals that comprise a tax filer's family for advance payments of the premium tax credit and cost-sharing reductions.

(B) To the extent that the applicant attests that the information described in paragraph (c)(1)(i) of this section represents an accurate projection of a tax filer's family size for the benefit year for which coverage is requested, the Exchange must determine the tax filer's eligibility for advance payments of the premium tax credit and cost-sharing reductions based on the family size data in paragraph (c)(1)(i) of this section.

(C) To the extent that the data described in paragraph (c)(1)(i) of this section is unavailable, or an applicant attests that a change in circumstances has occurred or is reasonably expected to occur, and so it does not represent an accurate projection of a tax filer's family size for the benefit year for which coverage is requested, the Exchange must verify the tax filer's family size for advance payments of the premium tax credit and cost-sharing reductions by accepting an applicant's attestation without further verification, except as specified in paragraph (c)(3)(i)(D) of this section.

(D) If Exchange finds that an applicant's attestation of a tax filer's family size is not reasonably compatible with other information provided by the application filer for the family or in the records of the Exchange, with the exception of the data described in paragraph (c)(1)(i) of this section, the Exchange must utilize data obtained through other electronic data sources to verify the attestation. If such data sources are unavailable or information in such data sources is not reasonably compatible with the applicant's attestation, the Exchange must request additional documentation to support the attestation within the procedures specified in § 155.315(f).

(ii) *Basic verification process for annual household income.* (A) The Exchange must compute annual household income for the family described in paragraph (c)(3)(i)(A) of this section based on the tax return data described in paragraph (c)(1)(i) of this section;

(B) The Exchange must require the applicant to attest regarding a tax filer's projected annual household income;

(C) To the extent that the applicant's attestation indicates that the information described in paragraph (c)(3)(ii)(A) of this section represents an accurate projection of the tax filer's household income for the benefit year for which coverage is requested, the Exchange must determine the tax filer's eligibility for advance payments of the premium tax credit and cost-sharing reductions based on the household income data in paragraph (c)(3)(ii)(A) of this section.

(D) To the extent that the data described in paragraph (c)(1)(i) of this section is unavailable, or an applicant attests that a change in circumstances has occurred or is reasonably expected to occur, and so it does not represent an accurate projection of the tax filer's household income for the benefit year for which coverage is requested, the Exchange must require the applicant to attest to the tax filer's projected household income for the benefit year for which coverage is requested.

(iii) *Verification process for increases in household income.* (A) If an applicant's attestation, in accordance with paragraph (c)(3)(ii)(B) of this section, indicates that a tax filer's annual household income has increased or is reasonably expected to increase from the data described in paragraph (c)(3)(ii)(A) of this section to the benefit year for which the applicant(s) in the tax filer's family are requesting coverage and the Exchange has not verified the applicant's MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section to be within the applicable Medicaid or CHIP MAGI-based income standard, the Exchange must accept the applicant's attestation for the tax filer's family without further verification, except as provided in paragraph (c)(3)(iii)(B) of this section.

(B) If the Exchange finds that an applicant's attestation of a tax filer's annual household income is not reasonably compatible with other information provided by the application filer or available to the Exchange in accordance with paragraph (c)(1)(ii) of this section, the Exchange must utilize data obtained through electronic data sources to verify the attestation. If such data sources are unavailable or information in such data sources is not reasonably compatible with the applicant's attestation, the Exchange must request additional documentation using the procedures specified in § 155.315(f).

(iv) *Eligibility for alternate verification process for decreases in annual household income and situations in which tax return data is unavailable.* The Exchange must determine a tax filer's annual household income for advance payments of the premium tax credit and cost-sharing reductions based on the alternate

verification procedures described in paragraph (c)(3)(v) of this section, if an applicant attests to projected annual household income in accordance with paragraph (c)(3)(ii)(B) of this section, the tax filer does not meet the criteria specified in paragraph (c)(3)(iii) of this section, the applicants in the tax filer's family have not established MAGI-based income through the process specified in paragraph (c)(2)(ii) of this section that is within the applicable Medicaid or CHIP MAGI-based income standard, and one of the following conditions is met—

(A) The Secretary of the Treasury does not have tax return data that may be disclosed under section 6103(l)(21) of the Code for the tax filer that is at least as recent as the calendar year two years prior to the calendar year for which advance payments of the premium tax credit or cost-sharing reductions would be effective;

(B) The applicant attests that the tax filer's applicable family size has changed or is reasonably expected to change for the benefit year for which the applicants in his or her family are requesting coverage, or the members of the tax filer's family have changed or are reasonably expected to change for the benefit year for which the applicants in his or her family are requesting coverage;

(C) The applicant attests that a change in circumstances has occurred or is reasonably expected to occur, and so the tax filer's annual household income has decreased or is reasonably expected to decrease from the data described in paragraph (c)(1)(i) of this section for the benefit year for which the applicants in his or her family are requesting coverage;

(D) The applicant attests that the tax filer's filing status has changed or is reasonably expected to change for the benefit year for which the applicants in his or her family are requesting coverage; or

(E) An applicant in the tax filer's family has filed an application for unemployment benefits.

(v) *Alternate verification process.* If a tax filer qualifies for an alternate verification process based on the requirements specified in paragraph (c)(3)(iv) of this section and the applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is no more than ten percent below the annual household income computed in accordance with paragraph (c)(3)(ii)(A) of this section, the Exchange must accept the applicant's attestation without further verification.

(vi) *Alternate verification process for decreases in annual household income and situations in which tax return data is unavailable.* If a tax filer qualifies for an alternate verification process based on the requirements specified in paragraph (c)(3)(iv) of this section and the applicant's attestation to projected annual household income, as described in paragraph (c)(3)(ii)(B) of this section, is greater than ten percent below the annual household income computed in accordance with paragraph (c)(3)(ii)(A), or if data described in paragraph (c)(1)(i) of this section is unavailable, the Exchange must attempt to verify the applicant's attestation of the tax filer's projected annual household income for the tax filer by—

(A) Using annualized data from the MAGI-based income sources specified in paragraph (c)(1)(ii) of this section;

(B) Using other electronic data sources that have been approved by HHS, based on evidence showing that such data sources are sufficiently accurate and offer less administrative complexity than paper verification; or

(C) If electronic data are unavailable or do not support an applicant's attestation, the Exchange must follow the procedures specified in §155.315(f)(1) through (4).

(D) If, following the 90-day period described in paragraph (c)(3)(vi)(C) of this section, an applicant has not responded to a request for additional information from the Exchange and the data sources specified in paragraph (c)(1) of this section indicate that an applicant in the tax filer's family is eligible for Medicaid or CHIP, the Exchange must not provide the applicant with eligibility for advance payments of the premium tax credit, cost-sharing reductions, Medicaid, CHIP or the BHP, if a BHP is operating in the service area of the Exchange.

(E) If, at the conclusion of the period specified in paragraph (c)(3)(vi)(C) of

this section, the Exchange remains unable to verify the applicant's attestation, the Exchange must determine the applicant's eligibility based on the information described in paragraph (c)(3)(ii)(A) of this section, notify the applicant of such determination in accordance with the notice requirements specified in § 155.310(g), and implement such determination in accordance with the effective dates specified in § 155.330(f).

(F) If, at the conclusion of the period specified in paragraph (c)(3)(vi)(C) of this section, the Exchange remains unable to verify the applicant's attestation for the tax filer and the information described in paragraph (c)(3)(ii)(A) of this section is unavailable, the Exchange must determine the tax filer ineligible for advance payments of the premium tax credit and cost-sharing reductions, notify the applicant of such determination in accordance with the notice requirement specified in § 155.310(g), and discontinue any advance payments of the premium tax credit and cost-sharing reductions in accordance with the effective dates specified in § 155.330(f).

(vii) For the purposes of this paragraph (c)(3), ''household income'' means household income as specified in section 36B(d)(2) of the Code.

(viii) For purposes of paragraph (c)(3) of this section, ''family size'' means family size as specified in section 36B(d)(1) of the Code.

(4) The Exchange must provide education and assistance to an applicant regarding the process specified in this paragraph.

(d) *Verification related to enrollment in an eligible employer-sponsored plan.* (1) Except as provided in paragraph (d)(2) of this section, the Exchange must verify whether an applicant who requested an eligibility determination for insurance affordability programs is enrolled in an eligible employer-sponsored plan or reasonably expects to be enrolled in an eligible employer-sponsored plan for the benefit year for which coverage is requested by accepting an applicant's attestation without further verification.

(2) If the Exchange finds that an applicant's attestation regarding enrollment in an eligible employer-sponsored plan is not reasonably compatible with other information provided by the applicant or in the records of the Exchange, the Exchange must utilize data obtained through electronic data sources to verify the attestation. If such data sources are unavailable or information in such data sources is not reasonably compatible with the applicant's attestation, the Exchange may request additional documentation to support the attestation within the procedures specified in § 155.315(f).

(e) *Verification related to eligibility for qualifying coverage in an eligible employer-sponsored plan.* (1) The Exchange must require an applicant to attest to an applicant's eligibility for qualifying coverage in an eligible employer-sponsored plan for the benefit year for which coverage is requested for the purposes of eligibility for advance payments of the premium tax credit and cost-sharing reductions, and to provide information identified in section 1411(b)(4) of the Affordable Care Act.

(2) The Exchange must verify whether an applicant is eligible for qualifying coverage in an eligible employer-sponsored plan for the purposes of eligibility for advance payments of the premium tax credit and cost-sharing reductions.

(f) *Additional verification related to immigration status for Medicaid and CHIP.* (1) For purposes of determining eligibility for Medicaid, the Exchange must verify whether an applicant who does not attest to being a citizen or a national has satisfactory immigration status to be eligible for Medicaid, as required by 42 CFR 435.406 and, if applicable under the State Medicaid plan, section 1903(v)(4) of the Act.

(2) For purposes of determining eligibility for CHIP, the Exchange must verify whether an applicant who does not attest to being a citizen or a national has satisfactory immigration status to be eligible for CHIP, in accordance with 42 CFR 457.320(b) and if applicable under the State Child Health Plan, section 2107(e)(1)(J) of the Act.

§ 155.330 Eligibility redetermination during a benefit year.

(a) *General requirement.* The Exchange must redetermine the eligibility of an

enrollee in a QHP through the Exchange during the benefit year if it receives and verifies new information reported by an enrollee or identifies updated information through the data matching described in paragraph (d) of this section.

(b) *Requirement for individuals to report changes.* (1) Except as specified in paragraphs (b)(2) and (3) of this section, the Exchange must require an enrollee to report any change with respect to the eligibility standards specified in § 155.305 within 30 days of such change.

(2) The Exchange must not require an enrollee who did not request an eligibility determination for insurance affordability programs to report changes that affect eligibility for insurance affordability programs.

(3) The Exchange may establish a reasonable threshold for changes in income, such that an enrollee who experiences a change in income that is below the threshold is not required to report such change.

(4) The Exchange must allow an enrollee, or an application filer, on behalf of the enrollee, to report changes via the channels available for the submission of an application, as described in § 155.405(c).

(c) *Verification of reported changes.* The Exchange must—

(1) Verify any information reported by an enrollee in accordance with the processes specified in §§ 155.315 and 155.320 prior to using such information in an eligibility redetermination; and

(2) Provide periodic electronic notifications regarding the requirements for reporting changes and an enrollee's opportunity to report any changes as described in paragraph (b)(3) of this section, to an enrollee who has elected to receive electronic notifications, unless he or she has declined to receive notifications under this paragraph (c)(2).

(d) *Periodic examination of data sources.* (1) The Exchange must periodically examine available data sources described in § 155.315(b)(1) and § 155.320(b) to identify the following changes:

(i) Death; and

(ii) Eligibility determinations for Medicare, Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange.

(2) *Flexibility.* The Exchange may make additional efforts to identify and act on changes that may affect an enrollee's eligibility for enrollment in a QHP through the Exchange or for insurance affordability programs, provided that such efforts—

(i) Would reduce the administrative costs and burdens on individuals while maintaining accuracy and minimizing delay, that it would not undermine coordination with Medicaid and CHIP, and that applicable requirements under §§ 155.260, 155.270, 155.315(i), and section 6103 of the Code with respect to the confidentiality, disclosure, maintenance, or use of such information will be met; and

(ii) Comply with the standards specified in paragraphs (e)(2) and (3) of this section.

(e) *Redetermination and notification of eligibility.* (1) *Enrollee-reported data.* If the Exchange verifies updated information reported by an enrollee, the Exchange must—

(i) Redetermine the enrollee's eligibility in accordance with the standards specified in § 155.305;

(ii) Notify the enrollee regarding the determination in accordance with the requirements specified in § 155.310(g); and

(iii) Notify the enrollee's employer, as applicable, in accordance with the requirements specified in § 155.310(h).

(2) *Data matching not regarding income, family size and family composition.* If the Exchange identifies updated information through the data matching taken in accordance with paragraph (d)(1) or through other data matching under paragraph (d)(2) of this section, with the exception of data matching related to income, the Exchange must—

(i) Notify the enrollee regarding the updated information, as well as the enrollee's projected eligibility determination after considering such information;

(ii) Allow an enrollee 30 days from the date of the notice to notify the Exchange that such information is inaccurate; and

(iii) If the enrollee responds contesting the updated information, proceed in accordance with § 155.315(f).

(iv) If the enrollee does not respond within the 30-day period specified in paragraph (e)(2)(ii), proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section.

(3) *Data matching regarding income, family size and family composition*. If the Exchange identifies updated information regarding income, family size and composition through the data matching taken in accordance with paragraph (c)(2) of this section, the Exchange must—

(i) Follow procedures described in paragraph (e)(2)(i) and (ii) of this section; and

(ii) If the enrollee responds confirming the updated information or providing more up to date information, proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section.

(iii) If the enrollee does not respond within the 30-day period specified in paragraph (e)(2)(ii) of this section, maintain the enrollee's existing eligibility determination without considering the updated information.

(f) *Effective dates*. (1) Except as specified in paragraphs (f)(2) or (3) of this section, the Exchange must implement changes resulting from a redetermination under this section on the first day of the month following the date of the notice described in paragraph (e)(1)(ii) of this section.

(2) The Exchange may determine a reasonable point in a month after which a change captured through a redetermination will not be effective until the first day of the month after the month specified in paragraph (f)(1) of this section. Such reasonable point in a month must be no earlier than the date described in § 155.420(b)(2).

(3) In the case of a redetermination that results in an enrollee being ineligible to continue his or her enrollment in a QHP through the Exchange, the Exchange must maintain his or her eligibility for enrollment in a QHP without advance payments of the premium tax credit and cost-sharing reductions, in accordance with the effective dates described in § 155.430(d)(3).

§ 155.335 Annual eligibility redetermination.

(a) *General requirement*. Except as specified in paragraph (l) of this section, the Exchange must redetermine the eligibility of an enrollee in a QHP through the Exchange on an annual basis.

(b) *Updated income and family size information*. In the case of an enrollee who requested an eligibility determination for insurance affordability programs in accordance with § 155.310(b), the Exchange must request updated tax return information, if the enrollee has authorized the request of such tax return information, and data regarding MAGI-based income as described in § 155.320(c)(1) for use in the enrollee's eligibility redetermination.

(c) *Notice to enrollee*. The Exchange must provide an enrollee with an annual redetermination notice including the following:

(1) The data obtained under paragraph (b) of this section, if applicable; and

(2) The data used in the enrollee's most recent eligibility determination; and

(3) The enrollee's projected eligibility determination for the following year, after considering any updated information described in paragraph (c)(1) of this section, including, if applicable, the amount of any advance payments of the premium tax credit and the level of any cost-sharing reductions or eligibility for Medicaid, CHIP or BHP.

(d) *Timing*. (1) For redeterminations under this section for coverage effective January 1, 2015, the Exchange must satisfy the notice provisions of paragraph (c) of this section and § 155.410(d) through a single, coordinated notice.

(2) For redeterminations under this section for coverage effective on or after January 1, 2017, the Exchange may send the notice specified in paragraph (c) of this section separately from the notice of annual open enrollment specified in § 155.410(d), provided that—

(i) The Exchange sends the notice specified in paragraph (c) of this section no earlier than the date of the notice of annual open enrollment specified in § 155.410(d); and

(ii) The timing of the notice specified in paragraph (c) of this section allows a reasonable amount of time for the enrollee to review the notice, provide a

timely response, and for the Exchange to implement any changes in coverage elected during the annual open enrollment period.

(e) *Changes reported by enrollees.* (1) The Exchange must require an enrollee to report any changes with respect to the information listed in the notice described in paragraph (c) of this section within 30 days from the date of the notice.

(2) The Exchange must allow an enrollee, or an application filer, on behalf of the enrollee, to report changes via the channels available for the submission of an application, as described in §155.405(c)(2).

(f) *Verification of reported changes.* The Exchange must verify any information reported by an enrollee under paragraph (e) of this section using the processes specified in §155.315 and §155.320, including the relevant provisions in those sections regarding inconsistencies, prior to using such information to determine eligibility.

(g) *Response to redetermination notice.* (1) The Exchange must require an enrollee, or an application filer, on behalf of the enrollee, to sign and return the notice described in paragraph (c) of this section.

(2) To the extent that an enrollee does not sign and return the notice described in paragraph (c) of this section within the 30-day period specified in paragraph (e) of this section, the Exchange must proceed in accordance with the procedures specified in paragraph (h)(1) of this section.

(h) *Redetermination and notification of eligibility.* (1) After the 30-day period specified in paragraph (e) of this section has elapsed, the Exchange must—

(i) Redetermine the enrollee's eligibility in accordance with the standards specified in §155.305 using the information provided to the individual in the notice specified in paragraph (c), as supplemented with any information reported by the enrollee and verified by the Exchange in accordance with paragraphs (e) and (f) of this section;

(ii) Notify the enrollee in accordance with the requirements specified in §155.310(g); and

(iii) If applicable, notify the enrollee's employer, in accordance with the requirements specified in §155.310(h).

(2) If an enrollee reports a change with respect to the information provided in the notice specified in paragraph (c) of this section that the Exchange has not verified as of the end of the 30-day period specified in paragraph (e) of this section, the Exchange must redetermine the enrollee's eligibility after completing verification, as specified in paragraph (f) of this section.

(i) *Effective date of annual redetermination.* The Exchange must ensure that a redetermination under this section is effective on the first day of the coverage year following the year in which the Exchange provided the notice in paragraph (c) of this section, or in accordance with the rules specified in §155.330(f) regarding effective dates, whichever is later.

(j) *Renewal of coverage.* If an enrollee remains eligible for coverage in a QHP upon annual redetermination, such enrollee will remain in the QHP selected the previous year unless such enrollee terminates coverage from such plan, including termination of coverage in connection with enrollment in a different QHP, in accordance with §155.430.

(k) *Authorization of the release of tax data to support annual redetermination.* (1) The Exchange must have authorization from an enrollee in order to obtain updated tax return information described in paragraph (b) of this section for purposes of conducting an annual redetermination.

(2) The Exchange is authorized to obtain the updated tax return information described in paragraph (b) of this section for a period of no more than five years based on a single authorization, provided that—

(i) An individual may decline to authorize the Exchange to obtain updated tax return information; or

(ii) An individual may authorize the Exchange to obtain updated tax return information for fewer than five years; and

(iii) The Exchange must allow an individual to discontinue, change, or renew his or her authorization at any time.

(l) *Limitation on redetermination.* To the extent that an enrollee has requested an eligibility determination for insurance affordability programs in

accordance with § 155.310(b) and the Exchange does not have an active authorization to obtain tax data as a part of the annual redetermination process, the Exchange must notify the enrollee in accordance with the timing described in paragraph (d) of this section. The Exchange may not proceed with the redetermination process described in paragraphs (c) and (e) through (j) of this section until such authorization has been obtained or the enrollee discontinues his or her request for an eligibility determination for insurance affordability programs in accordance with § 155.310(b).

§ 155.340 Administration of advance payments of the premium tax credit and cost-sharing reductions.

(a) *Requirement to provide information to enable advance payments of the premium tax credit and cost-sharing reductions.* In the event that the Exchange determines that a tax filer is eligible for advance payments of the premium tax credit, an applicant is eligible for cost-sharing reductions, or that such eligibility for such programs has changed, the Exchange must, simultaneously—

(1) Transmit eligibility and enrollment information to HHS necessary to enable HHS to begin, end, or change advance payments of the premium tax credit or cost-sharing reductions; and

(2) Notify and transmit information necessary to enable the issuer of the QHP to implement, discontinue the implementation, or modify the level of advance payments of the premium tax credit or cost-sharing reductions, as applicable, including:

(i) The dollar amount of the advance payment; and

(ii) The cost-sharing reductions eligibility category.

(b) *Requirement to provide information related to employer responsibility.* (1) In the event that the Exchange determines that an individual is eligible for advance payments of the premium tax credit or cost-sharing reductions based in part on a finding that an individual's employer does not provide minimum essential coverage, or provides minimum essential coverage that is unaffordable, within the standard of section 36B(c)(2)(C)(i) of the Code, or does not meet the minimum value requirement specified in section 36B(c)(2)(C)(ii) of the Code, the Exchange must transmit the individual's name and taxpayer identification number to HHS.

(2) If an enrollee for whom advance payments of the premium tax credit are made or who is receiving cost-sharing reductions notifies the Exchange that he or she has changed employers, the Exchange must transmit the enrollee's name and taxpayer identification number to HHS.

(3) In the event that an individual for whom advance payments of the premium tax credit are made or who is receiving cost-sharing reductions terminates coverage from a QHP through the Exchange during a benefit year, the Exchange must—

(i) Transmit the individual's name and taxpayer identification number, and the effective date of coverage termination, to HHS, which will transmit it to the Secretary of the Treasury; and,

(ii) Transmit the individual's name and the effective date of the termination of coverage to his or her employer.

(c) *Requirement to provide information related to reconciliation of advance payments of the premium tax credit.* The Exchange must comply with the requirements specified in section 36B(f)(3) of the Code regarding reporting to the IRS and to taxpayers.

(d) *Timeliness standard.* The Exchange must transmit all information required in accordance with paragraphs (a) and (b) of this section promptly and without undue delay.

§ 155.345 Coordination with Medicaid, CHIP, the Basic Health Program, and the Pre-existing Condition Insurance Plan.

(a) *Agreements.* The Exchange must enter into agreements with agencies administering Medicaid, CHIP, and the BHP as are necessary to fulfill the requirements of this subpart and provide copies of any such agreements to HHS upon request. Such agreements must include a clear delineation of the responsibilities of each program to—

(1) Minimize burden on individuals;

(2) Ensure prompt determinations of eligibility and enrollment in the appropriate program without undue delay, based on the date the application is submitted to or redetermination is initiated by the agency administering Medicaid, CHIP, or the BHP, or to the Exchange; and

(3) Ensure compliance with paragraphs (c), (d), (e), and (g) of this section.

(b) *Responsibilities related to individuals potentially eligible for Medicaid based on other information or through other coverage groups.* For an applicant who is not eligible for Medicaid based on the standards specified in §155.305(c), the Exchange must assess the information provided by the applicant on his or her application to determine whether he or she is potentially eligible for Medicaid based on factors not otherwise considered in this subpart.

(c) *Individuals requesting additional screening.* The Exchange must notify an applicant of the opportunity to request a full determination of eligibility for Medicaid based on eligibility criteria that are not described in §155.305(c), and provide such an opportunity. The Exchange must also make such notification to an enrollee and provide an enrollee such opportunity in any determination made in accordance with §155.330 or §155.335.

(d) *Notification of applicant and State Medicaid agency.* If an Exchange identifies an applicant as potentially eligible for Medicaid under paragraph (b) of this section or an applicant requests a full determination for Medicaid under paragraph (c) of this section, the Exchange must—

(1) Transmit all information provided on the application and any information obtained or verified by, the Exchange to the State Medicaid agency, promptly and without undue delay; and

(2) Notify the applicant of such transmittal.

(e) *Treatment of referrals to Medicaid on eligibility for advance payments of the premium tax credit and cost-sharing reductions.* The Exchange must consider an applicant who is described in paragraph (d) of this section and has not been determined eligible for Medicaid based on the standards specified in §155.305(c) as ineligible for Medicaid for purposes of eligibility for advance payments of the premium tax credit or cost-sharing reductions until the State Medicaid agency notifies the Exchange that the applicant is eligible for Medicaid.

(f) *Special rule.* If the Exchange verifies that a tax filer's household income, as defined in section 36B(d)(2) of the Code, is less than 100 percent of the FPL for the benefit year for which coverage is requested, determines that the tax filer is not eligible for advance payments of the premium tax credit based on §155.305(f)(2), and one or more applicants in the tax filer's household has been determined ineligible for Medicaid and CHIP based on income, the Exchange must—

(1) Provide the applicant with any information regarding income used in the Medicaid and CHIP eligibility determination; and

(2) Follow the procedures specified in §155.320(c)(3).

(g) *Determination of eligibility for individuals submitting applications directly to an agency administering Medicaid, CHIP, or the BHP.* The Exchange, in consultation with the agencies administering Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, must establish procedures to ensure that an eligibility determination for enrollment in a QHP, advance payments of the premium tax credit and cost-sharing reductions is performed when an application is submitted directly to an agency administering Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange. Under such procedures, the Exchange must—

(1) Accept, via secure electronic interface, all information provided on the application and any information obtained or verified by, the agency administering Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, for the individual, and not require submission of another application;

(2) Not duplicate any eligibility and verification findings already made by the transmitting agency, to the extent such findings are made in accordance with this subpart;

(3) Not request information or documentation from the individual already provided to another insurance affordability program and included in the transmission of information provided on the application or other information transmitted from the other program;

(4) Determine the individual's eligibility for enrollment in a QHP, advance payments of the premium tax credit, and cost-sharing reductions, promptly and without undue delay, and in accordance with this subpart; and

(5) Provide for following a streamlined process for eligibility determinations regardless of the agency that initially received an application.

(h) *Standards for sharing information between the Exchange and the agencies administering Medicaid, CHIP, and the BHP.* (1) The Exchange must utilize a secure electronic interface to exchange data with the agencies administering Medicaid, CHIP, and the BHP, if a BHP is operating in the service area of the Exchange, including to verify whether an applicant for insurance affordability programs has been determined eligible for Medicaid, CHIP, or the BHP, as specified in § 155.320(b)(2), and for other functions required under this subpart.

(2) *Model agreements.* The Exchange may utilize any model agreements as established by HHS for the purpose of sharing data as described in this section.

(i) *Transition from the Pre-existing Condition Insurance Plan (PCIP).* The Exchange must follow procedures established in accordance with 45 CFR 152.45 to transition PCIP enrollees to the Exchange to ensure that there are no lapses in health coverage.

[77 FR 18444, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

§ 155.350 Special eligibility standards and process for Indians.

(a) *Eligibility for cost-sharing reductions.* (1) The Exchange must determine an applicant who is an Indian eligible for cost-sharing reductions if he or she—

(i) Meets the requirements specified in § 155.305(a) and § 155.305(f);

(ii) Is expected to have a household income, as defined in section 36B(d)(2) of the Code, that does not exceed 300 percent of the FPL for the benefit year for which coverage is requested.

(2) The Exchange may only provide cost-sharing reductions to an individual who is an Indian if he or she is enrolled in a QHP through the Exchange.

(b) *Special cost-sharing rule for Indians regardless of income.* The Exchange must determine an applicant eligible for the special cost-sharing rule described in section 1402(d)(2) of the Affordable Care Act if he or she is an Indian, without requiring the applicant to request an eligibility determination for insurance affordability programs in accordance with § 155.310(b) in order to qualify for this rule.

(c) *Verification related to Indian status.* To the extent that an applicant attests that he or she is an Indian, the Exchange must verify such attestation by—

(1) Utilizing any relevant documentation verified in accordance with § 155.315(f);

(2) Relying on any electronic data sources that are available to the Exchange and which have been approved by HHS for this purpose, based on evidence showing that such data sources are sufficiently accurate and offer less administrative complexity than paper verification; or

(3) To the extent that approved data sources are unavailable, an individual is not represented in available data sources, or data sources are not reasonably compatible with an applicant's attestation, the Exchange must follow the procedures specified in § 155.315(f) and verify documentation provided by the applicant in accordance with the standards for acceptable documentation provided in section 1903(x)(3)(B)(v) of the Social Security Act.

§ 155.355 Right to appeal.

Individual appeals. The Exchange must include the notice of the right to appeal and instructions regarding how to file an appeal in any eligibility determination notice issued to the applicant in accordance with § 155.310(g), § 155.330(e)(1)(ii), or § 155.335(h)(1)(ii).

Subpart E—Exchange Functions in the Individual Market: Enrollment in Qualified Health Plans

§ 155.400 Enrollment of qualified individuals into QHPs.

(a) *General requirements.* The Exchange must accept a QHP selection from an applicant who is determined eligible for enrollment in a QHP in accordance with subpart D, and must—

(1) Notify the issuer of the applicant's selected QHP; and

(2) Transmit information necessary to enable the QHP issuer to enroll the applicant.

(b) *Timing of data exchange.* The Exchange must:

(1) Send eligibility and enrollment information to QHP issuers and HHS promptly and without undue delay; and

(2) Establish a process by which a QHP issuer acknowledges the receipt of such information.

(c) *Records.* The Exchange must maintain records of all enrollments in QHP issuers through the Exchange.

(d) *Reconcile files.* The Exchange must reconcile enrollment information with QHP issuers and HHS no less than on a monthly basis.

§ 155.405 Single streamlined application.

(a) *The application.* The Exchange must use a single streamlined application to determine eligibility and to collect information necessary for:

(1) Enrollment in a QHP;

(2) Advance payments of the premium tax credit;

(3) Cost-sharing reductions; and

(4) Medicaid, CHIP, or the BHP, where applicable.

(b) *Alternative application.* If the Exchange seeks to use an alternative application, such application, as approved by HHS, must request the minimum information necessary for the purposes identified in paragraph (a) of this section.

(c) *Filing the single streamlined application.* The Exchange must—

(1) Accept the single streamlined application from an application filer;

(2) Provide the tools to file an application—

(i) Via an Internet Web site;

(ii) By telephone through a call center;

(iii) By mail; and

(iv) In person, with reasonable accommodations for those with disabilities, as defined by the Americans with Disabilities Act.

§ 155.410 Initial and annual open enrollment periods.

(a) *General requirements.* (1) The Exchange must provide an initial open enrollment period and annual open enrollment periods consistent with this section, during which qualified individuals may enroll in a QHP and enrollees may change QHPs.

(2) The Exchange may only permit a qualified individual to enroll in a QHP or an enrollee to change QHPs during the initial open enrollment period specified in paragraph (b) of this section, the annual open enrollment period specified in paragraph (e) of this section, or a special enrollment period described in § 155.420 of this subpart for which the qualified individual has been determined eligible.

(b) *Initial open enrollment period.* The initial open enrollment period begins October 1, 2013 and extends through March 31, 2014.

(c) *Effective coverage dates for initial open enrollment period.* (1) *Regular effective dates.* For a QHP selection received by the Exchange from a qualified individual—

(i) On or before December 15, 2013, the Exchange must ensure a coverage effective date of January 1, 2014;

(ii) Between the first and fifteenth day of any subsequent month during the initial open enrollment period, the Exchange must ensure a coverage effective date of the first day of the following month; and

(iii) Between the sixteenth and last day of the month for any month between December 2013 and March 31, 2014, the Exchange must ensure a coverage effective date of the first day of the second following month.

(2) *Option for earlier effective dates.* Subject to the Exchange demonstrating to HHS that all of its participating QHP issuers agree to effectuate coverage in a timeframe shorter than discussed in paragraphs (c)(1)(ii) and (iii) of this section, the Exchange

may do one or both of the following for all applicable individuals:

(i) For a QHP selection received by the Exchange from a qualified individual in accordance with the dates specified in paragraph (c)(1)(ii) or (iii) of this section, the Exchange may provide a coverage effective date for a qualified individual earlier than specified in such paragraphs, provided that either—

(A) The qualified individual has not been determined eligible for advance payments of the premium tax credit or cost-sharing reductions; or

(B) The qualified individual pays the entire premium for the first partial month of coverage as well as all cost sharing, thereby waiving the benefit of advance payments of the premium tax credit and cost-sharing reduction payments until the first of the next month.

(ii) For a QHP selection received by the Exchange from a qualified individual on a date set by the Exchange after the fifteenth of the month for any month between December 2013 and March 31, 2014, the Exchange may provide a coverage effective date of the first of the following month.

(d) *Notice of annual open enrollment period.* Starting in 2014, the Exchange must provide a written annual open enrollment notification to each enrollee no earlier than September 1, and no later than September 30.

(e) *Annual open enrollment period.* For benefit years beginning on or after January 1, 2015, the annual open enrollment period begins October 15 and extends through December 7 of the preceding calendar year.

(f) *Effective date for coverage after the annual open enrollment period.* The Exchange must ensure coverage is effective as of the first day of the following benefit year for a qualified individual who has made a QHP selection during the annual open enrollment period.

(g) *Automatic enrollment.* The Exchange may automatically enroll qualified individuals, at such time and in such manner as HHS may specify, and subject to the Exchange demonstrating to HHS that it has good cause to perform such automatic enrollments.

§ 155.420 Special enrollment periods.

(a) *General requirements.* The Exchange must provide special enrollment periods consistent with this section, during which qualified individuals may enroll in QHPs and enrollees may change QHPs.

(b) *Effective dates.* (1) *Regular effective dates.* Except as specified in paragraphs (b)(2) and (3) of this section, for a QHP selection received by the Exchange from a qualified individual—

(i) Between the first and the fifteenth day of any month, the Exchange must ensure a coverage effective date of the first day of the following month; and

(ii) Between the sixteenth and the last day of any month, the Exchange must ensure a coverage effective date of the first day of the second following month.

(2) *Special effective dates.* (i) In the case of birth, adoption or placement for adoption, the Exchange must ensure that coverage is effective on the date of birth, adoption, or placement for adoption, but advance payments of the premium tax credit and cost-sharing reductions, if applicable, are not effective until the first day of the following month, unless the birth, adoption, or placement for adoption occurs on the first day of the month; and

(ii) In the case of marriage, or in the case where a qualified individual loses minimum essential coverage, as described in paragraph (d)(1) of this section, the Exchange must ensure coverage is effective on the first day of the following month.

(3) *Option for earlier effective dates.* Subject to the Exchange demonstrating to HHS that all of its participating QHP issuers agree to effectuate coverage in a timeframe shorter than discussed in paragraph (b)(1) or (b)(2)(ii) of this section, the Exchange may do one or both of the following for all applicable individuals:

(i) For a QHP selection received by the Exchange from a qualified individual in accordance with the dates specified in paragraph (b)(1) or (b)(2)(ii) of this section, the Exchange may provide a coverage effective date for a qualified individual earlier than specified in such paragraphs, provided that either—

(A) The qualified individual has not been determined eligible for advance payments of the premium tax credit or cost-sharing reductions; or

(B) The qualified individual pays the entire premium for the first partial month of coverage as well as all cost sharing, thereby waiving the benefit of advance payments of the premium tax credit and cost-sharing reduction payments until the first of the next month.

(ii) For a QHP selection received by the Exchange from a qualified individual on a date set by the Exchange after the fifteenth of the month, the Exchange may provide a coverage effective date of the first of the following month.

(c) *Length of special enrollment periods.* Unless specifically stated otherwise herein, a qualified individual or enrollee has 60 days from the date of a triggering event to select a QHP.

(d) *Special enrollment periods.* The Exchange must allow qualified individuals and enrollees to enroll in or change from one QHP to another as a result of the following triggering events:

(1) A qualified individual or dependent loses minimum essential coverage;

(2) A qualified individual gains a dependent or becomes a dependent through marriage, birth, adoption or placement for adoption;

(3) An individual, who was not previously a citizen, national, or lawfully present individual gains such status;

(4) A qualified individual's enrollment or non-enrollment in a QHP is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Exchange or HHS, or its instrumentalities as evaluated and determined by the Exchange. In such cases, the Exchange may take such action as may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction;

(5) An enrollee adequately demonstrates to the Exchange that the QHP in which he or she is enrolled substantially violated a material provision of its contract in relation to the enrollee;

(6) An individual is determined newly eligible or newly ineligible for advance payments of the premium tax credit or has a change in eligibility for cost-sharing reductions, regardless of whether such individual is already enrolled in a QHP. The Exchange must permit individuals whose existing coverage through an eligible employer-sponsored plan will no longer be affordable or provide minimum value for his or her employer's upcoming plan year to access this special enrollment period prior to the end of his or her coverage through such eligible employer-sponsored plan;

(7) A qualified individual or enrollee gains access to new QHPs as a result of a permanent move;

(8) An Indian, as defined by section 4 of the Indian Health Care Improvement Act, may enroll in a QHP or change from one QHP to another one time per month; and

(9) A qualified individual or enrollee demonstrates to the Exchange, in accordance with guidelines issued by HHS, that the individual meets other exceptional circumstances as the Exchange may provide.

(e) *Loss of minimum essential coverage.* Loss of minimum essential coverage includes those circumstances described in 26 CFR 54.9801–6(a)(3)(i) through (iii). Loss of coverage does not include termination or loss due to—

(1) Failure to pay premiums on a timely basis, including COBRA premiums prior to expiration of COBRA coverage, or

(2) Situations allowing for a rescission as specified in 45 CFR 147.128.

§ 155.430 Termination of coverage.

(a) *General requirements.* The Exchange must determine the form and manner in which coverage in a QHP may be terminated.

(b) *Termination events.* (1) The Exchange must permit an enrollee to terminate his or her coverage in a QHP, including as a result of the enrollee obtaining other minimum essential coverage, with appropriate notice to the Exchange or the QHP.

(2) The Exchange may initiate termination of an enrollee's coverage in a QHP, and must permit a QHP issuer to

terminate such coverage, in the following circumstances:

(i) The enrollee is no longer eligible for coverage in a QHP through the Exchange;

(ii) Non-payment of premiums for coverage of the enrollee, and

(A) The 3-month grace period required for individuals receiving advance payments of the premium tax credit has been exhausted as described in § 156.270(g); or,

(B) Any other grace period not described in paragraph (b)(2)(ii)(A) of this section has been exhausted;

(iii) The enrollee's coverage is rescinded in accordance with § 147.128 of this subtitle;

(iv) The QHP terminates or is decertified as described in § 155.1080; or

(v) The enrollee changes from one QHP to another during an annual open enrollment period or special enrollment period in accordance with § 155.410 or § 155.420.

(c) *Termination of coverage tracking and approval*. The Exchange must—

(1) Establish mandatory procedures for QHP issuers to maintain records of termination of coverage;

(2) Send termination information to the QHP issuer and HHS, promptly and without undue delay in accordance with § 155.400(b).

(3) Require QHP issuers to make reasonable accommodations for all individuals with disabilities (as defined by the Americans with Disabilities Act) before terminating coverage for such individuals; and

(4) Retain records in order to facilitate audit functions.

(d) *Effective dates for termination of coverage*. (1) For purposes of this section, reasonable notice is defined as fourteen days from the requested effective date of termination.

(2) In the case of a termination in accordance with paragraph (b)(1) of this section, the last day of coverage is—

(i) The termination date specified by the enrollee, if the enrollee provides reasonable notice;

(ii) Fourteen days after the termination is requested by the enrollee, if the enrollee does not provide reasonable notice; or

(iii) On a date determined by the enrollee's QHP issuer, if the enrollee's QHP issuer is able to effectuate termination in fewer than fourteen days and the enrollee requests an earlier termination effective date.

(iv) If the enrollee is newly eligible for Medicaid, CHIP, or the BHP, if a BHP is operating in the service area of the Exchange, the last day of coverage is the day before such coverage begins.

(3) In the case of a termination in accordance with paragraph (b)(2)(i) of this section, the last day of coverage is the last day of the month following the month in which the notice described in § 155.330(e)(1)(ii) is sent by the Exchange unless the individual requests an earlier termination effective date per paragraph (b)(1) of this section.

(4) In the case of a termination in accordance with paragraph (b)(2)(ii)(A) of this section, the last day of coverage will be the last day of the first month of the 3-month grace period.

(5) In the case of a termination in accordance with paragraph (b)(2)(ii)(B) of this section, the last day of coverage should be consistent with existing State laws regarding grace periods.

(6) In the case of a termination in accordance with paragraph (b)(2)(v) of this section, the last day of coverage in an enrollee's prior QHP is the day before the effective date of coverage in his or her new QHP.

[77 FR 18444, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

Subparts B Through G [Reserved]

Subpart H—Exchange Functions: Small Business Health Options Program (SHOP)

SOURCE: 77 FR 18464, Mar. 27, 2012, unless otherwise noted.

§ 155.700 Standards for the establishment of a SHOP.

(a) *General requirement*. An Exchange must provide for the establishment of a SHOP that meets the requirements of this subpart and is designed to assist qualified employers and facilitate the enrollment of qualified employees into qualified health plans.

(b) *Definition*. For the purposes of this subpart:

Group participation rule means a requirement relating to the minimum number of participants or beneficiaries that must be enrolled in relation to a specified percentage or number of eligible individuals or employees of an employer.

§ 155.705 Functions of a SHOP.

(a) *Exchange functions that apply to SHOP*. The SHOP must carry out all the required functions of an Exchange described in this subpart and in subparts C, E, and K of this part, except:

(1) Requirements related to individual eligibility determinations in subpart D of this part;

(2) Requirements related to enrollment of qualified individuals described in subpart E of this part;

(3) The requirement to issue certificates of exemption in accordance with § 155.200(b); and

(4) Requirements related to the payment of premiums by individuals, Indian tribes, tribal organizations and urban Indian organizations under § 155.240.

(b) *Unique functions of a SHOP*. The SHOP must also provide the following unique functions:

(1) *Enrollment and eligibility functions*. The SHOP must adhere to the requirements outlined in §§ 155.710, 155.715, 155.720, 155.725, and 155.730.

(2) *Employer choice requirements*. With regard to QHPs offered through the SHOP, the SHOP must allow a qualified employer to select a level of coverage as described in section 1302(d)(1) of the Affordable Care Act, in which all QHPs within that level are made available to the qualified employees of the employer.

(3) *SHOP options with respect to employer choice requirements*. With regard to QHPs offered through the SHOP, the SHOP may allow a qualified employer to make one or more QHPs available to qualified employees by a method other than the method described in paragraph (b)(2) of this section.

(4) *Premium aggregation*. The SHOP must perform the following functions related to premium payment administration:

(i) Provide each qualified employer with a bill on a monthly basis that identifies the employer contribution, the employee contribution, and the total amount that is due to the QHP issuers from the qualified employer;

(ii) Collect from each employer the total amount due and make payments to QHP issuers in the SHOP for all enrollees; and

(iii) Maintain books, records, documents, and other evidence of accounting procedures and practices of the premium aggregation program for each benefit year for at least 10 years.

(5) *QHP Certification*. With respect to certification of QHPs in the small group market, the SHOP must ensure each QHP meets the requirements specified in § 156.285 of this subchapter.

(6) *Rates and rate changes*. The SHOP must—

(i) Require all QHP issuers to make any change to rates at a uniform time that is either quarterly, monthly, or annually; and

(ii) Prohibit all QHP issuers from varying rates for a qualified employer during the employer's plan year.

(7) *QHP availability in merged markets*. If a State merges the individual market and the small group market risk pools in accordance with section 1312(c)(3) of the Affordable Care Act, the SHOP may permit a qualified employee to enroll in any QHP meeting the following requirements of the small group market:

(i) Deductible maximums described in section 1302(c) of the Affordable Care Act; and

(ii) Levels of coverage described in section 1302(d) of the Affordable Care Act.

(8) *QHP availability in unmerged markets*. If a State does not merge the individual and small group market risk pools, the SHOP must permit each qualified employee to enroll only in QHPs in the small group market.

(9) *SHOP expansion to large group market*. If a State elects to expand the SHOP to the large group market, a SHOP must allow issuers of health insurance coverage in the large group market in the State to offer QHPs in such market through a SHOP beginning in 2017 provided that a large employer meets the qualified employer requirements other than that it be a small employer.

(10) *Participation rules*. The SHOP may authorize uniform group participation rules for the offering of health insurance coverage in the SHOP. If the SHOP authorizes a minimum participation rate, such rate must be based on the rate of employee participation in the SHOP, not on the rate of employee participation in any particular QHP or QHPs of any particular issuer.

(11) *Premium calculator*. In the SHOP, the premium calculator described in § 155.205(b)(6) must facilitate the comparison of available QHPs after the application of any applicable employer contribution in lieu of any advance payment of the premium tax credit and any cost-sharing reductions.

§ 155.710 Eligibility standards for SHOP.

(a) *General requirement*. The SHOP must permit qualified employers to purchase coverage for qualified employees through the SHOP.

(b) *Employer eligibility requirements*. An employer is a qualified employer eligible to purchase coverage through a SHOP if such employer—

(1) Is a small employer;

(2) Elects to offer, at a minimum, all full-time employees coverage in a QHP through a SHOP; and

(3) Either—

(i) Has its principal business address in the Exchange service area and offers coverage to all its full-time employees through that SHOP; or

(ii) Offers coverage to each eligible employee through the SHOP serving that employee's primary worksite.

(c) *Participating in multiple SHOPs*. If an employer meets the criteria in paragraph (b) of this section and makes the election described in (b)(3)(ii) of this section, a SHOP shall allow the employer to offer coverage to those employees whose primary worksite is in the SHOP's service area.

(d) *Continuing eligibility*. The SHOP must treat a qualified employer which ceases to be a small employer solely by reason of an increase in the number of employees of such employer as a qualified employer until the qualified employer otherwise fails to meet the eligibility criteria of this section or elects to no longer purchase coverage for qualified employees through the SHOP.

(e) *Employee eligibility requirements*. An employee is a qualified employee eligible to enroll in coverage through a SHOP if such employee receives an offer of coverage from a qualified employer.

§ 155.715 Eligibility determination process for SHOP.

(a) *General requirement*. Before permitting the purchase of coverage in a QHP, the SHOP must determine that the employer or individual who requests coverage is eligible in accordance with the requirements of § 155.710.

(b) *Applications*. The SHOP must accept a SHOP single employer application form from employers and the SHOP single employee application form from employees wishing to elect coverage through the SHOP, in accordance with the relevant standards of § 155.730.

(c) *Verification of eligibility*. For the purpose of verifying employer and employee eligibility, the SHOP—

(1) Must verify that an individual applicant is identified by the employer as an employee to whom the qualified employer has offered coverage and must otherwise accept the information attested to within the application unless the information is inconsistent with the employer-provided information;

(2) May establish, in addition to or in lieu of reliance on the application, additional methods to verify the information provided by the applicant on the applicable application;

(3) Must collect only the minimum information necessary for verification of eligibility in accordance with the eligibility standards described in § 155.710; and

(4) May not perform individual eligibility determinations described in sections 1411(b)(2) or 1411(c) of the Affordable Care Act.

(d) *Eligibility adjustment period*. (1) When the information submitted on the SHOP single employer application is inconsistent with the eligibility standards described in § 155.710, the SHOP must—

(i) Make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors;

(ii) Notify the employer of the inconsistency;

(iii) Provide the employer with a period of 30 days from the date on which the notice described in paragraph (d)(1)(ii) of this section is sent to the employer to either present satisfactory documentary evidence to support the employer's application, or resolve the inconsistency; and

(iv) If, after the 30-day period described in paragraph (d)(1)(iii) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must—

(A) Notify the employer of its denial of eligibility in accordance with paragraph (e) of this section and of the employer's right to appeal such determination; and

(B) If the employer was enrolled pending the confirmation or verification of eligibility information, discontinue the employer's participation in the SHOP at the end of the month following the month in which the notice is sent.

(2) For an individual requesting eligibility to enroll in a QHP through the SHOP for whom the SHOP receives information on the application inconsistent with the employer provided information, the SHOP must—

(i) Make a reasonable effort to identify and address the causes of such inconsistency, including through typographical or other clerical errors;

(ii) Notify the individual of the inability to substantiate his or her employee status;

(iii) Provide the employee with a period of 30 days from the date on which the notice described in paragraph (d)(2)(ii) of this section is sent to the employee to either present satisfactory documentary evidence to support the employee's application, or resolve the inconsistency; and

(iv) If, after the 30-day period described in paragraph (d)(2)(iii) of this section, the SHOP has not received satisfactory documentary evidence, the SHOP must notify the employee of its denial of eligibility in accordance with paragraph (f) of this section.

(e) *Notification of employer eligibility*. The SHOP must provide an employer requesting eligibility to purchase coverage with a notice of approval or denial of eligibility and the employer's right to appeal such eligibility determination.

(f) *Notification of employee eligibility*. The SHOP must notify an employee seeking to enroll in a QHP offered through the SHOP of the determination by the SHOP whether the individual is eligible in accordance with § 155.710 and the employee's right to appeal such determination.

(g) *Notification of employer withdrawal from SHOP*. If a qualified employer ceases to purchase coverage through the SHOP, the SHOP must ensure that—

(1) Each QHP terminates the coverage of the employer's qualified employees enrolled in the QHP through the SHOP; and

(2) Each of the employer's qualified employees enrolled in a QHP through the SHOP is notified of the termination of coverage prior to such termination. Such notification must also provide information about other potential sources of coverage, including access to individual market coverage through the Exchange.

§ 155.720 Enrollment of employees into QHPs under SHOP.

(a) *General requirements*. The SHOP must process the SHOP single employee applications of qualified employees to the applicable QHP issuers and facilitate the enrollment of qualified employees in QHPs. All references to QHPs in this section refer to QHPs offered through the SHOP.

(b) *Enrollment timeline and process*. The SHOP must establish a uniform enrollment timeline and process for all QHP issuers and qualified employers to follow, which includes the following activities that must occur before the effective date of coverage for qualified employees:

(1) Determination of employer eligibility for purchase of coverage in the SHOP as described in § 155.715;

(2) Qualified employer selection of QHPs offered through the SHOP to qualified employees, consistent with § 155.705(b)(2) and (3);

(3) Provision of a specific timeframe during which the qualified employer can select the level of coverage or QHP offering, as appropriate;

(4) Provision of a specific timeframe for qualified employees to provide relevant information to complete the application process;

(5) Determination and verification of employee eligibility for enrollment through the SHOP;

(6) Processing enrollment of qualified employees into selected QHPs; and

(7) Establishment of effective dates of employee coverage.

(c) *Transfer of enrollment information.* In order to enroll qualified employees of a qualified employer participating in the SHOP, the SHOP must—

(1) Transmit enrollment information on behalf of qualified employees to QHP issuers in accordance with the timeline and process described in paragraph (b) of this section; and

(2) Follow requirements set forth in § 155.400(c) of this part.

(d) *Payment.* The SHOP must—

(1) Follow requirements set forth in § 155.705(b)(4) of this part; and

(2) Terminate participation of qualified employers that do not comply with the process established in § 155.705(b)(4).

(e) *Notification of effective date.* The SHOP must ensure that a QHP issuer notifies a qualified employee enrolled in a QHP of the effective date of coverage consistent with § 156.260(b).

(f) *Records.* The SHOP must receive and maintain for at least 10 years records of enrollment in QHPs, including identification of—

(1) Qualified employers participating in the SHOP; and

(2) Qualified employees enrolled in QHPs.

(g) *Reconcile files.* The SHOP must reconcile enrollment information and employer participation information with QHPs on no less than a monthly basis.

(h) *Employee termination of coverage from a QHP.* If any employee terminates coverage from a QHP, the SHOP must notify the employee's employer.

(i) *Reporting requirement for tax administration purposes.* The SHOP must report to the IRS employer participation, employer contribution, and employee enrollment information in a time and format to be determined by HHS.

§ 155.725 Enrollment periods under SHOP.

(a) *General requirements.* The SHOP must—

(1) Adhere to the start of the initial open enrollment period set forth in § 155.410;

(2) Ensure that enrollment transactions are sent to QHP issuers and that such issuers adhere to coverage effective dates in accordance with § 156.260 of this subchapter; and

(3) Provide the special enrollment periods described in § 155.420 excluding paragraphs (d)(3) and (6).

(b) *Rolling enrollment in the SHOP.* The SHOP must permit a qualified employer to purchase coverage for its small group at any point during the year. The employer's plan year must consist of the 12-month period beginning with the qualified employer's effective date of coverage.

(c) *Annual employer election period.* The SHOP must provide qualified employers with a period of no less than 30 days prior to the completion of the employer's plan year and before the annual employee open enrollment period, in which the qualified employer may change its participation in the SHOP for the next plan year, including—

(1) The method by which the qualified employer makes QHPs available to qualified employees pursuant to § 155.705(b)(2) and (3);

(2) The employer contribution towards the premium cost of coverage;

(3) The level of coverage offered to qualified employees as described in § 155.705(b)(2) and (3); and

(4) The QHP or QHPs offered to qualified employees in accordance with § 155.705.

(d) *Annual employer election period notice.* The SHOP must provide notification to a qualified employer of the annual election period in advance of such period.

(e) *Annual employee open enrollment period.* The SHOP must establish a standardized annual open enrollment period of no less than 30 days for qualified employees prior to the completion of the applicable qualified employer's

plan year and after that employer's annual election period.

(f) *Annual employee open enrollment period notice*. The SHOP must provide notification to a qualified employee of the annual open enrollment period in advance of such period.

(g) *Newly qualified employees*. The SHOP must provide an employee who becomes a qualified employee outside of the initial or annual open enrollment period an enrollment period to seek coverage in a QHP beginning on the first day of becoming a qualified employee.

(h) *Effective dates*. The SHOP must establish effective dates of coverage for qualified employees consistent with the effective dates of coverage described in § 155.720.

(i) *Renewal of coverage*. If a qualified employee enrolled in a QHP through the SHOP remains eligible for coverage, such employee will remain in the QHP selected the previous year unless—

(1) The qualified employee terminates coverage from such QHP in accordance with standards identified in § 155.430;

(2) The qualified employee enrolls in another QHP if such option exists; or

(3) The QHP is no longer available to the qualified employee.

§ 155.730 Application standards for SHOP.

(a) *General requirements*. Application forms used by the SHOP must meet the requirements set forth in this section.

(b) *Single employer application*. The SHOP must use a single application to determine employer eligibility and to collect information necessary for purchasing coverage. Such application must collect the following—

(1) Employer name and address of employer's locations;

(2) Number of employees;

(3) Employer Identification Number (EIN); and

(4) A list of qualified employees and their taxpayer identification numbers.

(c) *Single employee application*. The SHOP must use a single application for eligibility determination, QHP selection and enrollment for qualified employees and their dependents.

(d) *Model application*. The SHOP may use the model single employer application and the model single employee application provided by HHS.

(e) *Alternative employer and employee application*. The SHOP may use an alternative application if such application is approved by HHS and collects the following:

(1) In the case of the employer application, the information in described in paragraph (b); and

(2) In the case of the employee application, the information necessary to establish eligibility of the employee as a qualified employee and to complete the enrollment of the qualified employee and any dependents to be enrolled.

(f) *Filing*. The SHOP must allow an employer to file the SHOP single employer application and employees to file the single employee application in the form and manner described in § 155.405(c).

(g) *Additional safeguards*. The SHOP may not provide to the employer any information collected on the employee application with respect to spouses or dependents other than the name, address, and birth date of the spouse or dependent.

Subparts I–J [Reserved]

Subpart K—Exchange Functions: Certification of Qualified Health Plans

SOURCE: 77 FR 18467, Mar. 27, 2012, unless otherwise noted.

§ 155.1000 Certification standards for QHPs.

(a) *Definition*. The following definition applies in this subpart:

Multi-State plan means a health plan that is offered in accordance with section 1334 of the Affordable Care Act.

(b) *General requirement*. The Exchange must offer only health plans which have in effect a certification issued or are recognized as plans deemed certified for participation in an Exchange as a QHP, unless specifically provided for otherwise.

(c) *General certification criteria*. The Exchange may certify a health plan as a QHP in the Exchange if—

(1) The health insurance issuer provides evidence during the certification process in § 155.1010 that it complies with the minimum certification requirements outlined in subpart C of part 156, as applicable; and

(2) The Exchange determines that making the health plan available is in the interest of the qualified individuals and qualified employers, except that the Exchange must not exclude a health plan—

(i) On the basis that such plan is a fee-for-service plan;

(ii) Through the imposition of premium price controls; or

(iii) On the basis that the health plan provides treatments necessary to prevent patients' deaths in circumstances the Exchange determines are inappropriate or too costly.

§ 155.1010 Certification process for QHPs.

(a) *Certification procedures*. The Exchange must establish procedures for the certification of QHPs consistent with § 155.1000(c).

(1) *Completion date*. The Exchange must complete the certification of the QHPs that will be offered during the open enrollment period prior to the beginning of such period, as outlined in § 155.410.

(2) *Ongoing compliance*. The Exchange must monitor the QHP issuers for demonstration of ongoing compliance with the certification requirements in § 155.1000(c).

(b) *Exchange recognition of plans deemed certified for participation in an Exchange*. Notwithstanding paragraph (a) of this section, an Exchange must recognize as certified QHPs:

(1) A multi-State plan certified by and under contract with the U.S. Office of Personnel Management.

(2) A CO–OP QHP as described in subpart F of part 156 and deemed as certified under § 156.520(e).

§ 155.1020 QHP issuer rate and benefit information.

(a) *Receipt and posting of rate increase justification*. The Exchange must ensure that a QHP issuer submits a justification for a rate increase for a QHP prior to the implementation of such an increase, except for multi-State plans, for which the U.S. Office of Personnel Management will provide a process for the submission of rate increase justifications. The Exchange must ensure that the QHP issuer has prominently posted the justification on its Web site as required under § 156.210. To ensure consumer transparency, the Exchange must also provide access to the justification on its Internet Web site described in § 155.205(b).

(b) *Rate increase consideration*. (1) The Exchange must consider rate increases in accordance with section 1311(e)(2) of the Affordable Care Act, which includes consideration of the following:

(i) A justification for a rate increase prior to the implementation of the increase;

(ii) Recommendations provided to the Exchange by the State in accordance with section 2794(b)(1)(B) of the PHS Act; and

(iii) Any excess of rate growth outside the Exchange as compared to the rate of such growth inside the Exchange.

(2) This paragraph does not apply to multi-State plans for which the U.S. Office of Personnel Management will provide a process for rate increase consideration.

(c) *Benefit and rate information*. The Exchange must receive the information described in this paragraph, at least annually, from QHP issuers for each QHP in a form and manner to be specified by HHS. Information about multi-State plans may be provided in a form and manner determined by the U.S. Office of Personnel Management. The information identified in this paragraph is:

(1) Rates;

(2) Covered benefits; and

(3) Cost-sharing requirements.

[77 FR 18467, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

§ 155.1040 Transparency in coverage.

(a) *General requirement*. The Exchange must collect information relating to coverage transparency as described in § 156.220 of this subtitle from QHP issuers, and from multi-State plans in

a time and manner determined by the U.S. Office of Personnel Management.

(b) *Use of plain language*. The Exchange must determine whether the information required to be submitted and made available under paragraph (a) of this section is provided in plain language.

(c) *Transparency of cost-sharing information*. The Exchange must monitor whether a QHP issuer has made cost-sharing information available in a timely manner upon the request of an individual as required by §156.220(d) of this subtitle.

§155.1045 Accreditation timeline.

The Exchange must establish a uniform period following certification of a QHP within which a QHP issuer that is not already accredited must become accredited as required by §156.275 of this subtitle, except for multi-State plans. The U.S. Office of Personnel Management will establish the accreditation period for multi-State plans.

§155.1050 Establishment of Exchange network adequacy standards.

(a) An Exchange must ensure that the provider network of each QHP meets the standards specified in §156.230 of this subtitle, except for multi-State plans.

(b) The U.S. Office of Personnel Management will ensure compliance with the standards specified in §156.230 of this subtitle for multi-State plans.

(c) A QHP issuer in an Exchange may not be prohibited from contracting with any essential community provider designated under §156.235(c) of this subtitle.

§155.1055 Service area of a QHP.

The Exchange must have a process to establish or evaluate the service areas of QHPs to ensure such service areas meet the following minimum criteria:

(a) The service area of a QHP covers a minimum geographical area that is at least the entire geographic area of a county, or a group of counties defined by the Exchange, unless the Exchange determines that serving a smaller geographic area is necessary, nondiscriminatory, and in the best interest of the qualified individuals and employers.

(b) The service area of a QHP has been established without regard to racial, ethnic, language, health status-related factors specified under section 2705(a) of the PHS Act, or other factors that exclude specific high utilizing, high cost or medically-underserved populations.

§155.1065 Stand-alone dental plans.

(a) *General requirements*. The Exchange must allow the offering of a limited scope dental benefits plan through the Exchange, if—

(1) The plan meets the requirements of section 9832(c)(2)(A) of the Code and 2791(c)(2)(A) of the PHS Act; and

(2) The plan covers at least the pediatric dental essential health benefit as defined in section 1302(b)(1)(J) of the Affordable Care Act, provided that, with respect to this benefit, the plan satisfies the requirements of section 2711 of the PHS Act; and

(3) The plan and issuer of such plan meets QHP certification standards, including §155.1020(c), except for any certification requirement that cannot be met because the plan covers only the benefits described in paragraph (a)(2) of this section.

(b) *Offering options*. The Exchange may allow the dental plan to be offered—

(1) As a stand-alone dental plan; or

(2) In conjunction with a QHP.

(c) *Sufficient capacity*. An Exchange must consider the collective capacity of stand-alone dental plans during certification to ensure sufficient access to pediatric dental coverage.

(d) *QHP Certification standards*. If a plan described in paragraph (a) of this section is offered through an Exchange, another health plan offered through such Exchange must not fail to be treated as a QHP solely because the plan does not offer coverage of benefits offered through the stand-alone plan that are otherwise required under section 1302(b)(1)(J) of the Affordable Care Act.

§155.1075 Recertification of QHPs.

(a) *Recertification process*. Except with respect to multi-State plans and CO–OP QHPs, an Exchange must establish a process for recertification of QHPs that, at a minimum, includes a review

of the general certification criteria as outlined in § 155.1000(c). Upon determining the recertification status of a QHP, the Exchange must notify the QHP issuer.

(b) *Timing*. The Exchange must complete the QHP recertification process on or before September 15 of the applicable calendar year.

§ 155.1080 Decertification of QHPs.

(a) *Definition*. The following definition applies to this section:

Decertification means the termination by the Exchange of the certification status and offering of a QHP.

(b) *Decertification process*. Except with respect to multi-State plans and CO–OP QHPs, the Exchange must establish a process for the decertification of QHPs, which, at a minimum, meets the requirements in this section.

(c) *Decertification by the Exchange*. The Exchange may at any time decertify a health plan if the Exchange determines that the QHP issuer is no longer in compliance with the general certification criteria as outlined in § 155.1000(c).

(d) *Appeal of decertification*. The Exchange must establish a process for the appeal of a decertification of a QHP.

(e) *Notice of decertification*. Upon decertification of a QHP, the Exchange must provide notice of decertification to all affected parties, including:

(1) The QHP issuer;

(2) Exchange enrollees in the QHP who must receive information about a special enrollment period, as described in § 155.420;

(3) HHS; and

(4) The State department of insurance.

[77 FR 18467, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

Subparts L–M [Reserved]

Subpart N—State Flexibility

§ 155.1300 Basis and purpose.

(a) *Statutory basis*. This subpart implements provisions of section 1332 of the Affordable Care Act, relating to Waivers for State Innovation, which the Secretary may authorize for plan years beginning on or after January 1, 2017. Section 1332 of the Affordable Care Act requires the Secretary to issue regulations that provide for all of the following:

(1) A process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input.

(2) A process for the submission of an application that ensures the disclosure of all of the following:

(i) The provisions of law that the State involved seeks to waive.

(ii) The specific plans of the State to ensure that the waiver will meet all requirements specified in section 1332.

(3) A process for the provision of public notice and comment after a waiver application is received by the Secretary, that is sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedures Act, or requirements that are unreasonable or unnecessarily burdensome with respect to State compliance.

(4) A process for the submission of reports to the Secretary by a State relating to the implementation of a waiver.

(5) A process for the periodic evaluation by the Secretary of programs under waivers.

(b) *Purpose*. This subpart sets forth certain procedural requirements for Waivers for State Innovation under section 1332 of the Affordable Care Act.

§ 155.1302 Coordinated waiver process.

(a) *Coordination with applications for waivers under other Federal laws*. A State may submit a single application to the Secretary for a waiver under section 1332 of the Affordable Care Act and a waiver under one or more of the existing waiver processes applicable under titles XVIII, XIX, and XXI of the Act, or under any other Federal law relating to the provision of health care items or services, provided that such application is consistent with the procedures described in this part, the procedures for demonstrations under section 1115 of the Act, if applicable, and the procedures under any other applicable Federal law under which the State seeks a waiver.

(b) *Coordinated process for section 1332 waivers.* A State seeking a section 1332 waiver must submit a waiver application to the Secretary. Any application submitted to the Secretary that requests to waive sections 36B, 4980H, or 5000A of the Code, in accordance with section 1332(a)(2)(D) of the Affordable Care Act, shall upon receipt be transmitted by the Secretary to the Secretary of the Treasury to be reviewed in accordance with 31 CFR Part 33.

§ 155.1304 Definitions.

For the purposes of this subpart:

Complete application means an application that has been submitted and for which the Secretary and the Secretary of the Treasury, as applicable, have made a preliminary determination that it includes all required information and satisfies all requirements that are described in § 155.1308(f).

Public notice means a notice issued by a government agency or legislative body that contains sufficient detail to notify the public at large of a proposed action consistent with § 155.1312.

Section 1332 waiver means a Waiver for State Innovation under section 1332 of the Affordable Care Act.

§ 155.1308 Application procedures.

(a) *Acceptable formats for applications.* Applications for initial approval of a section 1332 waiver shall be submitted in electronic format to the Secretary.

(b) *Application timing.* Applications for initial approval of a section 1332 waiver must be submitted sufficiently in advance of the requested effective date to allow for an appropriate implementation timeline.

(c) *Preliminary review.* Each application for a section 1332 waiver will be subject to a preliminary review by the Secretary and the Secretary of the Treasury, as applicable, who will make a preliminary determination that the application is complete. A submitted application will not be deemed received until the Secretary and the Secretary of the Treasury, as applicable, have made the preliminary determination that the application is complete.

(1) The Secretary and the Secretary of the Treasury, as applicable, will complete the preliminary review of the application within 45 days after it is submitted.

(2) If the Secretary and the Secretary of the Treasury, as applicable, determine that the application is not complete, the Secretary will send the State a written notice of the elements missing from the application.

(3) The preliminary determination that an application is complete does not preclude a finding during the 180-day Federal decision-making period that a necessary element of the application is missing or insufficient.

(d) *Notification of preliminary determination.* Upon making the preliminary determination that an application is complete, as defined in this part, the Secretary will send the State a written notice informing the State that the Secretary and the Secretary of the Treasury, as applicable, have made such a preliminary determination. That date will also mark the beginning of the Federal public notice process and the 180-day Federal decision-making period.

(e) *Public notice of completed application.* Upon receipt of a complete application for an initial section 1332 waiver, the Secretary will—

(1) Make available to the public the application, and all related State submissions, including all supplemental information received from the State following the receipt of a complete application for a section 1332 waiver.

(2) Indicate the status of the application.

(f) *Criteria for a complete application.* An application for initial approval of a section 1332 waiver will not be considered complete unless the application meets all of the following conditions:

(1) Complies with paragraphs (a) through (f) of this section.

(2) Provides written evidence of the State's compliance with the public notice requirements set forth in § 155.1312, including a description of the key issues raised during the State public notice and comment period.

(3) Provides all of the following:

(i) A comprehensive description of the State legislation and program to implement a plan meeting the requirements for a waiver under section 1332;

(ii) A copy of the enacted State legislation that provides the State with authority to implement the proposed waiver, as required under section 1332(a)(1)(C) of the Affordable Care Act;

(iii) A list of the provisions of law that the State seeks to waive including a description of the reason for the specific requests; and

(iv) The analyses, actuarial certifications, data, assumptions, analysis, targets and other information set forth in paragraph (f)(4) of this section sufficient to provide the Secretary and the Secretary of the Treasury, as applicable, with the necessary data to determine that the State's proposed waiver:

(A) As required under section 1332(b)(1)(A) of the Affordable Care Act (the comprehensive coverage requirement), will provide coverage that is at least as comprehensive as the coverage defined in section 1302(b) of the Affordable Care Act and offered through Exchanges established under the Affordable Care Act as certified by the Office of the Actuary of the Centers for Medicare & Medicaid Services based on sufficient data from the State and from comparable States about their experience with programs created by the Affordable Care Act and the provisions of the Affordable Care Act that the State seeks to waive;

(B) As required under section 1332(b)(1)(B) of the Affordable Care Act (the affordability requirement), will provide coverage and cost sharing protections against excessive out-of-pocket spending that are at least as affordable as the provisions of Title I of the Affordable Care Act would provide;

(C) As required under section 1332(b)(1)(C) of the Affordable Care Act (the scope of coverage requirement), will provide coverage to at least a comparable number of its residents as the provisions of Title I of the Affordable Care Act would provide; and

(D) As prohibited under section 1332(b)(1)(D) of the Affordable Care Act (the Federal deficit requirement), will not increase the Federal deficit.

(4) Contains the following supporting information:

(i) *Actuarial analyses and actuarial certifications*. Actuarial analyses and actuarial certifications to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, and the scope of coverage requirement;

(ii) *Economic analyses*. Economic analyses to support the State's estimates that the proposed waiver will comply with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) A detailed 10-year budget plan that is deficit neutral to the Federal government, as prescribed by section 1332(a)(1)(B)(ii) of the Affordable Care Act, and includes all costs under the waiver, including administrative costs and other costs to the Federal government, if applicable; and

(B) A detailed analysis regarding the estimated impact of the waiver on health insurance coverage in the State.

(iii) *Data and assumptions*. The data and assumptions used to demonstrate that the State's proposed waiver is in compliance with the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement, including:

(A) Information on the age, income, health expenses and current health insurance status of the relevant State population; the number of employers by number of employees and whether the employer offers insurance; cross-tabulations of these variables; and an explanation of data sources and quality; and

(B) An explanation of the key assumptions used to develop the estimates of the effect of the waiver on coverage and the Federal budget, such as individual and employer participation rates, behavioral changes, premium and price effects, and other relevant factors.

(iv) *Implementation timeline*. A detailed draft timeline for the State's implementation of the proposed waiver.

(v) *Additional information*. Additional information supporting the State's proposed waiver, including:

(A) An explanation as to whether the waiver increases or decreases the administrative burden on individuals, insurers, and employers, and if so, how and why;

(B) An explanation of how the waiver will affect the implementation of the provisions of the Affordable Care Act which the State is not requesting to waive in the State and at the Federal level;

(C) An explanation of how the waiver will affect residents who need to obtain health care services out-of-State, as well as the States in which such residents may seek such services;

(D) If applicable, an explanation as to how the State will provide the Federal government with all information necessary to administer the waiver at the Federal level; and

(E) An explanation of how the State's proposal will address potential individual, employer, insurer, or provider compliance, waste, fraud and abuse within the State or in other States.

(vi) *Reporting targets*. Quarterly, annual, and cumulative targets for the comprehensive coverage requirement, the affordability requirement, the scope of coverage requirement and the Federal deficit requirement.

(vii) *Other information*. Other information consistent with guidance provided by the Secretary and the Secretary of the Treasury, as applicable.

(g) *Additional supporting information*. (1) During the Federal review process, the Secretary may request additional supporting information from the State as needed to address public comments or to address issues that arise in reviewing the application.

(2) Requests for additional information, and responses to such requests, will be made available to the public in the same manner as information described in § 155.1316(b).

§ 155.1312 State public notice requirements.

(a) *General*. (1) Prior to submitting an application for a new section 1332 waiver to the Secretary for review and consideration, a State must provide a public notice and comment period sufficient to ensure a meaningful level of public input for the application for a section 1332 waiver.

(2) Such public notice and comment period shall include, for a State with one or more Federally-recognized Indian tribes within its borders, a separate process for meaningful consultation with such tribes.

(b) *Public notice and comment period*. The State shall make available at the beginning of the public notice and comment period, through its Web site or other effective means of communication, and shall update as appropriate, a public notice that includes all of the following:

(1) A comprehensive description of the application for a section 1332 waiver to be submitted to the Secretary including information and assurances related to all statutory requirements and other information consistent with guidance provided by the Secretary and the Secretary of the Treasury, as applicable.

(2) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(3) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(4) The location, date, and time of public hearings that will be convened by the State to seek public input on the application for a section 1332 waiver.

(c) *Public hearings*. (1) After issuing the public notice and prior to submitting an application for a new section 1332 waiver, a State must conduct public hearings regarding the State's application.

(2) Such public hearings shall provide an interested party the opportunity to learn about and comment on the contents of the application for a section 1332 waiver.

(d) *Submission of initial application*. After the State public notice and comment period has concluded, the State may submit an application to the Secretary for an initial waiver in accordance with the requirements set forth in § 155.1308.

§ 155.1316 Federal public notice and approval process.

(a) *General*. The Federal public notice and approval process begins on the first business day after the Secretary and the Secretary of the Treasury, as applicable, determine that all elements for

a complete application were documented and submitted to the Secretary.

(b) *Public notice and comment period.* (1) Following a determination that a State's application for a section 1332 waiver is complete, the Secretary and the Secretary of the Treasury, as applicable, will provide for a public notice and comment period that is sufficient to ensure a meaningful level of public input and that does not impose requirements that are in addition to, or duplicative of, requirements imposed under the Administrative Procedures Act, or requirements that are unreasonable or unnecessarily burdensome with respect to State compliance.

(2) At the beginning of the Federal notice and comment period, the Secretary will make available through its Web site and otherwise, and shall update as appropriate, public notice that includes all of the following:

(i) The complete application for a section 1332 waiver, updates for the status of the State's application, and any supplemental materials received from the State prior to and during the Federal public notice and comment period.

(ii) Information relating to where copies of the application for a section 1332 waiver are available for public review and comment.

(iii) Information relating to how and where written comments may be submitted and reviewed by the public, and the timeframe during which comments will be accepted.

(iv) Any public comments received during the Federal public notice and comment period.

(c) *Approval of a section 1332 waiver application.* The final decision of the Secretary and the Secretary of the Treasury, as applicable, on a State application for a section 1332 waiver will be issued by the Secretary no later than 180 days after the determination by the Secretary and the Secretary of the Treasury, as applicable, that a complete application was received in accordance with § 155.1308.

§ 155.1320 Monitoring and compliance.

(a) *General.* (1) Following the issuance of a final decision to approve a section 1332 waiver by the Secretary and the Secretary of the Treasury, as applicable, a State must comply with all applicable Federal laws, regulations, interpretive policy statements and interpretive guidance unless expressly waived. A State must, within the timeframes specified in law, regulation, policy or guidance, come into compliance with any changes in Federal law, regulation, or policy affecting section 1332 waivers, unless the provision being changed is expressly waived.

(2) A State must comply with the terms and conditions of the agreement between the Secretary, the Secretary of the Treasury, as applicable, and the State to implement a section 1332 waiver.

(b) *Implementation reviews.* (1) The terms and conditions of an approved section 1332 waiver will provide that the State will perform periodic reviews of the implementation of the section 1332 waiver.

(2) The Secretary and the Secretary of the Treasury, as applicable, will review documented complaints that a State is failing to comply with requirements specified in the terms and conditions of any approved section 1332 waiver.

(3) The Secretary and the Secretary of the Treasury, as applicable, will promptly share with a State any complaint that the Secretary and the Secretary of the Treasury has received and will also provide notification of any applicable monitoring and compliance issues.

(c) *Post award.* Within at least 6 months after the implementation date of a section 1332 waiver and annually thereafter, a State must hold a public forum to solicit comments on the progress of a section 1332 waiver. The State must hold the public forum at which members of the public have an opportunity to provide comments and must provide a summary of the forum to the Secretary as part of the quarterly report specified in § 155.1324(a) that is associated with the quarter in which the forum was held, as well as in the annual report specified in § 155.1324(b) that is associated with the year in which the forum was held.

(1) The State must publish the date, time, and location of the public forum in a prominent location on the State's public web site, at least 30 days prior

to the date of the planned public forum.

(2) [Reserved]

(d) *Terminations and suspensions.* The Secretary and the Secretary of the Treasury, as applicable, reserve the right to suspend or terminate a section 1332 waiver in whole or in part, at any time before the date of expiration, whenever the Secretary or the Secretary of the Treasury, as applicable, determines that a State has materially failed to comply with the terms of a section 1332 waiver.

(e) *Closeout costs.* If all or part of a section 1332 waiver is terminated or suspended, or if a portion of a section 1332 waiver is withdrawn, Federal funding is limited to normal closeout costs associated with an orderly termination, suspension, or withdrawal, including service costs during any approved transition period, and administrative costs of disenrolling participants.

(f) *Federal evaluators.* (1) A State must fully cooperate with the Secretary, the Secretary of the Treasury, as applicable, or an independent evaluator selected by the Secretary or the Secretary of the Treasury, as applicable, to undertake an independent evaluation of any component of a section 1332 waiver.

(2) As part of this required cooperation, a State must submit all requested data and information to the Secretary, the Secretary of the Treasury, as applicable, or the independent evaluator.

§ 155.1324 State reporting requirements.

(a) *Quarterly reports.* A State must submit quarterly reports to the Secretary in accordance with the terms and conditions of the State's section 1332 waiver. These quarterly reports must include, but are not limited to, reports of any ongoing operational challenges and plans for and results of associated corrective actions.

(b) *Annual reports.* A State must submit an annual report to the Secretary documenting all of the following:

(1) The progress of the section 1332 waiver.

(2) Data on compliance with section 1332(b)(1)(A) through (D) of the Affordable Care Act.

(3) A summary of the annual post-award public forum, held in accordance with § 155.1320(c), including all public comments received at such forum regarding the progress of the section 1332 waiver and action taken in response to such concerns or comments.

(4) Other information consistent with the State's approved terms and conditions.

(c) *Submitting and publishing annual reports.* A State must submit a draft annual report to the Secretary no later than 90 days after the end of each waiver year, or as specified in the waiver's terms and conditions.

(1) Within 60 days of receipt of comments from the Secretary, a State must submit to the Secretary the final annual report for the waiver year.

(2) The draft and final annual reports are to be published on a State's public web site within 30 days of submission to and approval by the Secretary, respectively.

§ 155.1328 Periodic evaluation requirements.

(a) The Secretary and the Secretary of the Treasury, as applicable, shall periodically evaluate the implementation of a program under a section 1332 waiver consistent with guidance published by the Secretary and the Secretary of the Treasury, as applicable, and any terms and conditions governing the section 1332 waiver.

(b) Each periodic evaluation must include a review of the annual report or reports submitted by the State in accordance with § 155.1324 that relate to the period of time covered by the evaluation.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

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Subpart F—Consumer Operated and Oriented Plan Program

Sec.
156.500 Basis and scope.
156.505 Definitions.
156.510 Eligibility.
156.515 CO–OP Standards.
156.520 Loan terms.

AUTHORITY: Title I of the Affordable Care Act, Sections 1301–1304, 1311–1312, 1321, 1322, 1324, 1334, 1341–1343, and 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18042).

SOURCE: 76 FR 77411, Dec. 13, 2011, unless otherwise noted.

Subpart A—General Provisions

SOURCE: 77 FR 18468, Mar. 27, 2012, unless otherwise noted.

§ 156.10 Basis and scope.

(a) *Basis.* (1) This part is based on the following sections of title I of the Affordable Care Act:

(i) 1301. QHP defined.

(ii) 1302. Essential health benefits requirements.

(iii) 1303. Special rules.

(iv) 1304. Related definitions.

(v) 1311. Affordable choices of health benefit plans.

(vi) 1312. Consumer choice.

(vii) 1313. Financial integrity.

(viii) 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(ix) 1322. Federal program to assist establishment and operation of nonprofit, member-run health insurance issuers.

(x) 1331. State flexibility to establish Basic Health Programs for low-income individuals not eligible for Medicaid.

(xi) 1334. Multi-State plans.

(xii) 1402. Reduced cost-sharing for individuals enrolling in QHPs.

(xiii) 1411. Procedures for determining eligibility for Exchange participation, advance premium tax credits and reduced cost sharing, and individual responsibility exemptions.

(xiv) 1412. Advance determination and payment of premium tax credits and cost-sharing reductions.

(xv) 1413. Streamlining of procedures for enrollment through an Exchange and State, Medicaid, CHIP, and health subsidy programs.

(2) This part is based on section 1150A, Pharmacy Benefit Managers Transparency Requirements, of title I of the Act:

(b) *Scope.* This part establishes standards for QHPs under Exchanges, and addresses other health insurance issuer requirements.

§ 156.20 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Applicant has the meaning given to the term in § 155.20 of this subchapter.

Benefit design standards means coverage that provides for all of the following:

(1) The essential health benefits as described in section 1302(b) of the Affordable Care Act;

(2) Cost-sharing limits as described in section 1302(c) of the Affordable Care Act; and

(3) A bronze, silver, gold, or platinum level of coverage as described in section 1302(d) of the Affordable Care Act, or is a catastrophic plan as described in section 1302(e) of the Affordable Care Act.

Benefit year has the meaning given to the term in § 155.20 of this subtitle.

Cost-sharing has the meaning given to the term in § 155.20 of this subtitle.

Cost-sharing reductions has the meaning given to the term in § 155.20 of this subtitle.

Group health plan has the meaning given to the term in § 144.103 of this subtitle.

Health insurance coverage has the meaning given to the term in § 144.103 of this subtitle.

Health insurance issuer or issuer has the meaning given to the term in § 144.103 of this subtitle.

Level of coverage means one of four standardized actuarial values as defined by section 1302(d)(1) of the Affordable Care Act of plan coverage.

Plan year has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan has the meaning given to the term in § 155.20 of this subchapter.

Qualified health plan issuer has the meaning given to the term in § 155.20 of this subchapter.

Qualified individual has the meaning given to the term in § 155.20 of this subchapter.

[77 FR 18468, Mar. 27, 2012, as amended at 77 FR 31515, May 29, 2012]

§ 156.50 Financial support.

(a) *Definitions.* The following definitions apply for the purposes of this section:

Participating issuer means any issuer offering a plan that participates in the specific function that is funded by user fees. This term may include: health insurance issuers, QHP issuers, issuers of multi-State plans (as defined in § 155.1000(a) of this subchapter), issuers of stand-alone dental plans (as described in § 155.1065 of this subtitle), or other issuers identified by an Exchange.

(b) *Requirement for Exchanges user fees.* A participating issuer must remit user fee payments, or any other payments, charges, or fees, if assessed by the Federally-facilitated Exchange under 31 U.S.C. 9701 or a State-based Exchange under § 155.160 of this subchapter.

Subpart B—Standards for Essential Health Benefits, Actuarial Value, and Cost Sharing

SOURCE: 77 FR 42670, July 20, 2012, unless otherwise noted.

§ 156.120 Collection of data from certain issuers to define essential health benefits.

(a) *Definitions.* The following definitions apply to this section, unless the context indicates otherwise:

Health benefits means benefits for medical care, as defined at § 144.103 of this chapter, which may be delivered through the purchase of insurance or otherwise.

Health insurance product has the meaning given to the term in § 159.110 of this chapter.

Health plan has the meaning given to the term, ''Portal Plan'' in § 159.110 of this chapter.

Small group market has the meaning given to the term in § 155.20 of this chapter.

State has the meaning given to the term in § 155.20 of this chapter.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment. Treatment limitations include only quantitative treatment limitations. A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation.

(b) *Required information.* The issuers described in paragraph (c) of this section must provide the following information for the health plans described in paragraph (d) of this section in accordance with the standards in paragraph (e) of this section:

(1) Administrative data necessary to identify the health plan;

(2) Data and descriptive information for each plan on the following items:

(i) All health benefits in the plan;

(ii) Treatment limitations;

(iii) Drug coverage; and

(iv) Enrollment;

(c) *Issuers required to report*. The issuers that offer the three largest health insurance products by enrollment, as of March 31, 2012 (enrollment is determined by HHS based on data submitted in accordance with part 159 of this title) in each state's small group market must provide the information in paragraph (b) of this section.

(d) *Plans affected*. The issuers described in paragraph (c) of this section must provide the information described in paragraph (b) of this section for the health plan with the highest enrollment (as determined by the issuer) within the products described in paragraph (c) of this section.

(e) *Reporting requirement*. To ensure consistency in reporting, an issuer described in paragraph (c) of this section must submit, in a form and manner to be determined by HHS, the information described in paragraph (b) of this section to HHS no later than September 4, 2012.

Subpart C—Qualified Health Plan Minimum Certification Standards

SOURCE: 77 FR 18469, Mar. 27, 2012, unless otherwise noted.

§ 156.200 QHP issuer participation standards.

(a) *General requirement*. In order to participate in an Exchange, a health insurance issuer must have in effect a certification issued or recognized by the Exchange to demonstrate that each health plan it offers in the Exchange is a QHP.

(b) *QHP issuer requirement*. A QHP issuer must—

(1) Comply with the requirements of this subpart with respect to each of its QHPs on an ongoing basis;

(2) Comply with Exchange processes, procedures, and requirements set forth in accordance with subpart K of part 155 and, in the small group market, § 155.705 of this subchapter;

(3) Ensure that each QHP complies with benefit design standards, as defined in § 156.20;

(4) Be licensed and in good standing to offer health insurance coverage in each State in which the issuer offers health insurance coverage;

(5) Implement and report on a quality improvement strategy or strategies consistent with the standards of section 1311(g) of the Affordable Care Act, disclose and report information on health care quality and outcomes described in sections 1311(c)(1)(H) and (I) of the Affordable Care Act, and implement appropriate enrollee satisfaction surveys consistent with section 1311(c)(4) of the Affordable Care Act;

(6) Pay any applicable user fees assessed under § 156.50; and

(7) Comply with the standards related to the risk adjustment program under 45 CFR part 153.

(c) *Offering requirements*. A QHP issuer must offer through the Exchange:

(1) At least one QHP in the silver coverage level and at least one QHP in the gold coverage level as described in section 1302(d)(1) of the Affordable Care Act; and,

(2) A child-only plan at the same level of coverage, as described in section 1302(d)(1) of the Affordable Care Act, as any QHP offered through the Exchange to individuals who, as of the beginning of the plan year, have not attained the age of 21.

(d) *State requirements*. A QHP issuer certified by an Exchange must adhere to the requirements of this subpart and any provisions imposed by the Exchange, or a State in connection with its Exchange, that are conditions of participation or certification with respect to each of its QHPs.

(e) *Non-discrimination*. A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation.

§ 156.210 QHP rate and benefit information.

(a) *General rate requirement*. A QHP issuer must set rates for an entire benefit year, or for the SHOP, plan year.

(b) *Rate and benefit submission.* A QHP issuer must submit rate and benefit information to the Exchange.

(c) *Rate justification.* A QHP issuer must submit to the Exchange a justification for a rate increase prior to the implementation of the increase. A QHP issuer must prominently post the justification on its Web site.

§ 156.220 Transparency in coverage.

(a) *Required information.* A QHP issuer must provide the following information in accordance with the standards in paragraph (b) of this section:

(1) Claims payment policies and practices;

(2) Periodic financial disclosures;

(3) Data on enrollment;

(4) Data on disenrollment;

(5) Data on the number of claims that are denied;

(6) Data on rating practices;

(7) Information on cost-sharing and payments with respect to any out-of-network coverage; and

(8) Information on enrollee rights under title I of the Affordable Care Act.

(b) *Reporting requirement.* A QHP issuer must submit, in an accurate and timely manner, to be determined by HHS, the information described in paragraph (a) of this section to the Exchange, HHS and the State insurance commissioner, and make the information described in paragraph (a) of this section available to the public.

(c) *Use of plain language.* A QHP issuer must make sure that the information submitted under paragraph (b) is provided in plain language as defined under § 155.20 of this subtitle.

(d) *Enrollee cost sharing transparency.* A QHP issuer must make available the amount of enrollee cost sharing under the individual's plan or coverage with respect to the furnishing of a specific item or service by a participating provider in a timely manner upon the request of the individual. At a minimum, such information must be made available to such individual through an Internet Web site and such other means for individuals without access to the Internet.

§ 156.225 Marketing and Benefit Design of QHPs.

A QHP issuer and its officials, employees, agents and representatives must—

(a) *State law applies.* Comply with any applicable State laws and regulations regarding marketing by health insurance issuers; and

(b) *Non-discrimination.* Not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs.

§ 156.230 Network adequacy standards.

(a) *General requirement.* A QHP issuer must ensure that the provider network of each of its QHPs, as available to all enrollees, meets the following standards—

(1) Includes essential community providers in accordance with § 156.235;

(2) Maintains a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance abuse services, to assure that all services will be accessible without unreasonable delay; and,

(3) Is consistent with the network adequacy provisions of section 2702(c) of the PHS Act.

(b) *Access to provider directory.* A QHP issuer must make its provider directory for a QHP available to the Exchange for publication online in accordance with guidance from the Exchange and to potential enrollees in hard copy upon request. In the provider directory, a QHP issuer must identify providers that are not accepting new patients.

§ 156.235 Essential community providers.

(a) *General requirement.* (1) A QHP issuer must have a sufficient number and geographic distribution of essential community providers, where available, to ensure reasonable and timely access to a broad range of such providers for low-income, medically underserved individuals in the QHP's service area, in accordance with the Exchange's network adequacy standards.

(2) A QHP issuer that provides a majority of covered professional services

through physicians employed by the issuer or through a single contracted medical group may instead comply with the alternate standard described in paragraph (b) of this section.

(3) Nothing in this requirement shall be construed to require any QHP to provide coverage for any specific medical procedure provided by the essential community provider.

(b) *Alternate standard.* A QHP issuer described in paragraph (a)(2) of this section must have a sufficient number and geographic distribution of employed providers and hospital facilities, or providers of its contracted medical group and hospital facilities to ensure reasonable and timely access for low-income, medically underserved individuals in the QHP's service area, in accordance with the Exchange's network adequacy standards.

(c) *Definition.* Essential community providers are providers that serve predominantly low-income, medically underserved individuals, including providers that meet the criteria of paragraph (c)(1) or (2) of this section, and providers that met the criteria under paragraph (c)(1) or (2) of this section on the publication date of this regulation unless the provider lost its status under paragraph (c)(1) or (2) of this section thereafter as a result of violating Federal law:

(1) Health care providers defined in section 340B(a)(4) of the PHS Act; and

(2) Providers described in section 1927(c)(1)(D)(i)(IV) of the Act as set forth by section 221 of Public Law 111–8.

(d) *Payment rates.* Nothing in paragraph (a) of this section shall be construed to require a QHP issuer to contract with an essential community provider if such provider refuses to accept the generally applicable payment rates of such issuer.

(e) *Payment of federally-qualified health centers.* If an item or service covered by a QHP is provided by a federally-qualified health center (as defined in section 1905(l)(2)(B) of the Act) to an enrollee of a QHP, the QHP issuer must pay the federally-qualified health center for the item or service an amount that is not less than the amount of payment that would have been paid to the center under section 1902(bb) of the Act for such item or service. Nothing in this paragraph (e) would preclude a QHP issuer and federally-qualified health center from mutually agreeing upon payment rates other than those that would have been paid to the center under section 1902(bb) of the Act, as long as such mutually agreed upon rates are at least equal to the generally applicable payment rates of the issuer indicated in paragraph (d) of this section.

§ 156.245 Treatment of direct primary care medical homes.

A QHP issuer may provide coverage through a direct primary care medical home that meets criteria established by HHS, so long as the QHP meets all requirements that are otherwise applicable and the services covered by the direct primary care medical home are coordinated with the QHP issuer.

§ 156.250 Health plan applications and notices.

QHP issuers must provide all applications and notices to enrollees in accordance with the standards described in § 155.230(b) of this subtitle.

§ 156.255 Rating variations.

(a) *Rating areas.* A QHP issuer, including an issuer of a multi-State plan, may vary premiums by the geographic rating area established under section 2701(a)(2) of the PHS Act.

(b) *Same premium rates.* A QHP issuer must charge the same premium rate without regard to whether the plan is offered through an Exchange, or whether the plan is offered directly from the issuer or through an agent.

§ 156.260 Enrollment periods for qualified individuals.

(a) *Individual market requirement.* A QHP issuer must:

(1) Enroll a qualified individual during the initial and annual open enrollment periods described in § 155.410(b) and (e) of this subchapter, and abide by the effective dates of coverage established by the Exchange in accordance with § 155.410(c) and (f) of this subchapter; and

(2) Make available, at a minimum, special enrollment periods described in § 155.420(d) of this subchapter, for QHPs

and abide by the effective dates of coverage established by the Exchange in accordance with § 155.420(b) of this subchapter.

(b) *Notification of effective date.* A QHP issuer must notify a qualified individual of his or her effective date of coverage.

§ 156.265 Enrollment process for qualified individuals.

(a) *General requirement.* A QHP issuer must process enrollment in accordance with this section.

(b) *Enrollment through the Exchange for the individual market.* (1) A QHP issuer must enroll a qualified individual only if the Exchange—

(i) Notifies the QHP issuer that the individual is a qualified individual; and

(ii) Transmits information to the QHP issuer as provided in § 155.400(a) of this subchapter.

(2) If an applicant initiates enrollment directly with the QHP issuer for enrollment through the Exchange, the QHP issuer must either—

(i) Direct the individual to file an application with the Exchange in accordance with § 155.310, or

(ii) Ensure the applicant received an eligibility determination for coverage through the Exchange through the Exchange Internet Web site.

(c) *Acceptance of enrollment information.* A QHP issuer must accept enrollment information consistent with the privacy and security requirements established by the Exchange in accordance with § 155.260 and in an electronic format that is consistent with § 155.270.

(d) *Premium payment.* A QHP issuer must follow the premium payment process established by the Exchange in accordance with § 155.240.

(e) *Enrollment information package.* A QHP issuer must provide new enrollees an enrollment information package that is compliant with accessibility and readability standards established in § 155.230(b).

(f) *Enrollment reconciliation.* A QHP issuer must reconcile enrollment files with the Exchange no less than once a month in accordance with § 155.400(d).

(g) *Enrollment acknowledgement.* A QHP issuer must acknowledge receipt of enrollment information transmitted from the Exchange in accordance with Exchange standards established in accordance with § 155.400(b)(2) of this subchapter.

§ 156.270 Termination of coverage for qualified individuals.

(a) *General requirement.* A QHP issuer may only terminate coverage as permitted by the Exchange in accordance with § 155.430(b) of this subchapter.

(b) *Termination of coverage notice requirement.* If an enrollee's coverage in a QHP is terminated for any reason, the QHP issuer must:

(1) Provide the enrollee with a notice of termination of coverage that includes the reason for termination at least 30 days prior to the last day of coverage, consistent with the effective date established by the Exchange in accordance with § 155.430(d) of this subchapter.

(2) Notify the Exchange of the termination effective date and reason for termination.

(c) *Termination of coverage due to non-payment of premium.* A QHP issuer must establish a standard policy for the termination of coverage of enrollees due to non-payment of premium as permitted by the Exchange in § 155.430(b)(2)(ii) of this subchapter. This policy for the termination of coverage:

(1) Must include the grace period for enrollees receiving advance payments of the premium tax credits as described in paragraph (d) of this section; and

(2) Must be applied uniformly to enrollees in similar circumstances.

(d) *Grace period for recipients of advance payments of the premium tax credit.* A QHP issuer must provide a grace period of three consecutive months if an enrollee receiving advance payments of the premium tax credit has previously paid at least one full month's premium during the benefit year. During the grace period, the QHP issuer must:

(1) Pay all appropriate claims for services rendered to the enrollee during the first month of the grace period and may pend claims for services rendered to the enrollee in the second and third months of the grace period;

(2) Notify HHS of such non-payment; and,

(3) Notify providers of the possibility for denied claims when an enrollee is in

the second and third months of the grace period.

(e) *Advance payments of the premium tax credit.* For the 3-month grace period described in paragraph (d) of this section, a QHP issuer must:

(1) Continue to collect advance payments of the premium tax credit on behalf of the enrollee from the Department of the Treasury.

(2) Return advance payments of the premium tax credit paid on the behalf of such enrollee for the second and third months of the grace period if the enrollee exhausts the grace period as described in paragraph (g) of this section.

(f) *Notice of non-payment of premiums.* If an enrollee is delinquent on premium payment, the QHP issuer must provide the enrollee with notice of such payment delinquency.

(g) *Exhaustion of grace period.* If an enrollee receiving advance payments of the premium tax credit exhausts the 3-month grace period in paragraph (d) of this section without paying all outstanding premiums, the QHP issuer must terminate the enrollee's coverage on the effective date described in §155.430(d)(4) of this subchapter, provided that the QHP issuer meets the notice requirement specified in paragraph (b) of this section.

(h) *Records of termination of coverage.* QHP issuers must maintain records in accordance with Exchange standards established in accordance with §155.430(c) of this subchapter.

(i) *Effective date of termination of coverage.* QHP issuers must abide by the termination of coverage effective dates described in §155.430(d) of this subchapter.

§156.275 Accreditation of QHP issuers.

(a) *General requirement.* A QHP issuer must:

(1) Be accredited on the basis of local performance of its QHPs in the following categories by an accrediting entity recognized by HHS:

(i) Clinical quality measures, such as the Healthcare Effectiveness Data and Information Set;

(ii) Patient experience ratings on a standardized CAHPS survey;

(iii) Consumer access;

(iv) Utilization management;

(v) Quality assurance;

(vi) Provider credentialing;

(vii) Complaints and appeals;

(viii) Network adequacy and access; and

(ix) Patient information programs, and

(2) Authorize the accrediting entity that accredits the QHP issuer to release to the Exchange and HHS a copy of its most recent accreditation survey, together with any survey-related information that HHS may require, such as corrective action plans and summaries of findings.

(b) *Timeframe for accreditation.* A QHP issuer must be accredited within the timeframe established by the Exchange in accordance with §155.1045 of this subchapter. The QHP issuer must maintain accreditation so long as the QHP issuer offers QHPs.

(c) *Accreditation*—(1) *Recognition of accrediting entity by HHS.* Effective upon completion of conditions listed in paragraphs (c)(2), (c)(3), and (c)(4) of this section, at which time HHS will notify the public in the FEDERAL REGISTER, the National Committee for Quality Assurance (NCQA) and URAC are recognized as accrediting entities by the Secretary of HHS to provide accreditation of QHPs meeting the requirement of this section.

(2)(i) *Scope of accreditation.* Subject to paragraphs (c)(2)(ii), (iii), and (iv) of this section, recognized accrediting entities must provide accreditation within the categories identified in paragraphs (a)(1) of this section.

(ii) *Clinical quality measures.* Recognized accrediting entities must include a clinical quality measure set in their accreditation standards for health plans that:

(A) Spans a breadth of conditions and domains, including, but not limited to, preventive care, mental health and substance abuse disorders, chronic care, and acute care.

(B) Includes measures that are applicable to adults and measures that are applicable to children.

(C) Aligns with the priorities of the National Strategy for Quality Improvement in Health Care issued by the Secretary of HHS and submitted to Congress on March 12, 2011;

(D) Only includes measures that are either developed or adopted by a voluntary consensus standards setting body (such as those described in the National Technology and Transfer Advancement of Act of 1995 (NTTAA) and Office of Management and Budget (OMB) Circular A–119 (1998)) or, where appropriate endorsed measures are unavailable, are in common use for health plan quality measurement and meet health plan industry standards; and

(E) Is evidence-based.

(iii) *Level of accreditation*. Recognized accrediting entities must provide accreditation at the Exchange product type level unless the product type level of accreditation is not methodologically sound. In such cases, the recognized accrediting entity must demonstrate that the Exchange product type level accreditation is not methodologically sound as a condition of the Exchange granting an exception to authorize accreditation at an aggregated level.

(iv) *Network adequacy*. The network adequacy standards for accreditation used by the recognized accrediting entities must, at a minimum, be consistent with the general requirements for network adequacy for QHP issuers codified in § 156.230(a)(2) and (a)(3).

(3) *Methodological and scoring criteria for accreditation*. Recognized accrediting entities must use transparent and rigorous methodological and scoring criteria.

(4) *Documentation*. An accrediting entity must provide the following documentation:

(i) To be recognized, an accrediting entity must provide current accreditation standards and requirements, processes, and measure specifications for performance measures to demonstrate that each entity meets the conditions described in paragraphs (c)(2), and (c)(3) of this section to HHS within 60 days of the publication date of this final rule.

(ii) Recognized accrediting entities must provide to HHS any proposed changes or updates to the accreditation standards and requirements, processes, and measure specifications for performance measures with 60 days notice prior to public notification.

(5) *Data sharing requirements between the recognized accrediting entities and Exchanges*. When authorized by an accredited QHP issuer pursuant to paragraph (a)(2) of this section, recognized accrediting entities must provide the following QHP issuer's accreditation survey data elements to the Exchange, other than personally identifiable information (as described in OMB Memorandum M–07–16), in which the issuer plans to operate one or more QHPs during the annual certification period or as changes occur to these data throughout the coverage year—the name, address, Health Insurance Oversight System (HIOS) issuer identifier, and unique accreditation identifier(s) of the QHP issuer and its accredited product line(s) and type(s) which have been released; and for each accredited product type:

(i) HIOS product identifier (if applicable);

(ii) Accreditation status, survey type, or level (if applicable);

(iii) Accreditation score;

(iv) Expiration date of accreditation; and

(v) Clinical quality measure results and adult and child CAHPS measure survey results (and corresponding expiration dates of these data) at the level specified by the Exchange.

[77 FR 18469, Mar. 27, 2012, as amended at 77 FR 42671, July 20, 2012]

§ 156.280 Segregation of funds for abortion services.

(a) *State opt-out of abortion coverage*. A QHP issuer must comply with a State law that prohibits abortion coverage in QHPs.

(b) *Termination of opt out*. A QHP issuer may provide coverage of abortion services through the Exchange in a State described in paragraph (a) of this section if the State repeals such law.

(c) *Voluntary choice of coverage of abortion services*. Notwithstanding any other provision of title I of the Affordable Care Act (or any other amendment made under that title):

(1) Nothing in title I of the Affordable Care Act (or any amendments by that title) shall be construed to require a QHP issuer to provide coverage of services described in paragraph (d) of

this section as part of its essential health benefits, as described in section 1302(b) of the Affordable Care Act, for any plan year.

(2) Subject to paragraphs (a) and (b) of this section, the QHP issuer must determine whether or not the QHP provides coverage of services described in paragraph (d) of this section as part of such benefits for the plan year.

(d) *Abortion services*—(1) *Abortions for which public funding is prohibited.* The services described in this paragraph are abortion services for which the expenditure of Federal funds appropriated for HHS is not permitted, based on the law in effect 6 months before the beginning of the plan year involved.

(2) *Abortions for which public funding is allowed.* The services described in this paragraph are abortion services for which the expenditure of Federal funds appropriated for HHS is permitted, based on the law in effect 6 months before the beginning of the plan year involved.

(e) *Prohibition on the use of Federal funds.* (1) If a QHP provides coverage of services described in paragraph (d)(1) of this section, the QHP issuer must not use any amount attributable to any of the following for the purposes of paying for such services:

(i) The credit under section 36B of the Code and the amount (if any) of the advance payment of the credit under section 1412 of the Affordable Care Act;

(ii) Any cost-sharing reduction under section 1402 of the Affordable Care Act and the amount (if any) of the advance payments of the reduction under section 1412 of the Affordable Care Act.

(2) *Establishment of allocation accounts.* In the case of a QHP to which paragraph (e)(1) of this section applies, the QHP issuer must:

(i) Collect from each enrollee in the QHP (without regard to the enrollee's age, sex, or family status) a separate payment for each of the following:

(A) An amount equal to the portion of the premium to be paid directly by the enrollee for coverage under the QHP of services other than services described in (d)(1) of this section (after reductions for credits and cost-sharing reductions described in paragraph (e)(1) of this section); and

(B) An amount equal to the actuarial value of the coverage of services described in paragraph (d)(1) of this section.

(ii) Deposit all such separate payments into separate allocation accounts as provided in paragraph (e)(3) of this section. In the case of an enrollee whose premium for coverage under the QHP is paid through employee payroll deposit, the separate payments required under this subparagraph shall each be paid by a separate deposit.

(3) *Segregation of funds.* (i) The QHP issuer to which paragraph (e)(1) of this section applies must establish allocation accounts described in paragraph (e)(3)(ii) of this section for enrollees receiving the amounts described in paragraph (e)(1) of this section.

(ii) *Allocation accounts.* The QHP issuer to which paragraph (e)(1) of this section applies must deposit:

(A) All payments described in paragraph (e)(2)(i)(A) of this section into a separate account that consists solely of such payments and that is used exclusively to pay for services other than the services described in paragraph (d)(1) of this section;

(B) All payments described in paragraph (e)(2)(i)(B) of this section into a separate account that consists solely of such payments and that is used exclusively to pay for services described in paragraph (d)(1) of this section.

(4) *Actuarial value.* The QHP issuer must estimate the basic per enrollee, per month cost, determined on an average actuarial basis, for including coverage under the QHP of services described in paragraph (d)(1) of this section. In making such an estimate, the QHP issuer:

(i) May take into account the impact on overall costs of the inclusion of such coverage, but may not take into account any cost reduction estimated to result from such services, including prenatal care, delivery, or postnatal care;

(ii) Must estimate such costs as if such coverage were included for the entire population covered; and

(iii) May not estimate such a cost at less than one dollar per enrollee, per month.

(5) *Ensuring compliance with segregation requirements.* (i) Subject to paragraph (e)(5)(iv) of this section, the QHP issuer must comply with the efforts or direction of the State health insurance commissioner to ensure compliance with this section through the segregation of QHP funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget and guidance on accounting of the Government Accountability Office.

(ii) Each QHP issuer that participates in an Exchange and offers coverage for services described in paragraph (d)(1) of this section should, as a condition of participating in an Exchange, submit a plan that details its process and methodology for meeting the requirements of section 1303(b)(2)(C), (D), and (E) (hereinafter, ''segregation plan'') to the State health insurance commissioner. The segregation plan should describe the QHP issuer's financial accounting systems, including appropriate accounting documentation and internal controls, that would ensure the segregation of funds required by section 1303(b)(2)(C), (D), and (E), and should include:

(A) The financial accounting systems, including accounting documentation and internal controls, that would ensure the appropriate segregation of payments received for coverage of services described in paragraph (d)(1) of this section from those received for coverage of all other services;

(B) The financial accounting systems, including accounting documentation and internal controls, that would ensure that all expenditures for services described in paragraph (d)(1) of this section are reimbursed from the appropriate account; and

(C) An explanation of how the QHP issuer's systems, accounting documentation, and controls meet the requirements for segregation accounts under the law.

(iii) Each QHP issuer participating in the Exchange must provide to the State insurance commissioner an annual assurance statement attesting that the plan has complied with section 1303 of the Affordable Care Act and applicable regulations.

(iv) Nothing in this clause shall prohibit the right of an individual or QHP issuer to appeal such action in courts of competent jurisdiction.

(f) *Rules relating to notice.* (1) *Notice.* A QHP that provides for coverage of services in paragraph (d)(1) of this section, must provide a notice to enrollees, only as part of the summary of benefits and coverage explanation, at the time of enrollment, of such coverage.

(2) *Rules relating to payments.* The notice described in paragraph (f)(1) of this section, any advertising used by the QHP issuer with respect to the QHP, any information provided by the Exchange, and any other information specified by HHS must provide information only with respect to the total amount of the combined payments for services described in paragraph (d)(1) of this section and other services covered by the QHP.

(g) *No discrimination on basis of provision of abortion.* No QHP offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.

(h) *Application of State and Federal laws regarding abortions.* (1) *No preemption of State laws regarding abortion.* Nothing in the Affordable Care Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.

(2) *No effect on Federal laws regarding abortion.* Nothing in the Affordable Care Act shall be construed to have any effect on Federal laws regarding:

(i) Conscience protection;

(ii) Willingness or refusal to provide abortion; and

(iii) 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.

(3) *No effect on Federal civil rights law.* Nothing in section 1303(c) of the Affordable Care Act shall alter the rights and

obligations of employees and employers under Title VII of the Civil Rights Act of 1964.

(i) *Application of emergency services laws*. Nothing in the Affordable Care Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1867 of the Act (popularly known as ''EMTALA'').

§ 156.285 Additional standards specific to SHOP.

(a) *SHOP rating and premium payment requirements*. QHP issuers offering a QHP through a SHOP must:

(1) Accept payment from the SHOP on behalf of a qualified employer or an enrollee in accordance with § 155.705(b)(4) of this subchapter;

(2) Adhere to the SHOP timeline for rate setting as established in § 155.705(b)(6) of this subchapter; and

(3) Charge the same contract rate for a plan year.

(b) *Enrollment periods for the SHOP*. QHP issuers offering a QHP through the SHOP must:

(1) Enroll a qualified employee in accordance with the qualified employer's annual employee open enrollment period described in § 155.725 of this subchapter;

(2) Provide special enrollment periods described in § 155.420 excluding paragraphs (d)(3) and (6);

(3) Provide an enrollment period for an employee who becomes a qualified employee outside of the initial or annual open enrollment period as described in § 155.725(g) of this subchapter; and

(4) Adhere to effective dates of coverage in accordance with § 156.260 and those established through § 155.720 of this subchapter.

(c) *Enrollment process for the SHOP*. A QHP issuer offering a QHP through the SHOP must:

(1) Adhere to the enrollment timeline and process for the SHOP as described in § 155.720(b) of this subchapter;

(2) Receive enrollment information in an electronic format, in accordance with the requirements in §§ 155.260 and 155.270 of this subchapter, from the SHOP as described in § 155.720(c);

(3) Provide new enrollees with the enrollment information package as described in § 156.265(e);

(4) Reconcile enrollment files with the SHOP at least monthly;

(5) Acknowledge receipt of enrollment information in accordance with SHOP standards; and

(6) Enroll all qualified employees consistent with the plan year of the applicable qualified employer.

(d) *Termination of coverage in the SHOP*. QHP issuers offering a QHP through the SHOP must:

(1) Comply with the following requirements with respect to coverage termination of enrollees in the SHOP:

(i) General requirements regarding termination of coverage established in § 156.270(a);

(ii) Requirements for notices to be provided to enrollees and qualified employers in § 156.270(b) and § 156.290(b); and

(iii) Requirements regarding termination of coverage effective dates as set forth in § 156.270(i).

(2) If a qualified employer chooses to withdraw from participation in the SHOP, the QHP issuer must terminate coverage for all enrollees of the withdrawing qualified employer.

(e) *Participation rules*. QHP issuers offering a QHP through the SHOP may impose group participation rules for the offering of health insurance coverage in connection with a QHP only if and to the extent authorized by the SHOP in accordance with § 155.705 of this subchapter.

§ 156.290 Non-renewal and decertification of QHPs.

(a) *Non-renewal of recertification*. If a QHP issuer elects not to seek recertification with the Exchange, the QHP issuer, at a minimum, must—

(1) Notify the Exchange of its decision prior to the beginning of the recertification process and procedures adopted by the Exchange in accordance with § 155.1075 of this subchapter;

(2) Fulfill its obligation to cover benefits for each enrollee through the end of the plan or benefit year;

(3) Fulfill data reporting obligations from the last plan or benefit year of the certification;

(4) Provide notice to enrollees as described in paragraph (b) of this section; and

(5) Terminate coverage for enrollees in the QHP in accordance with § 156.270, as applicable.

(b) *Notice of QHP non-renewal.* If a QHP issuer elects not to seek recertification with the Exchange for its QHP, the QHP issuer must provide written notice to each enrollee.

(c) *Decertification.* If a QHP is decertified by the Exchange, the QHP issuer must terminate coverage for enrollees only after:

(1) The Exchange has made notification as described in § 155.1080 of this subchapter; and

(2) Enrollees have an opportunity to enroll in other coverage.

§ 156.295 Prescription drug distribution and cost reporting.

(a) *General requirement.* In a form, manner, and at such times specified by HHS, a QHP issuer must provide to HHS the following information:

(1) The percentage of all prescriptions that were provided under the QHP through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed compared to all drugs dispensed, broken down by pharmacy type, which includes an independent pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public, that is paid by the QHP issuer or the QHP issuer's contracted PBM;

(2) The aggregate amount, and the type of rebates, discounts or price concessions (excluding bona fide service fees) that the QHP issuer or its contracted PBM negotiates that are attributable to patient utilization under the QHP, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the QHP issuer, and the total number of prescriptions that were dispensed.

(i) Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

(ii) [Reserved]

(3) The aggregate amount of the difference between the amount the QHP issuer pays its contracted PBM and the amounts that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(b) *Confidentiality.* Information disclosed by a QHP issuer or a PBM under this section is confidential and shall not be disclosed by HHS or by a QHP receiving the information, except that HHS may disclose the information in a form which does not disclose the identity of a specific PBM, QHP, or prices charged for drugs, for the following purposes:

(1) As HHS determines to be necessary to carry out section 1150A or part D of title XVIII of the Act;

(2) To permit the Comptroller General to review the information provided;

(3) To permit the Director of the Congressional Budget Office to review the information provided; or

(4) To States to carry out section 1311 of the Affordable Care Act.

(c) *Penalties.* A QHP issuer that fails to report the information described in paragraph (a) of this section to HHS on a timely basis or knowingly provides false information will be subject to the provisions of subsection (b)(3)(C) of section 1927 of the Act.

Subparts D–E [Reserved]

Subpart F—Consumer Operated and Oriented Plan Program

§ 156.500 Basis and scope.

This subpart implements section 1322 of the Affordable Care Act by establishing the Consumer Operated and Oriented Plan (CO–OP) program to foster the creation of new consumer-governed, private, nonprofit health insurance issuers, known as ''CO–OPs.'' Under this program, loans are awarded to encourage the development of CO–

OPs. Applicants that meet the eligibility standards of the CO–OP program may apply to receive loans to help fund start-up costs and meet the solvency requirements of States in which the applicant seeks to be licensed to issue CO–OP qualified health plans. This subpart sets forth the eligibility and governance requirements for the CO–OP program, CO–OP standards, and the terms for loans awarded under the CO–OP program.

§ 156.505 Definitions.

The following definitions apply to this subpart:

Applicant means an entity eligible to apply for a loan described in § 156.520 of this subpart.

Consumer operated and oriented plan (CO–OP) means a loan recipient that satisfies the standards in section 1322(c) of the Affordable Care Act and § 156.515 of this subpart within the timeframes specified in this subpart.

CO–OP qualified health plan means a health plan that has in effect a certification that it meets the standards described in subpart C of this part, except that the plan can be deemed certified by CMS or an entity designated by CMS as described in § 156.520(e).

Exchange has the meaning given to the term in § 155.20 of this subchapter.

Formation board means the initial board of directors of the applicant or loan recipient before it has begun accepting enrollment and had an election by the members of the organization to the board of directors.

Individual market has the meaning given to the term in § 155.20 of this subchapter.

Issuer has the meaning given to the term in § 155.20 of this subchapter.

Member means an individual covered under health insurance policies issued by a loan recipient.

Nonprofit member organization or *nonprofit member corporation* means a nonprofit, not-for-profit, public benefit, or similar membership entity organized as appropriate under State law.

Operational board means the board of directors elected by the members of the loan recipient after it has begun accepting enrollment.

Predecessor, with respect to a new entity, means any entity that participates in a merger, consolidation, purchase or acquisition of property or stock, corporate separation, or other similar business transaction that results in the formation of the new entity.

Pre-existing issuer means a health insurance issuer that was in existence on July 16, 2009.

Qualified nonprofit health insurance issuer means an entity that satisfies or can reasonably be expected to satisfy the standards in section 1322(c) of the Affordable Care Act and § 156.515 of this subpart within the time frames specified in this subpart, until such time as CMS determines the entity does not satisfy or cannot reasonably be expected to satisfy these standards.

Related entity means an entity that shares common ownership, control, or governance structure (including management team or Board members) with a pre-existing issuer, and satisfies at least one of the following conditions:

(1) Retains responsibilities for the services to be provided by the issuer.

(2) Furnishes services to the issuer's enrollees under an oral or written agreement.

(3) Performs some of the issuer's management functions under contract or delegation.

Representative means an individual who stands or acts for an organization or group of organizations through a formal agreement or financial compensation such as a contractor, broker, official, or employee.

SHOP has the meaning given to the term in § 155.20 of this subchapter.

Small group market has the meaning given to the term in § 155.20 of this subchapter.

Solvency Loan means a loan provided by CMS to a loan recipient in order to meet State solvency and reserve requirements.

Sponsor means an organization or individual that is involved in the development, creation, or organization of the CO–OP or provides 40 percent or more in total funding to a CO–OP (excluding any loans received from the CO–OP Program).

Start-up Loan means a loan provided by CMS to a loan recipient for costs associated with establishing a CO–OP.

State has the meaning given to the term in § 155.20 of this subchapter.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012]

§ 156.510 Eligibility.

(a) *General.* In addition to the eligibility standards set forth in the CO–OP program Funding Opportunity Announcement (FOA), to be eligible to apply for and receive a loan under the CO–OP program, an organization must intend to become a CO–OP and be a nonprofit member organization.

(b) *Exclusions from eligibility.* (1) Subject to paragraph (b)(2) of this section, an organization is not eligible to apply for a loan if:

(i) The organization or a sponsor of the organization is a pre-existing issuer, a holding company (an organization that exists primarily to hold stock in other companies) that controls a pre-existing issuer, a trade association comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, a foundation established by a pre-existing issuer, a related entity, or a predecessor of either a pre-existing issuer or related entity;

(ii) The organization receives 25 percent or more of its total funding (excluding any loans received from the CO–OP Program) from pre-existing issuers, holding companies (organizations that exists primarily to hold stock in other companies) that control pre-existing issuers, trade associations comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, foundations established by a pre-existing issuer, a related entity, or a predecessor of either a pre-existing issuer or related entity; or

(iii) A State or local government, any political subdivision thereof, or any instrumentality of such government or political subdivision is a sponsor of the organization. The organization receives 40 percent or more of its total funding (excluding any loans received from the CO–OP Program) from a State or local government, any political subdivision thereof, or any instrumentality of such a government or political subdivision.

(2) The exclusions in paragraphs (b)(1)(i) and (b)(1)(ii) of this section do not exclude from eligibility an applicant that:

(i) Has as a sponsor a nonprofit, not-for-profit, public benefit, or similarly organized entity that is also a sponsor for a pre-existing issuer but is not an issuer, a foundation established by a pre-existing issuer, a holding company that controls a pre-existing issuer, or a trade association comprised of pre-existing issuers and whose purpose is to represent the interests of the health insurance industry, provided that the pre-existing issuer sponsored by the nonprofit organization does not share any of its board or the same chief executive with the applicant; or

(ii) Has purchased assets from a pre-existing issuer provided that it is an arm's-length transaction where each party acts independently and has no other relationship with the other party.

(3) The exclusion of any instrumentality of a State or local government in paragraph (b)(1)(iii) of this section does not exclude from eligibility or sponsorship an organization that:

(i) Is not a government organization under State law;

(ii) Has no employee of a State or local government serving in his or her official capacity as a senior executive (for example, President, Chief Executive Officer, or Chief Financial Officer) for the organization; and

(iii) Has a board of directors on which fewer than half of its directors are employees of a State or local government serving in their official capacities.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012]

§ 156.515 CO–OP standards.

(a) *General.* A CO–OP must satisfy the standards in this section in addition to all other statutory, regulatory, or other requirements.

(b) *Governance requirements.* A CO–OP must meet the following governance requirements:

(1) *Member control.* A CO–OP must implement policies and procedures to foster and ensure member control of the organization. Accordingly, a CO–OP must meet the following requirements:

(i) The CO–OP must be governed by an operational board with all of its directors elected by a majority vote of a

quorum of the CO–OP's members that are age 18 or older;

(ii) All members age 18 or older must be eligible to vote for each director on the organization's operational board;

(iii) Each member age 18 or older of the organization must have one vote in the election of each director of the organization's operational board;

(iv) The first elected directors of the organization's operational board must be elected no later than one year after the effective date on which the organization provides coverage to its first member; the entire operational board must be elected no later than two years after the same date;

(v) Elections of the directors on the organization's operational board must be contested so that the total number of candidates for vacant positions on the operational board exceeds the number of vacant positions, except in cases where a seat is vacated mid-term due to death, resignation, or removal; and

(vi) The majority of the voting directors on the operational board must be members of the organization.

(2) *Standards for board of directors.* The operational board for a CO–OP must meet the following standards:

(i) Each director must meet ethical, conflict-of-interest, and disclosure standards including that each director act in the sole interest of the CO–OP and, as appropriate, the health and wellbeing of its local geographic community;

(ii) Each director has one vote unless he or she is a non-voting director;

(iii) Positions on the board of directors may be designated for individuals with specialized expertise, experience, or affiliation (for example, providers, employers, and unions);

(iv) Positions on the operational board that are designated for individuals with specialized expertise, experience, or affiliation cannot constitute a majority of the operational board even if the individuals in those positions are members of the CO–OP. This provision does not prevent any individual from seeking election to the operational board based on being a member of the CO–OP; and

(v) *Limitation on government and issuer participation.* No representative of any Federal, State or local government (or of any political subdivision or instrumentality thereof) and no representative of any organization described in §156.510(b)(1)(i) may serve on the CO–OP's formation board or operational board.

(3) *Ethics and conflict of interest protections.* The CO–OP must have governing documents that incorporate ethics, conflict of interest, and disclosure standards. The standards must protect against insurance industry involvement and interference. In addition, the standards must ensure that each director acts in the sole interest of the CO–OP, its members, and its local geographic community as appropriate, avoids self dealing, and acts prudently and consistently with the terms of the CO–OP's governance documents and applicable State and Federal law. At a minimum, these standards must include:

(i) A mechanism to identify potential ethical or other conflicts of interest;

(ii) A duty on the CO–OP's executive officers and directors to disclose all potential conflicts of interest;

(iii) A process to determine the extent to which a conflict exists;

(iv) A process to address any conflict of interest; and

(v) A process to be followed in the event a director or executive officer of the CO–OP violates these standards.

(4) *Consumer focus.* The CO–OP must operate with a strong consumer focus, including timeliness, responsiveness, and accountability to members.

(c) *Standards for health plan issuance.* A CO–OP must meet several standards for the issuance of health plans in the individual and small group market.

(1) At least two-thirds of the policies or contracts for health insurance coverage issued by a CO–OP in each State in which it is licensed must be CO–OP qualified health plans offered in the individual and small group markets.

(2) Loan recipients must offer a CO–OP qualified health plan at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in every individual market Exchange that serves the geographic regions in which the organization is licensed and intends to provide health care coverage. If offering at least one plan in

the small group market, loan recipients must offer a CO–OP qualified health plan at both the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in each SHOP that serves the geographic regions in which the organization offers coverage in the small group market.

(3) Within the earlier of thirty-six months following the initial drawdown of the Start-up Loan or one year following the initial drawdown of the Solvency Loan, loan recipients must be licensed in a State and offer at least one CO–OP qualified health plan at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in the individual market Exchanges and if the loan recipient offers coverage in the small group market, at the silver and gold benefit levels, defined in section 1302(d) of the Affordable Care Act, in the SHOPs. Loan recipients may only begin offering plans and accepting enrollment in the Exchanges for new CO–OP qualified health plans during the open enrollment period for each applicable Exchange.

(d) *Requirement to become a CO–OP.* Loan recipients must meet the standards of § 156.515 no later than five years following initial drawdown of the Start-up Loan or three years following the initial drawdown of a Solvency Loan.

§ 156.520 Loan terms.

(a) *Overview of Loans.* Applicants may apply for the following loans under this section: Start-up Loans and Solvency Loans.

(1) *Use of loans.* All loans awarded under this subpart must be used in a manner that is consistent with the FOA, the loan agreement, and all other statutory, regulatory, or other requirements.

(2) *Solvency loans.* Solvency Loans awarded under this section will be structured in a manner that ensures that the loan amount is recognized by State insurance regulators as contributing to the State-determined reserve requirements or other solvency requirements (rather than debt) consistent with the insurance regulations for the States in which the loan recipient will offer a CO–OP qualified health plan.

(b) *Repayment period.* The loan recipient must make loan payments consistent with the approved repayment schedule in the loan agreement until the loan is paid in full consistent with State reserve requirements, solvency regulations, and requisite surplus note arrangements. Subject to their ability to meet State reserve requirements, solvency regulations, or requisite surplus note arrangements, the loan recipient must repay its loans and, if applicable, penalties within the repayment periods in paragraphs (b)(1), (b)(2), or (b)(3) of this section.

(1) The contractual repayment period for Start-up Loans and any applicable penalty pursuant to paragraph (c)(3) of this section is 5 years following each drawdown of loan funds consistent with the terms of the loan agreement.

(2) The contractual repayment period for Solvency Loans and any applicable penalty pursuant to paragraph (c)(3) of this section is 15 years following each drawdown of loan funds consistent with the terms of the loan agreement.

(3) Changes to the loan terms, including the repayment periods, may be executed if CMS determines that the loan recipient is unable to repay the loans as a result of State reserve requirements, solvency regulations, or requisite surplus note arrangements or without compromising coverage stability, member control, quality of care, or market stability. In the case of a loan modification or workout, the repayment period for loans awarded under this subpart is the repayment period established in the loan modification or workout. The revised terms must meet all other regulatory, statutory, and other requirements.

(c) *Interest rates.* Loan recipients will be charged interest for the loans awarded under this subpart. Interest will be accrued starting from the date of drawdown on the loan amounts that have been drawn down and not yet repaid by the loan recipient. The interest rate will be determined based on the date of award.

(1) *Start-up Loans.* Consistent with the terms of the loan agreement, the interest rate for Start-up Loans is

equal to the greater of the average interest rate on marketable Treasury securities of similar maturity minus one percentage point or zero percent. If the loan recipient's loan agreement is terminated by CMS, the loan recipient will be charged the interest and penalty described in paragraph (c)(3) of this section.

(2) *Solvency Loans.* Consistent with the terms of the loan agreement, the interest rate for Solvency Loans is equal to the greater of the average interest rate on marketable Treasury securities of similar maturity minus two percentage points or zero percent. If a loan recipient's loan agreement is terminated by CMS, the loan recipient will be charged the interest and penalty described in paragraph (c)(3) of this section.

(3) *Penalty payment.* If CMS terminates a loan recipient's loan agreement because the loan recipient is not in compliance with program rules or the terms of its loan agreement, or CMS has reason to believe that the organization engages in, or has engaged in, criminal or fraudulent activities or activities that cause material harm to the organization's members or the government, the loan recipient must repay 110 percent of the aggregate amount of loans received under this subpart. In addition, the loan recipient must pay interest on the aggregate amount of loans received for the period the loans were outstanding equal to the average interest rate on marketable Treasury securities of similar maturity.

(d) *Failure to pay.* Loan recipients that fail to make loan payments consistent with the repayment schedule or loan modification or workout approved by CMS will be subject to any and all remedies available to CMS under law to collect the debt.

(e) *Deeming of CO–OP qualified health plans.* Health plans offered by a loan recipient may be deemed certified as a CO–OP qualified health plan to participate in the Exchanges for two years and may be recertified every two years for up to ten years following the life of any loan awarded to the loan recipient under this subpart, consistent with section 1301(a)(2) of the Affordable Care Act.

(1) To be deemed as certified to participate in the Exchanges, the plan must comply with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange for qualified health plans operating in that Exchange, except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP, and the standards of the CO–OP program as set forth in this subpart.

(2) A loan recipient seeking to have a plan deemed as certified to participate in the Exchanges must provide evidence to CMS or an entity designated by CMS that the plan complies with the standards for CO–OP qualified health plans set forth pursuant to section 1311(c) of the Affordable Care Act, all State-specific standards established by an Exchange for qualified health plans operating in that Exchange, except for those State-specific standards that operate to exclude loan recipients due to being new issuers or based on other characteristics that are inherent in the design of a CO–OP, and the standards of the CO–OP program as set forth in this subpart.

(3) If a plan offered by a loan recipient is deemed to be certified to participate in the Exchanges or loses its deemed status and is no longer certified to participate in the Exchanges, CMS or an entity designated by CMS will provide notice to the Exchanges in which the loan recipient offers CO–OP qualified health plans.

(f) *Conversions.* The loan recipient shall not convert or sell to a for-profit or non-consumer operated entity at any time after receiving a loan under this subpart. The loan recipient shall not undertake any transaction that would result in the CO–OP implementing a governance structure that does not meet the standards in this subpart.

[76 FR 77411, Dec. 13, 2011, as amended at 77 FR 18474, Mar. 27, 2012]

PART 157—EMPLOYER INTERACTIONS WITH EXCHANGES AND SHOP PARTICIPATION

Subpart A—General Provisions

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157.20 Definitions.

Subpart B [Reserved]

Subpart C—Standards for Qualified Employers

157.200 Eligibility of qualified employers to participate in a SHOP.
157.205 Qualified employer participation process in a SHOP.

AUTHORITY: Title I of the Affordable Care Act, Sections 1311, 1312, 1321, 1411, 1412, Pub. L. 111–148, 124 Stat. 199.

SOURCE: 77 FR 18474, Mar. 27, 2012, unless otherwise noted.

Subpart A—General Provisions

§ 157.10 Basis and scope.

(a) *Basis.* This part is based on the following sections of title I of the Affordable Care:

(1) 1311. Affordable choices of health benefits plans.

(2) 1312. Consumer Choice.

(3) 1321. State flexibility in operation and enforcement of Exchanges and related requirements.

(4) 1411. Procedures for determining eligibility for Exchange participation, advance payments of the premium tax credit and cost-sharing reductions, and individual responsibility exemptions.

(5) 1412. Advance determination and payment of the premium tax credit and cost-sharing reductions.

(b) *Scope.* This part establishes the requirements for employers in connection with the operation of Exchanges.

§ 157.20 Definitions.

The following definitions apply to this part, unless otherwise indicated:

Qualified employee has the meaning given to the term in § 155.20 of this subchapter.

Qualified employer has the meaning given to the term in § 155.20 of this subchapter.

Small employer has the meaning given to the term in § 155.20 of this subchapter.

Subpart B [Reserved]

Subpart C—Standards for Qualified Employers

§ 157.200 Eligibility of qualified employers to participate in a SHOP.

(a) *General requirement.* Only a qualified employer may participate in the SHOP in accordance with § 155.710 of this subchapter.

(b) *Continuing participation for growing small employers.* A qualified employer may continue to participate in the SHOP if it ceases to be a small employer in accordance with § 155.710 of this subchapter.

(c) *Participation in multiple SHOPs.* A qualified employer may participate in multiple SHOPs in accordance with § 155.710 of this subchapter.

§ 157.205 Qualified employer participation process in a SHOP.

(a) *General requirements.* When joining the SHOP, a qualified employer must comply with the requirements, processes, and timelines set forth by this part and must remain in compliance for the duration of the employer's participation in the SHOP.

(b) *Selecting QHPs.* During an election period, a qualified employer may make coverage in a QHP available through the SHOP in accordance with the processes developed by the SHOP in accordance with § 155.705 of this subchapter.

(c) *Information dissemination to employees.* A qualified employer participating in the SHOP must disseminate information to its qualified employees about the process to enroll in a QHP through the SHOP.

(d) *Payment.* A qualified employer must submit any contribution towards the premiums of any qualified employee according to the standards and processes described in § 155.705 of this subchapter.

(e) *Employees hired outside of the initial or annual open enrollment period.* Qualified employers must provide employees hired outside of the initial or annual open enrollment period with:

(1) A period to seek coverage in a QHP beginning on the first day of becoming a qualified employee; and

(2) Information about the enrollment process in accordance with §155.725 of this subchapter.

(f) *New employees and changes in employee eligibility*. Qualified employers participating in the SHOP must provide the SHOP with information about dependents or employees whose eligibility status for coverage purchased through the employer in the SHOP has changed, including:

(1) Newly eligible dependents and employees; and

(2) Loss of qualified employee status.

(g) *Annual employer election period*. Qualified employers must adhere to the annual employer election period to change their program participation for the next plan year described in §155.725(c) of this subchapter.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

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AUTHORITY: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18, as amended.)

SOURCE: 75 FR 74921, Dec. 1, 2010, unless otherwise noted.

§ 158.101 Basis and scope.

(a) *Basis*. This Part implements section 2718 of the Public Health Service Act (PHS Act).

(b) *Scope*. Subpart A of this part establishes the requirements for health insurance issuers (''issuers'') offering group or individual health insurance coverage to report information concerning premium revenues and the use of such premium revenues for clinical services provided to enrollees, activities that improve health care quality, and all other non-claims costs. Subpart B describes how this information will be used to determine, with respect to each medical loss ratio (MLR) reporting year, whether the ratio of the amount of adjusted premium revenue expended by the issuer on permitted costs to the total amount of adjusted premium revenue (MLR) meets or exceeds the percentages established by section 2718(b)(1) of the PHS Act. Subpart B also addresses requirements for calculating any rebate amounts that may be due in the event an issuer does not meet the applicable MLR standard. Subpart C implements the provision of section 2718(b)(1)(A)(ii) of the PHS Act allowing the Secretary to adjust the MLR standard for the individual market in a State if requiring issuers to meet that standard may destabilize the individual market. Subparts D through F provide for enforcement of this part, including requirements for issuers to maintain records and civil monetary penalties that may be assessed against issuers who violate the requirements of this part.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010]

§ 158.102 Applicability.

General requirements. The requirements of this Part apply to issuers offering group or individual health insurance coverage, including a grandfathered health plan as defined in § 147.140 of this subpart.

§ 158.103 Definitions.

For the purposes of this Part, the following definitions apply unless specified otherwise.

Blended rate means a single rate charged for health insurance coverage provided to a single employer through two or more of an issuer's affiliated companies for employees in one or more States.

Contract reserves means reserves that are established by an issuer which, due to the gross premium pricing structure at issue, account for the value of the future benefits that at any time exceeds the value of any appropriate future valuation of net premiums at that time. Contract reserves must not include premium deficiency reserves. Contract reserves must not include reserves for expected MLR rebates.

Direct paid claims means claim payments before ceded reinsurance and excluding assumed reinsurance except as otherwise provided in this Part.

Enrollee means an individual who is enrolled, within the meaning of § 144.103 of this title, in group health insurance coverage, or an individual who is covered by individual insurance coverage, at any time during an MLR reporting year.

Experience rating refund means the return of a portion of premiums pursuant to a retrospectively rated funding arrangement when the sum of incurred losses, retention and margin are less than earned premium.

Group conversion charges means the portion of earned premium allocated to providing the privilege for a certificate holder terminated from a group health

plan to purchase individual health insurance without providing evidence of insurability.

Health Plan means health insurance coverage offered through either individual coverage or a group health plan.

Individual market has the meaning given the term in section 2791(e)(1) of the PHS Act and section 1304(a)(2) of the Affordable Care Act.

Large Employer has the meaning given the term in section 2791(e)(2) of the PHS Act and section 1304(b)(1) of the Affordable Care Act, except that as provided by section 1304(b)(3) of the Affordable Care Act, until 2016 a State may substitute ''51'' employees for ''101'' employees in the definition.

Large group market has the meaning given the term in section 2791(e)(3) of the PHS Act and section 1304(a)(3) of the Affordable Care Act.

MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer.

Policyholder means any entity that has entered into a contract with an issuer to receive health insurance coverage as defined in section 2791(b) of the PHS Act.

Situs of the contract means the jurisdiction in which the contract is issued or delivered as stated in the contract.

Small Employer has the meaning given the term in section 2791(e)(4) of the PHS Act and section 1304(b)(2) of the Affordable Care Act, except that as provided by section 1304(b)(3) of the Affordable Care Act, until 2016 a State may substitute ''50'' employees for ''100'' employees in the definition.

Small group market has the meaning in section 2791(e)(5) of the PHS Act and section 1304(a)(3) of the Affordable Care Act.

Student administrative health fee has the meaning given the term in § 147.145 of this subchapter.

Student health insurance coverage has the meaning given the term in § 147.145 of this subchapter.

Student market means the market for student health insurance coverage.

Subscriber refers to both the group market and the individual market. In the group market, subscriber means the individual, generally the employee, whose eligibility is the basis for the enrollment in the group health plan and who is responsible for the payment of premiums. In the individual market, subscriber means the individual who purchases an individual policy and who is responsible for the payment of premiums.

Unearned premium means that portion of the premium paid in the MLR reporting year that is intended to provide coverage during a period which extends beyond the MLR reporting year.

Unpaid Claim Reserves means reserves and liabilities established to account for claims that were incurred during the MLR reporting year but had not been paid within 3 months of the end of the MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012]

Subpart A—Disclosure and Reporting

§ 158.110 Reporting requirements related to premiums and expenditures.

(a) *General requirements*. For each MLR reporting year, an issuer must submit to the Secretary a report which complies with the requirements of this Part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued.

(b) *Timing and form of report*. The report for each MLR reporting year must be submitted to the Secretary by June 1 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary.

(c) *Transfer of Business*. Issuers that purchase a line or block of business from another issuer during an MLR reporting year are responsible for submitting the information and reports required by this Part for the assumed business, including for that part of the MLR reporting year that was prior to the purchase.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76592, Dec. 7, 2011]

§ 158.120 Aggregate reporting.

(a) *General requirements*. For purposes of submitting the report required in

§ 158.110 of this subpart, the issuer must submit a report for each State in which it is licensed to issue health insurance coverage that includes the experience of all policies issued in the State during the MLR reporting year covered by the report. The report must aggregate data for each entity licensed within a State, aggregated separately for the large group market, the small group market and the individual market. Experience with respect to each policy must be included on the report submitted with respect to the State where the contract was issued, except as specified in § 158.120(d) of this subpart.

(b) *Group Health Insurance Coverage in Multiple States.* Group coverage issued by a single issuer that covers employees in multiple States must be attributed to the applicable State based on the situs of the contract. Group coverage issued by multiple affiliated issuers that covers employees in multiple States must be attributed by each issuer to each State based on the situs of the contract.

(c) *Group Health Insurance Coverage With Dual Contracts.* Where a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, solely for the purpose of providing a group health plan that offers both in-network and out-of-network benefits, experience may be treated as if it were all related to the contract provided by the in-network issuer. However, if the issuer chooses this method of aggregation, it must apply it for a minimum of 3 MLR reporting years.

(d) *Exceptions.* (1) For individual market business sold through an association or trust, the experience of the issuer must be included in the State report for the issue State of the certificate of coverage.

(2) For employer business issued through a group trust or multiple employer welfare association (MEWA), the experience of the issuer must be included in the State report for the State where the employer (if sold through a trust) or the MEWA (if the MEWA is the policyholder) has its principal place of business.

(3) An issuer with policies that have a total annual limit of $250,000 or less must report the experience from such policies separately from other policies.

(4) An issuer with group policies that provide coverage to employees, substantially all of whom are: Working outside their country of citizenship; working outside of their country of citizenship and outside the employer's country of domicile; or non-U.S. citizens working in their home country, must aggregate and report the experience from these policies on a national basis, separately for the large group market and small group market, and separately from other policies.

(5) An issuer in the student market must aggregate and report the experience from these policies on a national basis, separately from other policies.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010; 76 FR 76592, Dec. 7, 2011; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012]

§ 158.121 Newer experience.

If, for any aggregation as defined in § 158.120, 50 percent or more of the total earned premium for an MLR reporting year is attributable to policies newly issued and with less than 12 months of experience in that MLR reporting year, then the experience of these policies may be excluded from the report required under § 158.110 of this subpart for that same MLR reporting year. If an issuer chooses to defer reporting of newer business as provided in this section, then the excluded experience must be added to the experience reported in the following MLR reporting year.

§ 158.130 Premium revenue.

(a) *General requirements.* An issuer must report to the Secretary earned premium for each MLR reporting year. Earned premium means all monies paid by a policyholder or subscriber as a condition of receiving coverage from the issuer, including any fees or other contributions associated with the health plan.

(1) Earned premium is to be reported on a direct basis except as provided in paragraph (b) of this section.

(2) All earned premium for policies issued by one issuer and later assumed

by another issuer must be reported by the assuming issuer for the entire MLR reporting year during which the policies were assumed and no earned premium for that MLR reporting year must be reported by the ceding issuer.

(3) Reinsured earned premium for a block of business that was subject to indemnity reinsurance and administrative agreements effective prior to March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(b) *Adjustments.* Earned premium must include adjustments to:

(1) Account for assessments paid to or subsidies received from Federal and State high risk pools.

(2) Account for portions of premiums associated with group conversion charges.

(3) Account for any experience rating refunds incurred, excluding any rebate paid based upon an issuer's MLR.

(4) Account for unearned premium.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 28790, May 16, 2012]

§ 158.140 Reimbursement for clinical services provided to enrollees.

(a) *General requirements.* The report required in § 158.110 must include direct claims paid to or received by providers, including under capitation contracts with physicians, whose services are covered by the policy for clinical services or supplies covered by the policy. In addition, the report must include claim reserves associated with claims incurred during the MLR reporting year, the change in contract reserves, reserves for contingent benefits and the medical claim portion of lawsuits, and any incurred experience rating refunds. Reimbursement for clinical services, as defined in this section, is referred to as ''incurred claims.'' All components of and adjustments to incurred claims, with the exception of contract reserves, must be calculated based on claims incurred only during the MLR reporting year and paid through March 31st of the following year. Contract reserves must be calculated as of December 31st of the applicable year.

(1) If there are any group conversion charges for a health plan, the conversion charges must be subtracted from the incurred claims for the aggregation that includes the conversion policies and this same amount must be added to the incurred claims for the aggregation that provides coverage that is intended to be replaced by the conversion policies. If an issuer transfers portions of earned premium associated with group conversion privileges between group and individual lines of business in its Annual Statement accounting, these amounts must be added to or subtracted from incurred claims.

(2) Incurred claims must include the current year's unpaid claims reserves, including claims reported in the process of adjustment, percentage withholds from payments made to contracted providers, claims that are recoverable for anticipated coordination of benefits (COB), and claim recoveries received as a result of subrogation.

(3) Incurred claims must include claims incurred but not reported based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(4) Incurred claims must include changes in other claims-related reserves.

(5) Incurred claims must include incurred experience rating refunds and exclude rebates paid as required by § 158.240 based upon prior MLR reporting year experience.

(b) *Adjustments to incurred claims.* (1) Adjustments that must be deducted from incurred claims:

(i) Prescription drug rebates received by the issuer.

(ii) Overpayment recoveries received from providers.

(2) Adjustments that must be included in incurred claims:

(i) Market stabilization payments or receipts by issuers that are directly tied to claims incurred and other claims based or census based assessments.

(ii) State subsidies based on a stop-loss payment methodology.

(iii) The amount of incentive and bonus payments made to providers.

(iv) The amount of claims payments recovered through fraud reduction efforts not to exceed the amount of fraud reduction expenses.

(3) Adjustments that must not be included in incurred claims:

(i) Amounts paid to third party vendors for secondary network savings.

(ii) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management. For example, if an issuer contracts with a behavioral health, chiropractic network, or high technology radiology vendor, or a pharmacy benefit manager, and the vendor reimburses the provider at one amount but bills the issuer a higher amount to cover its network development, utilization management costs, and profits, then the amount that exceeds the reimbursement to the provider must not be included in incurred claims.

(iii) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee. For example, medical record copying costs, attorneys' fees, subrogation vendor fees, compensation to paraprofessionals, janitors, quality assurance analysts, administrative supervisors, secretaries to medical personnel and medical record clerks must not be included in incurred claims.

(iv) Amounts paid to a provider for services that do not represent reimbursement for covered services provided to an enrollee and are directly covered by a student administrative health fee.

(4) Adjustments that must be either included in or deducted from incurred claims:

(i) Payment to and from unsubsidized State programs designed to address distribution of health risks across issuers via charges to low risk issuers that are distributed to high risk issuers must be included in or deducted from incurred claims, as applicable.

(ii) [Reserved]

(5) Other adjustments to incurred claims:

(i) Affiliated issuers that offer group coverage at a blended rate may choose whether to make an adjustment to each affiliate's incurred claims and activities to improve health care quality, to reflect the experience of the issuer with respect to the employer as a whole, according to an objective formula that will be defined prior to January 1, 2011, so as to result in each affiliate having the same ratio of incurred claims to earned premium for that employer group for the MLR reporting year as the ratio of incurred claims to earned premium calculated for the employer group in the aggregate. An issuer that chooses to use such an adjustment must use it for a minimum of three MLR reporting years.

(ii) [Reserved]

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82278, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012]

§ 158.150 Activities that improve health care quality.

(a) *General requirements.* The report required in § 158.110 of this subpart must include expenditures for activities that improve health care quality, as described in this section.

(b) *Activity requirements.* Activities conducted by an issuer to improve quality must meet the following requirements:

(1) The activity must be designed to:

(i) Improve health quality.

(ii) Increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(iii) Be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

(iv) Be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(2) The activity must be primarily designed to:

(i) Improve health outcomes including increasing the likelihood of desired

outcomes compared to a baseline and reduce health disparities among specified populations.

(A) Examples include the direct interaction of the issuer (including those services delegated by contract for which the issuer retains ultimate responsibility under the insurance policy), providers and the enrollee or the enrollee's representative (for example, face-to-face, telephonic, web-based interactions or other means of communication) to improve health outcomes, including activities such as:

(*1*) Effective case management, care coordination, chronic disease management, and medication and care compliance initiatives including through the use of the medical homes model as defined in section 3502 of the Affordable Care Act.

(*2*) Identifying and addressing ethnic, cultural or racial disparities in effectiveness of identified best clinical practices and evidence based medicine.

(*3*) Quality reporting and documentation of care in non-electronic format.

(*4*) Health information technology to support these activities.

(*5*) Accreditation fees directly related to quality of care activities.

(*6*) For each of the 2012 and 2013 MLR reporting years, implementing ICD–10 code sets that are designed to improve quality and are adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended, limited to 0.3 percent of an issuer's earned premium as defined in §158.130 of this subpart.

(B) [Reserved]

(ii) Prevent hospital readmissions through a comprehensive program for hospital discharge. Examples include:

(A) Comprehensive discharge planning (for example, arranging and managing transitions from one setting to another, such as hospital discharge to home or to a rehabilitation center) in order to help assure appropriate care that will, in all likelihood, avoid readmission to the hospital;

(B) Patient-centered education and counseling.

(C) Personalized post-discharge reinforcement and counseling by an appropriate health care professional.

(D) Any quality reporting and related documentation in non-electronic form for activities to prevent hospital readmission.

(E) Health information technology to support these activities.

(iii) Improve patient safety, reduce medical errors, and lower infection and mortality rates.

(A) Examples of activities primarily designed to improve patient safety, reduce medical errors, and lower infection and mortality rates include:

(*1*) The appropriate identification and use of best clinical practices to avoid harm.

(*2*) Activities to identify and encourage evidence-based medicine in addressing independently identified and documented clinical errors or safety concerns.

(*3*) Activities to lower the risk of facility-acquired infections.

(*4*) Prospective prescription drug Utilization Review aimed at identifying potential adverse drug interactions.

(*5*) Any quality reporting and related documentation in non-electronic form for activities that improve patient safety and reduce medical errors.

(*6*) Health information technology to support these activities.

(B) [Reserved]

(iv) Implement, promote, and increase wellness and health activities:

(A) Examples of activities primarily designed to implement, promote, and increase wellness and health activities, include—

(*1*) Wellness assessments;

(*2*) Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements;

(*3*) Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition;

(*4*) Public health education campaigns that are performed in conjunction with State or local health departments;

(*5*) Actual rewards, incentives, bonuses, reductions in copayments (excluding administration of such programs), that are not already reflected in premiums or claims should be allowed as a quality improvement activity for the group market to the extent permitted by section 2705 of the PHS Act;

(*6*) Any quality reporting and related documentation in non-electronic form for wellness and health promotion activities;

(*7*) Coaching or education programs and health promotion activities designed to change member behavior and conditions (for example, smoking or obesity); and

(*8*) Health information technology to support these activities.

(B) [Reserved]

(v) Enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology consistent with § 158.151 of this subpart.

(c) *Exclusions*. Expenditures and activities that must not be included in quality improving activities are:

(1) Those that are designed primarily to control or contain costs;

(2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans;

(3) Those which otherwise meet the definitions for quality improvement activities but which were paid for with grant money or other funding separate from premium revenue;

(4) Those activities that can be billed or allocated by a provider for care delivery and which are, therefore, reimbursed as clinical services;

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims, including maintenance of ICD–10 code sets adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended.

(6) That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality;

(7) All retrospective and concurrent utilization review;

(8) Fraud prevention activities;

(9) The cost of developing and executing provider contracts and fees associated with establishing or managing a provider network, including fees paid to a vendor for the same reason;

(10) Provider credentialing;

(11) Marketing expenses;

(12) Costs associated with calculating and administering individual enrollee or employee incentives;

(13) That portion of prospective utilization that does not meet the definition of activities that improve health quality; and

(14) Any function or activity not expressly included in paragraph (a) or (b) of this section, unless otherwise approved by and within the discretion of the Secretary, upon adequate showing by the issuer that the activity's costs support the definitions and purposes in this Part or otherwise support monitoring, measuring or reporting health care quality improvement.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76592, Dec. 7, 2011; 77 FR 28790, May 16, 2012]

§ 158.151 Expenditures related to Health Information Technology and meaningful use requirements.

(a) *General requirements*. An issuer may include as activities that improve health care quality such Health Information Technology (HIT) expenses as are required to accomplish the activities allowed in § 158.150 of this subpart and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, as well as those consistent with Medicare and/or Medicaid meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improvement or make new quality improvement initiatives possible by doing one or more of the following:

(1) Making incentive payments to health care providers for the adoption of certified electronic health record technologies and their ''meaningful use'' as defined by HHS to the extent such payments are not included in reimbursement for clinical services as defined in § 158.140 of this subpart;

(2) Implementing systems to track and verify the adoption and meaningful use of certified electronic health

records technologies by health care providers, including those not eligible for Medicare and Medicaid incentive payments;

(3) Providing technical assistance to support adoption and meaningful use of certified electronic health records technologies;

(4) Monitoring, measuring, or reporting clinical effectiveness including reporting and analysis of costs related to maintaining accreditation by nationally recognized accrediting organizations such as NCQA or URAC, or costs for public reporting of quality of care, including costs specifically required to make accurate determinations of defined measures (for example, CAHPS surveys or chart review of HEDIS measures and costs for public reporting mandated or encouraged by law.

(5) Tracking whether a specific class of medical interventions or a bundle of related services leads to better patient outcomes.

(6) Advancing the ability of enrollees, providers, issuers or other systems to communicate patient centered clinical or medical information rapidly, accurately and efficiently to determine patient status, avoid harmful drug interactions or direct appropriate care, which may include electronic Health Records accessible by enrollees and appropriate providers to monitor and document an individual patient's medical history and to support care management.

(7) Reformatting, transmitting or reporting data to national or international government-based health organizations for the purposes of identifying or treating specific conditions or controlling the spread of disease.

(8) Provision of electronic health records, patient portals, and tools to facilitate patient self-management.

(b) [Reserved]

§ 158.160 Other non-claims costs.

(a) *General requirements*. The report required in § 158.110 of this subpart must include non-claims costs described in paragraph (b) of this section and must provide an explanation of how premium revenue is used, other than to provide reimbursement for clinical services covered by the benefit plan, expenditures for activities that improve health care quality, and Federal and State taxes and licensing or regulatory fees as specified in this part.

(b) *Non-claims costs other than taxes and regulatory fees*. (1) The report required in § 158.110 of this subpart must include any expenses for administrative services that do not constitute adjustments to premium revenue as provided in § 158.130 of this subpart, reimbursement for clinical services to enrollees as defined in § 158.140 of this subpart, or expenditures on quality improvement activities as defined in §§ 158.150 and 158.151 of this subpart.

(2) Expenses for administrative services include the following:

(i) Cost-containment expenses not included as an expenditure related to an activity at § 158.150 of this subpart.

(ii) Loss adjustment expenses not classified as a cost containment expense.

(iii) Direct sales salaries, workforce salaries and benefits.

(iv) Agents and brokers fees and commissions.

(v) General and administrative expenses.

(vi) Community benefit expenditures.

§ 158.161 Reporting of Federal and State licensing and regulatory fees.

(a) *Licensing and regulatory fees included*. The report required in § 158.110 must include statutory assessments to defray operating expenses of any State or Federal department, and examination fees in lieu of premium taxes as specified by State law.

(b) *Licensing and regulatory fees excluded*. The report required in § 158.110 must include fines and penalties of regulatory authorities, and fees for examinations by any State or Federal departments other than as specified in § 158.161(a) as other non-claims costs, but not as an adjustment to premium revenue.''

[75 FR 82279, Dec. 30, 2010]

§ 158.162 Reporting of Federal and State taxes.

(a) *Federal taxes*. The report required in § 158.110 of this subpart must separately report:

(1) Federal taxes excluded from premium under subpart B which include

all Federal taxes and assessments allocated to health insurance coverage reported under section 2718 of the PHS Act.

(2) Federal taxes not excluded from premium under subpart B which include Federal income taxes on investment income and capital gains as other non-claims costs.

(b) *State taxes and assessments.* The report required in § 158.110 of this subpart must separately report:

(1) State taxes and assessments excluded from premium under subpart B which include:

(i) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly, or premium subsidies that are designed to cover the costs of providing indigent care or other access to health care throughout the State.

(ii) Guaranty fund assessments.

(iii) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(iv) Advertising required by law, regulation or ruling, except advertising associated with investments.

(v) State income, excise, and business taxes other than premium taxes.

(vi) State premium taxes plus State taxes based on policy reserves, if in lieu of premium taxes.

(vii) In lieu of reporting amounts described in paragraph (b)(1)(vi) of this section, an issuer may choose to report payment for community benefit expenditures as described in paragraph (c) of this section, limited to the highest premium tax rate in the State for which the report is being submitted.

(2) State taxes and assessments not excluded from premium under subpart B which include:

(i) State sales taxes if the issuer does not exercise options of including such taxes with the cost of goods and services purchased.

(ii) Any portion of commissions or allowances on reinsurance assumed that represent specific reimbursement of premium taxes.

(iii) Any portion of commissions or allowances on reinsurance ceded that represents specific reimbursement of premium taxes.

(c) *Community benefit expenditures.* Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden. This includes any of the following activities that:

(1) Are available broadly to the public and serve low-income consumers;

(2) Reduce geographic, financial, or cultural barriers to accessing health services, and if ceased to exist would result in access problems (for example, longer wait times or increased travel distances);

(3) Address Federal, State or local public health priorities such as advancing health care knowledge through education or research that benefits the public;

(4) Leverage or enhance public health department activities such as childhood immunization efforts; and

(5) Otherwise would become the responsibility of government or another tax-exempt organization.

[75 FR 74921, Dec. 1, 2010. Redesignated and amended at 75 FR 82279, Dec. 30, 2010; 76 FR 76593, Dec. 7, 2011]

§ 158.170 Allocation of expenses.

(a) *General requirements.* Each expense must be reported under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses. Expenditures that benefit lines of business or products other than those being reported, including but not limited to those that are for or benefit self-funded plans, must be reported on a pro rata share.

(b) *Description of the methods used to allocate expenses.* The report required in § 158.110 of this subpart must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed

description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

(1) Allocation to each category should be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories above will generally be the most accurate method. If a specific identification is not feasible, the issuer should provide an explanation of why it believes the more accurate result will be gained from allocation of expenses based upon pertinent factors or ratios such as studies of employee activities, salary ratios or similar analyses.

(2) Many entities operate within a group where personnel and facilities are shared. Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the entities incurring the expense.

(3) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses. Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

(c) *Disclosure of allocation methods.* The issuer must identify in the report required in § 158.110 of this subpart the specific basis used to allocate expenses reported under this Part to States and, within States, to lines of business including the individual market, small group market, large group market, supplemental health insurance coverage, health insurance coverage offered to beneficiaries of public programs (such as Medicare and Medicaid), and group health plans as defined in § 145.103 of this chapter and administered by the issuer.

(d) *Maintenance of records.* The issuer must maintain and make available to the Secretary upon request the data used to allocate expenses reported under this Part together with all supporting information required to determine that the methods identified and reported as required under paragraph (b) of this section were accurately implemented in preparing the report required in § 158.110 of this subpart.

Subpart B—Calculating and Providing the Rebate

§ 158.210 Minimum medical loss ratio.

Subject to the provisions of § 158.211 of this subpart:

(a) *Large group market.* For all policies issued in the large group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 85 percent, as determined in accordance with this part.

(b) *Small group market.* For all policies issued in the small group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80 percent, as determined in accordance with this part.

(c) *Individual market.* For all policies issued in the individual market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80 percent, as determined in accordance with this Part.

(d) *Adjustment by the Secretary.* If the Secretary has adjusted the percentage that issuers in the individual market in a specific State must meet, then the adjusted percentage determined by the Secretary in accordance with § 158.301 of this part *et seq.* must be substituted for 80 percent in paragraph (c) of this section.

§ 158.211 Requirement in States with a higher medical loss ratio.

(a) *State option to set higher minimum loss ratio.* For coverage offered in a State whose law provides that issuers in the State must meet a higher MLR than that set forth in § 158.210, the State's higher percentage must be substituted for the percentage stated in § 158.210 of this subpart.

(b) *Considerations in setting a higher minimum loss ratio.* In adopting a higher

minimum loss ratio than that set forth in § 158.210, a State must seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

§ 158.220 Aggregation of data in calculating an issuer's medical loss ratio.

(a) *Aggregation by State and by market.* In general, an issuer's MLR must be calculated separately for the large group market, small group market and individual market within each State. However, if, pursuant to section 1312(c)(3) of the Affordable Care Act, a State requires the small group market and individual market to be merged, then the data reported separately under subpart A for the small group and individual market in that State may be merged for purposes of calculating an issuer's MLR and any rebates owing.

(b) *Years of data to include in calculating MLR.* Subject to paragraphs (c) and (d) of this section, an issuer's MLR for an MLR reporting year is calculated according to the formula in § 158.221 of this subpart and aggregating the data reported under this Part for the following 3-year period:

(1) The data for the MLR reporting year whose MLR is being calculated; and

(2) The data for the two prior MLR reporting years.

(c) *Requirements for MLR reporting years 2011 and 2012.* (1) For the 2011 MLR reporting year, an issuer's MLR is calculated using the data reported under this Part for the 2011 MLR reporting year only.

(2) For the 2012 MLR reporting year—

(i) If an issuer's experience for the 2012 MLR reporting year is fully credible, as defined in § 158.230 of this subpart, an issuer's MLR is calculated using the data reported under this Part for the 2012 MLR reporting year.

(ii) If an issuer's experience for the 2012 MLR reporting year is partially credible or non-credible, as defined in § 158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2011 MLR reporting year and the 2012 MLR reporting year.

(d) *Requirements for MLR reporting years 2013 and 2014 for the student market only.*

(1) For the 2013 MLR reporting year, an issuer's MLR is calculated using the data reported under this part for the 2013 MLR reporting year only.

(2) For the 2014 MLR reporting year—

(i) If an issuer's experience for the 2014 MLR reporting year is fully credible, as defined in § 158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2014 MLR reporting year.

(ii) If an issuer's experience for the 2014 MLR reporting year is partially credible or non-credible, as defined in § 158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2013 MLR reporting year and the 2014 MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 16469, Mar. 21, 2012]

§ 158.221 Formula for calculating an issuer's medical loss ratio.

(a) *Medical loss ratio.* (1) An issuer's MLR is the ratio of the numerator, as defined in paragraph (b) of this section, to the denominator, as defined in paragraph (c) of this section, subject to the applicable credibility adjustment, if any, as provided in § 158.232 of this subpart.

(2) An issuer's MLR shall be rounded to three decimal places. For example, if an MLR is 0.7988, it shall be rounded to 0.799 or 79.9 percent. If an MLR is 0.8253 or 82.53 percent, it shall be rounded to 0.825 or 82.5 percent.

(b) *Numerator.* The numerator of an issuer's MLR for an MLR reporting year must be the issuer's incurred claims, as defined in § 158.140 of this part, plus the issuer's expenditures for activities that improve health care quality, as defined in § 158.150 and § 158.151 of this part, that are reported for the years specified in § 158.220 of this subpart.

(1) The numerator of the MLR for the 2012 MLR reporting year may include any rebate paid under § 158.240 of this subpart for the 2011 MLR reporting

year if the 2012 MLR reporting year experience is not fully credible as defined in § 158.230 of this subpart.

(2) The numerator of the MLR for the 2013 MLR reporting year may include any rebate paid under § 158.240 for the 2011 MLR reporting year or the 2012 MLR reporting year.

(3) The numerator of the MLR for policies that are reported separately under § 158.120(d)(3) of this part must be the amount specified in paragraph (b) of this section, except that for the 2012 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.75, for the 2013 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.50, and for the 2014 MLR reporting year, the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 1.25.

(4) The numerator of the MLR for policies that are reported separately under § 158.120(d)(4) of this part must be the amount specified in paragraph (b) of this section, except that the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of 2.00.

(5) The numerator of the MLR for policies that are reported separately under § 158.120(d)(5) of this part must be the amount specified in paragraph (b) of this section, except that for the 2013 MLR reporting year the total of the incurred claims and expenditures for activities that improve health care quality is then multiplied by a factor of 1.15.

[75 FR 74921, Dec. 1, 2010, as amended at 77 FR 16469, Mar. 21, 2012]

(c) *Denominator*. The denominator of an issuer's MLR must equal the issuer's premium revenue, as defined in § 158.130, minus the issuer's Federal and State taxes and licensing and regulatory fees, described in §§ 158.161(a) and 158.162(a)(1) and (b)(1) of this part.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011]

§ 158.230 Credibility adjustment.

(a) *General rule*. An issuer may add to the MLR calculated under § 158.221(a) of this subpart the credibility adjustment specified by § 158.232 of this section, if such MLR is based on partially credible experience as defined in paragraph (c)(2) of this section. An issuer may not apply the credibility adjustment if the issuer's experience is fully credible, as defined in paragraph (c)(1) of this section, or non-credible, as defined in paragraph (c)(3) of this section.

(b) *Life-years*. The credibility of an issuer's experience is based upon the number of life-years covered by the issuer. Life-years means the total number of months of coverage for enrollees whose premiums and claims experience is included in the report to the Secretary required by § 158.110 of this part, divided by 12.

(c) *Credible experience*. (1) An MLR calculated under § 158.221(a) through (c) of this subpart is fully credible if it is based on the experience of 75,000 or more life-years.

(2) An MLR calculated under § 158.221(a) through (c) of this subpart is partially credible if it is based on the experience of at least 1,000 life-years and fewer than 75,000 life-years.

(3) An MLR calculated under § 158.221(a) through (c) of this subpart is non-credible if it is based on the experience of less than 1,000 life-years.

(d) If an issuer's MLR is non-credible, it is presumed to meet or exceed the minimum percentage required by § 158.210 or § 158.211 of this subpart.

§ 158.231 Life-years used to determine credible experience.

(a) The life-years used to determine the credibility of an issuer's experience are the life-years for the MLR reporting year plus the life-years for the two prior MLR reporting years.

(b) For the 2011 MLR reporting year, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year only.

(c) For the 2012 MLR reporting year-

(1) If an issuer's experience for the 2012 MLR reporting year is fully credible, the life-years used to determine credibility are the life-years for the 2012 MLR reporting year only;

(2) If an issuer's experience for the 2012 MLR reporting year only is partially credible or non-credible, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year plus the life-years for the 2012 MLR reporting year.

(d) For the 2013 MLR reporting year for the student market only, the life-years used to determine credibility are the life-years for the 2013 MLR reporting year only.

(e) For the 2014 MLR reporting year for the student market only—

(1) If an issuer's experience for the 2014 MLR reporting year is fully credible, the life-years used to determine credibility are the life-years for the 2014 MLR reporting year only;

(2) If an issuer's experience for the 2014 MLR reporting year only is partially credible or non-credible, the life-years used to determine credibility are the life-years for the 2013 MLR reporting year plus the life-years for the 2014 MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82279, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012]

§ 158.232 Calculating the credibility adjustment.

(a) *Formula*. An issuer's credibility adjustment, if any, is the product of the base credibility factor, as determined under paragraph (b) of this section, multiplied by the deductible factor, as determined under paragraph (c) of this section.

(b) *Base credibility factor*. (1) The base credibility factor for fully credible experience or for non-credible experience is zero.

(2) The base credibility factor for partially credible experience is determined based on the number of life-years included in the aggregation, as determined under § 158.231 of this subpart, and the factors shown in Table 1. When the number of life-years used to determine credibility exactly matches a life-year category listed in Table 1, the value associated with that number of life-years is the base credibility factor. The base credibility factor for a number of life-years between the values shown in Table 1 is determined by linear interpolation.

TABLE 1 TO § 158.232: BASE CREDIBILITY FACTORS

Life-years	Base credibility factor
< 1,000	No Credibility.
1,000	8.3%.
2,500	5.2%.
5,000	3.7%.
10,000	2.6%.
25,000	1.6%.
50,000	1.2%.
≥ 75,000	0.0% (Full Credibility).

(c) *Deductible factor*. (1) The deductible factor is based on the average per person deductible of policies whose experience is included in the aggregation, as determined under § 158.231 of this subpart. When the weighted average deductible, as determined in accordance with this section, exactly matches a deductible category listed in Table 2, the value associated with that deductible is the deductible factor. The deductible factor for an average weighted deductible between the values shown in Table 2 is determined by linear interpolation.

(i) The per person deductible for a policy that covers a subscriber and the subscriber's dependents shall be the lesser of: The sum of the deductible applicable to each of the individual family members; or the overall family deductible for the subscriber and subscriber's family, divided by two (regardless of the total number of individuals covered through the subscriber).

(ii) The average deductible for an aggregation is calculated weighted by the life-years of experience for each deductible level of policies included in the aggregation.

(2) An issuer may choose to use a deductible factor of 1.0 in lieu of calculating a deductible factor based on the average of policies included in the aggregation.

TABLE 2 TO § 158.232: DEDUCTIBLE FACTOR

Health plan deductible	Deductible factor
<$2,500	1.000
$2,500	1.164
$5,000	1.402
≥ $10,000	1.736

(d) *No credibility adjustment*. For the 2013 MLR reporting year, the credibility adjustment for an MLR based on partially credible experience is zero if

both of the following conditions are met:

(1) The current MLR reporting year and each of the two previous MLR reporting years included experience of at least 1,000 life-years; and

(2) Without applying any credibility adjustment, the issuer's MLR for the current MLR reporting year and each of the two previous MLR reporting years were below the applicable MLR standard for each year as established under § 158.210 in this subpart.

(e) *No credibility adjustment.* Beginning with the 2015 MLR reporting year for the student market only, the credibility adjustment for an MLR based on partially credible experience is zero if both of the following conditions are met:

(1) The current MLR reporting year and each of the two previous MLR reporting years included experience of at least 1,000 life-years; and

(2) Without applying any credibility adjustment, the issuer's MLR for the current MLR reporting year and each of the two previous MLR reporting years were below the applicable MLR standard for each year as established under § 158.210 in this subpart.

[75 FR 74921, Dec. 1, 2010, as amended at 75 FR 82279, Dec. 30, 2010; 77 FR 16469, Mar. 21, 2012; 77 FR 28790, May 16, 2012]

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

(a) *General requirement.* For each MLR reporting year, an issuer must provide a rebate to each enrollee if the issuer's MLR does not meet or exceed the minimum percentage required by §§ 158.210 and 158.211 of this subpart.

(b) *Definition of enrollee for purposes of rebate.* For the sole purpose of determining whom is entitled to receive a rebate pursuant to this part, the term ''enrollee'' means the subscriber, policyholder, and/or government entity that paid the premium for health care coverage received by an individual during the respective MLR reporting year.

(c) *Amount of rebate to each enrollee.* (1) For each MLR reporting year, an issuer must rebate to the enrollee the total amount of premium revenue received by the issuer from the enrollee after subtracting Federal and State taxes and licensing and regulatory fees as provided in § 158.161(a), § 158.162(a)(1) and § 158.162(b)(1) of this part, multiplied by the difference between the MLR required by § 158.210 or § 158.211 of this subpart, and the issuer's MLR as calculated under § 158.221 of this subpart.

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the small group market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the small group market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting premium and subtracting taxes and fees as provided in paragraph (c) of this section. In this example, an enrollee may have paid $2,000 in premiums for the MLR reporting year. If the Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.161(a), § 158.161(a)(1) and § 158.162(b)(1) of this subpart are $150 for a premium of $2,000, then the issuer would subtract $150 from premium revenue, for a base of $1,850 in premium. The enrollee would be entitled to a rebate of 5 percent of $1,850, or $92.50.

(d) *Timing of rebate.* An issuer must provide any rebate owing to an enrollee no later than August 1 following the end of the MLR reporting year.

(e) *Late payment interest.* An issuer that fails to pay any rebate owing to an enrollee or subscriber in accordance with paragraph (d) of this section or to take other required action within the time periods set forth in this Part must, in addition to providing the required rebate to the enrollee, pay the enrollee interest at the current Federal Reserve Board lending rate or ten percent annually, whichever is higher, on the total amount of the rebate, accruing from the date payment was due under paragraph (d) of this section.

§ 158.241 Form of rebate.

(a) *Current enrollees.* (1) An issuer may choose to provide any rebates owing to current enrollees in the form of a premium credit, lump-sum check,

or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium.

(2) Any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR Reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

(b) *Former enrollees in the individual market.* Rebates owing to former enrollees in the individual market must be paid in the form of lump-sum check or lump-sum reimbursement using the same method that was used for payment, such as credit card or direct debit.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011]

§ 158.242 Recipients of rebates.

(a) *Individual market.* An issuer must meet its obligation to provide any rebate due to an enrollee in the individual market by providing it to the enrollee. For individual policies that cover more than one person, one lump-sum rebate may be provided to the subscriber on behalf of all enrollees covered by the policy.

(b) *Large group and small group markets.* Except as provided in paragraphs (b)(3) and (4) of this section, an issuer must meet its obligation to provide any rebate to persons covered under a group health plan by providing it to the policyholder.

(1) In the case of a policyholder that is a non-Federal governmental group health plan, the policyholder must use the amount of the rebate that is proportionate to the total amount of premium paid by all subscribers under the policy, for the benefit of subscribers in one of the following ways, at the option of the policyholder:

(i) For all subscribers covered under any option offered under the policyholder's group health plan at the time the rebate is received by the policyholder, to reduce the subscribers' portion of premium for the subsequent policy year;

(ii) For subscribers covered, at the time the rebate is received by the policyholder, under the group health plan option for which the issuer is providing a rebate, to reduce the subscribers' portion of premium for the subsequent policy year;

(iii) A cash refund to subscribers enrolled in the group health plan option, at the time the rebate is received by the policyholder, for which the issuer is providing a rebate; and

(iv) The reduction in future premium or the cash refund provided under paragraphs (b)(1)(i), (ii), or (iii) of this section may, at the option of the policyholder, be: Divided evenly among such subscribers; divided based on each subscriber's actual contributions to premium; or apportioned in a manner that reasonably reflects each subscriber's contributions to premium.

(2) In the case of a policyholder that is a non-Federal governmental group health plan, the portion of a rebate based upon former subscribers' contributions to premium must be aggregated and used for the benefit of current subscribers in the group health plan in any manner permitted by paragraph (b)(1) of this section.

(3) If the policyholder is a group health plan that is not a governmental plan and not subject to the Employee Retirement Income Security Act of 1974, as amended (29 U.S.C. 1001 *et seq.*) (ERISA), rebates may only be paid to the policyholder if the issuer receives a written assurance from the policyholder that the rebates will be used as provided in paragraphs (b)(1) and (2) of this section; otherwise, the issuer must distribute the rebate directly to the subscribers of the group health plan covered by the policy during the MLR reporting year on which the rebate is based by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without regard to how much each subscriber actually paid toward premiums.

(4) If the group health plan has been terminated at the time of rebate payment and the issuer cannot, despite reasonable efforts, locate the policyholder whose plan participants or employees were enrolled in the group

health plan, the issuer must distribute the rebate directly to the subscribers of the terminated group health plan by dividing the entire rebate, including the amount proportionate to the amount of premium paid by the policyholder, in equal amounts to all subscribers entitled to a rebate without regard to how much each subscriber actually paid toward premiums.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, 76599, Dec. 7, 2011]

§ 158.243 *De minimis* rebates.

(a) *Minimum threshold.* An issuer is not required to provide a rebate to an enrollee based upon the premium that enrollee paid, under the following circumstances:

(1) For a group policy for which the issuer distributes the rebate to the policyholder, if the total rebate owed to the policyholder and the subscribers combined is less than $20 for a given MLR reporting year; or for a group policy for which the issuer distributes the rebate directly to the subscribers, as provided in § 158.242(a)(3) and (4) of this subpart, if the total rebate owed to each subscriber is less than $5.

(2) In the individual market, if the total rebated owed to the subscriber is less than $5.

(b) *Distribution.* (1) An issuer must aggregate and distribute any rebates not provided because they did not meet the minimum threshold set forth in paragraph (a) of this section by aggregating the unpaid rebates by individual market, small group market and large group market in a State and use them to increase the rebates provided to enrollees who receive rebates based upon the same MLR reporting year as the aggregated unpaid rebates. An issuer must distribute such aggregated rebates by providing additional premium credit or payment divided evenly among enrollees who are being provided a rebate.

(2) For example, an issuer in the individual market has aggregated unpaid rebates totaling $2,000, and the issuer has 10,000 enrollees who are entitled to be provided a rebate above the minimum threshold for the applicable MLR reporting year. The $2,000 must be redistributed to the 10,000 and added on to their existing rebate amounts. The $2,000 is divided evenly among the 10,000 enrollees, so the issuer increases each enrollee's rebate by $0.20.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76593, Dec. 7, 2011]

§ 158.244 Unclaimed rebates.

An issuer must make a good faith effort to locate and deliver to an enrollee any rebate required under this Part. If, after making a good faith effort, an issuer is unable to locate a former enrollee, the issuer must comply with any applicable State law.

§ 158.250 Notice of rebates.

(a) *Notice of rebates to policyholders and subscribers of group health plans.* For each MLR reporting year, at the time any rebate of premium is provided to a policyholder of a group health plan in accordance with this part, an issuer must provide each policyholder who receives a rebate and subscribers whose policyholder receives a rebate, or each subscriber who receives a rebate directly from an issuer, the following information in a form prescribed by the Secretary:

(1) A general description of the concept of an MLR;

(2) The purpose of setting an MLR standard;

(3) The applicable MLR standard;

(4) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(5) The issuer's aggregate premium revenue as reported in accordance with § 158.130 of this part, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.162(a)(1) and (b)(1) of this part;

(6) The rebate percentage and the amount owed to enrollees, as defined in section 158.240(b), based upon the difference between the issuer's MLR and the applicable MLR standard; and

(7) The fact that, as provided by this subpart, the total aggregated rebate for the group health plan is being provided to the policyholder:

(i) If the policy provides benefits for a plan subject to ERISA, a statement that the policyholder may have additional obligations under ERISA's fiduciary responsibility provisions with respect to the handling of rebates and

contact information for questions regarding the rebate;

(ii) If the policyholder is a non-Federal governmental plan, the proportion of the rebate attributable to subscribers' contribution to premium must be used for the benefit of subscribers, using one of the methods set forth in § 158.242(b)(1) of this subpart; and

(iii) If the policyholder is a group health plan that is not a governmental plan and is not subject to ERISA,

(A) The policyholder has provided written assurance that the proportion of the rebate attributable to subscribers' contribution to premium will be used for the benefit of current subscribers, using one of the methods set forth in § 158.242(b)(1) of this subpart, or

(B) If the policyholder did not provide such written assurance, the issuer must distribute the rebate evenly among the policyholder's subscribers covered by the policy during the MLR reporting year on which the rebate is based.

(b) *Notice of rebates to subscribers in the individual market.* For each MLR reporting year, at the time any rebate of premium is provided to a subscriber in the individual market in accordance with this part, an issuer must provide each subscriber that is receiving the rebate the following information in a form prescribed by the Secretary:

(1) A general description of the concept of an MLR;

(2) The purpose of setting an MLR standard;

(3) The applicable MLR standard;

(4) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(5) The issuer's aggregate premium revenue as reported in accordance with § 158.130 of this part, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.162(a)(1) and (b)(1) of this part; and

(6) The rebate percentage and amount owed to enrollees based upon the difference between the issuer's MLR and the applicable MLR standard.

[76 FR 76593, Dec. 7, 2011]

§ 158.251 Notice of MLR information.

(a) *Notice of MLR information when the MLR standard is met or exceeded.*—(1) *General requirement.* Except as provided in paragraph (b) of this section, for the 2011 MLR reporting year, an issuer whose MLR meets or exceeds the applicable MLR standard required by § 158.210 or § 158.211 must provide each policyholder and subscriber of a group health plan, and each subscriber in the individual market, a notice in accordance with the requirements of this section.

(2) *Timing.* An issuer must provide the notice required in this paragraph (a) with the first plan document that the issuer provides to enrollees on or after July 1, 2012.

(3) *Form and appearance.* The notice must be prominently displayed in clear, conspicuous 14-point bold type on the front of the plan document or as a separate notice. The notice may be provided electronically, if the requirements for electronic disclosure under section 2715 of the Public Health Service Act are met.

(4) *Language.* The following language must be used to satisfy the notice requirement of this paragraph (a):

Medical Loss Ratio Information—The Affordable Care Act requires health insurers in the individual and small group markets to spend at least 80 percent of the premiums they receive on health care services and activities to improve health care quality (in the large group market, this amount is 85 percent). This is referred to as the Medical Loss Ratio (MLR) rule or the 80/20 rule. If a health insurer does not spend at least 80 percent of the premiums it receives on health care services and activities to improve health care quality, the insurer must rebate the difference.

A health insurer's Medical Loss Ratio is determined separately for each State's individual, small group and large group markets in which the health insurer offers health insurance. In some States, health insurers must meet a higher or lower Medical Loss Ratio. No later than August 1, 2012, health insurers must send any rebates due for 2011 and information to employers and individuals regarding any rebates due for 2011.

You are receiving this notice because your health insurer had a Medical Loss Ratio for 2011 that met or exceeded the required Medical Loss Ratio. For more information on Medical Loss Ratio and your health insurer's Medical Loss Ratio, visit *www.HealthCare.gov*.''

(b) *Exceptions*. The requirements of paragraph (a) of this section do not apply to an issuer that reports its experience separately under § 158.120(d)(3) or (d)(4), or to an issuer whose experience is non-credible as defined in § 158.230(c)(3) and determined in accordance with § 158.231.

[77 FR 28797, May 16, 2012]

§ 158.260 Reporting of rebates.

(a) *General requirement*. For each MLR reporting year, an issuer must submit to the Secretary a report concerning the rebates provided to and on behalf of enrollees pursuant to this subpart.

(b) *Aggregation of information in the report*. The information in the report must be aggregated in the same manner as required by § 158.120.

(c) *Information to report*. The report required by this section must include the total:

(1) Number of subscribers in the individual, small group and large group markets to whom the issuer paid a rebate directly, and number of small group and large group policyholders receiving a rebate on behalf of enrollees;

(2) Amount of rebates provided as premium credit;

(3) Amount of rebates provided as lump sum payment regardless of whether in cash, reimbursement to an enrollee's credit card, or direct payment to an enrollee's bank account;

(4) Amount of rebates that were de minimis as provided in § 158.243 of this subpart and the number of enrollees who did not receive a rebate because it was de minimis; and

(5) Amount of unclaimed rebates, a description of the methods used to locate the applicable enrollees, and a description of how the unclaimed rebates were disbursed.

(d) *Timing and form of report*. The data required by paragraphs (c)(1) through (4) of this section must be submitted with the report under § 158.110, on a form and in the manner prescribed by the Secretary. The data required by paragraph (c)(5) of this section must be submitted with the report under § 158.110 for the subsequent MLR reporting year.

[75 FR 74921, Dec. 1, 2010, as amended at 76 FR 76594, Dec. 7, 2011]

§ 158.270 Effect of rebate payments on solvency.

(a) If a State's insurance commissioner, superintendent, or other responsible official determines that the payment of rebates by a domestic issuer in that State will cause the issuer's risk based capital (RBC) level to fall below the Company Action Level RBC, as defined in the NAIC's Risk Based Capital (RBC) for Insurers Model Act, the commissioner, superintendent, or other responsible official must notify the Secretary. In such a circumstance, the commissioner, superintendent, or other responsible official may request that the Secretary defer all or a portion of the rebate payments owed by the issuer.

(b) In the event an insurance commissioner, superintendent, or other responsible official makes the request set forth in paragraph (a) of this section, the following should be provided to the Secretary along with the notification:

(1) The domestic issuer's RBC reports for the current calendar year and the 2 preceding calendar years; and

(2) A calculation of the amount of rebates that would be owed by the domestic issuer pursuant to this Part.

(c) Upon receipt of the notification under paragraph (a), the Secretary will examine the information provided by the insurance commissioner, superintendent, or other responsible official along with any other information the Secretary may request from the issuer, and determine whether the payment of rebates by the issuer will cause its RBC level to fall below the Company Action Level RBC.

(d) When the Secretary determines that the payment of rebates by an issuer will cause its RBC level to fall below the Company Action Level RBC, the Secretary may permit a deferral of all or a portion of the rebates owed, but only for a period determined by the Secretary in consultation with the State. The Secretary will require that

the issuer must pay these rebates with interest in a future year in which payment of the rebates would not cause the issuer's RBC level to fall below the Company Action Level RBC.

Subpart C—Potential Adjustment to the MLR for a State's Individual Market

§ 158.301 Standard for adjustment to the medical loss ratio.

The Secretary may adjust the MLR standard that must be met by issuers offering coverage in the individual market in a State, as defined in section 2791 of the PHS Act, for a given MLR reporting year if, in her discretion, she determines that application of the 80 percent MLR standard of section 2718(b)(1)(A)(ii) of the Public Health Service Act may destabilize the individual market in that State. Application of the 80 percent MLR standard may destabilize the individual market in a State only if there is a reasonable likelihood that application of the requirement will do so.

§ 158.310 Who may request adjustment to the medical loss ratio.

A request for an adjustment to the MLR standard for a State must be submitted by the State's insurance commissioner, superintendent, or comparable official of that State in order to be considered by the Secretary.

§ 158.311 Duration of adjustment to the medical loss ratio.

A State may request that an adjustment to the MLR standard be for up to three MLR reporting years.

§ 158.320 Information supporting a request for adjustment to the medical loss ratio.

A State must submit in electronic format the information required by §§ 158.321 through 158.323 of this subpart in order for the request for adjustment to the MLR standard for the State to be considered by the Secretary. A State may submit to the Secretary any additional information it determines would support its request. In the event that certain data are unavailable or that the collection of certain data is unduly burdensome, a State may provide written notice to the Secretary and the Secretary may, at her discretion, request alternative supporting data or move forward with her determination.

§ 158.321 Information regarding the State's individual health insurance market.

(a) *State MLR standard.* The State must describe its current MLR standard for the individual market, if any, and the formula used to assess compliance with such standard.

(b) *State market withdrawal requirements.* The State must describe any requirements it has with respect to withdrawals from the State's individual health insurance market. Such requirements include, but are not limited to, any notice that must be provided and any authority the State regulator may have to approve a withdrawal plan or ensure that enrollees of the exiting issuer have continuing coverage, as well as any penalties or sanctions that may be levied upon exit or limitations on re-entry.

(c) *Mechanisms to provide options to consumers.* The State must describe the mechanisms available to the State to provide consumers with options in the event an issuer withdraws from the individual market. Such mechanisms include, but are not limited to, a guaranteed issue requirement, limits on health status rating, an issuer of last resort, or a State-operated high risk pool. A description of each mechanism should include detail on the issuers participating in and products available under such mechanism, as well as any limitations with respect to eligibility, enrollment period, total enrollment, and coverage for pre-existing conditions.

(d) *Issuers in the State's individual market.* Subject to § 158.320 of this subpart, the State must provide:

(1) For each issuer who offers coverage in the individual market in the State its number of individual enrollees by product, available individual premium data by product, and individual health insurance market share within the State; and

(2) For each issuer who offers coverage in the individual market in the

State to more than 1,000 enrollees, the following additional information:

(i) Total earned premium on individual market health insurance products in the State;

(ii) Reported MLR pursuant to State law for the individual market business in the State;

(iii) Estimated MLR for the individual market business in the State, as determined in accordance with § 158.221 of this part;

(iv) Total agents' and brokers' commission expenses on individual health insurance products;

(v) Estimated rebate for the individual market business in the State, as determined in accordance with § 158.221 and § 158.240 of this part;

(vi) Net underwriting profit for the individual market business and consolidated business in the State;

(vii) After-tax profit and profit margin for the individual market business and consolidated business in the State;

(viii) Risk-based capital level; and

(ix) Whether the issuer has provided notice of exit to the State's insurance commissioner, superintendent, or comparable State authority.

§ 158.322 Proposal for adjusted medical loss ratio.

A State must provide its own proposal as to the adjustment it seeks to the MLR standard. This proposal must include:

(a) An explanation and justification of how the proposed adjustment to the MLR was determined;

(b) An explanation of how an adjustment to the MLR standard for the State's individual market will permit issuers to adjust current business models and practices in order to meet an 80 percent MLR as soon as is practicable;

(c) An estimate of the rebates that would be paid if the issuers offering coverage in the individual market in the State must meet an 80 percent MLR for the applicable MLR reporting years; and

(d) An estimate of the rebates that would be paid if the issuers offering coverage in the individual market in the State must meet the adjusted MLR proposed by the State for the applicable MLR reporting years.

§ 158.323 State contact information.

A State must provide the name, telephone number, e-mail address, and mailing address of the person the Secretary may contact regarding the request for an adjustment to the MLR standard.

§ 158.330 Criteria for assessing request for adjustment to the medical loss ratio.

The Secretary may consider the following criteria in assessing whether application of an 80 percent MLR, as calculated in accordance with this subpart, may destabilize the individual market in a State that has requested an adjustment to the 80 percent MLR:

(a) The number of issuers reasonably likely to exit the State or to cease offering coverage in the State absent an adjustment to the 80 percent MLR and the resulting impact on competition in the State. In making this determination the Secretary may consider as to each issuer that is reasonably likely to exit the State:

(1) Each issuer's MLR relative to an 80 percent MLR;

(2) Each issuer's solvency and profitability, as measured by factors such as surplus level, risked-based capital ratio, net income, and operating or underwriting gain;

(3) The requirements and limitations within the State with respect to market withdrawals; and

(4) Whether each issuer covers less than 1,000 life-years in the State's individual insurance market.

(b) The number of individual market enrollees covered by issuers that are reasonably likely to exit the State absent an adjustment to the 80 percent MLR.

(c) Whether absent an adjustment to the 80 percent MLR standard consumers may be unable to access agents and brokers.

(d) The alternate coverage options within the State available to individual market enrollees in the event an issuer exits the market, including:

(1) Any requirement that issuers who exit the State's individual market must have their block(s) of business assumed by another issuer;

(2) The issuers that may remain in the State subsequent to the implementation of the 80 percent MLR, as calculated in accordance with this Part, and the nature, terms, and price of the products offered by such issuers;

(3) The capacity of remaining issuers to write additional business, as measured by their risk based capital ratios;

(4) The mechanisms, such as guaranteed issue products, an issuer of last resort, or a State high risk pool, available to the State to provide coverage to consumers in the event of an issuer withdrawing from the market, and the affordability of these options compared to the coverage provided by exiting or potentially exiting issuers; and

(5) Any authority the State's insurance commissioner, superintendent, or comparable official may exercise with respect to stabilization of the individual insurance market.

(e) The impact on premiums charged, and on benefits and cost-sharing provided, to consumers by issuers remaining in the market in the event one or more issuers were to withdraw from the market.

(f) Any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

§ 158.340 Process for submitting request for adjustment to the medical loss ratio.

(a) *Electronic submission*. A State must submit electronically, to an address and in a format prescribed by the Secretary, all of the information required by this subpart in order for its request for an adjustment to the MLR standard for its individual market to be considered by the Secretary.

(b) *Submission by mail*. A State may also submit by overnight delivery service or by U.S mail, return receipt requested, to an address and in a format prescribed by the Secretary, its request for an adjustment to the MLR standard for its individual market.

§ 158.341 Treatment as a public document.

A State's request for an adjustment to the MLR standard, and all information submitted as part of its request, will be treated as a public document and will be posted promptly on the Secretary's Internet Web site devoted to health care coverage.

§ 158.342 Invitation for public comments.

The Secretary will invite public comment regarding a State's request for an adjustment to the MLR standard. All public comments must be submitted in writing within 10 days of the posting of the request, and must be submitted in the manner prescribed by the Secretary. The Secretary will consider timely public comments in assessing a State's request for an adjustment to the MLR standard.

§ 158.343 Optional State hearing.

Any State that submits a request for adjustment to the MLR standard may, at its option, hold a public hearing and create an evidentiary record with respect to its application. If a State does so, the Secretary will take the evidentiary record of the hearing into consideration in making her determination.

§ 158.344 Secretary's discretion to hold a hearing.

The Secretary may, at her discretion, conduct a public hearing with respect to a State's request for an adjustment to the MLR standard. All testimony and materials received in connection with any public hearing will be made part of the public record, and shall be considered by the Secretary in assessing a State's request for an adjustment to the MLR standard.

§ 158.345 Determination on a State's request for adjustment to the medical loss ratio.

(a) *General time frame*. The Secretary will make a determination as to whether to grant a State's request for an adjustment to the MLR standard within 30 days after determining that the information required by this subpart has been received.

(b) *Extension at the discretion of the Secretary*. The Secretary may, in her discretion, extend the 30 day time period in paragraph (a) of this section for as long a time as necessary not to exceed 30 days.

§ 158.346 Request for reconsideration.

(a) *Requesting reconsideration.* A State whose request for adjustment to the MLR standard has been denied by the Secretary may request reconsideration of that determination. A request for reconsideration must be submitted in writing to the Secretary within 10 days of her decision to deny the State's request for an adjustment, and may include any additional information in support of its request.

(b) *Reconsideration determination.* The Secretary will issue her determination on a State's request for reconsideration within 20 days of receiving the reconsideration request.

§ 158.350 Subsequent requests for adjustment to the medical loss ratio.

A State that has made a previous request for an adjustment to the MLR standard must, in addition to the other information required by this subpart, submit information as to what steps the State has taken since its initial and other prior requests, if any, to increase the likelihood that enrollees who have health coverage through issuers that are considered likely to exit the State's individual market will receive coverage at a comparable price and with comparable benefits if the issuer does exit the market.

Subpart D—HHS Enforcement

§ 158.401 HHS enforcement.

HHS enforces the reporting and rebate requirements described in subparts A and B, including but not limited to:

(a) The requirement that such reports be submitted timely.

(b) The requirement that the data reported complies with the definitions and criteria set forth in this part.

(c) The requirement that rebates be paid timely and accurately.

§ 158.402 Audits.

(a) *Notice of Audit.* HHS will provide 30 days advance notice of its intent to conduct an audit of an issuer.

(b) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(c) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, which will then have 30 days to respond to such findings. HHS may extend, for good cause, the time for an issuer to submit such a response.

(d) *Final Audit Findings.* If the issuer does not dispute the preliminary findings, the audit findings will become final. Alternatively, if the issuer responds to the preliminary findings, HHS will review and consider such response and finalize the audit findings.

(e) *Corrective actions.* HHS will send a copy of the final audit findings to the issuer as well as any corrective actions that issuer must undertake as a result of the audit findings.

(f) *Order to pay rebates.* If HHS determines as the result of an audit that an issuer has failed to pay rebates it is obligated to pay pursuant to this part, it may order the issuer to pay those rebates, together with interest from the date the rebates were due, in accordance with § 158.240(d) of this part.

§ 158.403 Circumstances in which a State is conducting audits of issuers.

(a) If a State conducts an audit of an issuer's MLR reporting and rebate obligations, HHS may, in the exercise of its discretion, accept the findings of that audit if HHS determines the following:

(1) The laws of the State permit public release of the findings of audits of issuers;

(2) The State's audit reports on the validity of the data regarding expenses and premiums that the issuer reported to the Secretary, including the appropriateness of the allocations of expenses used in such reporting and whether the activities associated with the issuer's reported expenditures for quality improving activities meet the definition of such activities;

(3) The State's audit reports on the accuracy of rebate calculations and the timeliness and accuracy of rebate payments;

(4) The State submits final audit reports to HHS within 30 days of finalization; and

(5) The State submits preliminary or draft audit reports to HHS within 6 months of the completion of audit field work unless they have already been finalized and reported under paragraph (a)(4) of this section.

(b) If HHS accepts an audit conducted by a State, and if the issuer makes additional rebate payments as a result of the audit, then HHS shall accept those payments as satisfying the issuer's obligation to pay rebates pursuant to this part.

Subpart E—Additional Requirements on Issuers

§ 158.501 Access to facilities and records.

(a) Each issuer subject to the reporting requirement of this part must allow access and entry to its premises, facilities and records, including computer and other electronic systems, to HHS, the Comptroller General, or their designees to evaluate, through inspection, audit, or other means, compliance with the requirements for reporting and calculation of data submitted to HHS, and the timeliness and accuracy of rebate payments made under this part.

(b) Each issuer must also allow access and entry to the facilities and records, including computer and other electronic systems, of its parent organization, subsidiaries, related entities, contractors, subcontractors, agents, or a transferee that pertain to any aspect of the data reported to HHS or to rebate payments calculated and made under this part. To the extent that the issuer does not control access to the facilities and records of its parent organization, related entities, or third parties, it will be the responsibility of the issuer to contractually obligate any such parent organization, related entities, or third parties to grant said access.

(c) The Comptroller General, HHS, or their designees may inspect, evaluate, and audit through 6 years from the date of the filing of a report required by this part or through 3 years after the completion of the audit and for such longer period set forth below provided that any of the following occur:

(1) HHS determines there is a special need to retain a particular record or group of records for a longer period and notifies the issuer at least 30 days before the disposition date.

(2) There has been a dispute, or allegation of fraud or similar fault by the issuer, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the dispute, fraud, or similar fault.

(3) HHS determines that there is a reasonable possibility of fraud or similar fault, in which case HHS may inspect, evaluate, and audit the issuer at any time.

§ 158.502 Maintenance of records.

(a) *Basic rule.* Each issuer subject to the requirements of this part must maintain all documents and other evidence necessary to enable HHS to verify that the data required to be submitted in accordance with this part comply with the definitions and criteria set forth in this part, and that the MLR is calculated and any rebates owing are calculated and provided in accordance with this part. This includes but is not limited to all administrative and financial books and records used in compiling data reported and rebates provided under this part and in determining what data to report and rebates to provide under this part, electronically stored information, and evidence of accounting procedures and practices. This also includes all administrative and financial books and records used by others in assisting an issuer with its obligations under this part.

(b) *Length of time information must be maintained.* All of the documents and other evidence required by this part must be maintained for the current year and six prior years, unless a longer time is required under § 158.501 of this subpart.

Subpart F—Federal Civil Penalties

§ 158.601 General rule regarding the imposition of civil penalties.

If any issuer fails to comply with the requirements of this part, civil penalties, as described in this subpart, may be imposed.

§ 158.602 Basis for imposing civil penalties.

Civil penalties. For the violations listed in this paragraph, HHS may impose civil penalties in the amounts specified in § 158.606 of this subpart on any issuer who fails to do the following:

(a) Submit to HHS a report concerning the data required under this part by the deadline established by HHS.

(b) Submit to HHS a substantially complete or accurate report concerning the data required under this part.

(c) Timely and accurately pay rebates owing pursuant to this part.

(d) Respond to HHS inquiries as part of an investigation of issuer non-compliance.

(e) Maintain records as required under this part for the periodic auditing of books and records used in compiling data reported to HHS and in calculating and paying rebates pursuant to this Part.

(f) Allow access and entry to premises, facilities and records that pertain to any aspect of the data reported to HHS or to rebates calculated and paid pursuant to this part.

(g) Comply with corrective actions resulting from audit findings.

(h) Accurately and truthfully represent data, reports or other information that it furnishes to a State or HHS.

§ 158.603 Notice to responsible entities.

If HHS learns of a potential violation described in § 158.602 of this subpart or if a State informs HHS of a potential violation prior to imposing any civil monetary penalty HHS must provide written notice to the issuer, to include the following:

(a) Describe the potential violation.

(b) Provide 30 days from the date of the notice for the responsible entity to respond and to provide additional information to refute an alleged violation.

(c) State that a civil monetary penalty may be assessed if the allegations are not, as determined by HHS, refuted.

§ 158.604 Request for extension.

In circumstances in which an entity cannot prepare a response to HHS within the 30 days provided in the notice, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the extension, the responsible entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in HHS's imposition of a civil monetary penalty based upon its determination of a potential violation described in § 158.602 of this subpart.

§ 158.605 Responses to allegations of noncompliance.

In determining whether to impose a civil monetary penalty, HHS may review and consider documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with Affordable Care Act requirements. The following are examples of documentation that a potential responsible entity may submit for HHS's consideration in determining whether a civil monetary penalty should be assessed and the amount of any civil monetary penalty:

(a) Any evidence that refutes an alleged noncompliance.

(b) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(c) Evidence documenting the development and implementation of internal policies and procedures by an issuer to ensure compliance with the Affordable Care Act requirements regarding MLR. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with Affordable Care Act requirements regarding MLRs and to provide reasonable assurance that

fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(d) Evidence documenting the entity's record of previous compliance with Affordable Care Act requirements regarding MLRs.

§ 158.606 Amount of penalty—general.

A civil monetary penalty for each violation of § 158.602 of this subpart may not exceed $100 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this Part are in addition to any other penalties prescribed or allowed by law.

§ 158.607 Factors HHS uses to determine the amount of penalty.

In determining the amount of any penalty, HHS may take into account the following:

(a) *The entity's previous record of compliance*. This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation(s), HHS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of Affordable Care Act requirements regarding minimum loss ratios.

(2) Evidence that the responsible entity has never had a complaint for noncompliance with Affordable Care Act requirements regarding MLRs filed with a State or HHS.

(3) Such other factors as justice may require.

(b) *The gravity of the violation*. This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

§ 158.608 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by § 158.606 of this subpart to reflect that fact. As guidelines for taking into account the factors listed in § 158.607 of this subpart, HHS considers the following:

(a) *Record of prior compliance*. It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under § 158.603 of this subpart, implemented and followed a compliance plan as described in § 158.605(c) of this subpart.

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s)*. It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with the requirements of this Part so that the following occur:

(i) Each enrollee adversely affected by the violation has been paid any amount of rebate owed so that, to the extent practicable, that enrollee is in the same position that he, she, or it would have been in had the violation not occurred.

(ii) The rebate payments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from HHS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

§ 158.609 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several aggravating circumstances, HHS may set the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by § 158.606 of this subpart to reflect that fact. HHS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 158.610 Determining the amount of penalty—other matters as justice may require.

HHS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this Part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 158.611 Settlement authority.

Nothing in § 158.606 through § 158.610 of this subpart limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with § 158.603 of this subpart or to compromise on any penalty provided for in §§ 158.606 through 158.610 of this subpart.

§ 158.612 Limitations on penalties.

(a) *Circumstances under which a civil monetary penalty is not imposed.* HHS does not impose any civil monetary penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. HHS also may not impose a civil monetary penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to HHS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 158.613 Notice of proposed penalty.

(a) *Contents of notice.* If HHS proposes to assess a penalty in accordance with this Part, it must provide the issuer written notice of its intent to assess a penalty, which includes the following:

(1) A description of the requirements under this Part that HHS has determined the issuer violated.

(2) A description of the information upon which HHS based its determination, including the basis for determining the number of affected individuals and the number of days or weeks for which the violations occurred.

(3) The amount of the proposed penalty as of the date of the notice.

(4) Any considerations described in § 158.607 through § 158.610 of this subpart that were taken into account in determining the amount of the proposed penalty.

(5) A specific statement of the issuer's right to a hearing.

(6) A statement that failure to request a hearing within 30 days after the date of the notice permits the assessment of the proposed penalty without right of appeal in accordance with § 158.615 of this subpart.

(b) *Delivery of Notice.* This notice must be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required.

§ 158.614 Appeal of proposed penalty.

Any issuer against which HHS has assessed a penalty under this Part may appeal that penalty in accordance with § 150.400 *et seq*.

§ 158.615 Failure to request a hearing.

If the issuer does not request a hearing within 30 days of the issuance of the notice described in § 158.613 of this subpart, HHS may assess the proposed civil monetary penalty indicated in such notice and may impose additional penalties as described in § 158.606 of this subpart. HHS must notify the issuer in writing of any penalty that has been assessed and of the means by which the issuer may satisfy the penalty. The issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 of this subchapter, unless the responsible entity can show good cause, as determined at § 150.405(b) of this subchapter, for failing to timely exercise its right to a hearing.

PART 159—HEALTH CARE REFORM INSURANCE WEB PORTAL

Sec.
159.100 Basis and Scope.
159.110 Definitions.
159.120 Data Submission for the individual and small group markets.

AUTHORITY: Section 1103 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

SOURCE: 75 FR 24482, May 5, 2010, unless otherwise noted.

§ 159.100 Basis and scope.

This part establishes provisions governing a Web portal that will provide information on health insurance coverage options in each of the 50 States and the District of Columbia. It sets forth data submission requirements for health insurance issuers. It covers the individual market and the small group market.

§ 159.110 Definitions.

For purposes of part 159, the following definitions apply unless otherwise provided:

Health Insurance Coverage: We adopt the Public Health Service Act (PHSA) definition of ''health insurance coverage'' found at section 2791(b)(1) of the Public Health Service Act (PHSA).

Health Insurance Issuer: We adopt the PHSA definition of ''health insurance issuer'' found at section 2791(b)(2) of the PHSA.

Health Insurance Product: Means a package of benefits that an issuer offers that is reported to State regulators in an insurance filing.

Individual Health Insurance Coverage: We adopt the PHSA definition of ''individual health insurance coverage'' found at section 2791(b)(5) of the PHSA.

Individual Market: We adopt the Affordable Care Act definition of ''individual market'' found at section 1304(a)(2) of the Affordable Care Act and 2791(e)(1)(A) of the PHSA.

Portal Plan: Means the discrete pairing of a package of benefits and a particular cost sharing option (not including premium rates or premium quotes).

Section 1101 High Risk Pools: We define section 1101 high risk pools as any entity described in regulations implementing section 1101 of the Affordable Care Act.

Small Employer: We adopt the Affordable Care Act definition of ''small employer'' found at section 1304(b)(2) and (3).

Small Group Coverage: Means health insurance coverage offered to employees of small employers in the small group market.

Small Group Market: We adopt the Affordable Care Act definition of ''small group market'' found at section 1304(a)(3).

State Health Benefits High Risk Pools: Means nonprofit organizations created by State law to offer comprehensive health insurance to individuals who otherwise would be unable to secure such coverage because of their health status.

§ 159.120 Data submission for the individual and small group markets.

(a) Health insurance issuers (hereinafter referred to as issuers) must, in accordance with guidance issued by the Secretary, submit corporate and contact information; administrative information; enrollment data by health insurance product; product names and types; whether enrollment is currently

open for each health insurance product; geographic availability information; customer service phone numbers; and Web site links to the issuer Web site, brochure documents, and provider networks; and financial ratings on or before May 21, 2010, and annually thereafter.

(b) Issuers must, as determined by the Secretary, submit pricing and benefit information for their portal plans on or before September 3, 2010, and annually thereafter.

(c) Issuers must submit updated pricing and benefit data for their portal plans whenever they change premiums, cost-sharing, types of services covered, coverage limitations, or exclusions for one or more of their individual or small group portal plans.

(d) Issuers must submit pricing and benefit data for portal plans associated with products that are newly open or newly reopened for enrollment within 30 days of opening for enrollment.

(e) Issuers must annually verify the data submitted under paragraphs (a) through (d) of this section, and make corrections to any errors that are found.

(f) Issuers must submit administrative data on products and portal plans, and these performance ratings, percent of individual market and small group market policies that are rescinded; the percent of individual market policies sold at the manual rate; the percent of claims that are denied under individual market and small group market policies; and the number and disposition of appeals on denials to insure, pay claims and provide required preauthorizations, for future releases of the Web portal in accordance with guidance issued by the Secretary.

(g) The issuer's CEO or CFO must electronically certify to the completeness and accuracy of all data submitted for the October 1, 2010, release of the Web portal and for any future updates to these requirements.

SUBCHAPTER C—ADMINISTRATIVE DATA STANDARDS AND RELATED REQUIREMENTS

PART 160—GENERAL ADMINISTRATIVE REQUIREMENTS

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160.552 Harmless error.

AUTHORITY: 42 U.S.C. 1302(a), 42 U.S.C. 1320d–1320d–8, sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2 (note)), 5 U.S.C. 552; secs. 13400 and 13402, Pub. L. 111–5, 123 Stat. 258–263, and sec. 1104 of Pub. L. 111–148, 124 Stat. 146–154.

SOURCE: 65 FR 82798, Dec. 28, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 160.101 Statutory basis and purpose.

The requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104–191, section 264 of Public Law 104–191, section 13402 of Public Law 111–5, section 13410(d) of Public Law 111–5, and section 1104 of Public Law 111–148.

[74 FR 56130, Oct. 30, 2009, as amended at 76 FR 40495, July 8, 2011]

§ 160.102 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) To the extent required under the Social Security Act, 42 U.S.C. 1320a–7c(a)(5), nothing in this subchapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978, as amended (5 U.S.C. App.).

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 160.103 Definitions.

Except as otherwise provided, the following definitions apply to this subchapter:

Act means the Social Security Act.

ANSI stands for the American National Standards Institute.

Business associate: (1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:

(i) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:

(A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or

(B) Any other function or activity regulated by this subchapter; or

(ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.

(3) A covered entity may be a business associate of another covered entity.

CMS stands for Centers for Medicare & Medicaid Services within the Department of Health and Human Services.

Compliance date means the date by which a covered entity must comply with a standard, implementation specification, requirement, or modification adopted under this subchapter.

Covered entity means:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

Disclosure means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.

EIN stands for the employer identification number assigned by the Internal Revenue Service, U.S. Department of the Treasury. The EIN is the taxpayer identifying number of an individual or other entity (whether or not an employer) assigned under one of the following:

(1) 26 U.S.C. 6011(b), which is the portion of the Internal Revenue Code dealing with identifying the taxpayer in tax returns and statements, or corresponding provisions of prior law.

(2) 26 U.S.C. 6109, which is the portion of the Internal Revenue Code dealing

with identifying numbers in tax returns, statements, and other required documents.

Electronic media means:

(1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

Electronic protected health information means information that comes within paragraphs (1)(i) or (1)(ii) of the definition of *protected health information* as specified in this section.

Employer is defined as it is in 26 U.S.C. 3401(d).

Group health plan (also see definition of *health plan* in this section) means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300gg–91(a)(2)), including items and services paid for as medical care, to employees or their dependents directly or through insurance, reimbursement, or otherwise, that:

(1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or

(2) Is administered by an entity other than the employer that established and maintains the plan.

HHS stands for the Department of Health and Human Services.

Health care means care, services, or supplies related to the health of an individual. *Health care* includes, but is not limited to, the following:

(1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and

(2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

Health care clearinghouse means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and ''value-added'' networks and switches, that does either of the following functions:

(1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

(2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

Health care provider means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

Health information means any information, whether oral or recorded in any form or medium, that:

(1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Health insurance issuer (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300gg–91(b)(2) and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.

Health maintenance organization (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg–91(b)(3) and used in the definition of *health plan* in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.

Health plan means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(1) *Health plan* includes the following, singly or in combination:

(i) A group health plan, as defined in this section.

(ii) A health insurance issuer, as defined in this section.

(iii) An HMO, as defined in this section.

(iv) Part A or Part B of the Medicare program under title XVIII of the Act.

(v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, *et seq*.

(vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).

(vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.

(viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

(ix) The health care program for active military personnel under title 10 of the United States Code.

(x) The veterans health care program under 38 U.S.C. chapter 17.

(xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) (as defined in 10 U.S.C. 1072(4)).

(xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, *et seq*.

(xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, *et seq*.

(xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, *et seq*.

(xv) The Medicare+Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w–21 through 1395w–28.

(xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.

(xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg–91(a)(2)).

(2) *Health plan* excludes:

(i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg–91(c)(1); and

(ii) A government-funded program (other than one listed in paragraph (1)(i)–(xvi) of this definition):

(A) Whose principal purpose is other than providing, or paying the cost of, health care; or

(B) Whose principal activity is:

(1) The direct provision of health care to persons; or

(2) The making of grants to fund the direct provision of health care to persons.

Implementation specification means specific requirements or instructions for implementing a standard.

Individual means the person who is the subject of protected health information.

Individually identifiable health information is information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

Modify or *modification* refers to a change adopted by the Secretary, through regulation, to a standard or an implementation specification.

Organized health care arrangement means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Person means a natural person, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Protected health information means individually identifiable health information:

(1) Except as provided in paragraph (2) of this definition, that is:

(i) Transmitted by electronic media;

(ii) Maintained in electronic media; or

(iii) Transmitted or maintained in any other form or medium.

(2) *Protected health information* excludes individually identifiable health information in:

(i) Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. 1232g;

(ii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and

(iii) Employment records held by a covered entity in its role as employer.

Secretary means the Secretary of Health and Human Services or any other officer or employee of HHS to whom the authority involved has been delegated.

Small health plan means a health plan with annual receipts of $5 million or less.

Standard means a rule, condition, or requirement:

(1) Describing the following information for products, systems, services or practices:

(i) Classification of components.

(ii) Specification of materials, performance, or operations; or

(iii) Delineation of procedures; or

(2) With respect to the privacy of individually identifiable health information.

(3) With the exception of operating rules as defined at § 162.103.

Standard setting organization (SSO) means an organization accredited by the American National Standards Institute that develops and maintains standards for information transactions or data elements, or any other standard that is necessary for, or will facilitate the implementation of, this part.

State refers to one of the following:

(1) For a health plan established or regulated by Federal law, State has the meaning set forth in the applicable section of the United States Code for such health plan.

(2) For all other purposes, *State* means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam.

Trading partner agreement means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

Transaction means the transmission of information between two parties to carry out financial or administrative activities related to health care. It includes the following types of information transmissions:

(1) Health care claims or equivalent encounter information.

(2) Health care payment and remittance advice.

(3) Coordination of benefits.

(4) Health care claim status.

(5) Enrollment and disenrollment in a health plan.

(6) Eligibility for a health plan.

(7) Health plan premium payments.

(8) Referral certification and authorization.

(9) First report of injury.

(10) Health claims attachments.

(11) Health care electronic funds transfers (EFT) and remittance advice.

(12) Other transactions that the Secretary may prescribe by regulation.

Use means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

Workforce means employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a covered entity, is under the direct control of such entity, whether or not they are paid by the covered entity.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002; 67 FR 53266, Aug. 14, 2002; 68 FR 8374, Feb. 20, 2003; 71 FR 8424, Feb. 16, 2006; 76 FR 40495, July 8, 2011; 77 FR 1589, Jan.10, 2012]

§ 160.104 Modifications.

(a) Except as provided in paragraph (b) of this section, the Secretary may adopt a modification to a standard or implementation specification adopted under this subchapter no more frequently than once every 12 months.

(b) The Secretary may adopt a modification at any time during the first year after the standard or implementation specification is initially adopted, if the Secretary determines that the modification is necessary to permit compliance with the standard or implementation specification.

(c) The Secretary will establish the compliance date for any standard or implementation specification modified under this section.

(1) The compliance date for a modification is no earlier than 180 days after the effective date of the final rule in which the Secretary adopts the modification.

(2) The Secretary may consider the extent of the modification and the time needed to comply with the modification in determining the compliance date for the modification.

(3) The Secretary may extend the compliance date for small health plans, as the Secretary determines is appropriate.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 38019, May 31, 2002]

Subpart B—Preemption of State Law

§ 160.201 Applicability.

The provisions of this subpart implement section 1178 of the Act, as added by section 262 of Public Law 104–191.

§ 160.202 Definitions.

For purposes of this subpart, the following terms have the following meanings:

Contrary, when used to compare a provision of State law to a standard, requirement, or implementation specification adopted under this subchapter, means:

(1) A covered entity would find it impossible to comply with both the State and federal requirements; or

(2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of part C of title XI of the Act, section 264 of Public Law 104–191, or section 13402 of Public Law 111–5, as applicable.

More stringent means, in the context of a comparison of a provision of State law and a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter, a State law that meets one or more of the following criteria:

(1) With respect to a use or disclosure, the law prohibits or restricts a use or disclosure in circumstances under which such use or disclosure otherwise would be permitted under this subchapter, except if the disclosure is:

(i) Required by the Secretary in connection with determining whether a covered entity is in compliance with this subchapter; or

(ii) To the individual who is the subject of the individually identifiable health information.

(2) With respect to the rights of an individual, who is the subject of the individually identifiable health information, regarding access to or amendment of individually identifiable health information, permits greater rights of access or amendment, as applicable.

(3) With respect to information to be provided to an individual who is the subject of the individually identifiable health information about a use, a disclosure, rights, and remedies, provides the greater amount of information.

(4) With respect to the form, substance, or the need for express legal permission from an individual, who is the subject of the individually identifiable health information, for use or disclosure of individually identifiable health information, provides requirements that narrow the scope or duration, increase the privacy protections afforded (such as by expanding the criteria for), or reduce the coercive effect of the circumstances surrounding the express legal permission, as applicable.

(5) With respect to recordkeeping or requirements relating to accounting of disclosures, provides for the retention or reporting of more detailed information or for a longer duration.

(6) With respect to any other matter, provides greater privacy protection for the individual who is the subject of the individually identifiable health information.

Relates to the privacy of individually identifiable health information means, with respect to a State law, that the State law has the specific purpose of protecting the privacy of health information or affects the privacy of health information in a direct, clear, and substantial way.

State law means a constitution, statute, regulation, rule, common law, or other State action having the force and effect of law.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 74 FR 42767, Aug. 24, 2009]

§ 160.203 General rule and exceptions.

A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of State law preempts the provision of State law. This general rule applies, except if one or more of the following conditions is met:

(a) A determination is made by the Secretary under § 160.204 that the provision of State law:

(1) Is necessary:

(i) To prevent fraud and abuse related to the provision of or payment for health care;

(ii) To ensure appropriate State regulation of insurance and health plans to

the extent expressly authorized by statute or regulation;

(iii) For State reporting on health care delivery or costs; or

(iv) For purposes of serving a compelling need related to public health, safety, or welfare, and, if a standard, requirement, or implementation specification under part 164 of this subchapter is at issue, if the Secretary determines that the intrusion into privacy is warranted when balanced against the need to be served; or

(2) Has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. 802), or that is deemed a controlled substance by State law.

(b) The provision of State law relates to the privacy of individually identifiable health information and is more stringent than a standard, requirement, or implementation specification adopted under subpart E of part 164 of this subchapter.

(c) The provision of State law, including State procedures established under such law, as applicable, provides for the reporting of disease or injury, child abuse, birth, or death, or for the conduct of public health surveillance, investigation, or intervention.

(d) The provision of State law requires a health plan to report, or to provide access to, information for the purpose of management audits, financial audits, program monitoring and evaluation, or the licensure or certification of facilities or individuals.

[65 FR 82798, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002]

§ 160.204 Process for requesting exception determinations.

(a) A request to except a provision of State law from preemption under § 160.203(a) may be submitted to the Secretary. A request by a State must be submitted through its chief elected official, or his or her designee. The request must be in writing and include the following information:

(1) The State law for which the exception is requested;

(2) The particular standard, requirement, or implementation specification for which the exception is requested;

(3) The part of the standard or other provision that will not be implemented based on the exception or the additional data to be collected based on the exception, as appropriate;

(4) How health care providers, health plans, and other entities would be affected by the exception;

(5) The reasons why the State law should not be preempted by the federal standard, requirement, or implementation specification, including how the State law meets one or more of the criteria at § 160.203(a); and

(6) Any other information the Secretary may request in order to make the determination.

(b) Requests for exception under this section must be submitted to the Secretary at an address that will be published in the FEDERAL REGISTER. Until the Secretary's determination is made, the standard, requirement, or implementation specification under this subchapter remains in effect.

(c) The Secretary's determination under this section will be made on the basis of the extent to which the information provided and other factors demonstrate that one or more of the criteria at § 160.203(a) has been met.

§ 160.205 Duration of effectiveness of exception determinations.

An exception granted under this subpart remains in effect until:

(a) Either the State law or the federal standard, requirement, or implementation specification that provided the basis for the exception is materially changed such that the ground for the exception no longer exists; or

(b) The Secretary revokes the exception, based on a determination that the ground supporting the need for the exception no longer exists.

Subpart C—Compliance and Investigations

SOURCE: 71 FR 8424, Feb. 16, 2006, unless otherwise noted.

§ 160.300 Applicability.

This subpart applies to actions by the Secretary, covered entities, and others with respect to ascertaining the compliance by covered entities with, and the enforcement of, the applicable

provisions of this part 160 and parts 162 and 164 of this subchapter.

§ 160.302 Definitions.

As used in this subpart and subparts D and E of this part, the following terms have the following meanings:

Administrative simplification provision means any requirement or prohibition established by:

(1) 42 U.S.C. 1320d—1320d–4, 1320d–7, and 1320d–8;

(2) Section 264 of Pub. L. 104–191; or

(3) This subchapter.

ALJ means Administrative Law Judge.

Civil money penalty or *penalty* means the amount determined under § 160.404 of this part and includes the plural of these terms.

Respondent means a covered entity upon which the Secretary has imposed, or proposes to impose, a civil money penalty.

Violation or *violate* means, as the context may require, failure to comply with an administrative simplification provision.

§ 160.304 Principles for achieving compliance.

(a) *Cooperation.* The Secretary will, to the extent practicable, seek the cooperation of covered entities in obtaining compliance with the applicable administrative simplification provisions.

(b) *Assistance.* The Secretary may provide technical assistance to covered entities to help them comply voluntarily with the applicable administrative simplification provisions.

§ 160.306 Complaints to the Secretary.

(a) *Right to file a complaint.* A person who believes a covered entity is not complying with the administrative simplification provisions may file a complaint with the Secretary.

(b) *Requirements for filing complaints.* Complaints under this section must meet the following requirements:

(1) A complaint must be filed in writing, either on paper or electronically.

(2) A complaint must name the person that is the subject of the complaint and describe the acts or omissions believed to be in violation of the applicable administrative simplification provision(s).

(3) A complaint must be filed within 180 days of when the complainant knew or should have known that the act or omission complained of occurred, unless this time limit is waived by the Secretary for good cause shown.

(4) The Secretary may prescribe additional procedures for the filing of complaints, as well as the place and manner of filing, by notice in the FEDERAL REGISTER.

(c) *Investigation.* The Secretary may investigate complaints filed under this section. Such investigation may include a review of the pertinent policies, procedures, or practices of the covered entity and of the circumstances regarding any alleged violation. At the time of initial written communication with the covered entity about the complaint, the Secretary will describe the act(s) and/or omission(s) that are the basis of the complaint.

§ 160.308 Compliance reviews.

The Secretary may conduct compliance reviews to determine whether covered entities are complying with the applicable administrative simplification provisions.

§ 160.310 Responsibilities of covered entities.

(a) *Provide records and compliance reports.* A covered entity must keep such records and submit such compliance reports, in such time and manner and containing such information, as the Secretary may determine to be necessary to enable the Secretary to ascertain whether the covered entity has complied or is complying with the applicable administrative simplification provisions.

(b) *Cooperate with complaint investigations and compliance reviews.* A covered entity must cooperate with the Secretary, if the Secretary undertakes an investigation or compliance review of the policies, procedures, or practices of the covered entity to determine whether it is complying with the applicable administrative simplification provisions.

(c) *Permit access to information.* (1) A covered entity must permit access by the Secretary during normal business hours to its facilities, books, records,

accounts, and other sources of information, including protected health information, that are pertinent to ascertaining compliance with the applicable administrative simplification provisions. If the Secretary determines that exigent circumstances exist, such as when documents may be hidden or destroyed, a covered entity must permit access by the Secretary at any time and without notice.

(2) If any information required of a covered entity under this section is in the exclusive possession of any other agency, institution, or person and the other agency, institution, or person fails or refuses to furnish the information, the covered entity must so certify and set forth what efforts it has made to obtain the information.

(3) Protected health information obtained by the Secretary in connection with an investigation or compliance review under this subpart will not be disclosed by the Secretary, except if necessary for ascertaining or enforcing compliance with the applicable administrative simplification provisions, or if otherwise required by law.

§ 160.312 Secretarial action regarding complaints and compliance reviews.

(a) *Resolution when noncompliance is indicated.* (1) If an investigation of a complaint pursuant to § 160.306 or a compliance review pursuant to § 160.308 indicates noncompliance, the Secretary will attempt to reach a resolution of the matter satisfactory to the Secretary by informal means. Informal means may include demonstrated compliance or a completed corrective action plan or other agreement.

(2) If the matter is resolved by informal means, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing.

(3) If the matter is not resolved by informal means, the Secretary will—

(i) So inform the covered entity and provide the covered entity an opportunity to submit written evidence of any mitigating factors or affirmative defenses for consideration under §§ 160.408 and 160.410 of this part. The covered entity must submit any such evidence to the Secretary within 30 days (computed in the same manner as prescribed under § 160.526 of this part) of receipt of such notification; and

(ii) If, following action pursuant to paragraph (a)(3)(i) of this section, the Secretary finds that a civil money penalty should be imposed, inform the covered entity of such finding in a notice of proposed determination in accordance with § 160.420 of this part.

(b) *Resolution when no violation is found.* If, after an investigation pursuant to § 160.306 or a compliance review pursuant to § 160.308, the Secretary determines that further action is not warranted, the Secretary will so inform the covered entity and, if the matter arose from a complaint, the complainant, in writing.

§ 160.314 Investigational subpoenas and inquiries.

(a) The Secretary may issue subpoenas in accordance with 42 U.S.C. 405(d) and (e), 1320a–7a(j), and 1320d–5 to require the attendance and testimony of witnesses and the production of any other evidence during an investigation or compliance review pursuant to this part. For purposes of this paragraph, a person other than a natural person is termed an ''entity.''

(1) A subpoena issued under this paragraph must—

(i) State the name of the person (including the entity, if applicable) to whom the subpoena is addressed;

(ii) State the statutory authority for the subpoena;

(iii) Indicate the date, time, and place that the testimony will take place;

(iv) Include a reasonably specific description of any documents or items required to be produced; and

(v) If the subpoena is addressed to an entity, describe with reasonable particularity the subject matter on which testimony is required. In that event, the entity must designate one or more natural persons who will testify on its behalf, and must state as to each such person that person's name and address and the matters on which he or she will testify. The designated person must testify as to matters known or reasonably available to the entity.

(2) A subpoena under this section must be served by—

(i) Delivering a copy to the natural person named in the subpoena or to the entity named in the subpoena at its last principal place of business; or

(ii) Registered or certified mail addressed to the natural person at his or her last known dwelling place or to the entity at its last known principal place of business.

(3) A verified return by the natural person serving the subpoena setting forth the manner of service or, in the case of service by registered or certified mail, the signed return post office receipt, constitutes proof of service.

(4) Witnesses are entitled to the same fees and mileage as witnesses in the district courts of the United States (28 U.S.C. 1821 and 1825). Fees need not be paid at the time the subpoena is served.

(5) A subpoena under this section is enforceable through the district court of the United States for the district where the subpoenaed natural person resides or is found or where the entity transacts business.

(b) Investigational inquiries are nonpublic investigational proceedings conducted by the Secretary.

(1) Testimony at investigational inquiries will be taken under oath or affirmation.

(2) Attendance of non-witnesses is discretionary with the Secretary, except that a witness is entitled to be accompanied, represented, and advised by an attorney.

(3) Representatives of the Secretary are entitled to attend and ask questions.

(4) A witness will have the opportunity to clarify his or her answers on the record following questioning by the Secretary.

(5) Any claim of privilege must be asserted by the witness on the record.

(6) Objections must be asserted on the record. Errors of any kind that might be corrected if promptly presented will be deemed to be waived unless reasonable objection is made at the investigational inquiry. Except where the objection is on the grounds of privilege, the question will be answered on the record, subject to objection.

(7) If a witness refuses to answer any question not privileged or to produce requested documents or items, or engages in conduct likely to delay or obstruct the investigational inquiry, the Secretary may seek enforcement of the subpoena under paragraph (a)(5) of this section.

(8) The proceedings will be recorded and transcribed. The witness is entitled to a copy of the transcript, upon payment of prescribed costs, except that, for good cause, the witness may be limited to inspection of the official transcript of his or her testimony.

(9)(i) The transcript will be submitted to the witness for signature.

(A) Where the witness will be provided a copy of the transcript, the transcript will be submitted to the witness for signature. The witness may submit to the Secretary written proposed corrections to the transcript, with such corrections attached to the transcript. If the witness does not return a signed copy of the transcript or proposed corrections within 30 days (computed in the same manner as prescribed under § 160.526 of this part) of its being submitted to him or her for signature, the witness will be deemed to have agreed that the transcript is true and accurate.

(B) Where, as provided in paragraph (b)(8) of this section, the witness is limited to inspecting the transcript, the witness will have the opportunity at the time of inspection to propose corrections to the transcript, with corrections attached to the transcript. The witness will also have the opportunity to sign the transcript. If the witness does not sign the transcript or offer corrections within 30 days (computed in the same manner as prescribed under § 160.526 of this part) of receipt of notice of the opportunity to inspect the transcript, the witness will be deemed to have agreed that the transcript is true and accurate.

(ii) The Secretary's proposed corrections to the record of transcript will be attached to the transcript.

(c) Consistent with § 160.310(c)(3), testimony and other evidence obtained in an investigational inquiry may be used by HHS in any of its activities and may be used or offered into evidence in any administrative or judicial proceeding.

§ 160.316 Refraining from intimidation or retaliation.

A covered entity may not threaten, intimidate, coerce, harass, discriminate against, or take any other retaliatory action against any individual or other person for—

(a) Filing of a complaint under § 160.306;

(b) Testifying, assisting, or participating in an investigation, compliance review, proceeding, or hearing under this part; or

(c) Opposing any act or practice made unlawful by this subchapter, provided the individual or person has a good faith belief that the practice opposed is unlawful, and the manner of opposition is reasonable and does not involve a disclosure of protected health information in violation of subpart E of part 164 of this subchapter.

Subpart D—Imposition of Civil Money Penalties

SOURCE: 71 FR 8426, Feb. 16, 2006, unless otherwise noted.

§ 160.400 Applicability.

This subpart applies to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d–5.

§ 160.401 Definitions.

As used in this subpart, the following terms have the following meanings:

Reasonable cause means circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated.

Reasonable diligence means the business care and prudence expected from a person seeking to satisfy a legal requirement under similar circumstances.

Willful neglect means conscious, intentional failure or reckless indifference to the obligation to comply with the administrative simplification provision violated.

[74 FR 56130, Oct. 30, 2009]

§ 160.402 Basis for a civil money penalty.

(a) *General rule.* Subject to § 160.410, the Secretary will impose a civil money penalty upon a covered entity if the Secretary determines that the covered entity has violated an administrative simplification provision.

(b) *Violation by more than one covered entity.* (1) Except as provided in paragraph (b)(2) of this section, if the Secretary determines that more than one covered entity was responsible for a violation, the Secretary will impose a civil money penalty against each such covered entity.

(2) A covered entity that is a member of an affiliated covered entity, in accordance with § 164.105(b) of this subchapter, is jointly and severally liable for a civil money penalty for a violation of part 164 of this subchapter based on an act or omission of the affiliated covered entity, unless it is established that another member of the affiliated covered entity was responsible for the violation.

(c) *Violation attributed to a covered entity.* A covered entity is liable, in accordance with the federal common law of agency, for a civil money penalty for a violation based on the act or omission of any agent of the covered entity, including a workforce member, acting within the scope of the agency, unless—

(1) The agent is a business associate of the covered entity;

(2) The covered entity has complied, with respect to such business associate, with the applicable requirements of §§ 164.308(b) and 164.502(e) of this subchapter; and

(3) The covered entity did not—

(i) Know of a pattern of activity or practice of the business associate, and

(ii) Fail to act as required by §§ 164.314(a)(1)(ii) and 164.504(e)(1)(ii) of this subchapter, as applicable.

§ 160.404 Amount of a civil money penalty.

(a) The amount of a civil money penalty will be determined in accordance with paragraph (b) of this section and §§ 160.406, 160.408, and 160.412.

(b) The amount of a civil money penalty that may be imposed is subject to the following limitations:

(1) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty—

(i) In the amount of more than $100 for each violation; or

(ii) In excess of $25,000 for identical violations during a calendar year (January 1 through the following December 31);

(2) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty—

(i) For a violation in which it is established that the covered entity did not know and, by exercising reasonable diligence, would not have known that the covered entity violated such provision,

(A) In the amount of less than $100 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(ii) For a violation in which it is established that the violation was due to reasonable cause and not to willful neglect,

(A) In the amount of less than $1,000 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iii) For a violation 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 liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than $10,000 or more than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31);

(iv) For a violation 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 liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred,

(A) In the amount of less than $50,000 for each violation; or

(B) In excess of $1,500,000 for identical violations during a calendar year (January 1 through the following December 31).

(3) If a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another administrative simplification provision in the same subpart, a civil money penalty may be imposed for a violation of only one of these administrative simplification provisions.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56130, Oct. 30, 2009]

§ 160.406 Violations of an identical requirement or prohibition.

The Secretary will determine the number of violations of an administrative simplification provision based on the nature of the covered entity's obligation to act or not act under the provision that is violated, such as its obligation to act in a certain manner, or within a certain time, or to act or not act with respect to certain persons. In the case of continuing violation of a provision, a separate violation occurs each day the covered entity is in violation of the provision.

§ 160.408 Factors considered in determining the amount of a civil money penalty.

In determining the amount of any civil money penalty, the Secretary may consider as aggravating or mitigating factors, as appropriate, any of the following:

(a) The nature of the violation, in light of the purpose of the rule violated.

(b) The circumstances, including the consequences, of the violation, including but not limited to:

(1) The time period during which the violation(s) occurred;

(2) Whether the violation caused physical harm;

(3) Whether the violation hindered or facilitated an individual's ability to obtain health care; and

(4) Whether the violation resulted in financial harm.

(c) The degree of culpability of the covered entity, including but not limited to:

(1) Whether the violation was intentional; and

(2) Whether the violation was beyond the direct control of the covered entity.

(d) Any history of prior compliance with the administrative simplification provisions, including violations, by the covered entity, including but not limited to:

(1) Whether the current violation is the same or similar to prior violation(s);

(2) Whether and to what extent the covered entity has attempted to correct previous violations;

(3) How the covered entity has responded to technical assistance from the Secretary provided in the context of a compliance effort; and

(4) How the covered entity has responded to prior complaints.

(e) The financial condition of the covered entity, including but not limited to:

(1) Whether the covered entity had financial difficulties that affected its ability to comply;

(2) Whether the imposition of a civil money penalty would jeopardize the ability of the covered entity to continue to provide, or to pay for, health care; and

(3) The size of the covered entity.

(f) Such other matters as justice may require.

§ 160.410 Affirmative defenses.

(a) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violations, including the following:

(1) The violation is an act punishable under 42 U.S.C. 1320d–6;

(2) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the federal common law of agency, and, by exercising reasonable diligence, would not have known that the violation occurred; or

(3) The violation is—

(i) Due to reasonable cause and not willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or by exercising reasonable diligence would have known, that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

(b) For violations occurring on or after February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violations, including the following:

(1) The violation is an act punishable under 42 U.S.C. 1320d–6; or

(2) The covered entity establishes to the satisfaction of the Secretary that the violation is—

(i) Not due to willful neglect; and

(ii) Corrected during either:

(A) The 30-day period beginning on the first date the covered entity liable for the penalty knew, or, by exercising reasonable diligence, would have known that the violation occurred; or

(B) Such additional period as the Secretary determines to be appropriate based on the nature and extent of the failure to comply.

[74 FR 56131, Oct. 30, 2009]

§ 160.412 Waiver.

For violations due to reasonable cause and not willful neglect that are not corrected within the period described in § 160.410(a)(3)(ii) or (b)(2)(ii), as applicable, the Secretary may waive the civil money penalty, in whole or in part, to the extent that the payment of the penalty would be excessive relative to the violation.

[74 FR 56131, Oct. 30, 2009]

§ 160.414 Limitations.

No action under this subpart may be entertained unless commenced by the Secretary, in accordance with § 160.420, within 6 years from the date of the occurrence of the violation.

§ 160.416 Authority to settle.

Nothing in this subpart limits the authority of the Secretary to settle any issue or case or to compromise any penalty.

§ 160.418 Penalty not exclusive.

Except as otherwise provided by 42 U.S.C. 1320d-5(b)(1), a penalty imposed under this part is in addition to any other penalty prescribed by law.

§ 160.420 Notice of proposed determination.

(a) If a penalty is proposed in accordance with this part, the Secretary must deliver, or send by certified mail with return receipt requested, to the respondent, written notice of the Secretary's intent to impose a penalty. This notice of proposed determination must include—

(1) Reference to the statutory basis for the penalty;

(2) A description of the findings of fact regarding the violations with respect to which the penalty is proposed (except that, in any case where the Secretary is relying upon a statistical sampling study in accordance with § 160.536 of this part, the notice must provide a copy of the study relied upon by the Secretary);

(3) The reason(s) why the violation(s) subject(s) the respondent to a penalty;

(4) The amount of the proposed penalty and a reference to the subparagraph of § 160.404 upon which it is based.

(5) Any circumstances described in § 160.408 that were considered in determining the amount of the proposed penalty; and

(6) Instructions for responding to the notice, including a statement of the respondent's right to a hearing, a statement that failure to request a hearing within 90 days permits the imposition of the proposed penalty without the right to a hearing under § 160.504 or a right of appeal under § 160.548 of this part, and the address to which the hearing request must be sent.

(b) The respondent may request a hearing before an ALJ on the proposed penalty by filing a request in accordance with § 160.504 of this part.

[71 FR 8426, Feb. 16, 2006, as amended at 74 FR 56131, Oct. 30, 2009]

§ 160.422 Failure to request a hearing.

If the respondent does not request a hearing within the time prescribed by § 160.504 of this part and the matter is not settled pursuant to § 160.416, the Secretary will impose the proposed penalty or any lesser penalty permitted by 42 U.S.C. 1320d–5. The Secretary will notify the respondent by certified mail, return receipt requested, of any penalty that has been imposed and of the means by which the respondent may satisfy the penalty, and the penalty is final on receipt of the notice. The respondent has no right to appeal a penalty under § 160.548 of this part with respect to which the respondent has not timely requested a hearing.

§ 160.424 Collection of penalty.

(a) Once a determination of the Secretary to impose a penalty has become final, the penalty will be collected by the Secretary, subject to the first sentence of 42 U.S.C. 1320a–7a(f).

(b) The penalty may be recovered in a civil action brought in the United States district court for the district where the respondent resides, is found, or is located.

(c) The amount of a penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States, or by a State agency, to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ, or in an appeal under 42 U.S.C. 1320a–7a(e), may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

§ 160.426 Notification of the public and other agencies.

Whenever a proposed penalty becomes final, the Secretary will notify, in such manner as the Secretary deems appropriate, the public and the following organizations and entities thereof and the reason it was imposed: the appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as

defined in 42 U.S.C. 1320a–7(h)), the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in 42 U.S.C. 1395aa(a), 1396a(a)(33)).

Subpart E—Procedures for Hearings

SOURCE: 71 FR 8428, Feb. 16, 2006, unless otherwise noted.

§ 160.500 Applicability.

This subpart applies to hearings conducted relating to the imposition of a civil money penalty by the Secretary under 42 U.S.C. 1320d–5.

§ 160.502 Definitions.

As used in this subpart, the following term has the following meaning:

Board means the members of the HHS Departmental Appeals Board, in the Office of the Secretary, who issue decisions in panels of three.

§ 160.504 Hearing before an ALJ.

(a) A respondent may request a hearing before an ALJ. The parties to the hearing proceeding consist of—

(1) The respondent; and

(2) The officer(s) or employee(s) of HHS to whom the enforcement authority involved has been delegated.

(b) The request for a hearing must be made in writing signed by the respondent or by the respondent's attorney and sent by certified mail, return receipt requested, to the address specified in the notice of proposed determination. The request for a hearing must be mailed within 90 days after notice of the proposed determination is received by the respondent. For purposes of this section, the respondent's date of receipt of the notice of proposed determination is presumed to be 5 days after the date of the notice unless the respondent makes a reasonable showing to the contrary to the ALJ.

(c) The request for a hearing must clearly and directly admit, deny, or explain each of the findings of fact contained in the notice of proposed determination with regard to which the respondent has any knowledge. If the respondent has no knowledge of a particular finding of fact and so states, the finding shall be deemed denied. The request for a hearing must also state the circumstances or arguments that the respondent alleges constitute the grounds for any defense and the factual and legal basis for opposing the penalty, except that a respondent may raise an affirmative defense under § 160.410(b)(1) at any time.

(d) The ALJ must dismiss a hearing request where—

(1) On motion of the Secretary, the ALJ determines that the respondent's hearing request is not timely filed as required by paragraphs (b) or does not meet the requirements of paragraph (c) of this section;

(2) The respondent withdraws the request for a hearing;

(3) The respondent abandons the request for a hearing; or

(4) The respondent's hearing request fails to raise any issue that may properly be addressed in a hearing.

§ 160.506 Rights of the parties.

(a) Except as otherwise limited by this subpart, each party may—

(1) Be accompanied, represented, and advised by an attorney;

(2) Participate in any conference held by the ALJ;

(3) Conduct discovery of documents as permitted by this subpart;

(4) Agree to stipulations of fact or law that will be made part of the record;

(5) Present evidence relevant to the issues at the hearing;

(6) Present and cross-examine witnesses;

(7) Present oral arguments at the hearing as permitted by the ALJ; and

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

(b) A party may appear in person or by a representative. Natural persons who appear as an attorney or other representative must conform to the standards of conduct and ethics required of practitioners before the courts of the United States.

(c) Fees for any services performed on behalf of a party by an attorney are not subject to the provisions of 42

U.S.C. 406, which authorizes the Secretary to specify or limit their fees.

§ 160.508 Authority of the ALJ.

(a) The ALJ must conduct a fair and impartial hearing, avoid delay, maintain order, and ensure that a record of the proceeding is made.

(b) The ALJ may—

(1) Set and change the date, time and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses at hearings and the production of documents at or in relation to hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of documentary discovery as permitted by this subpart;

(8) Regulate the course of the hearing and the conduct of representatives, parties, and witnesses;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Conduct any conference, argument or hearing in person or, upon agreement of the parties, by telephone; and

(13) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact. A summary judgment decision constitutes a hearing on the record for the purposes of this subpart.

(c) The ALJ—

(1) May not find invalid or refuse to follow Federal statutes, regulations, or Secretarial delegations of authority and must give deference to published guidance to the extent not inconsistent with statute or regulation;

(2) May not enter an order in the nature of a directed verdict;

(3) May not compel settlement negotiations;

(4) May not enjoin any act of the Secretary; or

(5) May not review the exercise of discretion by the Secretary with respect to whether to grant an extension under § 160.410(b)(3)(ii)(B) of this part or to provide technical assistance under 42 U.S.C. 1320d–5(b)(3)(B).

§ 160.510 Ex parte contacts.

No party or person (except employees of the ALJ's office) may communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for both parties to participate. This provision does not prohibit a party or person from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

§ 160.512 Prehearing conferences.

(a) The ALJ must schedule at least one prehearing conference, and may schedule additional prehearing conferences as appropriate, upon reasonable notice, which may not be less than 14 business days, to the parties.

(b) The ALJ may use prehearing conferences to discuss the following—

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of the other party) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery of documents as permitted by this subpart;

(9) The time and place for the hearing;

(10) The potential for the settlement of the case by the parties; and

(11) Other matters as may tend to encourage the fair, just and expeditious disposition of the proceedings, including the protection of privacy of individually identifiable health information that may be submitted into evidence or otherwise used in the proceeding, if appropriate.

(c) The ALJ must issue an order containing the matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

§ 160.514 Authority to settle.

The Secretary has exclusive authority to settle any issue or case without the consent of the ALJ.

§ 160.516 Discovery.

(a) A party may make a request to another party for production of documents for inspection and copying that are relevant and material to the issues before the ALJ.

(b) For the purpose of this section, the term ''documents'' includes information, reports, answers, records, accounts, papers and other data and documentary evidence. Nothing contained in this section may be interpreted to require the creation of a document, except that requested data stored in an electronic data storage system must be produced in a form accessible to the requesting party.

(c) Requests for documents, requests for admissions, written interrogatories, depositions and any forms of discovery, other than those permitted under paragraph (a) of this section, are not authorized.

(d) This section may not be construed to require the disclosure of interview reports or statements obtained by any party, or on behalf of any party, of persons who will not be called as witnesses by that party, or analyses and summaries prepared in conjunction with the investigation or litigation of the case, or any otherwise privileged documents.

(e)(1) When a request for production of documents has been received, within 30 days the party receiving that request must either fully respond to the request, or state that the request is being objected to and the reasons for that objection. If objection is made to part of an item or category, the part must be specified. Upon receiving any objections, the party seeking production may then, within 30 days or any other time frame set by the ALJ, file a motion for an order compelling discovery. The party receiving a request for production may also file a motion for protective order any time before the date the production is due.

(2) The ALJ may grant a motion for protective order or deny a motion for an order compelling discovery if the ALJ finds that the discovery sought—

(i) Is irrelevant;

(ii) Is unduly costly or burdensome;

(iii) Will unduly delay the proceeding; or

(iv) Seeks privileged information.

(3) The ALJ may extend any of the time frames set forth in paragraph (e)(1) of this section.

(4) The burden of showing that discovery should be allowed is on the party seeking discovery.

§ 160.518 Exchange of witness lists, witness statements, and exhibits.

(a) The parties must exchange witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 160.538, not more than 60, and not less than 15, days before the scheduled hearing, except that if a respondent intends to introduce the evidence of a statistical expert, the respondent must provide the Secretarial party with a copy of the statistical expert's report not less than 30 days before the scheduled hearing.

(b)(1) If, at any time, a party objects to the proposed admission of evidence not exchanged in accordance with paragraph (a) of this section, the ALJ must determine whether the failure to comply with paragraph (a) of this section should result in the exclusion of that evidence.

(2) Unless the ALJ finds that extraordinary circumstances justified the failure timely to exchange the information listed under paragraph (a) of this section, the ALJ must exclude from the party's case-in-chief—

(i) The testimony of any witness whose name does not appear on the witness list; and

(ii) Any exhibit not provided to the opposing party as specified in paragraph (a) of this section.

(3) If the ALJ finds that extraordinary circumstances existed, the ALJ must then determine whether the admission of that evidence would cause substantial prejudice to the objecting party.

(i) If the ALJ finds that there is no substantial prejudice, the evidence may be admitted.

(ii) If the ALJ finds that there is substantial prejudice, the ALJ may exclude the evidence, or, if he or she does not exclude the evidence, must postpone the hearing for such time as is necessary for the objecting party to prepare and respond to the evidence, unless the objecting party waives postponement.

(c) Unless the other party objects within a reasonable period of time before the hearing, documents exchanged in accordance with paragraph (a) of this section will be deemed to be authentic for the purpose of admissibility at the hearing.

§ 160.520 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any person at the hearing may make a motion requesting the ALJ to issue a subpoena if the appearance and testimony are reasonably necessary for the presentation of a party's case.

(b) A subpoena requiring the attendance of a person in accordance with paragraph (a) of this section may also require the person (whether or not the person is a party) to produce relevant and material evidence at or before the hearing.

(c) When a subpoena is served by a respondent on a particular employee or official or particular office of HHS, the Secretary may comply by designating any knowledgeable HHS representative to appear and testify.

(d) A party seeking a subpoena must file a written motion not less than 30 days before the date fixed for the hearing, unless otherwise allowed by the ALJ for good cause shown. That motion must—

(1) Specify any evidence to be produced;

(2) Designate the witnesses; and

(3) Describe the address and location with sufficient particularity to permit those witnesses to be found.

(e) The subpoena must specify the time and place at which the witness is to appear and any evidence the witness is to produce.

(f) Within 15 days after the written motion requesting issuance of a subpoena is served, any party may file an opposition or other response.

(g) If the motion requesting issuance of a subpoena is granted, the party seeking the subpoena must serve it by delivery to the person named, or by certified mail addressed to that person at the person's last dwelling place or principal place of business.

(h) The person to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service.

(i) The exclusive remedy for contumacy by, or refusal to obey a subpoena duly served upon, any person is specified in 42 U.S.C. 405(e).

§ 160.522 Fees.

The party requesting a subpoena must 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 must accompany the subpoena when served, except that, when a subpoena is issued on behalf of the Secretary, a check for witness fees and mileage need not accompany the subpoena.

§ 160.524 Form, filing, and service of papers.

(a) *Forms.* (1) Unless the ALJ directs the parties to do otherwise, documents filed with the ALJ must include an original and two copies.

(2) Every pleading and paper filed in the proceeding must contain a caption setting forth the title of the action, the case number, and a designation of the paper, such as motion to quash subpoena.

(3) Every pleading and paper must be signed by and must contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(4) Papers are considered filed when they are mailed.

(b) *Service.* A party filing a document with the ALJ or the Board must, at the time of filing, serve a copy of the document on the other party. Service upon any party of any document must be made by delivering a copy, or placing a copy of the document in the United States mail, postage prepaid and addressed, or with a private delivery service, to the party's last known address. When a party is represented by an attorney, service must be made upon the attorney in lieu of the party.

(c) *Proof of service.* A certificate of the natural person serving the document by personal delivery or by mail, setting forth the manner of service, constitutes proof of service.

§ 160.526 Computation of time.

(a) In computing any period of time under this subpart or in an order issued thereunder, the time begins with the day following the act, event or default, and includes the last day of the period unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government must be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days must be added to the time permitted for any response. This paragraph does not apply to requests for hearing under § 160.504.

§ 160.528 Motions.

(a) An application to the ALJ for an order or ruling must be by motion. Motions must state the relief sought, the authority relied upon and the facts alleged, and must 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 must be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 10 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to the motion.

(d) The ALJ may not grant a written motion before the time for filing responses has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny the motion without awaiting a response.

(e) The ALJ must make a reasonable effort to dispose of all outstanding motions before the beginning of the hearing.

§ 160.530 Sanctions.

The ALJ may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action or for other misconduct that interferes with the speedy, orderly or fair conduct of the hearing. The sanctions must reasonably relate to the severity and nature of the failure or misconduct. The sanctions may include—

(a) In the case of refusal to provide or permit discovery under the terms of this part, drawing negative factual inferences or treating the refusal as an admission by deeming the matter, or certain facts, to be established;

(b) Prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(c) Striking pleadings, in whole or in part;

(d) Staying the proceedings;

(e) Dismissal of the action;

(f) Entering a decision by default;

(g) Ordering the party or attorney to pay the attorney's fees and other costs caused by the failure or misconduct; and

(h) Refusing to consider any motion or other action that is not filed in a timely manner.

§ 160.532 Collateral estoppel.

When a final determination that the respondent violated an administrative simplification provision has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent

is bound by that determination in any proceeding under this part.

§ 160.534 The hearing.

(a) The ALJ must conduct a hearing on the record in order to determine whether the respondent should be found liable under this part.

(b) (1) The respondent has the burden of going forward and the burden of persuasion with respect to any:

(i) Affirmative defense pursuant to § 160.410 of this part;

(ii) Challenge to the amount of a proposed penalty pursuant to §§ 160.404–160.408 of this part, including any factors raised as mitigating factors; or

(iii) Claim that a proposed penalty should be reduced or waived pursuant to § 160.412 of this part.

(iv) Compliance with subpart D of part 164, as provided under § 164.414(b).

(2) The Secretary has the burden of going forward and the burden of persuasion with respect to all other issues, including issues of liability other than with respect to subpart D of part 164, and the existence of any factors considered aggravating factors in determining the amount of the proposed penalty.

(3) The burden of persuasion will be judged by a preponderance of the evidence.

(c) The hearing must be open to the public unless otherwise ordered by the ALJ for good cause shown.

(d)(1) Subject to the 15-day rule under § 160.518(a) and the admissibility of evidence under § 160.540, either party may introduce, during its case in chief, items or information that arose or became known after the date of the issuance of the notice of proposed determination or the request for hearing, as applicable. Such items and information may not be admitted into evidence, if introduced—

(i) By the Secretary, unless they are material and relevant to the acts or omissions with respect to which the penalty is proposed in the notice of proposed determination pursuant to § 160.420 of this part, including circumstances that may increase penalties; or

(ii) By the respondent, unless they are material and relevant to an admission, denial or explanation of a finding of fact in the notice of proposed determination under § 160.420 of this part, or to a specific circumstance or argument expressly stated in the request for hearing under § 160.504, including circumstances that may reduce penalties.

(2) After both parties have presented their cases, evidence may be admitted in rebuttal even if not previously exchanged in accordance with § 160.518.

[71 FR 8428, Feb. 16, 2006, as amended at 74 FR 42767, Aug. 24, 2009]

§ 160.536 Statistical sampling.

(a) In meeting the burden of proof set forth in § 160.534, the Secretary may introduce the results of a statistical sampling study as evidence of the number of violations under § 160.406 of this part, or the factors considered in determining the amount of the civil money penalty under § 160.408 of this part. Such statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitutes prima facie evidence of the number of violations and the existence of factors material to the proposed civil money penalty as described in §§ 160.406 and 160.408.

(b) Once the Secretary has made a prima facie case, as described in paragraph (a) of this section, the burden of going forward shifts to the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. The Secretary will then be given the opportunity to rebut this evidence.

§ 160.538 Witnesses.

(a) Except as provided in paragraph (b) of this section, testimony at the hearing must be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony of witnesses other than the testimony of expert witnesses may be admitted in the form of a written statement. The ALJ may, at his or her discretion, admit prior sworn testimony of experts that has been subject to adverse examination, such as a deposition or trial testimony. Any such written statement must be provided to the other party, along with the last known address of the witness, in a manner that allows sufficient time for the other party to subpoena the witness for

cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing must be exchanged as provided in § 160.518.

(c) The ALJ must exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to:

(1) Make the interrogation and presentation effective for the ascertainment of the truth;

(2) Avoid repetition or needless consumption of time; and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ must permit the parties to conduct cross-examination of witnesses as may be required for a full and true disclosure of the facts.

(e) The ALJ may order witnesses excluded so that they cannot hear the testimony of other witnesses, except that the ALJ may not order to be excluded—

(1) A party who is a natural person;

(2) In the case of a party that is not a natural person, the officer or employee of the party appearing for the entity pro se or designated as the party's representative; or

(3) A natural person whose presence is shown by a party to be essential to the presentation of its case, including a person engaged in assisting the attorney for the Secretary.

§ 160.540 Evidence.

(a) The ALJ must determine the admissibility of evidence.

(b) Except as provided in this subpart, the ALJ is not bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, for example, to exclude unreliable evidence.

(c) The ALJ must exclude irrelevant or immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence must be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement are inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) Evidence of crimes, wrongs, or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. This evidence is admissible regardless of whether the crimes, wrongs, or acts occurred during the statute of limitations period applicable to the acts or omissions that constitute the basis for liability in the case and regardless of whether they were referenced in the Secretary's notice of proposed determination under § 160.420 of this part.

(h) The ALJ must permit the parties to introduce rebuttal witnesses and evidence.

(i) All documents and other evidence offered or taken for the record must be open to examination by both parties, unless otherwise ordered by the ALJ for good cause shown.

§ 160.542 The record.

(a) The hearing must be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ. A party that requests a transcript of hearing proceedings must pay the cost of preparing the transcript unless, for good cause shown by the party, the payment is waived by the ALJ or the Board, as appropriate.

(b) The transcript of the testimony, exhibits, and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for decision by the ALJ and the Secretary.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by any person, unless otherwise ordered by the ALJ for good cause shown.

(d) For good cause, the ALJ may order appropriate redactions made to the record.

§ 160.544 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 must fix the time for filing the briefs. The time for filing may not exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated

record. The briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

§ 160.546 ALJ's decision.

(a) The ALJ must issue a decision, based only on the record, which must contain findings of fact and conclusions of law.

(b) The ALJ may affirm, increase, or reduce the penalties imposed by the Secretary.

(c) The ALJ must issue the decision to both parties within 60 days after the time for submission of post-hearing briefs and reply briefs, if permitted, has expired. If the ALJ fails to meet the deadline contained in this paragraph, he or she must notify the parties of the reason for the delay and set a new deadline.

(d) Unless the decision of the ALJ is timely appealed as provided for in § 160.548, the decision of the ALJ will be final and binding on the parties 60 days from the date of service of the ALJ's decision.

§ 160.548 Appeal of the ALJ's decision.

(a) Any party may appeal the decision of the ALJ to the Board by filing a notice of appeal with the Board within 30 days of the date of service of the ALJ decision. The Board may extend the initial 30 day period for a period of time not to exceed 30 days if a party files with the Board a request for an extension within the initial 30 day period and shows good cause.

(b) If a party files a timely notice of appeal with the Board, the ALJ must forward the record of the proceeding to the Board.

(c) A notice of appeal must be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions. Any party may file a brief in opposition to the exceptions, which may raise any relevant issue not addressed in the exceptions, within 30 days of receiving the notice of appeal and the accompanying brief. The Board may permit the parties to file reply briefs.

(d) There is no right to appear personally before the Board or to appeal to the Board any interlocutory ruling by the ALJ.

(e) Except for an affirmative defense under § 160.410(b)(1) of this part, the Board may not consider any issue not raised in the parties' briefs, nor any issue in the briefs that could have been raised before the ALJ but was not.

(f) If any party demonstrates to the satisfaction of the Board that additional evidence not presented at such hearing is relevant and material and that there were reasonable grounds for the failure to adduce such evidence at the hearing, the Board may remand the matter to the ALJ for consideration of such additional evidence.

(g) The Board may decline to review the case, or may affirm, increase, reduce, reverse or remand any penalty determined by the ALJ.

(h) The standard of review on a disputed issue of fact is whether the initial decision of the ALJ is supported by substantial evidence on the whole record. The standard of review on a disputed issue of law is whether the decision is erroneous.

(i) Within 60 days after the time for submission of briefs and reply briefs, if permitted, has expired, the Board must serve on each party to the appeal a copy of the Board's decision and a statement describing the right of any respondent who is penalized to seek judicial review.

(j)(1) The Board's decision under paragraph (i) of this section, including a decision to decline review of the initial decision, becomes the final decision of the Secretary 60 days after the date of service of the Board's decision, except with respect to a decision to remand to the ALJ or if reconsideration is requested under this paragraph.

(2) The Board will reconsider its decision only if it determines that the decision contains a clear error of fact or error of law. New evidence will not be a basis for reconsideration unless the party demonstrates that the evidence is newly discovered and was not previously available.

(3) A party may file a motion for reconsideration with the Board before the date the decision becomes final under paragraph (j)(1) of this section. A motion for reconsideration must be accompanied by a written brief specifying any alleged error of fact or law

and, if the party is relying on additional evidence, explaining why the evidence was not previously available. Any party may file a brief in opposition within 15 days of receiving the motion for reconsideration and the accompanying brief unless this time limit is extended by the Board for good cause shown. Reply briefs are not permitted.

(4) The Board must rule on the motion for reconsideration not later than 30 days from the date the opposition brief is due. If the Board denies the motion, the decision issued under paragraph (i) of this section becomes the final decision of the Secretary on the date of service of the ruling. If the Board grants the motion, the Board will issue a reconsidered decision, after such procedures as the Board determines necessary to address the effect of any error. The Board's decision on reconsideration becomes the final decision of the Secretary on the date of service of the decision, except with respect to a decision to remand to the ALJ.

(5) If service of a ruling or decision issued under this section is by mail, the date of service will be deemed to be 5 days from the date of mailing.

(k)(1) A respondent's petition for judicial review must be filed within 60 days of the date on which the decision of the Board becomes the final decision of the Secretary under paragraph (j) of this section.

(2) In compliance with 28 U.S.C. 2112(a), a copy of any petition for judicial review filed in any U.S. Court of Appeals challenging the final decision of the Secretary must be sent by certified mail, return receipt requested, to the General Counsel of HHS. The petition copy must be a copy showing that it has been time-stamped by the clerk of the court when the original was filed with the court.

(3) If the General Counsel of HHS received two or more petitions within 10 days after the final decision of the Secretary, the General Counsel will notify the U.S. Judicial Panel on Multidistrict Litigation of any petitions that were received within the 10 day period.

§ 160.550 Stay of the Secretary's decision.

(a) Pending judicial review, the respondent may file a request for stay of the effective date of any penalty with the ALJ. The request must be accompanied by a copy of the notice of appeal filed with the Federal court. The filing of the request automatically stays the effective date of the penalty until such time as the ALJ rules upon the request.

(b) The ALJ may not grant a respondent's request for stay of any penalty unless the respondent posts a bond or provides other adequate security.

(c) The ALJ must rule upon a respondent's request for stay within 10 days of receipt.

§ 160.552 Harmless error.

No error in either the admission or the exclusion of evidence, and no error or defect in any ruling or order or in any act done or omitted by the ALJ or by any of the parties is ground for vacating, modifying or otherwise disturbing an otherwise appropriate ruling or order or act, unless refusal to take such action appears to the ALJ or the Board inconsistent with substantial justice. The ALJ and the Board at every stage of the proceeding must disregard any error or defect in the proceeding that does not affect the substantial rights of the parties.

PART 162—ADMINISTRATIVE REQUIREMENTS

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AUTHORITY: Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d–1320d–9), as added by sec. 262 of Pub. L. 104–191, 110 Stat. 2021–2031, sec. 105 of Pub. L. 110–233, 122 Stat. 881–922, and sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note), and secs. 1104 and 10109 of Pub. L. 111–148, 124 Stat. 146–154 and 915–917.

SOURCE: 65 FR 50367, Aug. 17, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 162.100 Applicability.

Covered entities (as defined in § 160.103 of this subchapter) must comply with the applicable requirements of this part.

§ 162.103 Definitions.

For purposes of this part, the following definitions apply:

Code set means any set of codes used to encode data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes. A code set includes the codes and the descriptors of the codes.

Code set maintaining organization means an organization that creates and maintains the code sets adopted by the Secretary for use in the transactions for which standards are adopted in this part.

Data condition means the rule that describes the circumstances under which a covered entity must use a particular data element or segment.

Data content means all the data elements and code sets inherent to a transaction, and not related to the format of the transaction. Data elements that are related to the format are not data content.

Data element means the smallest named unit of information in a transaction.

Data set means a semantically meaningful unit of information exchanged between two parties to a transaction.

Descriptor means the text defining a code.

Designated standard maintenance organization (DSMO) means an organization designated by the Secretary under § 162.910(a).

Direct data entry means the direct entry of data (for example, using dumb terminals or web browsers) that is immediately transmitted into a health plan's computer.

Format refers to those data elements that provide or control the enveloping or hierarchical structure, or assist in identifying data content of, a transaction.

HCPCS stands for the Health [Care Financing Administration] Common Procedure Coding System.

Maintain or *maintenance* refers to activities necessary to support the use of a standard adopted by the Secretary, including technical corrections to an implementation specification, and enhancements or expansion of a code set. This term excludes the activities related to the adoption of a new standard or implementation specification, or modification to an adopted standard or implementation specification.

Maximum defined data set means all of the required data elements for a particular standard based on a specific implementation specification.

Operating rules means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.

Segment means a group of related data elements in a transaction.

Stage 1 payment initiation means a health plan's order, instruction or authorization to its financial institution to make a health care claims payment using an electronic funds transfer (EFT) through the ACH Network.

Standard transaction means a transaction that complies with an applicable standard and associated operating rules adopted under this part.

[65 FR 50367, Aug. 17, 2000, as amended at 68 FR 8374, Feb. 20, 2003; 74 FR 3324, Jan. 16, 2009; 76 FR 40495, July 8, 2011; 77 FR 1589, Jan. 10, 2012]

EFFECTIVE DATE NOTE: At 77 FR 54719, Sept. 5, 2012, § 162.103 was amended by adding the definitions of ''Controlling health plan (CHP),'' ''Covered health care provider,'' and ''Subhealth plan (SHP)'', effective Nov. 5, 2012. For the convenience of the user, the added text is set forth as follows:

§ 162.103 Definitions.

* * * * *

Controlling health plan (CHP) means a health plan that—

(1) Controls its own business activities, actions, or policies; or

(2)(i) Is controlled by an entity that is not a health plan; and

(ii) If it has a subhealth plan(s) (as defined in this section), exercises sufficient control over the subhealth plan(s) to direct its/their business activities, actions, or policies.

Covered health care provider means a health care provider that meets the definition at paragraph (3) of the definition of ''covered entity'' at § 160.103.

* * * * *

Subhealth plan (SHP) means a health plan whose business activities, actions, or policies are directed by a controlling health plan.

Subparts B–C [Reserved]

Subpart D—Standard Unique Health Identifier for Health Care Providers

SOURCE: 69 FR 3468, Jan. 23, 2004, unless otherwise noted.

§ 162.402 Definitions.

Covered health care provider means a health care provider that meets the definition at paragraph (3) of the definition of ''covered entity'' at § 160.103 of this subchapter.

EFFECTIVE DATE NOTE: At 77 FR 54719, Sept. 5, 2012, § 162.402 was removed and reserved, effective Nov. 5, 2012.

§ 162.404 Compliance dates of the implementation of the standard unique health identifier for health care providers.

(a) *Health care providers.* A covered health care provider must comply with the implementation specifications in § 162.410 no later than May 23, 2007.

(b) *Health plans.* A health plan must comply with the implementation specifications in § 162.412 no later than one of the following dates:

(1) A health plan that is not a small health plan—May 23, 2007.

(2) A small health plan—May 23, 2008.

(c) *Health care clearinghouses.* A health care clearinghouse must comply with the implementation specifications in § 162.414 no later than May 23, 2007.

EFFECTIVE DATE NOTE: At 77 FR 54719, Sept. 5, 2012, § 162.404 was amended by redesignating paragraph (a) as paragraph (a)(1); adding paragraph (a)(2), effective Nov. 5, 2012. For the convenience of the user, the added text is set forth as follows:

§ 162.404 Compliance dates of the implementation of the standard unique health identifier for health care providers.

(a) * * *

(2) An organization covered health care provider must comply with the implementation specifications in § 162.410(b) by May 6, 2013.

* * * * *

§ 162.406 Standard unique health identifier for health care providers.

(a) *Standard.* The standard unique health identifier for health care providers is the National Provider Identifier (NPI). The NPI is a 10-position numeric identifier, with a check digit in the 10th position, and no intelligence about the health care provider in the number.

(b) *Required and permitted uses for the NPI.* (1) The NPI must be used as stated in § 162.410, § 162.412, and § 162.414.

(2) The NPI may be used for any other lawful purpose.

§ 162.408 National Provider System.

National Provider System. The National Provider System (NPS) shall do the following:

(a) Assign a single, unique NPI to a health care provider, provided that—

(1) The NPS may assign an NPI to a subpart of a health care provider in accordance with paragraph (g); and

(2) The Secretary has sufficient information to permit the assignment to be made.

(b) Collect and maintain information about each health care provider that has been assigned an NPI and perform tasks necessary to update that information.

(c) If appropriate, deactivate an NPI upon receipt of appropriate information concerning the dissolution of the health care provider that is an organization, the death of the health care provider who is an individual, or other circumstances justifying deactivation.

(d) If appropriate, reactivate a deactivated NPI upon receipt of appropriate information.

(e) Not assign a deactivated NPI to any other health care provider.

(f) Disseminate NPS information upon approved requests.

(g) Assign an NPI to a subpart of a health care provider on request if the identifying data for the subpart are unique.

§ 162.410 Implementation specifications: Health care providers.

(a) A covered entity that is a covered health care provider must:

(1) Obtain, by application if necessary, an NPI from the National Provider System (NPS) for itself or for any subpart of the covered entity that would be a covered health care provider if it were a separate legal entity. A covered entity may obtain an NPI for any other subpart that qualifies for the assignment of an NPI.

(2) Use the NPI it obtained from the NPS to identify itself on all standard transactions that it conducts where its health care provider identifier is required.

(3) Disclose its NPI, when requested, to any entity that needs the NPI to identify that covered health care provider in a standard transaction.

(4) Communicate to the NPS any changes in its required data elements in the NPS within 30 days of the change.

(5) If it uses one or more business associates to conduct standard transactions on its behalf, require its business associate(s) to use its NPI and other NPIs appropriately as required by the transactions that the business associate(s) conducts on its behalf.

(6) If it has been assigned NPIs for one or more subparts, comply with the requirements of paragraphs (a)(2) through (a)(5) of this section with respect to each of those NPIs.

(b) A health care provider that is not a covered entity may obtain, by application if necessary, an NPI from the NPS.

EFFECTIVE DATE NOTE: At 77 FR 54719, Sept. 5, 2012, § 162.410 was amended by redesignating paragraph (b) as paragraph (c); adding a new paragraph (b), effective Nov. 5, 2012. For the convenience of the user, the added text is set forth as follows:

§ 162.410 Implementation specifications: Health care providers.

* * * * *

(b) An organization covered health care provider that has as a member, employs, or contracts with, an individual health care provider who is not a covered entity and is a prescriber, must require such health care provider to—

(1) Obtain an NPI from the National Plan and Provider Enumeration System (NPPES); and

(2) To the extent the prescriber writes a prescription while acting within the scope of the prescriber's relationship with the organization, disclose the NPI upon request to any entity that needs it to identify the prescriber in a standard transaction.

* * * * *

§ 162.412 Implementation specifications: Health plans.

(a) A health plan must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.

(b) A health plan may not require a health care provider that has been assigned an NPI to obtain an additional NPI.

§ 162.414 Implementation specifications: Health care clearinghouses.

A health care clearinghouse must use the NPI of any health care provider (or subpart(s), if applicable) that has been assigned an NPI to identify that health care provider on all standard transactions where that health care provider's identifier is required.

Subpart E—Standard Unique Health Identifier for Health Plans

SOURCE: 77 FR 54719, Sept. 5, 2012, unless otherwise noted.

EFFECTIVE DATE NOTE: At 77 FR 54719, Sept. 5, 2012, subpart E was added, effective Nov. 5, 2012.

§ 162.502 [Reserved]

§ 162.504 Compliance requirements for the implementation of the standard unique health plan identifier.

(a) *Covered entities.* A covered entity must comply with the implementation requirements in § 162.510 no later than November 5, 2014.

(b) *Health plans.* A health plan must comply with the implementation specifications in § 162.512 no later than one of the following dates:

(1) A health plan that November 5, 2014.

(2) A health plan that is a small health plan–

November 5, 2014.

§ 162.506 Standard unique health plan identifier.

(a) *Standard.* The standard unique health plan identifier is the Health Plan Identifier (HPID) that is assigned by the Enumeration System identified in § 162.508.

(b) *Required and permitted uses for the HPID.* (1) The HPID must be used as specified in § 162.510 and § 162.512.

(2) The HPID may be used for any other lawful purpose.

§ 162.508 Enumeration System.

The Enumeration System must do all of the following:

(a) Assign a single, unique—

(1) HPID to a health plan, provided that the Secretary has sufficient information to permit the assignment to be made; or

(2) OEID to an entity eligible to receive one under § 162.514(a), provided that the Secretary has sufficient information to permit the assignment to be made.

(b) Collect and maintain information about each health plan that applies for or has been assigned an HPID and each entity that applies for or has been assigned an OEID, and perform tasks necessary to update that information.

(c) If appropriate, deactivate an HPID or OEID upon receipt of sufficient information concerning circumstances justifying deactivation.

(d) If appropriate, reactivate a deactivated HPID or OEID upon receipt of sufficient information justifying reactivation.

(e) Not assign a deactivated HPID to any other health plan or OEID to any other entity.

(f) Disseminate Enumeration System information upon approved requests.

§ 162.510 Full implementation requirements: Covered entities.

(a) A covered entity must use an HPID to identify a health plan that has an HPID when a covered entity identifies a health plan in a transaction for which the Secretary has adopted a standard under this part.

(b) If a covered entity uses one or more business associates to conduct standard transactions on its behalf, it must require its business associate(s) to use an HPID to identify a health plan that has an HPID when the business associate(s) identifies a health plan in a transaction for which the Secretary has adopted a standard under this part.

§ 162.512 Implementation specifications: Health plans.

(a) A controlling health plan must do all of the following:

(1) Obtain an HPID from the Enumeration System for itself.

(2) Disclose its HPID, when requested, to any entity that needs the HPID to identify the health plan in a standard transaction.

(3) Communicate to the Enumeration System any changes in its required data elements in the Enumeration System within 30 days of the change.

(b) A controlling health plan may do the following:

(1) Obtain an HPID from the Enumeration System for a subhealth plan of the controlling health plan.

(2) Direct a subhealth plan of the controlling health plan to obtain an HPID from the Enumeration System.

(c) A subhealth plan may obtain an HPID from the Enumeration System.

(d) A subhealth plan that is assigned an HPID from the Enumeration System must comply with the requirements that apply to a controlling health plan in paragraphs (a)(2) and (a)(3) of this section.

§ 162.514 Other entity identifier.

(a) An entity may obtain an Other Entity Identifier (OEID) to identify

itself if the entity meets all of the following:

(1) Needs to be identified in a transaction for which the Secretary has adopted a standard under this part.

(2) Is not eligible to obtain an HPID.

(3) Is not eligible to obtain an NPI.

(4) Is not an individual.

(b) An OEID must be obtained from the Enumeration System identified in § 162.508.

(c) *Uses for the OEID.* (1) An other entity may use the OEID it obtained from the Enumeration System to identify itself or have itself identified on all covered transactions in which it needs to be identified.

(2) The OEID may be used for any other lawful purpose.

Subpart F—Standard Unique Employer Identifier

SOURCE: 67 FR 38020, May 31, 2002, unless otherwise noted.

§ 162.600 Compliance dates of the implementation of the standard unique employer identifier.

(a) *Health care providers.* Health care providers must comply with the requirements of this subpart no later than July 30, 2004.

(b) *Health plans.* A health plan must comply with the requirements of this subpart no later than one of the following dates:

(1) *Health plans other than small health plans*—July 30, 2004.

(2) *Small health plans*—August 1, 2005.

(c) *Health care clearinghouses.* Health care clearinghouses must comply with the requirements of this subpart no later than July 30, 2004.

§ 162.605 Standard unique employer identifier.

The Secretary adopts the EIN as the standard unique employer identifier provided for by 42 U.S.C. 1320d–2(b).

§ 162.610 Implementation specifications for covered entities.

(a) The standard unique employer identifier of an employer of a particular employee is the EIN that appears on that employee's IRS Form W–2, Wage and Tax Statement, from the employer.

(b) A covered entity must use the standard unique employer identifier (EIN) of the appropriate employer in standard transactions that require an employer identifier to identify a person or entity as an employer, including where situationally required.

(c) Required and permitted uses for the Employer Identifier.

(1) The Employer Identifier must be used as stated in § 162.610(b).

(2) The Employer Identifier may be used for any other lawful purpose.

[67 FR 38020, May 31, 2002, as amended at 69 FR 3469, Jan. 23, 2004]

Subparts G–H [Reserved]

Subpart I—General Provisions for Transactions

§ 162.900 [Reserved]

§ 162.910 Maintenance of standards and adoption of modifications and new standards.

(a) *Designation of DSMOs.* (1) The Secretary may designate as a DSMO an organization that agrees to conduct, to the satisfaction of the Secretary, the following functions:

(i) Maintain standards adopted under this subchapter.

(ii) Receive and process requests for adopting a new standard or modifying an adopted standard.

(2) The Secretary designates a DSMO by notice in the FEDERAL REGISTER.

(b) *Maintenance of standards.* Maintenance of a standard by the appropriate DSMO constitutes maintenance of the standard for purposes of this part, if done in accordance with the processes the Secretary may require.

(c) *Process for modification of existing standards and adoption of new standards.* The Secretary considers a recommendation for a proposed modification to an existing standard, or a proposed new standard, only if the recommendation is developed through a process that provides for the following:

(1) Open public access.

(2) Coordination with other DSMOs.

(3) An appeals process for each of the following, if dissatisfied with the decision on the request:

(i) The requestor of the proposed modification.

(ii) A DSMO that participated in the review and analysis of the request for the proposed modification, or the proposed new standard.

(4) Expedited process to address content needs identified within the industry, if appropriate.

(5) Submission of the recommendation to the National Committee on Vital and Health Statistics (NCVHS).

§ 162.915 Trading partner agreements.

A covered entity must not enter into a trading partner agreement that would do any of the following:

(a) Change the definition, data condition, or use of a data element or segment in a standard or operating rule, except where necessary to implement State or Federal law, or to protect against fraud and abuse.

(b) Add any data elements or segments to the maximum defined data set.

(c) Use any code or data elements that are either marked ''not used'' in the standard's implementation specification or are not in the standard's implementation specification(s).

(d) Change the meaning or intent of the standard's implementation specification(s).

[65 FR 50367, Aug. 17, 2000, as amended at 76 FR 40495, July 8, 2011]

§ 162.920 Availability of implementation specifications and operating rules.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 714–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. The materials are also available for inspection by the public at the Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244. For more information on the availability on the materials at CMS, call (410) 786–6597. The materials are also available from the sources listed below.

(a) *ASC X12N specifications and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3*. The implementation specifications for the ASC X12N and the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3 (and accompanying Errata or Type 1 Errata) may be obtained from the ASC X12, 7600 Leesburg Pike, Suite 430, Falls Church, VA 22043; Telephone (703) 970–4480; and FAX (703) 970–4488. They are also available through the internet at *http://www.X12.org*. A fee is charged for all implementation specifications, including Technical Reports Type 3. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

(1) The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1, as referenced in § 162.1102 and § 162.1802.

(2) The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1, as referenced in § 162.1102 and § 162.1802.

(3) The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1 as referenced in § 162.1102 and § 162.1802.

(4) The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010, October 2002, Washington

Publishing Company, 004010X091A1 as referenced in § 162.1602.

(5) ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1, as referenced in § 162.1502.

(6) The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1, as referenced in § 162.1702.

(7) The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1, as referenced in § 162.1302.

(8) The ASC X12N–276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1, as referenced in § 162.1402.

(9) The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1, as referenced in § 162.1202.

(10) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim Dental (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1, as referenced in § 162.1102 and § 162.1802.

(11) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12, 005010X222, as referenced in § 162.1102 and § 162.1802.

(12) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12/N005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1, as referenced in § 162.1102 and § 162.1802.

(13) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221, as referenced in § 162.1602.

(14) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220, as referenced in § 162.1502.

(15) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218, as referenced in § 162.1702.

(16) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1, as referenced in § 162.1302.

(17) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X212E1, as referenced in § 162.1402.

(18) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility

Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279, as referenced in § 162.1202.

(b) *Retail pharmacy specifications and Medicaid subrogation implementation guides*. The implementation specifications for the retail pharmacy standards and the implementation specifications for the batch standard for the Medicaid pharmacy subrogation transaction may be obtained from the National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260. Telephone (480) 477–1000; FAX (480) 767–1042. They are also available through the Internet at *http://www.ncpdp.org*. A fee is charged for all NCPDP Implementation Guides. Charging for such publications is consistent with the policies of other publishers of standards. The transaction implementation specifications are as follows:

(1) The Telecommunication Standard Implementation Guide Version 5, Release 1 (Version 5.1), September 1999, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, § 162.1602, and § 162.1802.

(2) The Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(3) The National Council for Prescription Drug Programs (NCPDP) equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 0, February 1, 1996, as referenced in § 162.1102, § 162.1202, § 162.1602, and § 162.1802.

(4) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(5) The Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006, National Council for Prescription Drug Programs, as referenced in § 162.1102, § 162.1202, § 162.1302, and § 162.1802.

(6) The Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902.

(c) Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE), 601 Pennsylvania Avenue, NW. South Building, Suite 500 Washington, DC 20004; Telephone (202) 861–1492; Fax (202) 861- 1454; E-mail *info@CAQH.org*; and Internet at *http://www.caqh.org/benefits.php*.

(1) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase I Policies and Operating Rules, Approved April 2006, v5010 Update March 2011.

(i) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(ii) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(v) Phase I CORE 156: Eligibility and Benefits Real Time Response Time Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(vi) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011, as referenced in § 162.1203.

(2) ACME Health Plan, HIPAA Transaction Standard Companion Guide, Refers to the Implementation Guides Based on ASC X12 version 005010, CORE v5010 Master Companion Guide Template, 005010, 1.2, (CORE v 5010 Master Companion Guide Template, 005010, 1.2), March 2011, as referenced in §§ 162.1203, 162.1403, and 162.1603.

(3) CAQH, Committee on Operating Rules for Information Exchange, CORE Phase II Policies and Operating Rules, Approved July 2008, v5010 Update March 2011.

(i) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, as referenced in § 162.1403.

(ii) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iii) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(iv) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011, as referenced in § 162.1203.

(v) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011, as referenced in § 162.1203 and § 162.1403.

(4) Council for Affordable Quality Healthcare (CAQH) Phase III Committee on Operating Rules for Information Exchange (CORE) EFT & ERA Operating Rule Set, Approved June 2012, as specified in this paragraph and referenced in § 162.1603.

(i) Phase III CORE 380 EFT Enrollment Data Rule, version 3.0.0, June 2012.

(ii) Phase III CORE 382 ERA Enrollment Data Rule, version 3.0.0, June 2012.

(iii) Phase III 360 CORE Uniform Use of CARCs and RARCs (835) Rule, version 3.0.0, June 2012.

(iv) CORE-required Code Combinations for CORE-defined Business Scenarios for the Phase III CORE 360 Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule, version 3.0.0, June 2012.

(v) Phase III CORE 370 EFT & ERA Reassociation (CCD+/835) Rule, version 3.0.0, June 2012.

(vi) Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012, except Requirement 4.2 titled ''Health Care Claim Payment/Advice Batch Acknowledgement Requirements''.

(d) The National Automated Clearing House Association (NACHA), The Electronic Payments Association, 1350 Sunrise Valle Drive, Suite 100, Herndon, Virginia 20171 (Phone) (703) 561–1100; (Fax) (703) 713–1641; Email: *info@nacha.org;* and Internet at *http://www.nacha.org*. The implementation specifications are as follows:

(1) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules, Appendix One: ACH File Exchange Specifications (Operating Rule 59) as referenced in § 162.1602.

(2) 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network, NACHA Operating Rules Appendix Three: ACH Record Format Specifications (Operating Rule 78), Part 3.1, Subpart 3.1.8 Sequence of Records for CCD Entries as referenced in § 162.1602.

[68 FR 8396, Feb. 20, 2003, as amended at 69 FR 18803, Apr. 9, 2004; 74 FR 3324, Jan. 16, 2009; 76 FR 40495, July 8, 2011; 77 FR 1590, Jan. 10, 2012; 77 FR 48043, Aug. 10, 2012]

§ 162.923 Requirements for covered entities.

(a) *General rule*. Except as otherwise provided in this part, if a covered entity conducts, with another covered entity that is required to comply with a transaction standard adopted under this part (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.

(b) *Exception for direct data entry transactions*. A health care provider electing to use direct data entry offered by a health plan to conduct a transaction for which a standard has been adopted under this part must use the applicable data content and data condition requirements of the standard when conducting the transaction. The health care provider is not required to use the format requirements of the standard.

(c) *Use of a business associate*. A covered entity may use a business associate, including a health care clearinghouse, to conduct a transaction covered by this part. If a covered entity chooses to use a business associate to conduct all or part of a transaction on behalf of the covered entity, the covered entity must require the business associate to do the following:

(1) Comply with all applicable requirements of this part.

(2) Require any agent or subcontractor to comply with all applicable requirements of this part.

[65 FR 50367, Aug. 17, 2000, as amended at 74 FR 3325, Jan. 16, 2009]

§ 162.925 Additional requirements for health plans.

(a) *General rules.* (1) If an entity requests a health plan to conduct a transaction as a standard transaction, the health plan must do so.

(2) A health plan may not delay or reject a transaction, or attempt to adversely affect the other entity or the transaction, because the transaction is a standard transaction.

(3) A health plan may not reject a standard transaction on the basis that it contains data elements not needed or used by the health plan (for example, coordination of benefits information).

(4) A health plan may not offer an incentive for a health care provider to conduct a transaction covered by this part as a transaction described under the exception provided for in § 162.923(b).

(5) A health plan that operates as a health care clearinghouse, or requires an entity to use a health care clearinghouse to receive, process, or transmit a standard transaction may not charge fees or costs in excess of the fees or costs for normal telecommunications that the entity incurs when it directly transmits, or receives, a standard transaction to, or from, a health plan.

(6) During the period from March 17, 2009 through December 31, 2011, a health plan may not delay or reject a standard transaction, or attempt to adversely affect the other entity or the transaction, on the basis that it does not comply with another adopted standard for the same period.

(b) *Coordination of benefits.* If a health plan receives a standard transaction and coordinates benefits with another health plan (or another payer), it must store the coordination of benefits data it needs to forward the standard transaction to the other health plan (or other payer).

(c) *Code sets.* A health plan must meet each of the following requirements:

(1) Accept and promptly process any standard transaction that contains codes that are valid, as provided in subpart J of this part.

(2) Keep code sets for the current billing period and appeals periods still open to processing under the terms of the health plan's coverage.

[65 FR 50367, Aug. 17, 2000, as amended at 74 FR 3325, Jan. 16, 2009]

§ 162.930 Additional rules for health care clearinghouses.

When acting as a business associate for another covered entity, a health care clearinghouse may perform the following functions:

(a) Receive a standard transaction on behalf of the covered entity and translate it into a nonstandard transaction (for example, nonstandard format and/or nonstandard data content) for transmission to the covered entity.

(b) Receive a nonstandard transaction (for example, nonstandard format and/or nonstandard data content) from the covered entity and translate it into a standard transaction for transmission on behalf of the covered entity.

§ 162.940 Exceptions from standards to permit testing of proposed modifications.

(a) *Requests for an exception.* An organization may request an exception from the use of a standard from the Secretary to test a proposed modification to that standard. For each proposed modification, the organization must meet the following requirements:

(1) *Comparison to a current standard.* Provide a detailed explanation, no more than 10 pages in length, of how the proposed modification would be a significant improvement to the current standard in terms of the following principles:

(i) Improve the efficiency and effectiveness of the health care system by leading to cost reductions for, or improvements in benefits from, electronic health care transactions.

(ii) Meet the needs of the health data standards user community, particularly health care providers, health plans, and health care clearinghouses.

(iii) Be uniform and consistent with the other standards adopted under this part and, as appropriate, with other

private and public sector health data standards.

(iv) Have low additional development and implementation costs relative to the benefits of using the standard.

(v) Be supported by an ANSI-accredited SSO or other private or public organization that would maintain the standard over time.

(vi) Have timely development, testing, implementation, and updating procedures to achieve administrative simplification benefits faster.

(vii) Be technologically independent of the computer platforms and transmission protocols used in electronic health transactions, unless they are explicitly part of the standard.

(viii) Be precise, unambiguous, and as simple as possible.

(ix) Result in minimum data collection and paperwork burdens on users.

(x) Incorporate flexibility to adapt more easily to changes in the health care infrastructure (such as new services, organizations, and provider types) and information technology.

(2) *Specifications for the proposed modification*. Provide specifications for the proposed modification, including any additional system requirements.

(3) *Testing of the proposed modification*. Provide an explanation, no more than 5 pages in length, of how the organization intends to test the standard, including the number and types of health plans and health care providers expected to be involved in the test, geographical areas, and beginning and ending dates of the test.

(4) *Trading partner concurrences*. Provide written concurrences from trading partners who would agree to participate in the test.

(b) *Basis for granting an exception*. The Secretary may grant an initial exception, for a period not to exceed 3 years, based on, but not limited to, the following criteria:

(1) An assessment of whether the proposed modification demonstrates a significant improvement to the current standard.

(2) The extent and length of time of the exception.

(3) Consultations with DSMOs.

(c) *Secretary's decision on exception*. The Secretary makes a decision and notifies the organization requesting the exception whether the request is granted or denied.

(1) *Exception granted*. If the Secretary grants an exception, the notification includes the following information:

(i) The length of time for which the exception applies.

(ii) The trading partners and geographical areas the Secretary approves for testing.

(iii) Any other conditions for approving the exception.

(2) *Exception denied*. If the Secretary does not grant an exception, the notification explains the reasons the Secretary considers the proposed modification would not be a significant improvement to the current standard and any other rationale for the denial.

(d) *Organization's report on test results*. Within 90 days after the test is completed, an organization that receives an exception must submit a report on the results of the test, including a cost-benefit analysis, to a location specified by the Secretary by notice in the FEDERAL REGISTER.

(e) *Extension allowed*. If the report submitted in accordance with paragraph (d) of this section recommends a modification to the standard, the Secretary, on request, may grant an extension to the period granted for the exception.

Subpart J—Code Sets

§ 162.1000 General requirements.

When conducting a transaction covered by this part, a covered entity must meet the following requirements:

(a) *Medical data code sets*. Use the applicable medical data code sets described in § 162.1002 as specified in the implementation specification adopted under this part that are valid at the time the health care is furnished.

(b) *Nonmedical data code sets*. Use the nonmedical data code sets as described in the implementation specifications adopted under this part that are valid at the time the transaction is initiated.

§ 162.1002 Medical data code sets.

The Secretary adopts the following maintaining organization's code sets as the standard medical data code sets:

(a) For the period from October 16, 2002 through October 15, 2003:

(1) *International Classification of Diseases, 9th Edition, Clinical Modification, (ICD–9–CM), Volumes 1 and 2* (including The Official ICD–9–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(2) *International Classification of Diseases, 9th Edition, Clinical Modification, Volume 3 Procedures* (including The Official ICD–9–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

(i) Prevention.

(ii) Diagnosis.

(iii) Treatment.

(iv) Management.

(3) *National Drug Codes* (NDC), as maintained and distributed by HHS, in collaboration with drug manufacturers, for the following:

(i) Drugs

(ii) Biologics.

(4) *Code on Dental Procedures and Nomenclature,* as maintained and distributed by the American Dental Association, for dental services.

(5) The combination of *Health Care Financing Administration Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, and *Current Procedural Terminology, Fourth Edition (CPT–4),* as maintained and distributed by the American Medical Association, for physician services and other health care services. These services include, but are not limited to, the following:

(i) Physician services.

(ii) Physical and occupational therapy services.

(iii) Radiologic procedures.

(iv) Clinical laboratory tests.

(v) Other medical diagnostic procedures.

(vi) Hearing and vision services.

(vii) Transportation services including ambulance.

(6) The *Health Care Financing Administration Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services. These items include, but are not limited to, the following:

(i) Medical supplies.

(ii) Orthotic and prosthetic devices.

(iii) Durable medical equipment.

(b) For the period on and after October 16, 2003 through September 30, 2013:

(1) The code sets specified in paragraphs (a)(1), (a)(2),(a)(4), and (a)(5) of this section.

(2) *National Drug Codes (NDC),* as maintained and distributed by HHS, for reporting the following by retail pharmacies:

(i) Drugs.

(ii) Biologics.

(3) *The Healthcare Common Procedure Coding System (HCPCS),* as maintained and distributed by HHS, for all other substances, equipment, supplies, or other items used in health care services, with the exception of drugs and biologics. These items include, but are not limited to, the following:

(i) Medical supplies.

(ii) Orthotic and prosthetic devices.

(iii) Durable medical equipment.

(c) For the period on and after October 1, 2013:

(1) The code sets specified in paragraphs (a)(4), (a)(5), (b)(2), and (b)(3) of this section.

(2) International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) (including The Official ICD–10–CM Guidelines for Coding and Reporting), as maintained and distributed by HHS, for the following conditions:

(i) Diseases.

(ii) Injuries.

(iii) Impairments.

(iv) Other health problems and their manifestations.

(v) Causes of injury, disease, impairment, or other health problems.

(3) International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) (including The Official ICD–10–PCS Guidelines for Coding and Reporting), as maintained

and distributed by HHS, for the following procedures or other actions taken for diseases, injuries, and impairments on hospital inpatients reported by hospitals:

(i) Prevention.

(ii) Diagnosis.

(iii) Treatment.

(iv) Management.

[65 FR 50367, Aug. 17, 2000, as amended at 68 FR 8397, Feb. 20, 2003; 74 FR 3362, Jan. 16, 2009]

EFFECTIVE DATE NOTE: At 77 FR 54720, Sept. 5, 2012, § 162.1002 was amended by revising paragraph (b) introductory text and paragraph (c) introductory text, effective Nov. 5, 2012. For the convenience of the user, the revised text is set forth as follows:

§ 162.1002 Medical data code sets.

* * * * *

(b) For the period on and after October 16, 2003 through September 30, 2014:

* * * * *

(c) For the period on and after October 1, 2014:

* * * * *

§ 162.1011 Valid code sets.

Each code set is valid within the dates specified by the organization responsible for maintaining that code set.

Subpart K—Health Care Claims or Equivalent Encounter Information

§ 162.1101 Health care claims or equivalent encounter information transaction.

The health care claims or equivalent encounter information transaction is the transmission of either of the following:

(a) A request to obtain payment, and the necessary accompanying information from a health care provider to a health plan, for health care.

(b) If there is no direct claim, because the reimbursement contract is based on a mechanism other than charges or reimbursement rates for specific services, the transaction is the transmission of encounter information for the purpose of reporting health care.

§ 162.1102 Standards for health care claims or equivalent encounter information transaction.

The Secretary adopts the following standards for the health care claims or equivalent encounter information transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drugs claims.* The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standards Implementation Guide, Version 5, Release 1, September 1999, and equivalent NCPDP Batch Standards Batch Implementation Guide, Version 1, Release 1, (Version 1.1), January 2000, supporting Telecomunication Version 5.1 for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097. and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claims: Professional, Volumes 1 and 2, Version 4010, may 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claims: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010x098A1. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X096A1. (Incorporated by reference in § 162.920).

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1)(i) The standards identified in paragraph (a) of this section; and

(ii) For retail pharmacy supplies and professional services claims, the following: The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096, October 2002 (Incorporated by reference in § 162.920); and

(2)(i) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007 and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837) ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1. (Incorporated by reference in § 162.920.)

(iii) *Professional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in § 162.920.)

(iv) *Institutional health care claims.* The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1. (Incorporated by reference in § 162.920.)

(v) *Retail pharmacy supplies and professional services claims.* (A) The Telecommunication Standard, Implementation Guide Version 5, Release 1, September 1999. (Incorporated by reference in § 162.920.)

(B) The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs (Incorporated by reference in § 162.920); and

(C) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in § 162.920.)

(c) For the period on and after the January 1, 2012, the standards identified in paragraph (b)(2) of this section, except the standard identified in paragraph (b)(2)(v)(A) of this section.

[68 FR 8397, Feb. 20, 2003; 68 FR 11445, Mar. 10, 2003, as amended at 74 FR 3325, Jan. 16, 2009]

Subpart L—Eligibility for a Health Plan

§ 162.1201 Eligibility for a health plan transaction.

The eligibility for a health plan transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan, or from one health plan to another health plan, to obtain any of the following information about a benefit plan for an enrollee:

(1) Eligibility to receive health care under the health plan.

(2) Coverage of health care under the health plan.

(3) Benefits associated with the benefit plan.

(b) A response from a health plan to a health care provider's (or another health plan's) inquiry described in paragraph (a) of this section.

§ 162.1202 Standards for eligibility for a health plan transaction.

The Secretary adopts the following standards for the eligibility for a health plan transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drugs.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP

Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional health care eligibility benefit inquiry and response*. The ASC X12N 270/271—Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1. (Incorporated by reference in § 162.920).

(b) For the period from March 17, 2009 through December 31, 2011 both:

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drugs*. The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental, professional, and institutional health care eligibility benefit inquiry and response*. The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Eligibility Benefit Inquiry and Response (270/271), April 2008, ASC X12N/005010X279. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

[68 FR 8398, Feb. 20, 2003; 68 FR 11445, Mar. 10, 2003, as amended at 74 FR 3326, Jan. 16, 2009]

§ 162.1203 Operating rules for eligibility for a health plan transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase I and Phase II operating rules (updated for Version 5010) for the eligibility for a health plan transaction:

(1) Phase I CORE 152: Eligibility and Benefit Real Time Companion Guide Rule, version 1.1.0, March 2011, and CORE v5010 Master Companion Guide Template. (Incorporated by reference in § 162.920).

(2) Phase I CORE 153: Eligibility and Benefits Connectivity Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(3) Phase I CORE 154: Eligibility and Benefits 270/271 Data Content Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(4) Phase I CORE 155: Eligibility and Benefits Batch Response Time Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(5) Phase I CORE 156: Eligibility and Benefits Real Time Response Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(6) Phase I CORE 157: Eligibility and Benefits System Availability Rule, version 1.1.0, March 2011. (Incorporated by reference in § 162.920).

(7) Phase II CORE 258: Eligibility and Benefits 270/271 Normalizing Patient Last Name Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920).

(8) Phase II CORE 259: Eligibility and Benefits 270/271 AAA Error Code Reporting Rule, version 2.1.0. (Incorporated by reference in § 162.920).

(9) Phase II CORE 260: Eligibility & Benefits Data Content (270/271) Rule, version 2.1.0, March 2011. (Incorporated by reference in § 162.920).

(10) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

[76 FR 40496, July 8, 2011]

Subpart M—Referral Certification and Authorization

§ 162.1301 Referral certification and authorization transaction.

The referral certification and authorization transaction is any of the following transmissions:

(a) A request from a health care provider to a health plan for the review of health care to obtain an authorization for the health care.

(b) A request from a health care provider to a health plan to obtain authorization for referring an individual to another health care provider.

(c) A response from a health plan to a health care provider to a request described in paragraph (a) or paragraph (b) of this section.

[74 FR 3326, Jan. 16, 2009]

§ 162.1302 Standards for referral certification and authorization transaction.

The Secretary adopts the following standards for the referral certification and authorization transaction:

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drug referral certification and authorization*. The NCPDP Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental, professional, and institutional referral certification and authorization*. The ASC X12N 278—Health Care Services Review—Request for Review and Response, Version 4010, May 2000, Washington Publishing Company, 004010X094 and Addenda to Health Care Services Review—Request for Review and Response, Version 4010, October 2002, Washington Publishing Company, 004010X094A1. (Incorporated by reference in § 162.920).

(b) For the period from March 17, 2009 through December 31, 2011 both—

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drugs*. The Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) *Dental, professional, and institutional request for review and response*. The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Services Review—Request for Review and Response (278), May 2006, ASC X12N/005010X217, and Errata to Health Care Services Review—Request for Review and Response (278), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008, ASC X12N/005010X217E1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

[68 FR 8398, Feb. 20, 2003, as amended at 74 FR 3326, Jan. 16, 2009]

Subpart N—Health Care Claim Status

§ 162.1401 Health care claim status transaction.

The health care claim status transaction is the transmission of either of the following:

(a) An inquiry from a health care provider to a health plan to determine the status of a health care claim.

(b) A response from a health plan to a health care provider about the status of a health care claim.

[74 FR 3326, Jan. 16, 2009]

§ 162.1402 Standards for health care claim status transaction.

The Secretary adopts the following standards for the health care claim status transaction:

(a) For the period from October 16, 2003 through March 16, 2009: The ASC X12N–276/277 Health Care Claim Status Request and Response, Version 4010, May 2000, Washington Publishing Company, 004010X093 and Addenda to Health Care Claim Status Request and Response, Version 4010, October 2002, Washington Publishing Company, 004010X093A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Status Request and Response (276/277), August 2006, ASC X12N/005010X212, and Errata to Health Care Claim Status Request and Response (276/277), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, April 2008,

ASC X12N/005010X212E1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3326, Jan. 16, 2009]

§ 162.1403 Operating rules for health care claim status transaction.

On and after January 1, 2013, the Secretary adopts the following:

(a) Except as specified in paragraph (b) of this section, the following CAQH CORE Phase II operating rules (updated for Version 5010) for the health care claim status transaction:

(1) Phase II CORE 250: Claim Status Rule, version 2.1.0, March 2011, and CORE v5010 Master Companion Guide, 00510, 1.2, March 2011. (Incorporated by reference in § 162.920).

(2) Phase II CORE 270: Connectivity Rule, version 2.2.0, March 2011. (Incorporated by reference in § 162.920).

(b) Excluding where the CAQH CORE rules reference and pertain to acknowledgements and CORE certification.

[76 FR 40496, July 8, 2011]

Subpart O—Enrollment and Disenrollment in a Health Plan

§ 162.1501 Enrollment and disenrollment in a health plan transaction.

The enrollment and disenrollment in a health plan transaction is the transmission of subscriber enrollment information from the sponsor of the insurance coverage, benefits, or policy, to a health plan to establish or terminate insurance coverage.

[74 FR 3327, Jan. 16, 2009]

§ 162.1502 Standards for enrollment and disenrollment in a health plan transaction.

The Secretary adopts the following standards for enrollment and disenrollment in a health plan transaction.

(a) For the period from October 16, 2003 through March 16, 2009: ASC X12N 834—Benefit Enrollment and Maintenance, Version 4010, May 2000, Washington Publishing Company, 004010X095 and Addenda to Benefit Enrollment and Maintenance, Version 4010, October 2002, Washington Publishing Company, 004010X095A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section; and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Benefit Enrollment and Maintenance (834), August 2006, ASC X12N/005010X220 (Incorporated by reference in § 162.920)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3327, Jan. 16, 2009]

Subpart P—Health Care Electronic Funds Transfers (EFT) and Remittance Advice

§ 162.1601 Health care electronic funds transfers (EFT) and remittance advice transaction.

The health care electronic funds transfers (EFT) and remittance advice transaction is the transmission of either of the following for health care:

(a) The transmission of any of the following from a health plan to a health care provider:

(1) Payment.

(2) Information about the transfer of funds.

(3) Payment processing information.

(b) The transmission of either of the following from a health plan to a health care provider:

(1) Explanation of benefits.

(2) Remittance advice.

[65 FR 50367, Aug. 17, 2000, as amended at 77 FR 1590, Jan. 10, 2012; 77 FR 48043, Aug. 10, 2012]

§ 162.1602 Standards for health care electronic funds transfers (EFT) and remittance advice transaction.

The Secretary adopts the following standards:

(a) For the period from October 16, 2003 through March 16, 2009: Health care claims and remittance advice. The ASC X12N 835—Health Care Claim Payment/Advice, Version 4010, May 2000, Washington Publishing Company, 004010X091, and Addenda to Health Care Claim Payment/Advice, Version 4010,

October 2002, Washington Publishing Company, 004010X091A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both of the following standards:

(1) The standard identified in paragraph (a) of this section.

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in § 162.920.)

(c) For the period from January 1, 2012 through December 31, 2013, the standard identified in paragraph (b)(2) of this section.

(d) For the period on and after January 1, 2014, the following standards:

(1) Except when transmissions as described in § 162.1601(a) and (b) are contained within the same transmission, for Stage 1 Payment Initiation transmissions described in § 162.1601(a), all of the following standards:

(i) The National Automated Clearing House Association (NACHA) Corporate Credit or Deposit Entry with Addenda Record (CCD+) implementation specifications as contained in the 2011 NACHA Operating Rules & Guidelines, A Complete Guide to the Rules Governing the ACH Network as follows (incorporated by reference in § 162.920)—

(A) NACHA Operating Rules, Appendix One: ACH File Exchange Specifications; and

(B) NACHA Operating Rules, Appendix Three: ACH Record Format Specifications, Subpart 3.1.8 Sequence of Records for CCD Entries.

(ii) For the CCD Addenda Record (''7''), field 3, of the standard identified in 1602(d)(1)(i), the Accredited Standards Committee (ASC) X12 Standards for Electronic Data Interchange Technical Report Type 3, ''Health Care Claim Payment/Advice (835), April 2006: Section 2.4: 835 Segment Detail: ''TRN Reassociation Trace Number,'' Washington Publishing Company, 005010X221 (Incorporated by reference in § 162.920).

(2) For transmissions described in § 162.1601(b), including when transmissions as described in § 162.1601(a) and (b) are contained within the same transmission, the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, ''Health Care Claim Payment/Advice (835), April 2006, ASC X12N/005010X221. (Incorporated by reference in § 162.920).

[77 FR 1590, Jan. 10, 2012]

§ 162.1603 Operating rules for health care electronic funds transfers (EFT) and remittance advice transaction.

On and after January 1, 2014, the Secretary adopts the following for the health care electronic funds transfers (EFT) and remittance advice transaction:

(a) The Phase III CORE EFT & ERA Operating Rule Set, Approved June 2012 (Incorporated by reference in § 162.920) which includes the following rules:

(1) Phase III CORE 380 EFT Enrollment Data Rule, version 3.0.0, June 2012.

(2) Phase III CORE 382 ERA Enrollment Data Rule, version 3.0.0, June 2012.

(3) Phase III 360 CORE Uniform Use of CARCs and RARCs (835) Rule, version 3.0.0, June 2012.

(4) CORE-required Code Combinations for CORE-defined Business Scenarios for the Phase III CORE 360 Uniform Use of Claim Adjustment Reason Codes and Remittance Advice Remark Codes (835) Rule, version 3.0.0, June 2012.

(5) Phase III CORE 370 EFT & ERA Reassociation (CCD+/835) Rule, version 3.0.0, June 2012.

(6) Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012, except Requirement 4.2 titled ''Health Care Claim Payment/Advice Batch Acknowledgement Requirements''.

(b) ACME Health Plan, CORE v5010 Master Companion Guide Template, 005010, 1.2, March 2011 (incorporated by reference in § 162.920), as required by the Phase III CORE 350 Health Care Claim Payment/Advice (835) Infrastructure Rule, version 3.0.0, June 2012.

[77 FR 48043, Aug. 10, 2012]

Subpart Q—Health Plan Premium Payments

§ 162.1701 Health plan premium payments transaction.

The health plan premium payment transaction is the transmission of any of the following from the entity that is arranging for the provision of health care or is providing health care coverage payments for an individual to a health plan:

(a) Payment.

(b) Information about the transfer of funds.

(c) Detailed remittance information about individuals for whom premiums are being paid.

(d) Payment processing information to transmit health care premium payments including any of the following:

(1) Payroll deductions.

(2) Other group premium payments.

(3) Associated group premium payment information.

§ 162.1702 Standards for health plan premium payments transaction.

The Secretary adopts the following standards for the health plan premium payments transaction:

(a) For the period from October 16, 2003 through March 16, 2009: The ASC X12N 820—Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, May 2000, Washington Publishing Company, 004010X061, and Addenda to Payroll Deducted and Other Group Premium Payment for Insurance Products, Version 4010, October 2002, Washington Publishing Company, 004010X061A1. (Incorporated by reference in § 162.920.)

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standard identified in paragraph (a) of this section, and

(2) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Payroll Deducted and Other Group Premium Payment for Insurance Products (820), February 2007, ASC X12N/005010X218. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standard identified in paragraph (b)(2) of this section.

[74 FR 3327, Jan. 16, 2009]

Subpart R—Coordination of Benefits

§ 162.1801 Coordination of benefits transaction.

The coordination of benefits transaction is the transmission from any entity to a health plan for the purpose of determining the relative payment responsibilities of the health plan, of either of the following for health care:

(a) Claims.

(b) Payment information.

§ 162.1802 Standards for coordination of benefits information transaction.

The Secretary adopts the following standards for the coordination of benefits information transaction.

(a) For the period from October 16, 2003 through March 16, 2009:

(1) *Retail pharmacy drug claims.* The National Council for Prescription Drug Programs Telecommunication Standard Implementation Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000, supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record. (Incorporated by reference in § 162.920).

(2) *Dental health care claims.* The ASC X12N 837—Health Care Claim: Dental, Version 4010, May 2000, Washington Publishing Company, 004010X097 and Addenda to Health Care Claim: Dental, Version 4010, October 2002, Washington Publishing Company, 004010X097A1. (Incorporated by reference in § 162.920).

(3) *Professional health care claims.* The ASC X12N 837—Health Care Claim: Professional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X098 and Addenda to Health Care Claim: Professional, Volumes 1 and 2, Version 4010, October 2002, Washington Publishing Company, 004010X098A1. (Incorporated by reference in § 162.920).

(4) *Institutional health care claims.* The ASC X12N 837—Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, May 2000, Washington Publishing Company, 004010X096 and Addenda to Health Care Claim: Institutional, Volumes 1 and 2, Version 4010, October

2002, Washington Publishing Company, 004010X096A1. (Incorporated by reference in § 162.920).

(b) For the period from March 17, 2009 through December 31, 2011, both:

(1) The standards identified in paragraph (a) of this section; and

(2)(i) *Retail pharmacy drug claims.* The Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, and equivalent Batch Standard Implementation Guide, Version 1, Release 2 (Version 1.2), National Council for Prescription Drug Programs. (Incorporated by reference in § 162.920.)

(ii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Dental (837), May 2006, ASC X12N/005010X224, and Type 1 Errata to Health Care Claim: Dental (837), ASC X12 Standards for Electronic Date Interchange Technical Report Type 3, October 2007, ASC X12N/005010X224A1. (Incorporated by reference in § 162.920.)

(iii) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Professional (837), May 2006, ASC X12N/005010X222. (Incorporated by reference in § 162.920.)

(iv) The ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837), ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X223A1. (Incorporated by reference in § 162.920.)

(c) For the period on and after January 1, 2012, the standards identified in paragraph (b)(2) of this section.

[68 FR 8399, Feb. 20, 2003, as amended at 74 FR 3327, Jan. 16, 2009]

Subpart S—Medicaid Pharmacy Subrogation

SOURCE: 74 FR 3328, Jan. 16, 2009, unless otherwise noted.

§ 162.1901 Medicaid pharmacy subrogation transaction.

The Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the State has paid on behalf of a Medicaid recipient.

§ 162.1902 Standard for Medicaid pharmacy subrogation transaction.

The Secretary adopts the Batch Standard Medicaid Subrogation Implementation Guide, Version 3, Release 0 (Version 3.0), July 2007, National Council for Prescription Drug Programs, as referenced in § 162.1902 (Incorporated by reference at § 162.920):

(a) For the period on and after January 1, 2012, for covered entities that are not small health plans;

(b) For the period on and after January 1, 2013 for small health plans.

PART 163 [RESERVED]

PART 164—SECURITY AND PRIVACY

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AUTHORITY: 42 U.S.C. 1320d–1320d–8; sec. 264, Public Law 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320–2 (note)); secs. 13400 and 13402, Public Law 111–5, 123 Stat. 258–263.

SOURCE: 65 FR 82802, Dec. 28, 2000, unless otherwise noted.

Subpart A—General Provisions

§ 164.102 Statutory basis.

The provisions of this part are adopted pursuant to the Secretary's authority to prescribe standards, requirements, and implementation specifications under part C of title XI of the Act, section 264 of Public Law 104–191, and section 13402 of Public Law 111–5.

[74 FR 42767, Aug. 24, 2009]

§ 164.103 Definitions.

As used in this part, the following terms have the following meanings:

Common control exists if an entity has the power, directly or indirectly, significantly to influence or direct the actions or policies of another entity.

Common ownership exists if an entity or entities possess an ownership or equity interest of 5 percent or more in another entity.

Covered functions means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

Health care component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with § 164.105(a)(2)(iii)(C).

Hybrid entity means a single legal entity:

(1) That is a covered entity;

(2) Whose business activities include both covered and non-covered functions; and

(3) That designates health care components in accordance with paragraph § 164.105(a)(2)(iii)(C).

Law enforcement official means an officer or employee of any agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, who is empowered by law to:

(1) Investigate or conduct an official inquiry into a potential violation of law; or

(2) Prosecute or otherwise conduct a criminal, civil, or administrative proceeding arising from an alleged violation of law.

Plan sponsor is defined as defined at section 3(16)(B) of ERISA, 29 U.S.C. 1002(16)(B).

Required by law means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. *Required by law* includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an

authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

[68 FR 8374, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009]

§ 164.104 Applicability.

(a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this part apply to the following entities:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

(b) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, or other than as a business associate of a covered entity, the clearinghouse must comply with § 164.105 relating to organizational requirements for covered entities, including the designation of health care components of a covered entity.

[68 FR 8375, Feb. 20, 2003]

§ 164.105 Organizational requirements.

(a)(1) *Standard: Health care component.* If a covered entity is a hybrid entity, the requirements of subparts C and E of this part, other than the requirements of this section, § 164.314, and § 164.504, apply only to the health care component(s) of the entity, as specified in this section.

(2) *Implementation specifications:*

(i) *Application of other provisions.* In applying a provision of subparts C and E of this part, other than the requirements of this section, § 164.314, and § 164.504, to a hybrid entity:

(A) A reference in such provision to a ''covered entity'' refers to a health care component of the covered entity;

(B) A reference in such provision to a ''health plan,'' ''covered health care provider,'' or ''health care clearinghouse,'' refers to a health care component of the covered entity if such health care component performs the functions of a health plan, health care provider, or health care clearinghouse, as applicable;

(C) A reference in such provision to ''protected health information'' refers to protected health information that is created or received by or on behalf of the health care component of the covered entity; and

(D) A reference in such provision to ''electronic protected health information'' refers to electronic protected health information that is created, received, maintained, or transmitted by or on behalf of the health care component of the covered entity.

(ii) *Safeguard requirements.* The covered entity that is a hybrid entity must ensure that a health care component of the entity complies with the applicable requirements of this section and subparts C and E of this part. In particular, and without limiting this requirement, such covered entity must ensure that:

(A) Its health care component does not disclose protected health information to another component of the covered entity in circumstances in which subpart E of this part would prohibit such disclosure if the health care component and the other component were separate and distinct legal entities;

(B) Its health care component protects electronic protected health information with respect to another component of the covered entity to the same extent that it would be required under subpart C of this part to protect such information if the health care component and the other component were separate and distinct legal entities;

(C) A component that is described by paragraph (a)(2)(iii)(C)(*2*) of this section does not use or disclose protected health information that it creates or receives from or on behalf of the health care component in a way prohibited by subpart E of this part;

(D) A component that is described by paragraph (a)(2)(iii)(C)(*2*) of this section that creates, receives, maintains, or transmits electronic protected health information on behalf of the health care component is in compliance with subpart C of this part; and

(E) If a person performs duties for both the health care component in the capacity of a member of the workforce of such component and for another component of the entity in the same capacity with respect to that component, such workforce member must not use or disclose protected health information created or received in the course of or incident to the member's work for the health care component in a way prohibited by subpart E of this part.

(iii) *Responsibilities of the covered entity*. A covered entity that is a hybrid entity has the following responsibilities:

(A) For purposes of subpart C of part 160 of this subchapter, pertaining to compliance and enforcement, the covered entity has the responsibility of complying with subpart E of this part.

(B) The covered entity is responsible for complying with §164.316(a) and §164.530(i), pertaining to the implementation of policies and procedures to ensure compliance with applicable requirements of this section and subparts C and E of this part, including the safeguard requirements in paragraph (a)(2)(ii) of this section.

(C) The covered entity is responsible for designating the components that are part of one or more health care components of the covered entity and documenting the designation in accordance with paragraph (c) of this section, provided that, if the covered entity designates a health care component or components, it must include any component that would meet the definition of covered entity if it were a separate legal entity. Health care component(s) also may include a component only to the extent that it performs:

(*1*) Covered functions; or

(*2*) Activities that would make such component a business associate of a component that performs covered functions if the two components were separate legal entities.

(b)(1) *Standard: Affiliated covered entities*. Legally separate covered entities that are affiliated may designate themselves as a single covered entity for purposes of subparts C and E of this part.

(1) *Implementation specifications:*

(i) *Requirements for designation of an affiliated covered entity*. (A) Legally separate covered entities may designate themselves (including any health care component of such covered entity) as a single affiliated covered entity, for purposes of subparts C and E of this part, if all of the covered entities designated are under common ownership or control.

(B) The designation of an affiliated covered entity must be documented and the documentation maintained as required by paragraph (c) of this section.

(ii) *Safeguard requirements*. An affiliated covered entity must ensure that:

(A) The affiliated covered entity's creation, receipt, maintenance, or transmission of electronic protected health information complies with the applicable requirements of subpart C of this part;

(B) The affiliated covered entity's use and disclosure of protected health information comply with the applicable requirements of subpart E of this part; and

(C) If the affiliated covered entity combines the functions of a health plan, health care provider, or health care clearinghouse, the affiliated covered entity complies with §164.308(a)(4)(ii)(A) and §164.504(g), as applicable.

(c)(1) *Standard: Documentation*. A covered entity must maintain a written or electronic record of a designation as required by paragraphs (a) or (b) of this section.

(2) *Implementation specification: Retention period*. A covered entity must retain the documentation as required by paragraph (c)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

[68 FR 8375, Feb. 20, 2003]

§164.106 Relationship to other parts.

In complying with the requirements of this part, covered entities are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.

Subpart B [Reserved]

Subpart C—Security Standards for the Protection of Electronic Protected Health Information

AUTHORITY: 42 U.S.C. 1320d-2 and 1320d-4.

SOURCE: 68 FR 8376, Feb. 20, 2003, unless otherwise noted.

§ 164.302 Applicability.

A covered entity must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information.

§ 164.304 Definitions.

As used in this subpart, the following terms have the following meanings:

Access means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource. (This definition applies to ''access'' as used in this subpart, not as used in subparts D or E of this part.)

Administrative safeguards are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's workforce in relation to the protection of that information.

Authentication means the corroboration that a person is the one claimed.

Availability means the property that data or information is accessible and useable upon demand by an authorized person.

Confidentiality means the property that data or information is not made available or disclosed to unauthorized persons or processes.

Encryption means the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key.

Facility means the physical premises and the interior and exterior of a building(s).

Information system means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.

Integrity means the property that data or information have not been altered or destroyed in an unauthorized manner.

Malicious software means software, for example, a virus, designed to damage or disrupt a system.

Password means confidential authentication information composed of a string of characters.

Physical safeguards are physical measures, policies, and procedures to protect a covered entity's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

Security or Security measures encompass all of the administrative, physical, and technical safeguards in an information system.

Security incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in an information system.

Technical safeguards means the technology and the policy and procedures for its use that protect electronic protected health information and control access to it.

User means a person or entity with authorized access.

Workstation means an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment.

[68 FR 8376, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009]

§ 164.306 Security standards: General rules.

(a) *General requirements*. Covered entities must do the following:

(1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity creates, receives, maintains, or transmits.

(2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.

(3) Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under subpart E of this part.

(4) Ensure compliance with this subpart by its workforce.

(b) *Flexibility of approach.* (1) Covered entities may use any security measures that allow the covered entity to reasonably and appropriately implement the standards and implementation specifications as specified in this subpart.

(2) In deciding which security measures to use, a covered entity must take into account the following factors:

(i) The size, complexity, and capabilities of the covered entity.

(ii) The covered entity's technical infrastructure, hardware, and software security capabilities.

(iii) The costs of security measures.

(iv) The probability and criticality of potential risks to electronic protected health information.

(c) *Standards.* A covered entity must comply with the standards as provided in this section and in § 164.308, § 164.310, § 164.312, § 164.314, and § 164.316 with respect to all electronic protected health information.

(d) *Implementation specifications.* In this subpart:

(1) Implementation specifications are required or addressable. If an implementation specification is required, the word ''Required'' appears in parentheses after the title of the implementation specification. If an implementation specification is addressable, the word ''Addressable'' appears in parentheses after the title of the implementation specification.

(2) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes required implementation specifications, a covered entity must implement the implementation specifications.

(3) When a standard adopted in § 164.308, § 164.310, § 164.312, § 164.314, or § 164.316 includes addressable implementation specifications, a covered entity must—

(i) Assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting the entity's electronic protected health information; and

(ii) As applicable to the entity—

(A) Implement the implementation specification if reasonable and appropriate; or

(B) If implementing the implementation specification is not reasonable and appropriate—

$(*1*) Document why it would not be reasonable and appropriate to implement the implementation specification; and

$(*2*) Implement an equivalent alternative measure if reasonable and appropriate.

(e) *Maintenance.* Security measures implemented to comply with standards and implementation specifications adopted under § 164.105 and this subpart must be reviewed and modified as needed to continue provision of reasonable and appropriate protection of electronic protected health information as described at § 164.316.

[68 FR 8376, Feb. 20, 2003; 68 FR 17153, Apr. 8, 2003]

§ 164.308 Administrative safeguards.

(a) A covered entity must, in accordance with § 164.306:

(1)(i) *Standard: Security management process.* Implement policies and procedures to prevent, detect, contain, and correct security violations.

(ii) *Implementation specifications:*

(A) *Risk analysis* (Required). Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity.

(B) *Risk management* (Required). Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with § 164.306(a).

(C) *Sanction policy* (Required). Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity.

(D) *Information system activity review* (Required). Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

(2) *Standard: Assigned security responsibility*. Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the entity.

(3)(i) *Standard: Workforce security*. Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this section, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.

(ii) *Implementation specifications:*

(A) *Authorization and/or supervision* (Addressable). Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed.

(B) *Workforce clearance procedure* (Addressable). Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate.

(C) *Termination procedures* (Addressable). Implement procedures for terminating access to electronic protected health information when the employment of a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

(4)(i) *Standard: Information access management*. Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part.

(ii) *Implementation specifications:*

(A) *Isolating health care clearinghouse functions* (Required). If a health care clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization.

(B) *Access authorization* (Addressable). Implement policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism.

(C) *Access establishment and modification* (Addressable). Implement policies and procedures that, based upon the entity's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.

(5)(i) *Standard: Security awareness and training*. Implement a security awareness and training program for all members of its workforce (including management).

(ii) *Implementation specifications*. Implement:

(A) *Security reminders* (Addressable). Periodic security updates.

(B) *Protection from malicious software* (Addressable). Procedures for guarding against, detecting, and reporting malicious software.

(C) *Log-in monitoring* (Addressable). Procedures for monitoring log-in attempts and reporting discrepancies.

(D) *Password management* (Addressable). Procedures for creating, changing, and safeguarding passwords.

(6)(i) *Standard: Security incident procedures*. Implement policies and procedures to address security incidents.

(ii) *Implementation specification: Response and Reporting* (Required). Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity; and document security incidents and their outcomes.

(7)(i) *Standard: Contingency plan*. Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information.

(ii) *Implementation specifications:*

(A) *Data backup plan* (Required). Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information.

(B) *Disaster recovery plan* (Required). Establish (and implement as needed) procedures to restore any loss of data.

(C) *Emergency mode operation plan* (Required). Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode.

(D) *Testing and revision procedures* (Addressable). Implement procedures for periodic testing and revision of contingency plans.

(E) *Applications and data criticality analysis* (Addressable). Assess the relative criticality of specific applications and data in support of other contingency plan components.

(8) *Standard: Evaluation*. Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, that establishes the extent to which an entity's security policies and procedures meet the requirements of this subpart.

(b)(1) *Standard: Business associate contracts and other arrangements*. A covered entity, in accordance with § 164.306, may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a) that the business associate will appropriately safeguard the information.

(2) This standard does not apply with respect to—

(i) The transmission by a covered entity of electronic protected health information to a health care provider concerning the treatment of an individual.

(ii) The transmission of electronic protected health information by a group health plan or an HMO or health insurance issuer on behalf of a group health plan to a plan sponsor, to the extent that the requirements of § 164.314(b) and § 164.504(f) apply and are met; or

(iii) The transmission of electronic protected health information from or to other agencies providing the services at § 164.502(e)(1)(ii)(C), when the covered entity is a health plan that is a government program providing public benefits, if the requirements of § 164.502(e)(1)(ii)(C) are met.

(3) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.314(a).

(4) *Implementation specifications: Written contract or other arrangement* (Required). Document the satisfactory assurances required by paragraph (b)(1) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of § 164.314(a).

§ 164.310 Physical safeguards.

A covered entity must, in accordance with § 164.306:

(a)(1) *Standard: Facility access controls*. Implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

(2) *Implementation specifications:*

(i) *Contingency operations* (Addressable). Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency.

(ii) *Facility security plan* (Addressable). Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.

(iii) *Access control and validation procedures* (Addressable). Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.

(iv) *Maintenance records* (Addressable). Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors, and locks).

(b) *Standard: Workstation use*. Implement policies and procedures that

specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information.

(c) *Standard: Workstation security*. Implement physical safeguards for all workstations that access electronic protected health information, to restrict access to authorized users.

(d)(1) *Standard: Device and media controls*. Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility.

(2) *Implementation specifications:*

(i) *Disposal* (Required). Implement policies and procedures to address the final disposition of electronic protected health information, and/or the hardware or electronic media on which it is stored.

(ii) *Media re-use* (Required). Implement procedures for removal of electronic protected health information from electronic media before the media are made available for re-use.

(iii) *Accountability* (Addressable). Maintain a record of the movements of hardware and electronic media and any person responsible therefore.

(iv) *Data backup and storage* (Addressable). Create a retrievable, exact copy of electronic protected health information, when needed, before movement of equipment.

§ 164.312 Technical safeguards.

A covered entity must, in accordance with § 164.306:

(a)(1) *Standard: Access control*. Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).

(2) *Implementation specifications:*

(i) *Unique user identification* (Required). Assign a unique name and/or number for identifying and tracking user identity.

(ii) *Emergency access procedure* (Required). Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency.

(iii) *Automatic logoff* (Addressable). Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.

(iv) *Encryption and decryption* (Addressable). Implement a mechanism to encrypt and decrypt electronic protected health information.

(b) *Standard: Audit controls*. Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information.

(c)(1) *Standard: Integrity*. Implement policies and procedures to protect electronic protected health information from improper alteration or destruction.

(2) *Implementation specification: Mechanism to authenticate electronic protected health information* (Addressable). Implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner.

(d) *Standard: Person or entity authentication*. Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed.

(e)(1) *Standard: Transmission security*. Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network.

(2) *Implementation specifications:*

(i) *Integrity controls* (Addressable). Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of.

(ii) *Encryption* (Addressable). Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate.

§ 164.314 Organizational requirements.

(a)(1) *Standard: Business associate contracts or other arrangements*. (i) The contract or other arrangement between

the covered entity and its business associate required by §164.308(b) must meet the requirements of paragraph (a)(2)(i) or (a)(2)(ii) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in §164.502(e) and paragraph (a) of this section if the covered entity knew of a pattern of an activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful—

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) *Implementation specifications* (Required).

(i) *Business associate contracts.* The contract between a covered entity and a business associate must provide that the business associate will—

(A) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the covered entity as required by this subpart;

(B) Ensure that any agent, including a subcontractor, to whom it provides such information agrees to implement reasonable and appropriate safeguards to protect it;

(C) Report to the covered entity any security incident of which it becomes aware;

(D) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(ii) *Other arrangements.* (A) When a covered entity and its business associate are both governmental entities, the covered entity is in compliance with paragraph (a)(1) of this section, if—

(*1*) It enters into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (a)(2)(i) of this section; or

(*2*) Other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (a)(2)(i) of this section.

(B) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of business associate as specified in §160.103 of this subchapter to a covered entity, the covered entity may permit the business associate to create, receive, maintain, or transmit electronic protected health information on its behalf to the extent necessary to comply with the legal mandate without meeting the requirements of paragraph (a)(2)(i) of this section, provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (a)(2)(ii)(A) of this section, and documents the attempt and the reasons that these assurances cannot be obtained.

(C) The covered entity may omit from its other arrangements authorization of the termination of the contract by the covered entity, as required by paragraph (a)(2)(i)(D) of this section if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(b)(1) *Standard: Requirements for group health plans.* Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to §164.504(f)(1)(ii) or (iii), or as authorized under §164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan.

(2) *Implementation specifications* (Required). The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to—

(i) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the

confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan;

(ii) Ensure that the adequate separation required by §164.504(f)(2)(iii) is supported by reasonable and appropriate security measures;

(iii) Ensure that any agent, including a subcontractor, to whom it provides this information agrees to implement reasonable and appropriate security measures to protect the information; and

(iv) Report to the group health plan any security incident of which it becomes aware.

§ 164.316 Policies and procedures and documentation requirements.

A covered entity must, in accordance with §164.306:

(a) *Standard: Policies and procedures.* Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in §164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

(b)(1) *Standard: Documentation.* (i) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and

(ii) If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

(2) *Implementation specifications:*

(i) *Time limit* (Required). Retain the documentation required by paragraph (b)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

(ii) *Availability* (Required). Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

(iii) *Updates* (Required). Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic protected health information.

§ 164.318 Compliance dates for the initial implementation of the security standards.

(a) *Health plan.* (1) A health plan that is not a small health plan must comply with the applicable requirements of this subpart no later than April 20, 2005.

(2) A small health plan must comply with the applicable requirements of this subpart no later than April 20, 2006.

(b) *Health care clearinghouse.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 20, 2005.

(c) *Health care provider.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 20, 2005.

APPENDIX A TO SUBPART C OF PART 164—SECURITY STANDARDS: MATRIX

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
Administrative Safeguards		
Security Management Process	164.308(a)(1)	Risk Analysis (R) Risk Management (R) Sanction Policy (R) Information System Activity Review (R)
Assigned Security Responsibility	164.308(a)(2)	(R)
Workforce Security	164.308(a)(3)	Authorization and/or Supervision (A) Workforce Clearance Procedure Termination Procedures (A)
Information Access Management	164.308(a)(4)	Isolating Health care Clearinghouse Function (R)

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
		Access Authorization (A)
		Access Establishment and Modification (A)
Security Awareness and Training	164.308(a)(5)	Security Reminders (A)
		Protection from Malicious Software (A)
		Log-in Monitoring (A)
		Password Management (A)
Security Incident Procedures	164.308(a)(6)	Response and Reporting (R)
Contingency Plan	164.308(a)(7)	Data Backup Plan (R)
		Disaster Recovery Plan (R)
		Emergency Mode Operation Plan (R)
		Testing and Revision Procedure (A)
		Applications and Data Criticality Analysis (A)
Evaluation	164.308(a)(8)	(R)
Business Associate Contracts and Other Arrangement.	164.308(b)(1)	Written Contract or Other Arrangement (R)
Physical Safeguards		
Facility Access Controls	164.310(a)(1)	Contingency Operations (A)
		Facility Security Plan (A)
		Access Control and Validation Procedures (A)
		Maintenance Records (A)
Workstation Use	164.310(b)	(R)
Workstation Security	164.310(c)	(R)
Device and Media Controls	164.310(d)(1)	Disposal (R)
		Media Re-use (R)
		Accountability (A)
		Data Backup and Storage (A)
Technical Safeguards (see § 164.312)		
Access Control	164.312(a)(1)	Unique User Identification (R)
		Emergency Access Procedure (R)
		Automatic Logoff (A)
		Encryption and Decryption (A)
Audit Controls	164.312(b)	(R)
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication	164.312(d)	(R)
Transmission Security	164.312(e)(1)	Integrity Controls (A)
		Encryption (A)

Subpart D—Notification in the Case of Breach of Unsecured Protected Health Information

SOURCE: 74 FR 42767, Aug. 24, 2009, unless otherwise noted.

§ 164.400 Applicability.

The requirements of this subpart shall apply with respect to breaches of protected health information occurring on or after September 23, 2009.

§ 164.402 Definitions.

As used in this subpart, the following terms have the following meanings:

Breach means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which compromises the security or privacy of the protected health information.

(1)(i) For purposes of this definition, *compromises the security or privacy of the protected health information* means poses a significant risk of financial, reputational, or other harm to the individual.

(ii) A use or disclosure of protected health information that does not include the identifiers listed at § 164.514(e)(2), date of birth, and zip code does not compromise the security or privacy of the protected health information.

(2) Breach excludes:

(i) Any unintentional acquisition, access, or use of protected health information by a workforce member or person acting under the authority of a covered entity or a business associate, if such acquisition, access, or use was

made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under subpart E of this part.

(ii) Any inadvertent disclosure by a person who is authorized to access protected health information at a covered entity or business associate to another person authorized to access protected health information at the same covered entity or business associate, or organized health care arrangement in which the covered entity participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under subpart E of this part.

(iii) A disclosure of protected health information where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

Unsecured protected health information means protected health information that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2) of Public Law 111–5 on the HHS Web site.

§ 164.404 Notification to individuals.

(a) *Standard*—(1) *General rule*. A covered entity shall, following the discovery of a breach of unsecured protected health information, notify each individual whose unsecured protected health information has been, or is reasonably believed by the covered entity to have been, accessed, acquired, used, or disclosed as a result of such breach.

(2) *Breaches treated as discovered*. For purposes of paragraph (a)(1) of this section, §§164.406(a), and 164.408(a), a breach shall be treated as discovered by a covered entity as of the first day on which such breach is known to the covered entity, or, by exercising reasonable diligence would have been known to the covered entity. A covered entity shall be deemed to have knowledge of a breach if such breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is a workforce member or agent of the covered entity (determined in accordance with the federal common law of agency).

(b) *Implementation specification: Timeliness of notification*. Except as provided in §164.412, a covered entity shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification*—(1) *Elements*. The notification required by paragraph (a) of this section shall include, to the extent possible:

(A) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known;

(B) A description of the types of unsecured protected health information that were involved in the breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(C) Any steps individuals should take to protect themselves from potential harm resulting from the breach;

(D) A brief description of what the covered entity involved is doing to investigate the breach, to mitigate harm to individuals, and to protect against any further breaches; and

(E) Contact procedures for individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.

(2) *Plain language requirement*. The notification required by paragraph (a) of this section shall be written in plain language.

(d) *Implementation specifications: Methods of individual notification*. The notification required by paragraph (a) of this section shall be provided in the following form:

(1) *Written notice*. (i) Written notification by first-class mail to the individual at the last known address of the individual or, if the individual agrees to electronic notice and such agreement has not been withdrawn, by electronic mail. The notification may be

provided in one or more mailings as information is available.

(ii) If the covered entity knows the individual is deceased and has the address of the next of kin or personal representative of the individual (as specified under §164.502(g)(4) of subpart E), written notification by first-class mail to either the next of kin or personal representative of the individual. The notification may be provided in one or more mailings as information is available.

(2) *Substitute notice.* In the case in which there is insufficient or out-of-date contact information that precludes written notification to the individual under paragraph (d)(1)(i) of this section, a substitute form of notice reasonably calculated to reach the individual shall be provided. Substitute notice need not be provided in the case in which there is insufficient or out-of-date contact information that precludes written notification to the next of kin or personal representative of the individual under paragraph (d)(1)(ii).

(i) In the case in which there is insufficient or out-of-date contact information for fewer than 10 individuals, then such substitute notice may be provided by an alternative form of written notice, telephone, or other means.

(ii) In the case in which there is insufficient or out-of-date contact information for 10 or more individuals, then such substitute notice shall:

(A) Be in the form of either a conspicuous posting for a period of 90 days on the home page of the Web site of the covered entity involved, or conspicuous notice in major print or broadcast media in geographic areas where the individuals affected by the breach likely reside; and

(B) Include a toll-free phone number that remains active for at least 90 days where an individual can learn whether the individual's unsecured protected health information may be included in the breach.

(3) *Additional notice in urgent situations.* In any case deemed by the covered entity to require urgency because of possible imminent misuse of unsecured protected health information, the covered entity may provide information to individuals by telephone or other means, as appropriate, in addition to notice provided under paragraph (d)(1) of this section.

§164.406 Notification to the media.

(a) *Standard.* For a breach of unsecured protected health information involving more than 500 residents of a State or jurisdiction, a covered entity shall, following the discovery of the breach as provided in §164.404(a)(2), notify prominent media outlets serving the State or jurisdiction. For purposes of this section, *State* includes American Samoa and the Northern Mariana Islands.

(b) *Implementation specification: Timeliness of notification.* Except as provided in §164.412, a covered entity shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification.* The notification required by paragraph (a) of this section shall meet the requirements of §164.404(c).

§164.408 Notification to the Secretary.

(a) *Standard.* A covered entity shall, following the discovery of a breach of unsecured protected health information as provided in §164.404(a)(2), notify the Secretary.

(b) *Implementation specifications: Breaches involving 500 or more individuals.* For breaches of unsecured protected health information involving 500 or more individuals, a covered entity shall, except as provided in §164.412, provide the notification required by paragraph (a) of this section contemporaneously with the notice required by §164.404(a) and in the manner specified on the HHS Web site.

(c) *Implementation specifications: Breaches involving less than 500 individuals.* For breaches of unsecured protected health information involving less than 500 individuals, a covered entity shall maintain a log or other documentation of such breaches and, not later than 60 days after the end of each calendar year, provide the notification required by paragraph (a) of this section for breaches occurring during the preceding calendar year, in the manner specified on the HHS Web site.

§ 164.410 Notification by a business associate.

(a) *Standard.* (1) A business associate shall, following the discovery of a breach of unsecured protected health information, notify the covered entity of such breach.

(2) *Breaches treated as discovered.* For purposes of paragraph (1) of this section, a breach shall be treated as discovered by a business associate as of the first day on which such breach is known to the business associate or, by exercising reasonable diligence, would have been known to the business associate. A business associate shall be deemed to have knowledge of a breach if the breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the breach, who is an employee, officer, or other agent of the business associate (determined in accordance with the federal common law of agency).

(b) *Implementation specifications: Timeliness of notification.* Except as provided in § 164.412, a business associate shall provide the notification required by paragraph (a) of this section without unreasonable delay and in no case later than 60 calendar days after discovery of a breach.

(c) *Implementation specifications: Content of notification.* (1) The notification required by paragraph (a) of this section shall include, to the extent possible, the identification of each individual whose unsecured protected health information has been, or is reasonably believed by the business associate to have been, accessed, acquired, used, or disclosed during the breach.

(2) A business associate shall provide the covered entity with any other available information that the covered entity is required to include in notification to the individual under § 164.404(c) at the time of the notification required by paragraph (a) of this section or promptly thereafter as information becomes available.

§ 164.412 Law enforcement delay.

If a law enforcement official states to a covered entity or business associate that a notification, notice, or posting required under this subpart would impede a criminal investigation or cause damage to national security, a covered entity or business associate shall:

(a) If the statement is in writing and specifies the time for which a delay is required, delay such notification, notice, or posting for the time period specified by the official; or

(b) If the statement is made orally, document the statement, including the identity of the official making the statement, and delay the notification, notice, or posting temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in paragraph (a) of this section is submitted during that time.

§ 164.414 Administrative requirements and burden of proof.

(a) *Administrative requirements.* A covered entity is required to comply with the administrative requirements of § 164.530(b), (d), (e), (g), (h), (i), and (j) with respect to the requirements of this subpart.

(b) *Burden of proof.* In the event of a use or disclosure in violation of subpart E, the covered entity or business associate, as applicable, shall have the burden of demonstrating that all notifications were made as required by this subpart or that the use or disclosure did not constitute a breach, as defined at § 164.402.

Subpart E—Privacy of Individually Identifiable Health Information

AUTHORITY: 42 U.S.C. 1320d–2 and 1320d–4, sec. 264 of Pub. L. 104–191, 110 Stat. 2033–2034 (42 U.S.C. 1320d–2(note)).

§ 164.500 Applicability.

(a) Except as otherwise provided herein, the standards, requirements, and implementation specifications of this subpart apply to covered entities with respect to protected health information.

(b) Health care clearinghouses must comply with the standards, requirements, and implementation specifications as follows:

(1) When a health care clearinghouse creates or receives protected health information as a business associate of another covered entity, the clearinghouse must comply with:

(i) Section 164.500 relating to applicability;

(ii) Section 164.501 relating to definitions;

(iii) Section 164.502 relating to uses and disclosures of protected health information, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(iv) Section 164.504 relating to the organizational requirements for covered entities;

(v) Section 164.512 relating to uses and disclosures for which individual authorization or an opportunity to agree or object is not required, except that a clearinghouse is prohibited from using or disclosing protected health information other than as permitted in the business associate contract under which it created or received the protected health information;

(vi) Section 164.532 relating to transition requirements; and

(vii) Section 164.534 relating to compliance dates for initial implementation of the privacy standards.

(2) When a health care clearinghouse creates or receives protected health information other than as a business associate of a covered entity, the clearinghouse must comply with all of the standards, requirements, and implementation specifications of this subpart.

(c) The standards, requirements, and implementation specifications of this subpart do not apply to the Department of Defense or to any other federal agency, or non-governmental organization acting on its behalf, when providing health care to overseas foreign national beneficiaries.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

§ 164.501 Definitions.

As used in this subpart, the following terms have the following meanings:

Correctional institution means any penal or correctional facility, jail, reformatory, detention center, work farm, halfway house, or residential community program center operated by, or under contract to, the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, for the confinement or rehabilitation of persons charged with or convicted of a criminal offense or other persons held in lawful custody. *Other persons* held in lawful custody includes juvenile offenders adjudicated delinquent, aliens detained awaiting deportation, persons committed to mental institutions through the criminal justice system, witnesses, or others awaiting charges or trial.

Data aggregation means, with respect to protected health information created or received by a business associate in its capacity as the business associate of a covered entity, the combining of such protected health information by the business associate with the protected health information received by the business associate in its capacity as a business associate of another covered entity, to permit data analyses that relate to the health care operations of the respective covered entities.

Designated record set means:

(1) A group of records maintained by or for a covered entity that is:

(i) The medical records and billing records about individuals maintained by or for a covered health care provider;

(ii) The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or

(iii) Used, in whole or in part, by or for the covered entity to make decisions about individuals.

(2) For purposes of this paragraph, the term record means any item, collection, or grouping of information that includes protected health information and is maintained, collected, used, or disseminated by or for a covered entity.

Direct treatment relationship means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities;

(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable;

(4) Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs;

(5) Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies; and

(6) Business management and general administrative activities of the entity, including, but not limited to:

(i) Management activities relating to implementation of and compliance with the requirements of this subchapter;

(ii) Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer.

(iii) Resolution of internal grievances;

(iv) The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity; and

(v) Consistent with the applicable requirements of § 164.514, creating de-identified health information or a limited data set, and fundraising for the benefit of the covered entity.

Health oversight agency means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, 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 authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

Indirect treatment relationship means a relationship between an individual and a health care provider in which:

(1) The health care provider delivers health care to the individual based on the orders of another health care provider; and

(2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

Inmate means a person incarcerated in or otherwise confined to a correctional institution.

Marketing means:

(1) To make a communication about a product or service that encourages recipients of the communication to

purchase or use the product or service, unless the communication is made:

(i) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.

(ii) For treatment of the individual; or

(iii) For case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.

(2) An arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.

Payment means:

(1) The activities undertaken by:

(i) A health plan to obtain premiums or to determine or fulfill its responsibility for coverage and provision of benefits under the health plan; or

(ii) A health care provider or health plan to obtain or provide reimbursement for the provision of health care; and

(2) The activities in paragraph (1) of this definition relate to the individual to whom health care is provided and include, but are not limited to:

(i) Determinations of eligibility or coverage (including coordination of benefits or the determination of cost sharing amounts), and adjudication or subrogation of health benefit claims;

(ii) Risk adjusting amounts due based on enrollee health status and demographic characteristics;

(iii) Billing, claims management, collection activities, obtaining payment under a contract for reinsurance (including stop-loss insurance and excess of loss insurance), and related health care data processing;

(iv) Review of health care services with respect to medical necessity, coverage under a health plan, appropriateness of care, or justification of charges;

(v) Utilization review activities, including precertification and preauthorization of services, concurrent and retrospective review of services; and

(vi) Disclosure to consumer reporting agencies of any of the following protected health information relating to collection of premiums or reimbursement:

(A) Name and address;

(B) Date of birth;

(C) Social security number;

(D) Payment history;

(E) Account number; and

(F) Name and address of the health care provider and/or health plan.

Psychotherapy notes means notes recorded (in any medium) by a health care provider who is a mental health professional documenting or analyzing the contents of conversation during a private counseling session or a group, joint, or family counseling session and that are separated from the rest of the individual's medical record. *Psychotherapy notes* excludes medication prescription and monitoring, counseling session start and stop times, the modalities and frequencies of treatment furnished, results of clinical tests, and any summary of the following items: Diagnosis, functional status, the treatment plan, symptoms, prognosis, and progress to date.

Public health authority means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, 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.

Research means a systematic investigation, including research development, testing, and evaluation, designed

to develop or contribute to generalizable knowledge.

Treatment means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53266, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003; 74 FR 42769, Aug. 24, 2009]

§ 164.502 Uses and disclosures of protected health information: general rules.

(a) *Standard.* A covered entity may not use or disclose protected health information, except as permitted or required by this subpart or by subpart C of part 160 of this subchapter.

(1) *Permitted uses and disclosures.* A covered entity is permitted to use or disclose protected health information as follows:

(i) To the individual;

(ii) For treatment, payment, or health care operations, as permitted by and in compliance with § 164.506;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, provided that the covered entity has complied with the applicable requirements of § 164.502(b), § 164.514(d), and § 164.530(c) with respect to such otherwise permitted or required use or disclosure;

(iv) Pursuant to and in compliance with a valid authorization under § 164.508;

(v) Pursuant to an agreement under, or as otherwise permitted by, § 164.510; and

(vi) As permitted by and in compliance with this section, § 164.512, or § 164.514(e), (f), or (g).

(2) *Required disclosures.* A covered entity is required to disclose protected health information:

(i) To an individual, when requested under, and required by § 164.524 or § 164.528; and

(ii) When required by the Secretary under subpart C of part 160 of this subchapter to investigate or determine the covered entity's compliance with this subpart.

(b) *Standard: Minimum necessary*—(1) *Minimum necessary applies.* When using or disclosing protected health information or when requesting protected health information from another covered entity, a covered entity must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

(2) *Minimum necessary does not apply.* This requirement does not apply to:

(i) Disclosures to or requests by a health care provider for treatment;

(ii) Uses or disclosures made to the individual, as permitted under paragraph (a)(1)(i) of this section or as required by paragraph (a)(2)(i) of this section;

(iii) Uses or disclosures made pursuant to an authorization under § 164.508;

(iv) Disclosures made to the Secretary in accordance with subpart C of part 160 of this subchapter;

(v) Uses or disclosures that are required by law, as described by § 164.512(a); and

(vi) Uses or disclosures that are required for compliance with applicable requirements of this subchapter.

(c) *Standard: Uses and disclosures of protected health information subject to an agreed upon restriction.* A covered entity that has agreed to a restriction pursuant to § 164.522(a)(1) may not use or disclose the protected health information covered by the restriction in violation of such restriction, except as otherwise provided in § 164.522(a).

(d) *Standard: Uses and disclosures of de-identified protected health information.*(1) *Uses and disclosures to create de-identified information.* A covered entity may use protected health information to create information that is not individually identifiable health information or disclose protected health information only to a business associate for such purpose, whether or not the de-identified information is to be used by the covered entity.

(2) *Uses and disclosures of de-identified information.* Health information that meets the standard and implementation specifications for de-identification under § 164.514(a) and (b) is considered

not to be individually identifiable health information, *i.e.*, de-identified. The requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514, provided that:

(i) Disclosure of a code or other means of record identification designed to enable coded or otherwise de-identified information to be re-identified constitutes disclosure of protected health information; and

(ii) If de-identified information is re-identified, a covered entity may use or disclose such re-identified information only as permitted or required by this subpart.

(e)(1) *Standard: Disclosures to business associates.* (i) A covered entity may disclose protected health information to a business associate and may allow a business associate to create or receive protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information.

(ii) This standard does not apply:

(A) With respect to disclosures by a covered entity to a health care provider concerning the treatment of the individual;

(B) With respect to disclosures by a group health plan or a health insurance issuer or HMO with respect to a group health plan to the plan sponsor, to the extent that the requirements of § 164.504(f) apply and are met; or

(C) With respect to uses or disclosures by a health plan that is a government program providing public benefits, if eligibility for, or enrollment in, the health plan is determined by an agency other than the agency administering the health plan, or if the protected health information used to determine enrollment or eligibility in the health plan is collected by an agency other than the agency administering the health plan, and such activity is authorized by law, with respect to the collection and sharing of individually identifiable health information for the performance of such functions by the health plan and the agency other than the agency administering the health plan.

(iii) A covered entity that violates the satisfactory assurances it provided as a business associate of another covered entity will be in noncompliance with the standards, implementation specifications, and requirements of this paragraph and § 164.504(e).

(2) *Implementation specification: documentation.* A covered entity must document the satisfactory assurances required by paragraph (e)(1) of this section through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of § 164.504(e).

(f) *Standard: Deceased individuals.* A covered entity must comply with the requirements of this subpart with respect to the protected health information of a deceased individual.

(g)(1) *Standard: Personal representatives.* As specified in this paragraph, a covered entity must, except as provided in paragraphs (g)(3) and (g)(5) of this section, treat a personal representative as the individual for purposes of this subchapter.

(2) *Implementation specification: adults and emancipated minors.* If under applicable law a person has authority to act on behalf of an individual who is an adult or an emancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(3)(i) *Implementation specification: unemancipated minors.* If under applicable law a parent, guardian, or other person acting *in loco parentis* has authority to act on behalf of an individual who is an unemancipated minor in making decisions related to health care, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation, except that such person may not be a personal representative of an unemancipated minor, and the minor has the authority to act as an individual, with respect to protected health information pertaining to a health care service, if:

(A) The minor consents to such health care service; no other consent to

such health care service is required by law, regardless of whether the consent of another person has also been obtained; and the minor has not requested that such person be treated as the personal representative;

(B) The minor may lawfully obtain such health care service without the consent of a parent, guardian, or other person acting *in loco parentis*, and the minor, a court, or another person authorized by law consents to such health care service; or

(C) A parent, guardian, or other person acting *in loco parentis* assents to an agreement of confidentiality between a covered health care provider and the minor with respect to such health care service.

(ii) Notwithstanding the provisions of paragraph (g)(3)(i) of this section:

(A) If, and to the extent, permitted or required by an applicable provision of State or other law, including applicable case law, a covered entity may disclose, or provide access in accordance with §164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*;

(B) If, and to the extent, prohibited by an applicable provision of State or other law, including applicable case law, a covered entity may not disclose, or provide access in accordance with §164.524 to, protected health information about an unemancipated minor to a parent, guardian, or other person acting *in loco parentis*; and

(C) Where the parent, guardian, or other person acting *in loco parentis*, is not the personal representative under paragraphs (g)(3)(i)(A), (B), or (C) of this section and where there is no applicable access provision under State or other law, including case law, a covered entity may provide or deny access under §164.524 to a parent, guardian, or other person acting *in loco parentis*, if such action is consistent with State or other applicable law, provided that such decision must be made by a licensed health care professional, in the exercise of professional judgment.

(4) *Implementation specification: Deceased individuals.* If under applicable law an executor, administrator, or other person has authority to act on behalf of a deceased individual or of the individual's estate, a covered entity must treat such person as a personal representative under this subchapter, with respect to protected health information relevant to such personal representation.

(5) *Implementation specification: Abuse, neglect, endangerment situations.* Notwithstanding a State law or any requirement of this paragraph to the contrary, a covered entity may elect not to treat a person as the personal representative of an individual if:

(i) The covered entity has a reasonable belief that:

(A) The individual has been or may be subjected to domestic violence, abuse, or neglect by such person; or

(B) Treating such person as the personal representative could endanger the individual; and

(ii) The covered entity, in the exercise of professional judgment, decides that it is not in the best interest of the individual to treat the person as the individual's personal representative.

(h) *Standard: Confidential communications.* A covered health care provider or health plan must comply with the applicable requirements of §164.522(b) in communicating protected health information.

(i) *Standard: Uses and disclosures consistent with notice.* A covered entity that is required by §164.520 to have a notice may not use or disclose protected health information in a manner inconsistent with such notice. A covered entity that is required by §164.520(b)(1)(iii) to include a specific statement in its notice if it intends to engage in an activity listed in §164.520(b)(1)(iii)(A)–(C), may not use or disclose protected health information for such activities, unless the required statement is included in the notice.

(j) *Standard: Disclosures by whistleblowers and workforce member crime victims*—(1) *Disclosures by whistleblowers.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce or a business associate discloses protected health information, provided that:

(i) The workforce member or business associate believes in good faith that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards,

or that the care, services, or conditions provided by the covered entity potentially endangers one or more patients, workers, or the public; and

(ii) The disclosure is to:

(A) A health oversight agency or public health authority authorized by law to investigate or otherwise oversee the relevant conduct or conditions of the covered entity or to an appropriate health care accreditation organization for the purpose of reporting the allegation of failure to meet professional standards or misconduct by the covered entity; or

(B) An attorney retained by or on behalf of the workforce member or business associate for the purpose of determining the legal options of the workforce member or business associate with regard to the conduct described in paragraph (j)(1)(i) of this section.

(2) *Disclosures by workforce members who are victims of a crime.* A covered entity is not considered to have violated the requirements of this subpart if a member of its workforce who is the victim of a criminal act discloses protected health information to a law enforcement official, provided that:

(i) The protected health information disclosed is about the suspected perpetrator of the criminal act; and

(ii) The protected health information disclosed is limited to the information listed in § 164.512(f)(2)(i).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002]

§ 164.504 Uses and disclosures: Organizational requirements.

(a) *Definitions.* As used in this section:

Plan administration functions means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

Summary health information means information, that may be individually identifiable health information, and:

(1) That summarizes the claims history, claims expenses, or type of claims experienced by individuals for whom a plan sponsor has provided health benefits under a group health plan; and

(2) From which the information described at § 164.514(b)(2)(i) has been deleted, except that the geographic information described in § 164.514(b)(2)(i)(B) need only be aggregated to the level of a five digit zip code.

(b)–(d)

(e)(1) *Standard: Business associate contracts.* (i) The contract or other arrangement between the covered entity and the business associate required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2) or (e)(3) of this section, as applicable.

(ii) A covered entity is not in compliance with the standards in § 164.502(e) and paragraph (e) of this section, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(A) Terminated the contract or arrangement, if feasible; or

(B) If termination is not feasible, reported the problem to the Secretary.

(2) *Implementation specifications: Business associate contracts.* A contract between the covered entity and a business associate must:

(i) Establish the permitted and required uses and disclosures of such information by the business associate. The contract may not authorize the business associate to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity, except that:

(A) The contract may permit the business associate to use and disclose protected health information for the proper management and administration of the business associate, as provided in paragraph (e)(4) of this section; and

(B) The contract may permit the business associate to provide data aggregation services relating to the health care operations of the covered entity.

(ii) Provide that the business associate will:

(A) Not use or further disclose the information other than as permitted or required by the contract or as required by law;

(B) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by its contract;

(C) Report to the covered entity any use or disclosure of the information not provided for by its contract of which it becomes aware;

(D) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from, or created or received by the business associate on behalf of, the covered entity agrees to the same restrictions and conditions that apply to the business associate with respect to such information;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity available to the Secretary for purposes of determining the covered entity's compliance with this subpart; and

(I) At termination of the contract, if feasible, return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity that the business associate still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.

(iii) Authorize termination of the contract by the covered entity, if the covered entity determines that the business associate has violated a material term of the contract.

(3) *Implementation specifications: Other arrangements.* (i) If a covered entity and its business associate are both governmental entities:

(A) The covered entity may comply with paragraph (e) of this section by entering into a memorandum of understanding with the business associate that contains terms that accomplish the objectives of paragraph (e)(2) of this section.

(B) The covered entity may comply with paragraph (e) of this section, if other law (including regulations adopted by the covered entity or its business associate) contains requirements applicable to the business associate that accomplish the objectives of paragraph (e)(2) of this section.

(ii) If a business associate is required by law to perform a function or activity on behalf of a covered entity or to provide a service described in the definition of *business associate* in § 160.103 of this subchapter to a covered entity, such covered entity may disclose protected health information to the business associate to the extent necessary to comply with the legal mandate without meeting the requirements of this paragraph (e), provided that the covered entity attempts in good faith to obtain satisfactory assurances as required by paragraph (e)(3)(i) of this section, and, if such attempt fails, documents the attempt and the reasons that such assurances cannot be obtained.

(iii) The covered entity may omit from its other arrangements the termination authorization required by paragraph (e)(2)(iii) of this section, if such authorization is inconsistent with the statutory obligations of the covered entity or its business associate.

(4) *Implementation specifications: Other requirements for contracts and other arrangements.* (i) The contract or other arrangement between the covered entity and the business associate may permit the business associate to use the information received by the business associate in its capacity as a business associate to the covered entity, if necessary:

(A) For the proper management and administration of the business associate; or

(B) To carry out the legal responsibilities of the business associate.

(ii) The contract or other arrangement between the covered entity and the business associate may permit the business associate to disclose the information received by the business associate in its capacity as a business associate for the purposes described in paragraph (e)(4)(i) of this section, if:

(A) The disclosure is required by law; or

(B)(*1*) The business associate obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and

(*2*) The person notifies the business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(f)(1) *Standard: Requirements for group health plans.* (i) Except as provided under paragraph (f)(1)(ii) or (iii) of this section or as otherwise authorized under § 164.508, a group health plan, in order to disclose protected health information to the plan sponsor or to provide for or permit the disclosure of protected health information to the plan sponsor by a health insurance issuer or HMO with respect to the group health plan, must ensure that the plan documents restrict uses and disclosures of such information by the plan sponsor consistent with the requirements of this subpart.

(ii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose summary health information to the plan sponsor, if the plan sponsor requests the summary health information for the purpose of :

(A) Obtaining premium bids from health plans for providing health insurance coverage under the group health plan; or

(B) Modifying, amending, or terminating the group health plan.

(iii) The group health plan, or a health insurance issuer or HMO with respect to the group health plan, may disclose to the plan sponsor information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) *Implementation specifications: Requirements for plan documents.* The plan documents of the group health plan must be amended to incorporate provisions to:

(i) Establish the permitted and required uses and disclosures of such information by the plan sponsor, provided that such permitted and required uses and disclosures may not be inconsistent with this subpart.

(ii) Provide that the group health plan will disclose protected health information to the plan sponsor only upon receipt of a certification by the plan sponsor that the plan documents have been amended to incorporate the following provisions and that the plan sponsor agrees to:

(A) Not use or further disclose the information other than as permitted or required by the plan documents or as required by law;

(B) Ensure that any agents, including a subcontractor, to whom it provides protected health information received from the group health plan agree to the same restrictions and conditions that apply to the plan sponsor with respect to such information;

(C) Not use or disclose the information for employment-related actions and decisions or in connection with any other benefit or employee benefit plan of the plan sponsor;

(D) Report to the group health plan any use or disclosure of the information that is inconsistent with the uses or disclosures provided for of which it becomes aware;

(E) Make available protected health information in accordance with § 164.524;

(F) Make available protected health information for amendment and incorporate any amendments to protected health information in accordance with § 164.526;

(G) Make available the information required to provide an accounting of disclosures in accordance with § 164.528;

(H) Make its internal practices, books, and records relating to the use

and disclosure of protected health information received from the group health plan available to the Secretary for purposes of determining compliance by the group health plan with this subpart;

(I) If feasible, return or destroy all protected health information received from the group health plan that the sponsor still maintains in any form and retain no copies of such information when no longer needed for the purpose for which disclosure was made, except that, if such return or destruction is not feasible, limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible; and

(J) Ensure that the adequate separation required in paragraph (f)(2)(iii) of this section is established.

(iii) Provide for adequate separation between the group health plan and the plan sponsor. The plan documents must:

(A) Describe those employees or classes of employees or other persons under the control of the plan sponsor to be given access to the protected health information to be disclosed, provided that any employee or person who receives protected health information relating to payment under, health care operations of, or other matters pertaining to the group health plan in the ordinary course of business must be included in such description;

(B) Restrict the access to and use by such employees and other persons described in paragraph (f)(2)(iii)(A) of this section to the plan administration functions that the plan sponsor performs for the group health plan; and

(C) Provide an effective mechanism for resolving any issues of noncompliance by persons described in paragraph (f)(2)(iii)(A) of this section with the plan document provisions required by this paragraph.

(3) *Implementation specifications: Uses and disclosures.* A group health plan may:

(i) Disclose protected health information to a plan sponsor to carry out plan administration functions that the plan sponsor performs only consistent with the provisions of paragraph (f)(2) of this section;

(ii) Not permit a health insurance issuer or HMO with respect to the group health plan to disclose protected health information to the plan sponsor except as permitted by this paragraph;

(iii) Not disclose and may not permit a health insurance issuer or HMO to disclose protected health information to a plan sponsor as otherwise permitted by this paragraph unless a statement required by §164.520(b)(1)(iii)(C) is included in the appropriate notice; and (iv) Not disclose protected health information to the plan sponsor for the purpose of employment-related actions or decisions or in connection with any other benefit or employee benefit plan of the plan sponsor.

(g) *Standard: Requirements for a covered entity with multiple covered functions.* (1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.

(2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53267, Aug. 14, 2002; 68 FR 8381, Feb. 20, 2003]

§ 164.506 Uses and disclosures to carry out treatment, payment, or health care operations.

(a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under §164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.

(b) *Standard: Consent for uses and disclosures permitted.* (1) A covered entity may obtain consent of the individual to use or disclose protected health information to carry out treatment, payment, or health care operations.

(2) Consent, under paragraph (b) of this section, shall not be effective to permit a use or disclosure of protected health information when an authorization, under § 164.508, is required or when another condition must be met for such use or disclosure to be permissible under this subpart.

(c) *Implementation specifications: Treatment, payment, or health care operations.* (1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.

(2) A covered entity may disclose protected health information for treatment activities of a health care provider.

(3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.

(4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or

(ii) For the purpose of health care fraud and abuse detection or compliance.

(5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

[67 FR 53268, Aug. 14, 2002]

§ 164.508 Uses and disclosures for which an authorization is required.

(a) *Standard: authorizations for uses and disclosures*—(1) *Authorization required: general rule.* Except as otherwise permitted or required by this subchapter, a covered entity may not use or disclose protected health information without an authorization that is valid under this section. When a covered entity obtains or receives a valid authorization for its use or disclosure of protected health information, such use or disclosure must be consistent with such authorization.

(2) *Authorization required: psychotherapy notes.* Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of psychotherapy notes, except:

(i) To carry out the following treatment, payment, or health care operations:

(A) Use by the originator of the psychotherapy notes for treatment;

(B) Use or disclosure by the covered entity for its own training programs in which students, trainees, or practitioners in mental health learn under supervision to practice or improve their skills in group, joint, family, or individual counseling; or

(C) Use or disclosure by the covered entity to defend itself in a legal action or other proceeding brought by the individual; and

(ii) A use or disclosure that is required by § 164.502(a)(2)(ii) or permitted by § 164.512(a); § 164.512(d) with respect to the oversight of the originator of the psychotherapy notes; § 164.512(g)(1); or § 164.512(j)(1)(i).

(3) *Authorization required: Marketing.* (i) Notwithstanding any provision of this subpart, other than the transition provisions in § 164.532, a covered entity must obtain an authorization for any use or disclosure of protected health information for marketing, except if the communication is in the form of:

(A) A face-to-face communication made by a covered entity to an individual; or

(B) A promotional gift of nominal value provided by the covered entity.

(ii) If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

(b) *Implementation specifications: general requirements*—(1) *Valid authorizations.* (i) A valid authorization is a document that meets the requirements in paragraphs (a)(3)(ii), (c)(1), and (c)(2) of this section, as applicable.

(ii) A valid authorization may contain elements or information in addition to the elements required by this section, provided that such additional elements or information are not inconsistent with the elements required by this section.

(2) *Defective authorizations.* An authorization is not valid, if the document submitted has any of the following defects:

(i) The expiration date has passed or the expiration event is known by the covered entity to have occurred;

(ii) The authorization has not been filled out completely, with respect to an element described by paragraph (c) of this section, if applicable;

(iii) The authorization is known by the covered entity to have been revoked;

(iv) The authorization violates paragraph (b)(3) or (4) of this section, if applicable;

(v) Any material information in the authorization is known by the covered entity to be false.

(3) *Compound authorizations.* An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

(i) An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

(ii) An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

(iii) An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization under this section, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under paragraph (b)(4) of this section on the provision of one of the authorizations.

(4) *Prohibition on conditioning of authorizations.* A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization, except:

(i) A covered health care provider may condition the provision of research-related treatment on provision of an authorization for the use or disclosure of protected health information for such research under this section;

(ii) A health plan may condition enrollment in the health plan or eligibility for benefits on provision of an authorization requested by the health plan prior to an individual's enrollment in the health plan, if:

(A) The authorization sought is for the health plan's eligibility or enrollment determinations relating to the individual or for its underwriting or risk rating determinations; and

(B) The authorization is not for a use or disclosure of psychotherapy notes under paragraph (a)(2) of this section; and

(iii) A covered entity may condition the provision of health care that is solely for the purpose of creating protected health information for disclosure to a third party on provision of an authorization for the disclosure of the protected health information to such third party.

(5) *Revocation of authorizations.* An individual may revoke an authorization provided under this section at any time, provided that the revocation is in writing, except to the extent that:

(i) The covered entity has taken action in reliance thereon; or

(ii) If the authorization was obtained as a condition of obtaining insurance coverage, other law provides the insurer with the right to contest a claim under the policy or the policy itself.

(6) *Documentation*. A covered entity must document and retain any signed authorization under this section as required by § 164.530(j).

(c) *Implementation specifications: Core elements and requirements*—(1) Core elements. A valid authorization under this section must contain at least the following elements:

(i) A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

(ii) The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

(iii) The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

(iv) A description of each purpose of the requested use or disclosure. The statement ''at the request of the individual'' is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.

(v) An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. The statement ''end of the research study,'' ''none,'' or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

(vi) Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

(2) *Required statements*. In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

(i) The individual's right to revoke the authorization in writing, and either:

(A) The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

(B) To the extent that the information in paragraph (c)(2)(i)(A) of this section is included in the notice required by § 164.520, a reference to the covered entity's notice.

(ii) The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

(A) The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization when the prohibition on conditioning of authorizations in paragraph (b)(4) of this section applies; or

(B) The consequences to the individual of a refusal to sign the authorization when, in accordance with paragraph (b)(4) of this section, the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

(iii) The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

(3) *Plain language requirement*. The authorization must be written in plain language.

(4) *Copy to the individual*. If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

[67 FR 53268, Aug. 14, 2002]

§ 164.510 Uses and disclosures requiring an opportunity for the individual to agree or to object.

A covered entity may use or disclose protected health information, provided that the individual is informed in advance of the use or disclosure and has the opportunity to agree to or prohibit or restrict the use or disclosure, in accordance with the applicable requirements of this section. The covered entity may orally inform the individual of and obtain the individual's oral agreement or objection to a use or disclosure permitted by this section.

(a) *Standard: use and disclosure for facility directories*—(1) *Permitted uses and disclosure*. Except when an objection is

expressed in accordance with paragraphs (a)(2) or (3) of this section, a covered health care provider may:

(i) Use the following protected health information to maintain a directory of individuals in its facility:

(A) The individual's name;

(B) The individual's location in the covered health care provider's facility;

(C) The individual's condition described in general terms that does not communicate specific medical information about the individual; and

(D) The individual's religious affiliation; and

(ii) Disclose for directory purposes such information:

(A) To members of the clergy; or

(B) Except for religious affiliation, to other persons who ask for the individual by name.

(2) *Opportunity to object.* A covered health care provider must inform an individual of the protected health information that it may include in a directory and the persons to whom it may disclose such information (including disclosures to clergy of information regarding religious affiliation) and provide the individual with the opportunity to restrict or prohibit some or all of the uses or disclosures permitted by paragraph (a)(1) of this section.

(3) *Emergency circumstances.* (i) If the opportunity to object to uses or disclosures required by paragraph (a)(2) of this section cannot practicably be provided because of the individual's incapacity or an emergency treatment circumstance, a covered health care provider may use or disclose some or all of the protected health information permitted by paragraph (a)(1) of this section for the facility's directory, if such disclosure is:

(A) Consistent with a prior expressed preference of the individual, if any, that is known to the covered health care provider; and

(B) In the individual's best interest as determined by the covered health care provider, in the exercise of professional judgment.

(ii) The covered health care provider must inform the individual and provide an opportunity to object to uses or disclosures for directory purposes as required by paragraph (a)(2) of this section when it becomes practicable to do so.

(b) *Standard: uses and disclosures for involvement in the individual's care and notification purposes*—(1) *Permitted uses and disclosures.* (i) A covered entity may, in accordance with paragraphs (b)(2) or (3) of this section, disclose to a family member, other relative, or a close personal friend of the individual, or any other person identified by the individual, the protected health information directly relevant to such person's involvement with the individual's care or payment related to the individual's health care.

(ii) A covered entity may use or disclose protected health information to notify, or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (3), or (4) of this section, as applicable.

(2) *Uses and disclosures with the individual present.* If the individual is present for, or otherwise available prior to, a use or disclosure permitted by paragraph (b)(1) of this section and has the capacity to make health care decisions, the covered entity may use or disclose the protected health information if it:

(i) Obtains the individual's agreement;

(ii) Provides the individual with the opportunity to object to the disclosure, and the individual does not express an objection; or

(iii) Reasonably infers from the circumstances, based the exercise of professional judgment, that the individual does not object to the disclosure.

(3) *Limited uses and disclosures when the individual is not present.* If the individual is not present, or the opportunity to agree or object to the use or disclosure cannot practicably be provided because of the individual's incapacity or an emergency circumstance, the covered entity may, in the exercise of professional judgment, determine

whether the disclosure is in the best interests of the individual and, if so, disclose only the protected health information that is directly relevant to the person's involvement with the individual's health care. A covered entity may use professional judgment and its experience with common practice to make reasonable inferences of the individual's best interest in allowing a person to act on behalf of the individual to pick up filled prescriptions, medical supplies, X-rays, or other similar forms of protected health information.

(4) *Use and disclosures for disaster relief purposes.* A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of this section. The requirements in paragraphs (b)(2) and (3) of this section apply to such uses and disclosure to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

(a) *Standard: Uses and disclosures required by law.* (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

(b) *Standard: uses and disclosures for public health activities*—(1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

(ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;

(iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:

(A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;

(B) To track FDA-regulated products;

(C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or

(D) To conduct post marketing surveillance;

(iv) A person who may have been exposed to a communicable disease or

may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or

(v) An employer, about an individual who is a member of the workforce of the employer, if:

(A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer:

(*1*) To conduct an evaluation relating to medical surveillance of the workplace; or

(*2*) To evaluate whether the individual has a work-related illness or injury;

(B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;

(C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and

(D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:

(*1*) By giving a copy of the notice to the individual at the time the health care is provided; or

(*2*) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.

(2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.

(c) *Standard: Disclosures about victims of abuse, neglect or domestic violence*—(1) *Permitted disclosures.* Except for reports of child abuse or neglect permitted by paragraph (b)(1)(ii) of this section, a covered entity may disclose protected health information about an individual whom the covered entity reasonably believes to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency, authorized by law to receive reports of such abuse, neglect, or domestic violence:

(i) To the extent the disclosure is required by law and the disclosure complies with and is limited to the relevant requirements of such law;

(ii) If the individual agrees to the disclosure; or

(iii) To the extent the disclosure is expressly authorized by statute or regulation and:

(A) The covered entity, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to the individual or other potential victims; or

(B) If the individual is unable to agree because of incapacity, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against the individual and that an immediate enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure.

(2) *Informing the individual.* A covered entity that makes a disclosure permitted by paragraph (c)(1) of this section must promptly inform the individual that such a report has been or will be made, except if:

(i) The covered entity, in the exercise of professional judgment, believes informing the individual would place the individual at risk of serious harm; or

(ii) The covered entity would be informing a personal representative, and the covered entity reasonably believes the personal representative is responsible for the abuse, neglect, or other injury, and that informing such person would not be in the best interests of the individual as determined by the

covered entity, in the exercise of professional judgment.

(d) *Standard: Uses and disclosures for health oversight activities*—(1) *Permitted disclosures*. A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:

(i) The health care system;

(ii) Government benefit programs for which health information is relevant to beneficiary eligibility;

(iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or

(iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

(2) *Exception to health oversight activities*. For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:

(i) The receipt of health care;

(ii) A claim for public benefits related to health; or

(iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.

(3) *Joint activities or investigations*. Nothwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.

(4) *Permitted uses*. If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

(e) *Standard: Disclosures for judicial and administrative proceedings*—(1) *Permitted disclosures*. A covered entity may disclose protected health information in the course of any judicial or administrative proceeding:

(i) In response to an order of a court or administrative tribunal, provided that the covered entity discloses only the protected health information expressly authorized by such order; or

(ii) In response to a subpoena, discovery request, or other lawful process, that is not accompanied by an order of a court or administrative tribunal, if:

(A) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iii) of this section, from the party seeking the information that reasonable efforts have been made by such party to ensure that the individual who is the subject of the protected health information that has been requested has been given notice of the request; or

(B) The covered entity receives satisfactory assurance, as described in paragraph (e)(1)(iv) of this section, from the party seeking the information that reasonable efforts have been made by such party to secure a qualified protective order that meets the requirements of paragraph (e)(1)(v) of this section.

(iii) For the purposes of paragraph (e)(1)(ii)(A) of this section, a covered entity receives satisfactory assurances from a party seeking protecting health information if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The party requesting such information has made a good faith attempt to provide written notice to the individual (or, if the individual's location is unknown, to mail a notice to the individual's last known address);

(B) The notice included sufficient information about the litigation or proceeding in which the protected health information is requested to permit the individual to raise an objection to the court or administrative tribunal; and

(C) The time for the individual to raise objections to the court or administrative tribunal has elapsed, and:

(*1*) No objections were filed; or

(*2*) All objections filed by the individual have been resolved by the court or the administrative tribunal and the disclosures being sought are consistent with such resolution.

(iv) For the purposes of paragraph (e)(1)(ii)(B) of this section, a covered entity receives satisfactory assurances from a party seeking protected health information, if the covered entity receives from such party a written statement and accompanying documentation demonstrating that:

(A) The parties to the dispute giving rise to the request for information have agreed to a qualified protective order and have presented it to the court or administrative tribunal with jurisdiction over the dispute; or

(B) The party seeking the protected health information has requested a qualified protective order from such court or administrative tribunal.

(v) For purposes of paragraph (e)(1) of this section, a qualified protective order means, with respect to protected health information requested under paragraph (e)(1)(ii) of this section, an order of a court or of an administrative tribunal or a stipulation by the parties to the litigation or administrative proceeding that:

(A) Prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation or proceeding for which such information was requested; and

(B) Requires the return to the covered entity or destruction of the protected health information (including all copies made) at the end of the litigation or proceeding.

(vi) Nothwithstanding paragraph (e)(1)(ii) of this section, a covered entity may disclose protected health information in response to lawful process described in paragraph (e)(1)(ii) of this section without receiving satisfactory assurance under paragraph (e)(1)(ii)(A) or (B) of this section, if the covered entity makes reasonable efforts to provide notice to the individual sufficient to meet the requirements of paragraph (e)(1)(iii) of this section or to seek a qualified protective order sufficient to meet the requirements of paragraph (e)(1)(iv) of this section.

(2) *Other uses and disclosures under this section*. The provisions of this paragraph do not supersede other provisions of this section that otherwise permit or restrict uses or disclosures of protected health information.

(f) *Standard: Disclosures for law enforcement purposes*. A covered entity may disclose protected health information for a law enforcement purpose to a law enforcement official if the conditions in paragraphs (f)(1) through (f)(6) of this section are met, as applicable.

(1) *Permitted disclosures: Pursuant to process and as otherwise required by law*. A covered entity may disclose protected health information:

(i) As required by law including laws that require the reporting of certain types of wounds or other physical injuries, except for laws subject to paragraph (b)(1)(ii) or (c)(1)(i) of this section; or

(ii) In compliance with and as limited by the relevant requirements of:

(A) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;

(B) A grand jury subpoena; or

(C) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided that:

(*1*) The information sought is relevant and material to a legitimate law enforcement inquiry;

(*2*) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and

(*3*) De-identified information could not reasonably be used.

(2) *Permitted disclosures: Limited information for identification and location purposes*. Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information for the purpose of identifying or locating a suspect, fugitive, material witness, or missing person, provided that:

(i) The covered entity may disclose only the following information:

(A) Name and address;

(B) Date and place of birth;

(C) Social security number;

(D) ABO blood type and rh factor;

(E) Type of injury;

(F) Date and time of treatment;

(G) Date and time of death, if applicable; and

(H) A description of distinguishing physical characteristics, including height, weight, gender, race, hair and eye color, presence or absence of facial hair (beard or moustache), scars, and tattoos.

(ii) Except as permitted by paragraph (f)(2)(i) of this section, the covered entity may not disclose for the purposes of identification or location under paragraph (f)(2) of this section any protected health information related to the individual's DNA or DNA analysis, dental records, or typing, samples or analysis of body fluids or tissue.

(3) *Permitted disclosure: Victims of a crime.* Except for disclosures required by law as permitted by paragraph (f)(1) of this section, a covered entity may disclose protected health information in response to a law enforcement official's request for such information about an individual who is or is suspected to be a victim of a crime, other than disclosures that are subject to paragraph (b) or (c) of this section, if:

(i) The individual agrees to the disclosure; or

(ii) The covered entity is unable to obtain the individual's agreement because of incapacity or other emergency circumstance, provided that:

(A) The law enforcement official represents that such information is needed to determine whether a violation of law by a person other than the victim has occurred, and such information is not intended to be used against the victim;

(B) The law enforcement official represents that immediate law enforcement activity that depends upon the disclosure would be materially and adversely affected by waiting until the individual is able to agree to the disclosure; and

(C) The disclosure is in the best interests of the individual as determined by the covered entity, in the exercise of professional judgment.

(4) *Permitted disclosure: Decedents.* A covered entity may disclose protected health information about an individual who has died to a law enforcement official for the purpose of alerting law enforcement of the death of the individual if the covered entity has a suspicion that such death may have resulted from criminal conduct.

(5) *Permitted disclosure: Crime on premises.* A covered entity may disclose to a law enforcement official protected health information that the covered entity believes in good faith constitutes evidence of criminal conduct that occurred on the premises of the covered entity.

(6) *Permitted disclosure: Reporting crime in emergencies.* (i) A covered health care provider providing emergency health care in response to a medical emergency, other than such emergency on the premises of the covered health care provider, may disclose protected health information to a law enforcement official if such disclosure appears necessary to alert law enforcement to:

(A) The commission and nature of a crime;

(B) The location of such crime or of the victim(s) of such crime; and

(C) The identity, description, and location of the perpetrator of such crime.

(ii) If a covered health care provider believes that the medical emergency described in paragraph (f)(6)(i) of this section is the result of abuse, neglect, or domestic violence of the individual in need of emergency health care, paragraph (f)(6)(i) of this section does not apply and any disclosure to a law enforcement official for law enforcement purposes is subject to paragraph (c) of this section.

(g) *Standard: Uses and disclosures about decedents*—(1) *Coroners and medical examiners.* A covered entity may disclose protected health information to a coroner or medical examiner for the purpose of identifying a deceased person, determining a cause of death, or other duties as authorized by law. A covered entity that also performs the duties of a coroner or medical examiner may use protected health information for the purposes described in this paragraph.

(2) *Funeral directors.* A covered entity may disclose protected health information to funeral directors, consistent with applicable law, as necessary to carry out their duties with respect to the decedent. If necessary for funeral

directors to carry out their duties, the covered entity may disclose the protected health information prior to, and in reasonable anticipation of, the individual's death.

(h) *Standard: Uses and disclosures for cadaveric organ, eye or tissue donation purposes.* A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

(i) *Standard: Uses and disclosures for research purposes*—(1) *Permitted uses and disclosures.* A covered entity may use or disclose protected health information for research, regardless of the source of funding of the research, provided that:

(i) *Board approval of a waiver of authorization.* The covered entity obtains documentation that an alteration to or waiver, in whole or in part, of the individual authorization required by §164.508 for use or disclosure of protected health information has been approved by either:

(A) An Institutional Review Board (IRB), established in accordance with 7 CFR lc.107, 10 CFR 745.107, 14 CFR 1230.107, 15 CFR 27.107, 16 CFR 1028.107, 21 CFR 56.107, 22 CFR 225.107, 24 CFR 60.107, 28 CFR 46.107, 32 CFR 219.107, 34 CFR 97.107, 38 CFR 16.107, 40 CFR 26.107, 45 CFR 46.107, 45 CFR 690.107, or 49 CFR 11.107; or

(B) A privacy board that:

(*1*) Has members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests;

(*2*) Includes at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of such entities; and

(*3*) Does not have any member participating in a review of any project in which the member has a conflict of interest.

(ii) *Reviews preparatory to research.* The covered entity obtains from the researcher representations that:

(A) Use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;

(B) No protected health information is to be removed from the covered entity by the researcher in the course of the review; and

(C) The protected health information for which use or access is sought is necessary for the research purposes.

(iii) *Research on decedent's information.* The covered entity obtains from the researcher:

(A) Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

(B) Documentation, at the request of the covered entity, of the death of such individuals; and

(C) Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

(2) *Documentation of waiver approval.* For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, under paragraph (i)(1)(i) of this section, the documentation must include all of the following:

(i) *Identification and date of action.* A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

(ii) *Waiver criteria.* A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements;

(*1*) An adequate plan to protect the identifiers from improper use and disclosure;

(*2*) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(*3*) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

(iii) *Protected health information needed.* A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board has determined, pursuant to paragraph (i)(2)(ii)(C) of this section;

(iv) *Review and approval procedures.* A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures, as follows:

(A) An IRB must follow the requirements of the Common Rule, including the normal review procedures (7 CFR 1c.108(b), 10 CFR 745.108(b), 14 CFR 1230.108(b), 15 CFR 27.108(b), 16 CFR 1028.108(b), 21 CFR 56.108(b), 22 CFR 225.108(b), 24 CFR 60.108(b), 28 CFR 46.108(b), 32 CFR 219.108(b), 34 CFR 97.108(b), 38 CFR 16.108(b), 40 CFR 26.108(b), 45 CFR 46.108(b), 45 CFR 690.108(b), or 49 CFR 11.108(b)) or the expedited review procedures (7 CFR 1c.110, 10 CFR 745.110, 14 CFR 1230.110, 15 CFR 27.110, 16 CFR 1028.110, 21 CFR 56.110, 22 CFR 225.110, 24 CFR 60.110, 28 CFR 46.110, 32 CFR 219.110, 34 CFR 97.110, 38 CFR 16.110, 40 CFR 26.110, 45 CFR 46.110, 45 CFR 690.110, or 49 CFR 11.110);

(B) A privacy board must review the proposed research at convened meetings at which a majority of the privacy board members are present, including at least one member who satisfies the criterion stated in paragraph (i)(1)(i)(B)(2) of this section, and the alteration or waiver of authorization must be approved by the majority of the privacy board members present at the meeting, unless the privacy board elects to use an expedited review procedure in accordance with paragraph (i)(2)(iv)(C) of this section;

(C) A privacy board may use an expedited review procedure if the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought. If the privacy board elects to use an expedited review procedure, the review and approval of the alteration or waiver of authorization may be carried out by the chair of the privacy board, or by one or more members of the privacy board as designated by the chair; and

(v) *Required signature.* The documentation of the alteration or waiver of authorization must be signed by the chair or other member, as designated by the chair, of the IRB or the privacy board, as applicable.

(j) *Standard: Uses and disclosures to avert a serious threat to health or safety*—(1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:

(i)(A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and

(B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or

(ii) Is necessary for law enforcement authorities to identify or apprehend an individual:

(A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or

(B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.

(2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:

(i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or

(ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.

(3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.

(4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

(k) *Standard: Uses and disclosures for specialized government functions*—(1) *Military and veterans activities*—(i) *Armed Forces personnel.* A covered entity may use and disclose the protected health information of individuals who are Armed Forces personnel for activities deemed necessary by appropriate military command authorities to assure the proper execution of the military mission, if the appropriate military authority has published by notice in the FEDERAL REGISTER the following information:

(A) Appropriate military command authorities; and

(B) The purposes for which the protected health information may be used or disclosed.

(ii) *Separation or discharge from military service.* A covered entity that is a component of the Departments of Defense or Transportation may disclose to the Department of Veterans Affairs (DVA) the protected health information of an individual who is a member of the Armed Forces upon the separation or discharge of the individual from military service for the purpose of a determination by DVA of the individual's eligibility for or entitlement to benefits under laws administered by the Secretary of Veterans Affairs.

(iii) *Veterans.* A covered entity that is a component of the Department of Veterans Affairs may use and disclose protected health information to components of the Department that determine eligibility for or entitlement to, or that provide, benefits under the laws administered by the Secretary of Veterans Affairs.

(iv) *Foreign military personnel.* A covered entity may use and disclose the protected health information of individuals who are foreign military personnel to their appropriate foreign military authority for the same purposes for which uses and disclosures are permitted for Armed Forces personnel under the notice published in the FEDERAL REGISTER pursuant to paragraph (k)(1)(i) of this section.

(2) *National security and intelligence activities.* A covered entity may disclose protected health information to authorized federal officials for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401, *et seq.*) and implementing authority (*e.g.*, Executive Order 12333).

(3) *Protective services for the President and others.* A covered entity may disclose protected health information to authorized federal officials for the provision of protective services to the President or other persons authorized by 18 U.S.C. 3056, or to foreign heads of state or other persons authorized by 22 U.S.C. 2709(a)(3), or to for the conduct of investigations authorized by 18 U.S.C. 871 and 879.

(4) *Medical suitability determinations.* A covered entity that is a component of the Department of State may use protected health information to make medical suitability determinations and may disclose whether or not the individual was determined to be medically suitable to the officials in the Department of State who need access to such information for the following purposes:

(i) For the purpose of a required security clearance conducted pursuant to Executive Orders 10450 and 12698;

(ii) As necessary to determine worldwide availability or availability for mandatory service abroad under sections 101(a)(4) and 504 of the Foreign Service Act; or

(iii) For a family to accompany a Foreign Service member abroad, consistent with section 101(b)(5) and 904 of the Foreign Service Act.

(5) *Correctional institutions and other law enforcement custodial situations.* (i) *Permitted disclosures.* A covered entity may disclose to a correctional institution or a law enforcement official having lawful custody of an inmate or other individual protected health information about such inmate or individual, if the correctional institution or such law enforcement official represents that such protected health information is necessary for:

(A) The provision of health care to such individuals;

(B) The health and safety of such individual or other inmates;

(C) The health and safety of the officers or employees of or others at the correctional institution;

(D) The health and safety of such individuals and officers or other persons responsible for the transporting of inmates or their transfer from one institution, facility, or setting to another;

(E) Law enforcement on the premises of the correctional institution; and

(F) The administration and maintenance of the safety, security, and good order of the correctional institution.

(ii) *Permitted uses.* A covered entity that is a correctional institution may use protected health information of individuals who are inmates for any purpose for which such protected health information may be disclosed.

(iii) *No application after release.* For the purposes of this provision, an individual is no longer an inmate when released on parole, probation, supervised release, or otherwise is no longer in lawful custody.

(6) *Covered entities that are government programs providing public benefits.* (i) A health plan that is a government program providing public benefits may disclose protected health information relating to eligibility for or enrollment in the health plan to another agency administering a government program providing public benefits if the sharing of eligibility or enrollment information among such government agencies or the maintenance of such information in a single or combined data system accessible to all such government agencies is required or expressly authorized by statute or regulation.

(ii) A covered entity that is a government agency administering a government program providing public benefits may disclose protected health information relating to the program to another covered entity that is a government agency administering a government program providing public benefits if the programs serve the same or similar populations and the disclosure of protected health information is necessary to coordinate the covered functions of such programs or to improve administration and management relating to the covered functions of such programs.

(l) *Standard: Disclosures for workers' compensation.* A covered entity may disclose protected health information as authorized by and to the extent necessary to comply with laws relating to workers' compensation or other similar programs, established by law, that provide benefits for work-related injuries or illness without regard to fault.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

§ 164.514 Other requirements relating to uses and disclosures of protected health information.

(a) *Standard: de-identification of protected health information.* Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information.

(b) *Implementation specifications: requirements for de-identification of protected health information.* A covered entity may determine that health information is not individually identifiable health information only if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(i) Applying such principles and methods, determines that the risk is

very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

(ii) Documents the methods and results of the analysis that justify such determination; or

(2)(i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(*1*) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(*2*) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(c) *Implementation specifications: re-identification*. A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

(1) *Derivation*. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and

(2) *Security*. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

(d)(1) *Standard: minimum necessary requirements*. In order to comply with § 164.502(b) and this section, a covered entity must meet the requirements of paragraphs (d)(2) through (d)(5) of this section with respect to a request for, or the use and disclosure of, protected health information.

(2) *Implementation specifications: minimum necessary uses of protected health information*. (i) A covered entity must identify:

(A) Those persons or classes of persons, as appropriate, in its workforce who need access to protected health information to carry out their duties; and

(B) For each such person or class of persons, the category or categories of protected health information to which access is needed and any conditions appropriate to such access.

(ii) A covered entity must make reasonable efforts to limit the access of such persons or classes identified in paragraph (d)(2)(i)(A) of this section to protected health information consistent with paragraph (d)(2)(i)(B) of this section.

(3) *Implementation specification: Minimum necessary disclosures of protected health information.* (i) For any type of disclosure that it makes on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information disclosed to the amount reasonably necessary to achieve the purpose of the disclosure.

(ii) For all other disclosures, a covered entity must:

(A) Develop criteria designed to limit the protected health information disclosed to the information reasonably necessary to accomplish the purpose for which disclosure is sought; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(iii) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when:

(A) Making disclosures to public officials that are permitted under §164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s);

(B) The information is requested by another covered entity;

(C) The information is requested by a professional who is a member of its workforce or is a business associate of the covered entity for the purpose of providing professional services to the covered entity, if the professional represents that the information requested is the minimum necessary for the stated purpose(s); or

(D) Documentation or representations that comply with the applicable requirements of §164.512(i) have been provided by a person requesting the information for research purposes.

(4) *Implementation specifications: Minimum necessary requests for protected health information.* (i) A covered entity must limit any request for protected health information to that which is reasonably necessary to accomplish the purpose for which the request is made, when requesting such information from other covered entities.

(ii) For a request that is made on a routine and recurring basis, a covered entity must implement policies and procedures (which may be standard protocols) that limit the protected health information requested to the amount reasonably necessary to accomplish the purpose for which the request is made.

(iii) For all other requests, a covered entity must:

(A) Develop criteria designed to limit the request for protected health information to the information reasonably necessary to accomplish the purpose for which the request is made; and

(B) Review requests for disclosure on an individual basis in accordance with such criteria.

(5) *Implementation specification: Other content requirement.* For all uses, disclosures, or requests to which the requirements in paragraph (d) of this section apply, a covered entity may not use, disclose or request an entire medical record, except when the entire medical record is specifically justified as the amount that is reasonably necessary to accomplish the purpose of the use, disclosure, or request.

(e)(1) *Standard: Limited data set.* A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set:* A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;

(iv) Fax numbers;

(v) Electronic mail addresses;

(vi) Social security numbers;

(vii) Medical record numbers;

(viii) Health plan beneficiary numbers;

(ix) Account numbers;

(x) Certificate/license numbers;

(xi) Vehicle identifiers and serial numbers, including license plate numbers;

(xii) Device identifiers and serial numbers;

(xiii) Web Universal Resource Locators (URLs);

(xiv) Internet Protocol (IP) address numbers;

(xv) Biometric identifiers, including finger and voice prints; and

(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.* (i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations.

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) *Implementation specifications: Data use agreement*—(i) *Agreement required.* A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(*4*) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(*5*) Not identify the information or contact the individuals.

(iii) *Compliance.* (A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(1) Discontinued disclosure of protected health information to the recipient; and

(2) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

(f)(1) *Standard: Uses and disclosures for fundraising.* A covered entity may use, or disclose to a business associate or to an institutionally related foundation, the following protected health information for the purpose of raising funds for its own benefit, without an authorization meeting the requirements of § 164.508:

(i) Demographic information relating to an individual; and

(ii) Dates of health care provided to an individual.

(2) *Implementation specifications: Fundraising requirements.* (i) The covered entity may not use or disclose protected health information for fundraising purposes as otherwise permitted by paragraph (f)(1) of this section unless a statement required by

§ 164.520(b)(1)(iii)(B) is included in the covered entity's notice;

(ii) The covered entity must include in any fundraising materials it sends to an individual under this paragraph a description of how the individual may opt out of receiving any further fundraising communications.

(iii) The covered entity must make reasonable efforts to ensure that individuals who decide to opt out of receiving future fundraising communications are not sent such communications.

(g) *Standard: Uses and disclosures for underwriting and related purposes.* If a health plan receives protected heath information for the purpose of underwriting, premium rating, or other activities relating to the creation, renewal, or replacement of a contract of health insurance or health benefits, and if such health insurance or health benefits are not placed with the health plan, such health plan may not use or disclose such protected health information for any other purpose, except as may be required by law.

(h)(1) *Standard: Verification requirements.* Prior to any disclosure permitted by this subpart, a covered entity must:

(i) Except with respect to disclosures under § 164.510, verify the identity of a person requesting protected health information and the authority of any such person to have access to protected health information under this subpart, if the identity or any such authority of such person is not known to the covered entity; and

(ii) Obtain any documentation, statements, or representations, whether oral or written, from the person requesting the protected health information when such documentation, statement, or representation is a condition of the disclosure under this subpart.

(2) *Implementation specifications: Verification.* (i) *Conditions on disclosures.* If a disclosure is conditioned by this subpart on particular documentation, statements, or representations from the person requesting the protected health information, a covered entity may rely, if such reliance is reasonable under the circumstances, on documentation, statements, or representations that, on their face, meet the applicable requirements.

(A) The conditions in § 164.512(f)(1)(ii)(C) may be satisfied by the administrative subpoena or similar process or by a separate written statement that, on its face, demonstrates that the applicable requirements have been met.

(B) The documentation required by § 164.512(i)(2) may be satisfied by one or more written statements, provided that each is appropriately dated and signed in accordance with § 164.512(i)(2)(i) and (v).

(ii) *Identity of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify identity when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) If the request is made in person, presentation of an agency identification badge, other official credentials, or other proof of government status;

(B) If the request is in writing, the request is on the appropriate government letterhead; or

(C) If the disclosure is to a person acting on behalf of a public official, a written statement on appropriate government letterhead that the person is acting under the government's authority or other evidence or documentation of agency, such as a contract for services, memorandum of understanding, or purchase order, that establishes that the person is acting on behalf of the public official.

(iii) *Authority of public officials.* A covered entity may rely, if such reliance is reasonable under the circumstances, on any of the following to verify authority when the disclosure of protected health information is to a public official or a person acting on behalf of the public official:

(A) A written statement of the legal authority under which the information is requested, or, if a written statement would be impracticable, an oral statement of such legal authority;

(B) If a request is made pursuant to legal process, warrant, subpoena, order, or other legal process issued by a grand jury or a judicial or administrative tribunal is presumed to constitute legal authority.

(iv) *Exercise of professional judgment.* The verification requirements of this paragraph are met if the covered entity relies on the exercise of professional judgment in making a use or disclosure in accordance with § 164.510 or acts on a good faith belief in making a disclosure in accordance with § 164.512(j).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53270, Aug. 14, 2002]

§ 164.520 Notice of privacy practices for protected health information.

(a) *Standard: notice of privacy practices*—(1) *Right to notice.* Except as provided by paragraph (a)(2) or (3) of this section, an individual has a right to adequate notice of the uses and disclosures of protected health information that may be made by the covered entity, and of the individual's rights and the covered entity's legal duties with respect to protected health information.

(2) *Exception for group health plans.* (i) An individual enrolled in a group health plan has a right to notice:

(A) From the group health plan, if, and to the extent that, such an individual does not receive health benefits under the group health plan through an insurance contract with a health insurance issuer or HMO; or

(B) From the health insurance issuer or HMO with respect to the group health plan through which such individuals receive their health benefits under the group health plan.

(ii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and that creates or receives protected health information in addition to summary health information as defined in § 164.504(a) or information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, must:

(A) Maintain a notice under this section; and

(B) Provide such notice upon request to any person. The provisions of paragraph (c)(1) of this section do not apply to such group health plan.

(iii) A group health plan that provides health benefits solely through an insurance contract with a health insurance issuer or HMO, and does not create or receive protected health information other than summary health information as defined in § 164.504(a) or information on whether an individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan, is not required to maintain or provide a notice under this section.

(3) *Exception for inmates.* An inmate does not have a right to notice under this section, and the requirements of this section do not apply to a correctional institution that is a covered entity.

(b) *Implementation specifications: content of notice*—(1) *Required elements.* The covered entity must provide a notice that is written in plain language and that contains the elements required by this paragraph.

(i) *Header.* The notice must contain the following statement as a header or otherwise prominently displayed: ''THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.''

(ii) *Uses and disclosures.* The notice must contain:

(A) A description, including at least one example, of the types of uses and disclosures that the covered entity is permitted by this subpart to make for each of the following purposes: treatment, payment, and health care operations.

(B) A description of each of the other purposes for which the covered entity is permitted or required by this subpart to use or disclose protected health information without the individual's written authorization.

(C) If a use or disclosure for any purpose described in paragraphs (b)(1)(ii)(A) or (B) of this section is prohibited or materially limited by other applicable law, the description of such use or disclosure must reflect the more stringent law as defined in § 160.202 of this subchapter.

(D) For each purpose described in paragraph (b)(1)(ii)(A) or (B) of this section, the description must include

sufficient detail to place the individual on notice of the uses and disclosures that are permitted or required by this subpart and other applicable law.

(E) A statement that other uses and disclosures will be made only with the individual's written authorization and that the individual may revoke such authorization as provided by § 164.508(b)(5).

(iii) *Separate statements for certain uses or disclosures.* If the covered entity intends to engage in any of the following activities, the description required by paragraph (b)(1)(ii)(A) of this section must include a separate statement, as applicable, that:

(A) The covered entity may contact the individual to provide appointment reminders or information about treatment alternatives or other health-related benefits and services that may be of interest to the individual;

(B) The covered entity may contact the individual to raise funds for the covered entity; or

(C) A group health plan, or a health insurance issuer or HMO with respect to a group health plan, may disclose protected health information to the sponsor of the plan.

(iv) *Individual rights.* The notice must contain a statement of the individual's rights with respect to protected health information and a brief description of how the individual may exercise these rights, as follows:

(A) The right to request restrictions on certain uses and disclosures of protected health information as provided by § 164.522(a), including a statement that the covered entity is not required to agree to a requested restriction;

(B) The right to receive confidential communications of protected health information as provided by § 164.522(b), as applicable;

(C) The right to inspect and copy protected health information as provided by § 164.524;

(D) The right to amend protected health information as provided by § 164.526;

(E) The right to receive an accounting of disclosures of protected health information as provided by § 164.528; and

(F) The right of an individual, including an individual who has agreed to receive the notice electronically in accordance with paragraph (c)(3) of this section, to obtain a paper copy of the notice from the covered entity upon request.

(v) *Covered entity's duties.* The notice must contain:

(A) A statement that the covered entity is required by law to maintain the privacy of protected health information and to provide individuals with notice of its legal duties and privacy practices with respect to protected health information;

(B) A statement that the covered entity is required to abide by the terms of the notice currently in effect; and

(C) For the covered entity to apply a change in a privacy practice that is described in the notice to protected health information that the covered entity created or received prior to issuing a revised notice, in accordance with § 164.530(i)(2)(ii), a statement that it reserves the right to change the terms of its notice and to make the new notice provisions effective for all protected health information that it maintains. The statement must also describe how it will provide individuals with a revised notice.

(vi) *Complaints.* The notice must contain a statement that individuals may complain to the covered entity and to the Secretary if they believe their privacy rights have been violated, a brief description of how the individual may file a complaint with the covered entity, and a statement that the individual will not be retaliated against for filing a complaint.

(vii) *Contact.* The notice must contain the name, or title, and telephone number of a person or office to contact for further information as required by § 164.530(a)(1)(ii).

(viii) *Effective date.* The notice must contain the date on which the notice is first in effect, which may not be earlier than the date on which the notice is printed or otherwise published.

(2) *Optional elements.* (i) In addition to the information required by paragraph (b)(1) of this section, if a covered entity elects to limit the uses or disclosures that it is permitted to make under this subpart, the covered entity may describe its more limited uses or disclosures in its notice, provided that the

covered entity may not include in its notice a limitation affecting its right to make a use or disclosure that is required by law or permitted by §164.512(j)(1)(i).

(ii) For the covered entity to apply a change in its more limited uses and disclosures to protected health information created or received prior to issuing a revised notice, in accordance with §164.530(i)(2)(ii), the notice must include the statements required by paragraph (b)(1)(v)(C) of this section.

(3) *Revisions to the notice.* The covered entity must promptly revise and distribute its notice whenever there is a material change to the uses or disclosures, the individual's rights, the covered entity's legal duties, or other privacy practices stated in the notice. Except when required by law, a material change to any term of the notice may not be implemented prior to the effective date of the notice in which such material change is reflected.

(c) *Implementation specifications: Provision of notice.* A covered entity must make the notice required by this section available on request to any person and to individuals as specified in paragraphs (c)(1) through (c)(3) of this section, as applicable.

(1) *Specific requirements for health plans.* (i) A health plan must provide notice:

(A) No later than the compliance date for the health plan, to individuals then covered by the plan;

(B) Thereafter, at the time of enrollment, to individuals who are new enrollees; and

(C) Within 60 days of a material revision to the notice, to individuals then covered by the plan.

(ii) No less frequently than once every three years, the health plan must notify individuals then covered by the plan of the availability of the notice and how to obtain the notice.

(iii) The health plan satisfies the requirements of paragraph (c)(1) of this section if notice is provided to the named insured of a policy under which coverage is provided to the named insured and one or more dependents.

(iv) If a health plan has more than one notice, it satisfies the requirements of paragraph (c)(1) of this section by providing the notice that is relevant to the individual or other person requesting the notice.

(2) *Specific requirements for certain covered health care providers.* A covered health care provider that has a direct treatment relationship with an individual must:

(i) Provide the notice:

(A) No later than the date of the first service delivery, including service delivered electronically, to such individual after the compliance date for the covered health care provider; or

(B) In an emergency treatment situation, as soon as reasonably practicable after the emergency treatment situation.

(ii) Except in an emergency treatment situation, make a good faith effort to obtain a written acknowledgment of receipt of the notice provided in accordance with paragraph (c)(2)(i) of this section, and if not obtained, document its good faith efforts to obtain such acknowledgment and the reason why the acknowledgment was not obtained;

(iii) If the covered health care provider maintains a physical service delivery site:

(A) Have the notice available at the service delivery site for individuals to request to take with them; and

(B) Post the notice in a clear and prominent location where it is reasonable to expect individuals seeking service from the covered health care provider to be able to read the notice; and

(iv) Whenever the notice is revised, make the notice available upon request on or after the effective date of the revision and promptly comply with the requirements of paragraph (c)(2)(iii) of this section, if applicable.

(3) *Specific requirements for electronic notice.* (i) A covered entity that maintains a web site that provides information about the covered entity's customer services or benefits must prominently post its notice on the web site and make the notice available electronically through the web site.

(ii) A covered entity may provide the notice required by this section to an individual by e-mail, if the individual agrees to electronic notice and such agreement has not been withdrawn. If the covered entity knows that the e-mail transmission has failed, a paper

copy of the notice must be provided to the individual. Provision of electronic notice by the covered entity will satisfy the provision requirements of paragraph (c) of this section when timely made in accordance with paragraph (c)(1) or (2) of this section.

(iii) For purposes of paragraph (c)(2)(i) of this section, if the first service delivery to an individual is delivered electronically, the covered health care provider must provide electronic notice automatically and contemporaneously in response to the individual's first request for service. The requirements in paragraph (c)(2)(ii) of this section apply to electronic notice.

(iv) The individual who is the recipient of electronic notice retains the right to obtain a paper copy of the notice from a covered entity upon request.

(d) *Implementation specifications: Joint notice by separate covered entities.* Covered entities that participate in organized health care arrangements may comply with this section by a joint notice, provided that:

(1) The covered entities participating in the organized health care arrangement agree to abide by the terms of the notice with respect to protected health information created or received by the covered entity as part of its participation in the organized health care arrangement;

(2) The joint notice meets the implementation specifications in paragraph (b) of this section, except that the statements required by this section may be altered to reflect the fact that the notice covers more than one covered entity; and

(i) Describes with reasonable specificity the covered entities, or class of entities, to which the joint notice applies;

(ii) Describes with reasonable specificity the service delivery sites, or classes of service delivery sites, to which the joint notice applies; and

(iii) If applicable, states that the covered entities participating in the organized health care arrangement will share protected health information with each other, as necessary to carry out treatment, payment, or health care operations relating to the organized health care arrangement.

(3) The covered entities included in the joint notice must provide the notice to individuals in accordance with the applicable implementation specifications of paragraph (c) of this section. Provision of the joint notice to an individual by any one of the covered entities included in the joint notice will satisfy the provision requirement of paragraph (c) of this section with respect to all others covered by the joint notice.

(e) *Implementation specifications: Documentation.* A covered entity must document compliance with the notice requirements, as required by § 164.530(j), by retaining copies of the notices issued by the covered entity and, if applicable, any written acknowledgments of receipt of the notice or documentation of good faith efforts to obtain such written acknowledgment, in accordance with paragraph (c)(2)(ii) of this section.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§ 164.522 Rights to request privacy protection for protected health information.

(a)(1) *Standard: Right of an individual to request restriction of uses and disclosures.* (i) A covered entity must permit an individual to request that the covered entity restrict:

(A) Uses or disclosures of protected health information about the individual to carry out treatment, payment, or health care operations; and

(B) Disclosures permitted under § 164.510(b).

(ii) A covered entity is not required to agree to a restriction.

(iii) A covered entity that agrees to a restriction under paragraph (a)(1)(i) of this section may not use or disclose protected health information in violation of such restriction, except that, if the individual who requested the restriction is in need of emergency treatment and the restricted protected health information is needed to provide the emergency treatment, the covered entity may use the restricted protected health information, or may disclose such information to a health care provider, to provide such treatment to the individual.

(iv) If restricted protected health information is disclosed to a health care provider for emergency treatment under paragraph (a)(1)(iii) of this section, the covered entity must request that such health care provider not further use or disclose the information.

(v) A restriction agreed to by a covered entity under paragraph (a) of this section, is not effective under this subpart to prevent uses or disclosures permitted or required under §§164.502(a)(2)(ii), 164.510(a) or 164.512.

(2) *Implementation specifications: Terminating a restriction.* A covered entity may terminate its agreement to a restriction, if :

(i) The individual agrees to or requests the termination in writing;

(ii) The individual orally agrees to the termination and the oral agreement is documented; or

(iii) The covered entity informs the individual that it is terminating its agreement to a restriction, except that such termination is only effective with respect to protected health information created or received after it has so informed the individual.

(3) *Implementation specification: Documentation.* A covered entity that agrees to a restriction must document the restriction in accordance with §164.530(j).

(b)(1) *Standard: Confidential communications requirements.* (i) A covered health care provider must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the covered health care provider by alternative means or at alternative locations.

(ii) A health plan must permit individuals to request and must accommodate reasonable requests by individuals to receive communications of protected health information from the health plan by alternative means or at alternative locations, if the individual clearly states that the disclosure of all or part of that information could endanger the individual.

(2) *Implementation specifications: Conditions on providing confidential communications.* (i) A covered entity may require the individual to make a request for a confidential communication described in paragraph (b)(1) of this section in writing.

(ii) A covered entity may condition the provision of a reasonable accommodation on:

(A) When appropriate, information as to how payment, if any, will be handled; and

(B) Specification of an alternative address or other method of contact.

(iii) A covered health care provider may not require an explanation from the individual as to the basis for the request as a condition of providing communications on a confidential basis.

(iv) A health plan may require that a request contain a statement that disclosure of all or part of the information to which the request pertains could endanger the individual.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§164.524 Access of individuals to protected health information.

(a) *Standard: Access to protected health information*—(1) *Right of access.* Except as otherwise provided in paragraph (a)(2) or (a)(3) of this section, an individual has a right of access to inspect and obtain a copy of protected health information about the individual in a designated record set, for as long as the protected health information is maintained in the designated record set, except for:

(i) Psychotherapy notes;

(ii) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and

(iii) Protected health information maintained by a covered entity that is:

(A) Subject to the Clinical Laboratory Improvements Amendments of 1988, 42 U.S.C. 263a, to the extent the provision of access to the individual would be prohibited by law; or

(B) Exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR 493.3(a)(2).

(2) *Unreviewable grounds for denial.* A covered entity may deny an individual access without providing the individual an opportunity for review, in the following circumstances.

(i) The protected health information is excepted from the right of access by paragraph (a)(1) of this section.

(ii) A covered entity that is a correctional institution or a covered health care provider acting under the direction of the correctional institution may deny, in whole or in part, an inmate's request to obtain a copy of protected health information, if obtaining such copy would jeopardize the health, safety, security, custody, or rehabilitation of the individual or of other inmates, or the safety of any officer, employee, or other person at the correctional institution or responsible for the transporting of the inmate.

(iii) An individual's access to protected health information created or obtained by a covered health care provider in the course of research that includes treatment may be temporarily suspended for as long as the research is in progress, provided that the individual has agreed to the denial of access when consenting to participate in the research that includes treatment, and the covered health care provider has informed the individual that the right of access will be reinstated upon completion of the research.

(iv) An individual's access to protected health information that is contained in records that are subject to the Privacy Act, 5 U.S.C. 552a, may be denied, if the denial of access under the Privacy Act would meet the requirements of that law.

(v) An individual's access may be denied if the protected health information was obtained from someone other than a health care provider under a promise of confidentiality and the access requested would be reasonably likely to reveal the source of the information.

(3) *Reviewable grounds for denial.* A covered entity may deny an individual access, provided that the individual is given a right to have such denials reviewed, as required by paragraph (a)(4) of this section, in the following circumstances:

(i) A licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person;

(ii) The protected health information makes reference to another person (unless such other person is a health care provider) and a licensed health care professional has determined, in the exercise of professional judgment, that the access requested is reasonably likely to cause substantial harm to such other person; or

(iii) The request for access is made by the individual's personal representative and a licensed health care professional has determined, in the exercise of professional judgment, that the provision of access to such personal representative is reasonably likely to cause substantial harm to the individual or another person.

(4) *Review of a denial of access.* If access is denied on a ground permitted under paragraph (a)(3) of this section, the individual has the right to have the denial reviewed by a licensed health care professional who is designated by the covered entity to act as a reviewing official and who did not participate in the original decision to deny. The covered entity must provide or deny access in accordance with the determination of the reviewing official under paragraph (d)(4) of this section.

(b) *Implementation specifications: requests for access and timely action*—(1) *Individual's request for access.* The covered entity must permit an individual to request access to inspect or to obtain a copy of the protected health information about the individual that is maintained in a designated record set. The covered entity may require individuals to make requests for access in writing, provided that it informs individuals of such a requirement.

(2) *Timely action by the covered entity.* (i) Except as provided in paragraph (b)(2)(ii) of this section, the covered entity must act on a request for access no later than 30 days after receipt of the request as follows.

(A) If the covered entity grants the request, in whole or in part, it must inform the individual of the acceptance of the request and provide the access requested, in accordance with paragraph (c) of this section.

(B) If the covered entity denies the request, in whole or in part, it must provide the individual with a written

denial, in accordance with paragraph (d) of this section.

(ii) If the request for access is for protected health information that is not maintained or accessible to the covered entity on-site, the covered entity must take an action required by paragraph (b)(2)(i) of this section by no later than 60 days from the receipt of such a request.

(iii) If the covered entity is unable to take an action required by paragraph (b)(2)(i)(A) or (B) of this section within the time required by paragraph (b)(2)(i) or (ii) of this section, as applicable, the covered entity may extend the time for such actions by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) or (ii) of this section, as applicable, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for access.

(c) *Implementation specifications: Provision of access.* If the covered entity provides an individual with access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Providing the access requested.* The covered entity must provide the access requested by individuals, including inspection or obtaining a copy, or both, of the protected health information about them in designated record sets. If the same protected health information that is the subject of a request for access is maintained in more than one designated record set or at more than one location, the covered entity need only produce the protected health information once in response to a request for access.

(2) *Form of access requested.* (i) The covered entity must provide the individual with access to the protected health information in the form or format requested by the individual, if it is readily producible in such form or format; or, if not, in a readable hard copy form or such other form or format as agreed to by the covered entity and the individual.

(ii) The covered entity may provide the individual with a summary of the protected health information requested, in lieu of providing access to the protected health information or may provide an explanation of the protected health information to which access has been provided, if:

(A) The individual agrees in advance to such a summary or explanation; and

(B) The individual agrees in advance to the fees imposed, if any, by the covered entity for such summary or explanation.

(3) *Time and manner of access.* The covered entity must provide the access as requested by the individual in a timely manner as required by paragraph (b)(2) of this section, including arranging with the individual for a convenient time and place to inspect or obtain a copy of the protected health information, or mailing the copy of the protected health information at the individual's request. The covered entity may discuss the scope, format, and other aspects of the request for access with the individual as necessary to facilitate the timely provision of access.

(4) *Fees.* If the individual requests a copy of the protected health information or agrees to a summary or explanation of such information, the covered entity may impose a reasonable, cost-based fee, provided that the fee includes only the cost of:

(i) Copying, including the cost of supplies for and labor of copying, the protected health information requested by the individual;

(ii) Postage, when the individual has requested the copy, or the summary or explanation, be mailed; and

(iii) Preparing an explanation or summary of the protected health information, if agreed to by the individual as required by paragraph (c)(2)(ii) of this section.

(d) *Implementation specifications: Denial of access.* If the covered entity denies access, in whole or in part, to protected health information, the covered entity must comply with the following requirements.

(1) *Making other information accessible.* The covered entity must, to the extent possible, give the individual access to

any other protected health information requested, after excluding the protected health information as to which the covered entity has a ground to deny access.

(2) *Denial*. The covered entity must provide a timely, written denial to the individual, in accordance with paragraph (b)(2) of this section. The denial must be in plain language and contain:

(i) The basis for the denial;

(ii) If applicable, a statement of the individual's review rights under paragraph (a)(4) of this section, including a description of how the individual may exercise such review rights; and

(iii) A description of how the individual may complain to the covered entity pursuant to the complaint procedures in § 164.530(d) or to the Secretary pursuant to the procedures in § 160.306. The description must include the name, or title, and telephone number of the contact person or office designated in § 164.530(a)(1)(ii).

(3) *Other responsibility*. If the covered entity does not maintain the protected health information that is the subject of the individual's request for access, and the covered entity knows where the requested information is maintained, the covered entity must inform the individual where to direct the request for access.

(4) Review of denial requested. If the individual has requested a review of a denial under paragraph (a)(4) of this section, the covered entity must designate a licensed health care professional, who was not directly involved in the denial to review the decision to deny access. The covered entity must promptly refer a request for review to such designated reviewing official. The designated reviewing official must determine, within a reasonable period of time, whether or not to deny the access requested based on the standards in paragraph (a)(3) of this section. The covered entity must promptly provide written notice to the individual of the determination of the designated reviewing official and take other action as required by this section to carry out the designated reviewing official's determination.

(e) *Implementation specification: Documentation*. A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The designated record sets that are subject to access by individuals; and

(2) The titles of the persons or offices responsible for receiving and processing requests for access by individuals.

§ 164.526 Amendment of protected health information.

(a) *Standard: Right to amend*. (1) *Right to amend*. An individual has the right to have a covered entity amend protected health information or a record about the individual in a designated record set for as long as the protected health information is maintained in the designated record set.

(2) *Denial of amendment*. A covered entity may deny an individual's request for amendment, if it determines that the protected health information or record that is the subject of the request:

(i) Was not created by the covered entity, unless the individual provides a reasonable basis to believe that the originator of protected health information is no longer available to act on the requested amendment;

(ii) Is not part of the designated record set;

(iii) Would not be available for inspection under § 164.524; or

(iv) Is accurate and complete.

(b) *Implementation specifications: requests for amendment and timely action*. (1) *Individual's request for amendment*. The covered entity must permit an individual to request that the covered entity amend the protected health information maintained in the designated record set. The covered entity may require individuals to make requests for amendment in writing and to provide a reason to support a requested amendment, provided that it informs individuals in advance of such requirements.

(2) *Timely action by the covered entity*. (i) The covered entity must act on the individual's request for an amendment no later than 60 days after receipt of such a request, as follows.

(A) If the covered entity grants the requested amendment, in whole or in part, it must take the actions required

by paragraphs (c)(1) and (2) of this section.

(B) If the covered entity denies the requested amendment, in whole or in part, it must provide the individual with a written denial, in accordance with paragraph (d)(1) of this section.

(ii) If the covered entity is unable to act on the amendment within the time required by paragraph (b)(2)(i) of this section, the covered entity may extend the time for such action by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (b)(2)(i) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will complete its action on the request; and

(B) The covered entity may have only one such extension of time for action on a request for an amendment.

(c) *Implementation specifications: Accepting the amendment.* If the covered entity accepts the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Making the amendment.* The covered entity must make the appropriate amendment to the protected health information or record that is the subject of the request for amendment by, at a minimum, identifying the records in the designated record set that are affected by the amendment and appending or otherwise providing a link to the location of the amendment.

(2) *Informing the individual.* In accordance with paragraph (b) of this section, the covered entity must timely inform the individual that the amendment is accepted and obtain the individual's identification of and agreement to have the covered entity notify the relevant persons with which the amendment needs to be shared in accordance with paragraph (c)(3) of this section.

(3) *Informing others.* The covered entity must make reasonable efforts to inform and provide the amendment within a reasonable time to:

(i) Persons identified by the individual as having received protected health information about the individual and needing the amendment; and

(ii) Persons, including business associates, that the covered entity knows have the protected health information that is the subject of the amendment and that may have relied, or could foreseeably rely, on such information to the detriment of the individual.

(d) *Implementation specifications: Denying the amendment.* If the covered entity denies the requested amendment, in whole or in part, the covered entity must comply with the following requirements.

(1) *Denial.* The covered entity must provide the individual with a timely, written denial, in accordance with paragraph (b)(2) of this section. The denial must use plain language and contain:

(i) The basis for the denial, in accordance with paragraph (a)(2) of this section;

(ii) The individual's right to submit a written statement disagreeing with the denial and how the individual may file such a statement;

(iii) A statement that, if the individual does not submit a statement of disagreement, the individual may request that the covered entity provide the individual's request for amendment and the denial with any future disclosures of the protected health information that is the subject of the amendment; and

(iv) A description of how the individual may complain to the covered entity pursuant to the complaint procedures established in §164.530(d) or to the Secretary pursuant to the procedures established in §160.306. The description must include the name, or title, and telephone number of the contact person or office designated in §164.530(a)(1)(ii).

(2) *Statement of disagreement.* The covered entity must permit the individual to submit to the covered entity a written statement disagreeing with the denial of all or part of a requested amendment and the basis of such disagreement. The covered entity may reasonably limit the length of a statement of disagreement.

(3) *Rebuttal statement.* The covered entity may prepare a written rebuttal to the individual's statement of disagreement. Whenever such a rebuttal is prepared, the covered entity must provide

a copy to the individual who submitted the statement of disagreement.

(4) *Recordkeeping*. The covered entity must, as appropriate, identify the record or protected health information in the designated record set that is the subject of the disputed amendment and append or otherwise link the individual's request for an amendment, the covered entity's denial of the request, the individual's statement of disagreement, if any, and the covered entity's rebuttal, if any, to the designated record set.

(5) *Future disclosures*. (i) If a statement of disagreement has been submitted by the individual, the covered entity must include the material appended in accordance with paragraph (d)(4) of this section, or, at the election of the covered entity, an accurate summary of any such information, with any subsequent disclosure of the protected health information to which the disagreement relates.

(ii) If the individual has not submitted a written statement of disagreement, the covered entity must include the individual's request for amendment and its denial, or an accurate summary of such information, with any subsequent disclosure of the protected health information only if the individual has requested such action in accordance with paragraph (d)(1)(iii) of this section.

(iii) When a subsequent disclosure described in paragraph (d)(5)(i) or (ii) of this section is made using a standard transaction under part 162 of this subchapter that does not permit the additional material to be included with the disclosure, the covered entity may separately transmit the material required by paragraph (d)(5)(i) or (ii) of this section, as applicable, to the recipient of the standard transaction.

(e) *Implementation specification: Actions on notices of amendment*. A covered entity that is informed by another covered entity of an amendment to an individual's protected health information, in accordance with paragraph (c)(3) of this section, must amend the protected health information in designated record sets as provided by paragraph (c)(1) of this section.

(f) *Implementation specification: Documentation*. A covered entity must document the titles of the persons or offices responsible for receiving and processing requests for amendments by individuals and retain the documentation as required by § 164.530(j).

§ 164.528 Accounting of disclosures of protected health information.

(a) *Standard: Right to an accounting of disclosures of protected health information*. (1) An individual has a right to receive an accounting of disclosures of protected health information made by a covered entity in the six years prior to the date on which the accounting is requested, except for disclosures:

(i) To carry out treatment, payment and health care operations as provided in § 164.506;

(ii) To individuals of protected health information about them as provided in § 164.502;

(iii) Incident to a use or disclosure otherwise permitted or required by this subpart, as provided in § 164.502;

(iv) Pursuant to an authorization as provided in § 164.508;

(v) For the facility's directory or to persons involved in the individual's care or other notification purposes as provided in § 164.510;

(vi) For national security or intelligence purposes as provided in § 164.512(k)(2);

(vii) To correctional institutions or law enforcement officials as provided in § 164.512(k)(5);

(viii) As part of a limited data set in accordance with § 164.514(e); or

(ix) That occurred prior to the compliance date for the covered entity.

(2)(i) The covered entity must temporarily suspend an individual's right to receive an accounting of disclosures to a health oversight agency or law enforcement official, as provided in § 164.512(d) or (f), respectively, for the time specified by such agency or official, if such agency or official provides the covered entity with a written statement that such an accounting to the individual would be reasonably likely to impede the agency's activities and specifying the time for which such a suspension is required.

(ii) If the agency or official statement in paragraph (a)(2)(i) of this section is made orally, the covered entity must:

(A) Document the statement, including the identity of the agency or official making the statement;

(B) Temporarily suspend the individual's right to an accounting of disclosures subject to the statement; and

(C) Limit the temporary suspension to no longer than 30 days from the date of the oral statement, unless a written statement pursuant to paragraph (a)(2)(i) of this section is submitted during that time.

(3) An individual may request an accounting of disclosures for a period of time less than six years from the date of the request.

(b) *Implementation specifications: Content of the accounting.* The covered entity must provide the individual with a written accounting that meets the following requirements.

(1) Except as otherwise provided by paragraph (a) of this section, the accounting must include disclosures of protected health information that occurred during the six years (or such shorter time period at the request of the individual as provided in paragraph (a)(3) of this section) prior to the date of the request for an accounting, including disclosures to or by business associates of the covered entity.

(2) Except as otherwise provided by paragraphs (b)(3) or (b)(4) of this section, the accounting must include for each disclosure:

(i) The date of the disclosure;

(ii) The name of the entity or person who received the protected health information and, if known, the address of such entity or person;

(iii) A brief description of the protected health information disclosed; and

(iv) A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §§164.502(a)(2)(ii) or 164.512, if any.

(3) If, during the period covered by the accounting, the covered entity has made multiple disclosures of protected health information to the same person or entity for a single purpose under §§164.502(a)(2)(ii) or 164.512, the accounting may, with respect to such multiple disclosures, provide:

(i) The information required by paragraph (b)(2) of this section for the first disclosure during the accounting period;

(ii) The frequency, periodicity, or number of the disclosures made during the accounting period; and

(iii) The date of the last such disclosure during the accounting period.

(4)(i) If, during the period covered by the accounting, the covered entity has made disclosures of protected health information for a particular research purpose in accordance with §164.512(i) for 50 or more individuals, the accounting may, with respect to such disclosures for which the protected health information about the individual may have been included, provide:

(A) The name of the protocol or other research activity;

(B) A description, in plain language, of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;

(C) A brief description of the type of protected health information that was disclosed;

(D) The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;

(E) The name, address, and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed; and

(F) A statement that the protected health information of the individual may or may not have been disclosed for a particular protocol or other research activity.

(ii) If the covered entity provides an accounting for research disclosures, in accordance with paragraph (b)(4) of this section, and if it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, the covered entity shall, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

(c) *Implementation specifications: Provision of the accounting.* (1) The covered entity must act on the individual's request for an accounting, no later than

60 days after receipt of such a request, as follows.

(i) The covered entity must provide the individual with the accounting requested; or

(ii) If the covered entity is unable to provide the accounting within the time required by paragraph (c)(1) of this section, the covered entity may extend the time to provide the accounting by no more than 30 days, provided that:

(A) The covered entity, within the time limit set by paragraph (c)(1) of this section, provides the individual with a written statement of the reasons for the delay and the date by which the covered entity will provide the accounting; and

(B) The covered entity may have only one such extension of time for action on a request for an accounting.

(2) The covered entity must provide the first accounting to an individual in any 12 month period without charge. The covered entity may impose a reasonable, cost-based fee for each subsequent request for an accounting by the same individual within the 12 month period, provided that the covered entity informs the individual in advance of the fee and provides the individual with an opportunity to withdraw or modify the request for a subsequent accounting in order to avoid or reduce the fee.

(d) *Implementation specification: Documentation.* A covered entity must document the following and retain the documentation as required by § 164.530(j):

(1) The information required to be included in an accounting under paragraph (b) of this section for disclosures of protected health information that are subject to an accounting under paragraph (a) of this section;

(2) The written accounting that is provided to the individual under this section; and

(3) The titles of the persons or offices responsible for receiving and processing requests for an accounting by individuals.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53271, Aug. 14, 2002]

§ 164.530 Administrative requirements.

(a)(1) *Standard: Personnel designations.* (i) A covered entity must designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity.

(ii) A covered entity must designate a contact person or office who is responsible for receiving complaints under this section and who is able to provide further information about matters covered by the notice required by § 164.520.

(2) *Implementation specification: Personnel designations.* A covered entity must document the personnel designations in paragraph (a)(1) of this section as required by paragraph (j) of this section.

(b)(1) *Standard: Training.* A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information required by this subpart and subpart D of this part, as necessary and appropriate for the members of the workforce to carry out their functions within the covered entity.

(2) *Implementation specifications: Training.* (i) A covered entity must provide training that meets the requirements of paragraph (b)(1) of this section, as follows:

(A) To each member of the covered entity's workforce by no later than the compliance date for the covered entity;

(B) Thereafter, to each new member of the workforce within a reasonable period of time after the person joins the covered entity's workforce; and

(C) To each member of the covered entity's workforce whose functions are affected by a material change in the policies or procedures required by this subpart or subpart D of this part, within a reasonable period of time after the material change becomes effective in accordance with paragraph (i) of this section.

(ii) A covered entity must document that the training as described in paragraph (b)(2)(i) of this section has been provided, as required by paragraph (j) of this section.

(c)(1) *Standard: Safeguards.* A covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information.

(2)(i) *Implementation specification: Safeguards.* A covered entity must reasonably safeguard protected health information from any intentional or unintentional use or disclosure that is in violation of the standards, implementation specifications or other requirements of this subpart.

(ii) A covered entity must reasonably safeguard protected health information to limit incidental uses or disclosures made pursuant to an otherwise permitted or required use or disclosure.

(d)(1) *Standard: Complaints to the covered entity.* A covered entity must provide a process for individuals to make complaints concerning the covered entity's policies and procedures required by this subpart and subpart D of this part or its compliance with such policies and procedures or the requirements of this subpart or subpart D of this part.

(2) *Implementation specification: Documentation of complaints.* As required by paragraph (j) of this section, a covered entity must document all complaints received, and their disposition, if any.

(e)(1) *Standard: Sanctions.* A covered entity must have and apply appropriate sanctions against members of its workforce who fail to comply with the privacy policies and procedures of the covered entity or the requirements of this subpart or subpart D of this part. This standard does not apply to a member of the covered entity's workforce with respect to actions that are covered by and that meet the conditions of § 164.502(j) or paragraph (g)(2) of this section.

(2) *Implementation specification: Documentation.* As required by paragraph (j) of this section, a covered entity must document the sanctions that are applied, if any.

(f) *Standard: Mitigation.* A covered entity must mitigate, to the extent practicable, any harmful effect that is known to the covered entity of a use or disclosure of protected health information in violation of its policies and procedures or the requirements of this subpart by the covered entity or its business associate.

(g) *Standard: Refraining from intimidating or retaliatory acts.* A covered entity—

(1) May not intimidate, threaten, coerce, discriminate against, or take other retaliatory action against any individual for the exercise by the individual of any right established, or for participation in any process provided for, by this subpart or subpart D of this part, including the filing of a complaint under this section; and

(2) Must refrain from intimidation and retaliation as provided in § 160.316 of this subchapter.

(h) *Standard: Waiver of rights.* A covered entity may not require individuals to waive their rights under § 160.306 of this subchapter, this subpart, or subpart D of this part, as a condition of the provision of treatment, payment, enrollment in a health plan, or eligibility for benefits.

(i)(1) *Standard: Policies and procedures.* A covered entity must implement policies and procedures with respect to protected health information that are designed to comply with the standards, implementation specifications, or other requirements of this subpart and subpart D of this part. The policies and procedures must be reasonably designed, taking into account the size and the type of activities that relate to protected health information undertaken by a covered entity, to ensure such compliance. This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirement of this subpart.

(2) *Standard: Changes to policies and procedures.* (i) A covered entity must change its policies and procedures as necessary and appropriate to comply with changes in the law, including the standards, requirements, and implementation specifications of this subpart or subpart D of this part.

(ii) When a covered entity changes a privacy practice that is stated in the notice described in § 164.520, and makes corresponding changes to its policies and procedures, it may make the changes effective for protected health information that it created or received prior to the effective date of the notice revision, if the covered entity has, in accordance with § 164.520(b)(1)(v)(C), included in the notice a statement reserving its right to make such a change in its privacy practices; or

(iii) A covered entity may make any other changes to policies and procedures at any time, provided that the changes are documented and implemented in accordance with paragraph (i)(5) of this section.

(3) *Implementation specification: Changes in law.* Whenever there is a change in law that necessitates a change to the covered entity's policies or procedures, the covered entity must promptly document and implement the revised policy or procedure. If the change in law materially affects the content of the notice required by §164.520, the covered entity must promptly make the appropriate revisions to the notice in accordance with §164.520(b)(3). Nothing in this paragraph may be used by a covered entity to excuse a failure to comply with the law.

(4) *Implementation specifications: Changes to privacy practices stated in the notice.* (i) To implement a change as provided by paragraph (i)(2)(ii) of this section, a covered entity must:

(A) Ensure that the policy or procedure, as revised to reflect a change in the covered entity's privacy practice as stated in its notice, complies with the standards, requirements, and implementation specifications of this subpart;

(B) Document the policy or procedure, as revised, as required by paragraph (j) of this section; and

(C) Revise the notice as required by §164.520(b)(3) to state the changed practice and make the revised notice available as required by §164.520(c). The covered entity may not implement a change to a policy or procedure prior to the effective date of the revised notice.

(ii) If a covered entity has not reserved its right under §164.520(b)(1)(v)(C) to change a privacy practice that is stated in the notice, the covered entity is bound by the privacy practices as stated in the notice with respect to protected health information created or received while such notice is in effect. A covered entity may change a privacy practice that is stated in the notice, and the related policies and procedures, without having reserved the right to do so, provided that:

(A) Such change meets the implementation specifications in paragraphs (i)(4)(i)(A)–(C) of this section; and

(B) Such change is effective only with respect to protected health information created or received after the effective date of the notice.

(5) *Implementation specification: Changes to other policies or procedures.* A covered entity may change, at any time, a policy or procedure that does not materially affect the content of the notice required by §164.520, provided that:

(i) The policy or procedure, as revised, complies with the standards, requirements, and implementation specifications of this subpart; and

(ii) Prior to the effective date of the change, the policy or procedure, as revised, is documented as required by paragraph (j) of this section.

(j)(1) *Standard: Documentation.* A covered entity must:

(i) Maintain the policies and procedures provided for in paragraph (i) of this section in written or electronic form;

(ii) If a communication is required by this subpart to be in writing, maintain such writing, or an electronic copy, as documentation; and

(iii) If an action, activity, or designation is required by this subpart to be documented, maintain a written or electronic record of such action, activity, or designation.

(iv) Maintain documentation sufficient to meet its burden of proof under §164.414(b).

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation required by paragraph (j)(1) of this section for six years from the date of its creation or the date when it last was in effect, whichever is later.

(k) *Standard: Group health plans.* (1) A group health plan is not subject to the standards or implementation specifications in paragraphs (a) through (f) and (i) of this section, to the extent that:

(i) The group health plan provides health benefits solely through an insurance contract with a health insurance issuer or an HMO; and

(ii) The group health plan does not create or receive protected health information, except for:

(A) Summary health information as defined in § 164.504(a); or

(B) Information on whether the individual is participating in the group health plan, or is enrolled in or has disenrolled from a health insurance issuer or HMO offered by the plan.

(2) A group health plan described in paragraph (k)(1) of this section is subject to the standard and implementation specification in paragraph (j) of this section only with respect to plan documents amended in accordance with § 164.504(f).

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002; 71 FR 8433, Feb. 16, 2006; 74 FR 42769, Aug. 24, 2009]

§ 164.532 Transition provisions.

(a) *Standard: Effect of prior authorizations.* Notwithstanding §§ 164.508 and 164.512(i), a covered entity may use or disclose protected health information, consistent with paragraphs (b) and (c) of this section, pursuant to an authorization or other express legal permission obtained from an individual permitting the use or disclosure of protected health information, informed consent of the individual to participate in research, or a waiver of informed consent by an IRB.

(b) *Implementation specification: Effect of prior authorization for purposes other than research.* Notwithstanding any provisions in § 164.508, a covered entity may use or disclose protected health information that it created or received prior to the applicable compliance date of this subpart pursuant to an authorization or other express legal permission obtained from an individual prior to the applicable compliance date of this subpart, provided that the authorization or other express legal permission specifically permits such use or disclosure and there is no agreed-to restriction in accordance with § 164.522(a).

(c) *Implementation specification: Effect of prior permission for research.* Notwithstanding any provisions in §§ 164.508 and 164.512(i), a covered entity may, to the extent allowed by one of the following permissions, use or disclose, for research, protected health information that it created or received either before or after the applicable compliance date of this subpart, provided that there is no agreed-to restriction in accordance with § 164.522(a), and the covered entity has obtained, prior to the applicable compliance date, either:

(1) An authorization or other express legal permission from an individual to use or disclose protected health information for the research;

(2) The informed consent of the individual to participate in the research; or

(3) A waiver, by an IRB, of informed consent for the research, in accordance with 7 CFR 1c.116(d), 10 CFR 745.116(d), 14 CFR 1230.116(d), 15 CFR 27.116(d), 16 CFR 1028.116(d), 21 CFR 50.24, 22 CFR 225.116(d), 24 CFR 60.116(d), 28 CFR 46.116(d), 32 CFR 219.116(d), 34 CFR 97.116(d), 38 CFR 16.116(d), 40 CFR 26.116(d), 45 CFR 46.116(d), 45 CFR 690.116(d), or 49 CFR 11.116(d), provided that a covered entity must obtain authorization in accordance with § 164.508 if, after the compliance date, informed consent is sought from an individual participating in the research.

(d) *Standard: Effect of prior contracts or other arrangements with business associates.* Notwithstanding any other provisions of this subpart, a covered entity, other than a small health plan, may disclose protected health information to a business associate and may allow a business associate to create, receive, or use protected health information on its behalf pursuant to a written contract or other written arrangement with such business associate that does not comply with §§ 164.502(e) and 164.504(e) consistent with the requirements, and only for such time, set forth in paragraph (e) of this section.

(e) *Implementation specification: Deemed compliance*—(1) *Qualification.* Notwithstanding other sections of this subpart, a covered entity, other than a small health plan, is deemed to be in compliance with the documentation and contract requirements of §§ 164.502(e) and 164.504(e), with respect to a particular business associate relationship, for the time period set forth in paragraph (e)(2) of this section, if:

(i) Prior to October 15, 2002, such covered entity has entered into and is operating pursuant to a written contract or other written arrangement with a business associate for such business associate to perform functions or activities or provide services that make the entity a business associate; and

(ii) The contract or other arrangement is not renewed or modified from October 15, 2002, until the compliance date set forth in § 164.534.

(2) *Limited deemed compliance period.* A prior contract or other arrangement that meets the qualification requirements in paragraph (e) of this section, shall be deemed compliant until the earlier of:

(i) The date such contract or other arrangement is renewed or modified on or after the compliance date set forth in § 164.534; or

(ii) April 14, 2004.

(3) *Covered entity responsibilities.* Nothing in this section shall alter the requirements of a covered entity to comply with part 160, subpart C of this subchapter and §§ 164.524, 164.526, 164.528, and 164.530(f) with respect to protected health information held by a business associate.

[65 FR 82802, Dec. 28, 2000, as amended at 67 FR 53272, Aug. 14, 2002]

§ 164.534 Compliance dates for initial implementation of the privacy standards.

(a) *Health care providers.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 14, 2003.

(b) *Health plans.* A health plan must comply with the applicable requirements of this subpart no later than the following as applicable:

(1) *Health plans other han small health plans.* April 14, 2003.

(2) *Small health plans.* April 14, 2004.

(c) *Health clearinghouses.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 14, 2003.

[66 FR 12434, Feb. 26, 2001]

PARTS 165–169 [RESERVED]

SUBCHAPTER D—HEALTH INFORMATION TECHNOLOGY

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

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AUTHORITY: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

SOURCE: 75 FR 2042, Jan. 13, 2010, unless otherwise noted.

Subpart A—General Provisions

§ 170.100 Statutory basis and purpose.

The provisions of this subchapter implement sections 3001(c)(5) and 3004 of the Public Health Service Act.

[75 FR 36203, June 24, 2010]

§ 170.101 Applicability.

The standards, implementation specifications, and certification criteria adopted in this part apply to Complete EHRs and EHR Modules and the testing and certification of such Complete EHRs and EHR Modules.

§ 170.102 Definitions.

For the purposes of this part:

Certification criteria means criteria:

(1) To establish that health information technology meets applicable standards and implementation specifications adopted by the Secretary; or

(2) That are used to test and certify that health information technology includes required capabilities.

Certified EHR Technology means:

(1) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary; or

(2) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary, and the resultant combination also meets the requirements included in the definition of a Qualified EHR.

Complete EHR means EHR technology that has been developed to meet, at a minimum, all applicable certification criteria adopted by the Secretary.

Disclosure is defined as it is in 45 CFR 160.103.

EHR Module means any service, component, or combination thereof that can meet the requirements of at least one certification criterion adopted by the Secretary.

Human readable format means a format that enables a human to read and easily comprehend the information presented to him or her regardless of the method of presentation.

Implementation specification means specific requirements or instructions for implementing a standard.

Qualified EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists; and

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality; and

(iv) To exchange electronic health information with, and integrate such information from other sources.

Standard means a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes, data, materials, characteristics, or actions.

[75 FR 2042, Jan. 13, 2010, as amended at 75 FR 36203, June 24, 2010; 75 FR 44649, July 28, 2010]

EFFECTIVE DATE NOTE: At 77 FR 54283, Sept. 4, 2012, § 170.102 was amended by removing the ''Complete EHR'' definition; adding in alphanumeric order the definitions ''2011 Edition EHR certification criteria,'' ''2014 Edition EHR certification criteria,'' ''Base EHR,'' ''Common MU Data Set,'' ''Complete EHR, 2011 Edition,'' and ''Complete EHR, 2014 Edition,''; and revising the definition of ''Certified EHR Technology'', effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.102 Definitions.

2011 Edition EHR certification criteria means the certification criteria at §§ 170.302, 170.304, and 170.306.

2014 Edition EHR certification criteria means the certification criteria at § 170.314.

Base EHR means an electronic record of health-related information on an individual that:

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity:

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to health care quality;

(iv) To exchange electronic health information with, and integrate such information from other sources;

(v) To protect the confidentiality, integrity, and availability of health information stored and exchanged; and

(3) Has been certified to the certification criteria adopted by the Secretary at: §170.314(a)(1), (3), and (5) through (8); (b)(1), (2), and (7); (c)(1) through (3); (d)(1) through (8).

(4) Has been certified to the certification criteria at §170.314(c)(1) and (2):

(i) For no fewer than 9 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible professionals, including at least 6 clinical quality measures from the recommended core set identified by CMS; or

(ii) For no fewer than 16 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible hospitals and critical access hospitals.

* * * * *

Certified EHR Technology means:

(1) For any Federal fiscal year (FY) or calendar year (CY) up to and including 2013:

(i) A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria; or

(ii) A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria, and the resultant combination also meets the requirements included in the definition of a Qualified EHR; or

(iii) EHR technology that satisfies the definition for FY and CY 2014 and subsequent years specified in paragraph (2);

(2) For FY and CY 2014 and subsequent years, the following: EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that has:

(i) The capabilities required to meet the Base EHR definition; and

(ii) All other capabilities that are necessary to meet the objectives and associated measures under 42 CFR 495.6 and successfully report the clinical quality measures selected by CMS in the form and manner specified by CMS (or the States, as applicable) for the stage of meaningful use that an eligible professional, eligible hospital, or critical access hospital seeks to achieve.

Common MU Data Set means the following data expressed, where indicated, according to the specified standard(s):

(1) Patient name.

(2) Sex.

(3) Date of birth.

(4) Race—the standard specified in §170.207(f).

(5) Ethnicity—the standard specified in §170.207(f).

(6) Preferred language—the standard specified in §170.207(g).

(7) Smoking status—the standard specified in §170.207(h).

(8) Problems—at a minimum, the version of the standard specified in §170.207(a)(3).

(9) Medications—at a minimum, the version of the standard specified in §170.207(d)(2).

(10) Medication allergies—at a minimum, the version of the standard specified in §170.207(d)(2).

(11) Laboratory test(s)—at a minimum, the version of the standard specified in §170.207(c)(2).

(12) Laboratory value(s)/result(s).

(13) Vital signs—height, weight, blood pressure, BMI.

(14) Care plan field(s), including goals and instructions.

(15) Procedures—

(i) At a minimum, the version of the standard specified in §170.207(a)(3) or §170.207(b)(2).

(ii) *Optional.* The standard specified at §170.207(b)(3).

(iii) *Optional.* The standard specified at §170.207(b)(4).

(16) Care team member(s).

Complete EHR, 2011 Edition means EHR technology that has been developed to meet, at a minimum, all mandatory 2011 Edition EHR certification criteria for either an ambulatory setting or inpatient setting.

Complete EHR, 2014 Edition means EHR technology that meets the Base EHR definition and has been developed to meet, at a minimum, all mandatory 2014 Edition EHR certification criteria for either an ambulatory setting or inpatient setting.

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Subpart B—Standards and Implementation Specifications for Health Information Technology

SOURCE: 75 FR 44649, July 28, 2010, unless otherwise noted.

§ 170.200 Applicability.

The standards and implementation specifications adopted in this part apply with respect to Complete EHRs and EHR Modules.

§ 170.202 Transport standards.

The Secretary adopts the following transport standards:

(a) *Standard*. ONC Applicability Statement for Secure Health Transport (incorporated by reference in § 170.299).

(b) *Standard*. ONC XDR and XDM for Direct Messaging Specification (incorporated by reference in § 170.299).

(c) *Standard*. ONC Transport and Security Specification (incorporated by reference in § 170.299).

EFFECTIVE DATE NOTE: At 77 FR 54284, Sept. 4, 2012, § 170.202 was added, effective Oct. 4, 2012.

§ 170.204 Functional standards.

The Secretary adopts the following functional standards:

(a) *Accessibility*. *Standard*. Web Content Accessibility Guidelines (WCAG) 2.0, Level A Conformance (incorporated by reference in § 170.299).

(b) *Reference source*. *Standard*. HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton) (incorporated by reference in § 170.299). (1) *Implementation specifications*. HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, (incorporated by reference in § 170.299).

(2) *Implementation specifications*. HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide, (incorporated by reference in § 170.299).

(c) *Clinical quality measure-by-measure data*. Data Element Catalog, (incorporated by reference in § 170.299).

EFFECTIVE DATE NOTE: At 77 FR 54284, Sept. 4, 2012, § 170.204 was added, effective Oct. 4, 2012.

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) *Patient summary record*—(1) *Standard*. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in § 170.299). *Implementation specifications*. The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in § 170.299).

(2) *Standard*. ASTM E2369 Standard Specification for Continuity of Care Record and Adjunct to ASTM E2369 (incorporated by reference in § 170.299).

(b) *Electronic prescribing*—(1) *Standard*. The National Council for the Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide, Version 8, Release 1 (Version 8.1) October 2005 (incorporated by reference in § 170.299)

(2) *Standard*. NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 (incorporated by reference in § 170.299).

(c) *Electronic submission of lab results to public health agencies*. *Standard*. HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications*. HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299).

(d) *Electronic submission to public health agencies for surveillance or reporting*. *(1) Standard*. HL7 2.3.1 (incorporated by reference in § 170.299).

(2) *Standard*. HL7 2.5.1 (incorporated by reference in § 170.299).

(e) *Electronic submission to immunization registries*—(1) *Standard*. HL7 2.3.1 (incorporated by reference in § 170.299). *Implementation specifications*. Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2 (incorporated by reference in § 170.299).

(2) Standard. HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0 (incorporated by reference in § 170.299).

(f) *Quality reporting. Standard.* The CMS Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification (incorporated by reference in § 170.299). *Implementation specifications.* Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry (incorporated by reference in § 170.299).

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010]

EFFECTIVE DATE NOTE: At 77 FR 54284, Sept. 4, 2012, § 170.205 was amended by adding paragraphs (a)(3), (d)(3), (e)(3), and (g) through (k), effective Oct. 4, 2012. For the convenience of the user, the added text is set forth as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

The Secretary adopts the following content exchange standards and associated implementation specifications:

(a) * * *

(3) *Standard.* HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, (incorporated by reference in § 170.299). The use of the ''unstructured document'' document-level template is prohibited.

* * * * *

(d) * * *

(3) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* PHIN Messaging Guide for Syndromic Surveillance (incorporated by reference in § 170.299) and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance (incorporated by reference in § 170.299).

(e) * * *

(3) *Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, (incorporated by reference in § 170.299).

* * * * *

(g) *Electronic transmission of lab results to public health agencies. Standard.* HL7 2.5.1 (incorporated by reference in § 170.299). *Implementation specifications.* HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) (incorporated by reference in § 170.299) with Errata and Clarifications, (incorporated by reference in § 170.299) and ELR 2.5.1 Clarification Document for EHR Technology Certification, (incorporated by reference in § 170.299).

(h) *Clinical quality measure data import, export, and electronic submission. Standard.* HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, (incorporated by reference in § 170.299).

(i) *Cancer information. Standard.* HL7 Clinical Document Architecture (CDA), Release 2.0, Normative Edition (incorporated by reference in § 170.299). *Implementation specifications.* Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), (incorporated by reference in § 170.299).

(j) *Electronic incorporation and transmission of lab results. Standard.* HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, (incorporated by reference in § 170.299).

(k) *Clinical quality measure aggregate electronic submission. Standard.* Quality Reporting Document Architecture Category III, Implementation Guide for CDA Release 2 (incorporated by reference in § 170.299).

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) *Problems*—(1) *Standard.* The code set specified at 45 CFR 162.1002(a)(1) for the indicated conditions.

(2) *Standard.* International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) July 2009 version (incorporated by reference in § 170.299).

(b) *Procedures*—(1) *Standard.* The code set specified at 45 CFR 162.1002(a)(2).

(2) *Standard.* The code set specified at 45 CFR 162.1002(a)(5).

(c) *Laboratory test results. Standard.* Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transaction from a laboratory (incorporated by reference in § 170.299).

(d) *Medications. Standard.* Any source vocabulary that is included in RxNorm,

a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.

(e) *Immunizations. Standard.* HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version (incorporated by reference in § 170.299).

(f) *Race and Ethnicity. Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997 (available at *http://www.whitehouse.gov/omb/rewrite/fedreg/ombdir15.html*).

EFFECTIVE DATE NOTE: At 77 FR 54284, Sept. 4, 2012, § 170.207 was amended by adding paragraphs (a)(3), (b)(3), (b)(4), revising paragraphs (c), (d), (e), and (f) and adding paragraphs (g) through (j), effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.207 Vocabulary standards for representing electronic health information.

The Secretary adopts the following code sets, terminology, and nomenclature as the vocabulary standards for the purpose of representing electronic health information:

(a) * * *

(3) *Standard.* IHTSDO SNOMED CT® International Release July 2012 (incorporated by reference in § 170.299) and US Extension to SNOMED CT® March 2012 Release (incorporated by reference in § 170.299).

(b) * * *

(3) *Standard.* The code set specified at 45 CFR 162.1002(a)(4).

(4) *Standard.* The code set specified at 45 CFR 162.1002(c)(3) for the indicated procedures or other actions taken.

(c) *Laboratory tests.* (1) *Standard.* Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, when such codes were received within an electronic transaction from a laboratory (incorporated by reference in § 170.299).

(2) *Standard.* Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. (incorporated by reference in § 170.299).

(d) *Medications.* (1) *Standard.* Any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine.

(2) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, August 6, 2012 Release (incorporated by reference in § 170.299).

(e) *Immunizations.* (1) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009 version (incorporated by reference in § 170.299).

(2) *Standard.* HL7 Standard Code Set CVX—Vaccines Administered, updates through July 11, 2012 (incorporated by reference in § 170.299).

(f) *Race and Ethnicity. Standard.* The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997 (see ''Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity,'' available at *http://www.whitehouse.gov/omb/fedreg_1997standards*).

(g) *Preferred language. Standard.* As specified by the Library of Congress, ISO 639–2 alpha-3 codes limited to those that also have a corresponding alpha-2 code in ISO 639–1. (incorporated by reference in § 170.299).

(h) *Smoking status. Standard.* Smoking status must be coded in one of the following SNOMED CT® codes:

(1) *Current every day smoker.* 449868002
(2) *Current some day smoker.* 428041000124106
(3) *Former smoker.* 8517006
(4) *Never smoker.* 266919005
(5) *Smoker, current status unknown.* 77176002
(6) *Unknown if ever smoked.* 266927001
(7) *Heavy tobacco smoker.* 428071000124103
(8) *Light tobacco smoker.* 428061000124105

(i) *Encounter diagnoses. Standard.* The code set specified at 45 CFR 162.1002(c)(2) for the indicated conditions.

(j) *Family health history.* HL7 Version 3 Standard: Clinical Genomics; Pedigree, (incorporated by reference in § 170.299).

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:

(a) *Encryption and decryption of electronic health information*—(1) *General.* Any encryption algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the Federal Information Processing Standards (FIPS) Publication 140–2 (incorporated by reference in § 170.299).

(2) *Exchange.* Any encrypted and integrity protected link.

(b) *Record actions related to electronic health information.* The date, time, patient identification, and user identification must be recorded when electronic health information is created, modified, accessed, or deleted; and an

indication of which action(s) occurred and by whom must also be recorded.

(c) *Verification that electronic health information has not been altered in transit. Standard.* A hashing algorithm with a security strength equal to or greater than SHA–1 (Secure Hash Algorithm (SHA–1) as specified by the National Institute of Standards and Technology (NIST) in FIPS PUB 180–3 (October, 2008)) must be used to verify that electronic health information has not been altered.

(d) *Record treatment, payment, and health care operations disclosures.* The date, time, patient identification, user identification, and a description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations, as these terms are defined at 45 CFR 164.501.

EFFECTIVE DATE NOTE: At 77 FR 54285, Sept. 4, 2012, § 170.210 was amended in paragraph (a)(1), by adding the phrase '', (January 27, 2010)'' after ''140–2''; in paragraph (c), by removing ''180–3 (October, 2008))'' and add in its place ''180–4 (March 2012))''; and adding paragraphs (e) through (h), effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.210 Standards for health information technology to protect electronic health information created, maintained, and exchanged.

The Secretary adopts the following standards to protect electronic health information created, maintained, and exchanged:

* * * * *

(e) *Record actions related to electronic health information, audit log status, and encryption of end-user devices.* (1)(i) The audit log must record the information specified in sections 7.2 through 7.4, 7.6, and 7.7 of the standard specified at § 170.210(h) when EHR technology is in use.

(ii) The date and time must be recorded in accordance with the standard specified at § 170.210(g).

(2)(i) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the audit log status is changed.

(ii) The date and time each action occurs in accordance with the standard specified at § 170.210(g).

(3) The audit log must record the information specified in sections 7.2 and 7.4 of the standard specified at § 170.210(h) when the encryption status of electronic health information locally stored by EHR technology on end-user devices is changed. The date and time each action occurs in accordance with the standard specified at § 170.210(g).

(f) *Encryption and hashing of electronic health information.* Any encryption and hashing algorithm identified by the National Institute of Standards and Technology (NIST) as an approved security function in Annex A of the FIPS Publication 140–2 (incorporated by reference in § 170.299).

(g) *Synchronized clocks.* The date and time recorded utilize a system clock that has been synchronized following (RFC 1305) Network Time Protocol, (incorporated by reference in § 170.299) or (RFC 5905) Network Time Protocol Version 4, (incorporated by reference in § 170.299).

(h) *Audit log content.* ASTM E2147–01(Reapproved 2009), (incorporated by reference in § 170.299)

§ 170.299 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the sources listed below.

(b) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777 or *http://www.hl7.org/.*

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for § 170.205.

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic

Data Exchange in Healthcare Environments, February 21, 2007, IBR approved for § 170.205.

(3) Health Level Seven Implementation Guide: Clinical Document Architecture (CDA) Release 2—Continuity of Care Document (CCD), April 01, 2007, IBR approved for § 170.205.

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, February, 2010, IBR approved for § 170.205.

(5) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959 USA; Telephone (610) 832–9585 or *http://www.astm.org/*.

(1) ASTM E2369–05: Standard Specification for Continuity of Care Record (CCR), year of adoption 2005, ASTM approved July 17, 2006, IBR approved for § 170.205.

(2) ASTM E2369–05 (Adjunct to E2369): Standard Specification Continuity of Care Record,—Final Version 1.0 (V1.0), November 7, 2005, IBR approved for § 170.205.

(d) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or *http://www.ncpdp.org*.

(1) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, IBR approved for § 170.205.

(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for § 170.205.

(3) [Reserved]

(e) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202–3012; Telephone (317) 423–5558 or *http://loinc.org/*.

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.207.

(2) [Reserved]

(f) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594–5983 or *http://www.nlm.nih.gov/*.

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for § 170.207.

(2) [Reserved]

(g) Centers for Disease Control and Prevention, National Centers for Immunization and Respiratory Diseases Immunization Information System Support Branch—Informatics 1600 Clifton Road Mailstop: E–62 Atlanta, GA 30333.

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.207.

(2) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for § 170.205.

(3) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(4) [Reserved]

(h) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786–3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for § 170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version 3.0, December 8, 2008 IBR approved for § 170.205.

(i) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, *http://csrc.nist.gov/groups/STM/cmvp/standards.html*.

(1) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR approved for § 170.210.

(2) [Reserved]

(j) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, *http://www.hitsp.org*

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

[75 FR 44649, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010]

EFFECTIVE DATE NOTE: At 77 FR 54285, Sept. 4, 2012, § 170.299 was amended by revising paragraphs (b) through (j) and adding paragraphs (k) through (n), effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.299 Incorporation by reference.

* * * * *

(b) American National Standards Institute, Health Information Technology Standards Panel (HITSP) Secretariat, 25 West 43rd Street—Fourth Floor, New York, NY 10036, *http://www.hitsp.org*.

(1) HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, HITSP/C32, July 8, 2009, Version 2.5, IBR approved for § 170.205.

(2) [Reserved]

(c) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428–2959 USA; Telephone (610) 832–9585 or *http://www.astm.org/*.

(1) ASTM E2147–01 (Reapproved 2009) Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems, approved September 1, 2009, IBR approved for § 170.210.

(2) ASTM E2369–05: Standard Specification for Continuity of Care Record (CCR), year of adoption 2005, ASTM approved July 17, 2006, IBR approved for § 170.205.

(3) ASTM E2369–05 (Adjunct to E2369): Standard Specification Continuity of Care Record,—Final Version 1.0 (V1.0), November 7, 2005, IBR approved for § 170.205.

(d) Centers for Disease Control and Prevention, 2500 Century Parkway, Mailstop E–78, Atlanta, GA 30333, USA (800–232–4636); *http://www.cdc.gov/ehrmeaningfuluse/*.

(1) HL7 Standard Code Set CVX—Vaccines Administered, July 30, 2009, IBR approved for § 170.207.

(2) IIS: HL7 Standard Code Set CVX—Vaccines Administered, updates through July 11, 2012, IBR approved for § 170.207.

(3) Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7)Standard Protocol Implementation Guide Version 2.2, June 2006, IBR approved for § 170.205.

(4) HL7 2.5.1 Implementation Guide for Immunization Messaging Release 1.0, May 1, 2010, IBR approved for § 170.205.

(5) PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data, ADT Messages A01, A03, A04, and A08, HL7 Version 2.5.1 (Version 2.3.1 Compatible), Release 1.1, August 2012, IBR approved for § 170.205.

(6) Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, ADT MESSAGES A01, A03, A04, and A08, HL7 Version 2.5.1, Addendum to PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data (Release 1.1), August 2012, IBR approved for § 170.205.

(7) HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4, August 1, 2012, IBR approved for § 170.205.

(8) Implementation Guide for Ambulatory Healthcare Provider Reporting to Central Cancer Registries, HL7 Clinical Document Architecture (CDA), Release 1.0, August 2012, IBR approved for § 170.205.

(9) ELR 2.5.1 Clarification Document for EHR Technology Certification, July 16, 2012, IBR approved for § 170.205.

(e) Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, 7500 Security Boulevard, Baltimore, Maryland 21244; Telephone (410) 786–3000

(1) CMS PQRI 2009 Registry XML Specifications, IBR approved for § 170.205.

(2) 2009 Physician Quality Reporting Initiative Measure Specifications Manual for Claims and Registry, Version 3.0, December 8, 2008 IBR approved for § 170.205.

(f) Health Level Seven, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104; Telephone (734) 677–7777 or *http://www.hl7.org/*

(1) Health Level Seven Standard Version 2.3.1 (HL7 2.3.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, April 14, 1999, IBR approved for § 170.205.

(2) Health Level Seven Messaging Standard Version 2.5.1 (HL7 2.5.1), An Application Protocol for Electronic Data Exchange in Healthcare Environments, February 21, 2007, IBR approved for § 170.205.

(3) Health Level Seven Implementation Guide: Clinical Document Architecture (CDA) Release 2—Continuity of Care Document (CCD), April 01, 2007, IBR approved for § 170.205.

(4) HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm) HL7 Version 2.5.1: ORU^R01, HL7 Informative Document, February, 2010, IBR approved for § 170.205.

(5) HL7 Version 3 Standard: Context-Aware Retrieval Application (Infobutton); Release 1, July 2010, IBR approved for § 170.204.

(6) HL7 Version 3 Implementation Guide: URL-Based Implementations of the Context-Aware Information Retrieval (Infobutton) Domain, Release 3, December 2010, IBR approved for § 170.204.

(7) HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton) Service-Oriented Architecture Implementation Guide, Release 1, HL7 Draft Standard for Trial Use, March 2011, IBR approved for § 170.204.

(8) HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use July 2012, IBR approved for § 170.205.

(9) HL7 Clinical Document Architecture, Release 2.0, Normative Edition, May 2005, IBR approved for § 170.205.

(10) HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU − R01] Draft Standard for Trial Use, July 2012, IBR approved for § 170.205.

(11) HL7 Version 3 Standard: Clinical Genomics; Pedigree, Release 1, Edition 2011, March 2012, IBR approved for § 170.207.

(12) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture, DTSU Release 2 (Universal Realm), Draft Standard for Trial Use, July 2012, IBR approved for § 170.205.

(13) HL7 v2.5.1 IG: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 Errata and Clarifications, September, 29, 2011, IBR approved for § 170.205.

(14) Quality Reporting Document Architecture Category III, Release 1, Implementation Guide for CDA Release 2 (US Realm) Based on HL7 CDA Release 2.0, August 2012, IBR approved for § 170.205.

(g) Internet Engineering Task Force (IETF), University of Delaware, Newark, DE 19716, Telephone (302) 831–8247, *http://www.ietf.org/rfc.html*.

(1) Network Time Protocol (Version 3) Specification, Implementation and Analysis, March 1992, IBR approved for § 170.210.

(2) Network Time Protocol Version 4: Protocol and Algorithms Specification, June 2010, IBR approved for § 170.210.

(h) Library of Congress, Network Development and MARC Standards Office, Washington, DC 20540–4402, Tel: (202) 707–6237 or *http://www.loc.gov/standards/iso639-2/*.

(1) ISO 639–2. Codes for the Representation of Names of Languages Part 2: Alpha-3 Code, April 8, 2011, IBR approved for § 170.207.

(2) [Reserved]

(i) National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260– 7518; Telephone (480) 477–1000; and Facsimile (480) 767–1042 or *http://www.ncpdp.org*.

(1) National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005, IBR approved for § 170.205.

(2) SCRIPT Standard, Implementation Guide, Version 10.6, October, 2008, (Approval date for ANSI: November 12, 2008), IBR approved for § 170.205.

(j) National Institute of Standards and Technology, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, *http://csrc.nist.gov/groups/STM/cmvp/standards.html*.

(1) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, January 27, 2010, IBR approved for § 170.210.

(2) Annex A: Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, Draft, May 30, 2012, IBR approved for § 170.210.

(k) Office of the National Coordinator for Health Information Technology (ONC), 200 Independence Avenue SW., Suite 729–D, Washington, DC 20201, *http://healthit.hhs.gov*.

(1) Applicability Statement for Secure Health Transport, Version 1.1, July 10, 2012, IBR approved for § 170.202; available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov___direct_project/3338*.

(2) XDR and XDM for Direct Messaging Specification, Version 1, March 9, 2011, IBR approved for § 170.202; available at *http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov___direct_project/3338*.

(3) Transport and Security Specification, Version 1.0, June 19, 2012, IBR approved for § 170.202.

(l) Regenstrief Institute, Inc., LOINC® c/o Medical Informatics The Regenstrief Institute, Inc 410 West 10th Street, Suite 2000 Indianapolis, IN 46202–3012; Telephone (317) 423–5983 or *http://loinc.org/*.

(1) Logical Observation Identifiers Names and Codes (LOINC®) version 2.27, June 15, 2009, IBR approved for § 170.207.

(2) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.40, Released June 2012, IBR approved for § 170.207.

(m) U.S. National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894; Telephone (301) 594–5983 or *http://www.nlm.nih.gov/*.

(1) International Health Terminology Standards Development Organization Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), International Release, July 2009, IBR approved for § 170.207.

(2) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 31, 2012, IBR approved for § 170.207.

(3) US Extension to SNOMED CT® March 2012 Release, IBR approved for § 170.207.

(4) RxNorm, August 6, 2012 Full Release Update, IBR approved for § 170.207.

(5) Data Element Catalog, Version: August 2012, IBR approved for § 170.204.

(n) World Wide Web Consortium (W3C)/MIT, 32 Vassar Street, Room 32–G515, Cambridge, MA 02139 USA, *http://www.w3.org/standards/*

(1) Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008, IBR approved for § 170.204.

(2) [Reserved]

Subpart C—Certification Criteria for Health Information Technology

SOURCE: 75 FR 44651, July 28, 2010, unless otherwise noted.

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules.

(b) When a certification criterion refers to two or more standards as alternatives, use of at least one of the alternative standards will be considered compliant.

(c) Complete EHRs and EHR Modules are not required to be compliant with certification criteria that are designated as optional.

EFFECTIVE DATE NOTE: At 77 FR 54286, Sept. 4, 2012, § 170.300 was amended by revising paragraph (c) and add paragraph (d), effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.300 Applicability.

(a) The certification criteria adopted in this subpart apply to the testing and certification of Complete EHRs and EHR Modules.

(b) When a certification criterion refers to two or more standards as alternatives, the use of at least one of the alternative standards will be considered compliant.

(c) Complete EHRs and EHR Modules are not required to be compliant with certification criteria or capabilities specified within a certification criterion that are designated as optional.

(d) In § 170.314, all certification criteria and all capabilities specified within a certification criterion have general applicability (i.e., apply to both ambulatory and inpatient settings) unless designated as ''inpatient setting only'' or ''ambulatory setting only.''

(1) ''*Inpatient setting only*'' means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an inpatient setting.

(2) ''*Ambulatory setting only*'' means that the criterion or capability within the criterion is only required for certification of EHR technology designed for use in an ambulatory setting.

§ 170.302 General certification criteria for Complete EHRs or EHR Modules.

The Secretary adopts the following general certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Drug-drug, drug-allergy interaction checks—(1) Notifications.* Automatically and electronically generate and indicate in real-time, notifications at the point of care for drug-drug and drug-allergy contraindications based on medication list, medication allergy list, and computerized provider order entry (CPOE).

(2) Adjustments. Provide certain users with the ability to adjust notifications provided for drug-drug and drug-allergy interaction checks.

(b) *Drug-formulary checks.* Enable a user to electronically check if drugs are in a formulary or preferred drug list.

(c) *Maintain up-to-date problem list.* Enable a user to electronically record, modify, and retrieve a patient's problem list for longitudinal care in accordance with:

(1) The standard specified in § 170.207(a)(1); or

(2) At a minimum, the version of the standard specified in § 170.207(a)(2).

(d) *Maintain active medication list.* Enable a user to electronically record, modify, and retrieve a patient's active medication list as well as medication history for longitudinal care.

(e) *Maintain active medication allergy list.* Enable a user to electronically record, modify, and retrieve a patient's active medication allergy list as well as medication allergy history for longitudinal care.

(f) *Record and chart vital signs—(1) Vital signs.* Enable a user to electronically record, modify, and retrieve a patient's vital signs including, at a minimum, height, weight, and blood pressure.

(2) *Calculate body mass index.* Automatically calculate and display body mass index (BMI) based on a patient's height and weight.

(3) *Plot and display growth charts.* Plot and electronically display, upon request, growth charts for patients 2–20 years old.

(g) *Smoking status.* Enable a user to electronically record, modify, and retrieve the smoking status of a patient. Smoking status types must include: current every day smoker; current some day smoker; former smoker; never smoker; smoker, current status unknown; and unknown if ever smoked.

(h) *Incorporate laboratory test results—* (1) *Receive results.* Electronically receive clinical laboratory test results in a structured format and display such results in human readable format.

(2) *Display test report information.* Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(3) *Incorporate results.* Electronically attribute, associate, or link a laboratory test result to a laboratory order or patient record.

(i) *Generate patient lists.* Enable a user to electronically select, sort, retrieve, and generate lists of patients according to, at a minimum, the data elements included in:

(1) Problem list;

(2) Medication list;

(3) Demographics; and

(4) Laboratory test results.

(j) *Medication reconciliation.* Enable a user to electronically compare two or more medication lists.

(k) *Submission to immunization registries.* Electronically record, modify, retrieve, and submit immunization information in accordance with:

(1) The standard (and applicable implementation specifications) specified in § 170.205(e)(1) or § 170.205(e)(2); and

(2) At a minimum, the version of the standard specified in § 170.207(e).

(l) *Public health surveillance.* Electronically record, modify, retrieve, and submit syndrome-based public health surveillance information in accordance with the standard specified in § 170.205(d)(1) or § 170.205(d)(2).

(m) *Patient-specific education resources.* Enable a user to electronically identify and provide patient-specific education resources according to, at a minimum, the data elements included in the patient's: problem list; medication list; and laboratory test results; as well as provide such resources to the patient.

(n) *Automated measure calculation.* For each meaningful use objective with a percentage-based measure, electronically record the numerator and denominator and generate a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(o) *Access control.* Assign a unique name and/or number for identifying and tracking user identity and establish controls that permit only authorized users to access electronic health information.

(p) *Emergency access.* Permit authorized users (who are authorized for emergency situations) to access electronic health information during an emergency.

(q) *Automatic log-off.* Terminate an electronic session after a predetermined time of inactivity.

(r) *Audit log*—(1) *Record actions.* Record actions related to electronic health information in accordance with the standard specified in § 170.210(b).

(2) *Generate audit log.* Enable a user to generate an audit log for a specific time period and to sort entries in the audit log according to any of the elements specified in the standard at § 170.210(b).

(s) *Integrity.* (1) Create a message digest in accordance with the standard specified in § 170.210(c).

(2) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(3) *Detection.* Detect the alteration of audit logs.

(t) *Authentication.* Verify that a person or entity seeking access to electronic health information is the one

claimed and is authorized to access such information.

(u) *General encryption*. Encrypt and decrypt electronic health information in accordance with the standard specified in § 170.210(a)(1), unless the Secretary determines that the use of such algorithm would pose a significant security risk for Certified EHR Technology.

(v) *Encryption when exchanging electronic health information*. Encrypt and decrypt electronic health information when exchanged in accordance with the standard specified in § 170.210(a)(2).

(w) *Optional. Accounting of disclosures*. Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

[75 FR 44651, July 28, 2010, as amended at 75 FR 62690, Oct. 13, 2010]

§ 170.304 Specific certification criteria for Complete EHRs or EHR Modules designed for an ambulatory setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an ambulatory setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Computerized provider order entry*. Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

(1) Medications;

(2) Laboratory; and

(3) Radiology/imaging.

(b) *Electronic prescribing*. Enable a user to electronically generate and transmit prescriptions and prescription-related information in accordance with:

(1) The standard specified in § 170.205(b)(1) or § 170.205(b)(2); and

(2) The standard specified in § 170.207(d).

(c) *Record demographics*. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, and date of birth. Enable race and ethnicity to be recorded in accordance with the standard specified at § 170.207(f).

(d) *Patient reminders*. Enable a user to electronically generate a patient reminder list for preventive or follow-up care according to patient preferences based on, at a minimum, the data elements included in:

(1) Problem list;

(2) Medication list;

(3) Medication allergy list;

(4) Demographics; and

(5) Laboratory test results.

(e) *Clinical decision support*—(1) *Implement rules*. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) *Notifications*. Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(f) *Electronic copy of health information*. Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in:

(1) Human readable format; and

(2) On electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems*. The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) *Laboratory test results*. At a minimum, the version of the standard specified in § 170.207(c); and

(C) *Medications*. The standard specified in § 170.207(d).

(g) *Timely access*. Enable a user to provide patients with online access to their clinical information, including, at a minimum, lab test results, problem list, medication list, and medication allergy list.

(h) *Clinical summaries*. Enable a user to provide clinical summaries to patients for each office visit that include, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list. If the clinical summary is provided electronically it must be:

(1) Provided in human readable format; and

(2) Provided on electronic media or through some other electronic means in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems*. The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) *Laboratory test results*. At a minimum, the version of the standard specified in § 170.207(c); and

(C) *Medications*. The standard specified in § 170.207(d).

(i) *Exchange clinical information and patient summary record*—(1) *Electronically receive and display*. Electronically receive and display a patient's summary record, from other providers and organizations including, at a minimum, diagnostic tests results, problem list, medication list, and medication allergy list in accordance with the standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.

(2) *Electronically transmit*. Enable a user to electronically transmit a patient summary record to other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, and medication allergy list in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems*. The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) *Laboratory test results*. At a minimum, the version of the standard specified in § 170.207(c); and

(C) *Medications*. The standard specified in § 170.207(d).

(j) *Calculate and submit clinical quality measures*—(1) *Calculate* (i) Electronically calculate all of the core clinical measures specified by CMS for eligible professionals.

(ii) Electronically calculate, at a minimum, three clinical quality measures specified by CMS for eligible professionals, in addition to those clinical quality measures specified in paragraph (1)(i).

(2) *Submission*. Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in § 170.205(f).

§ 170.306 Specific certification criteria for Complete EHRs or EHR Modules designed for an inpatient setting.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules designed to be used in an inpatient setting. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically and in accordance with all applicable standards and implementation specifications adopted in this part:

(a) *Computerized provider order entry*. Enable a user to electronically record, store, retrieve, and modify, at a minimum, the following order types:

(1) Medications;

(2) Laboratory; and

(3) Radiology/imaging.

(b) *Record demographics*. Enable a user to electronically record, modify, and retrieve patient demographic data including preferred language, gender, race, ethnicity, date of birth, and date and preliminary cause of death in the event of mortality. Enable race and ethnicity to be recorded in accordance with the standard specified at § 170.207(f).

(c) *Clinical decision support*—(1) *Implement rules*. Implement automated, electronic clinical decision support rules (in addition to drug-drug and drug-allergy contraindication checking) based

on the data elements included in: problem list; medication list; demographics; and laboratory test results.

(2) *Notifications.* Automatically and electronically generate and indicate in real-time, notifications and care suggestions based upon clinical decision support rules.

(d) *Electronic copy of health information.* (1) Enable a user to create an electronic copy of a patient's clinical information, including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures:

(i) In human readable format; and

(ii) On electronic media or through some other electronic means in accordance with:

(A) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(B) For the following data elements the applicable standard must be used:

(*1*) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(*2*) *Procedures.* The standard specified in § 170.207(b)(1) or § 170.207(b)(2);

(*3*) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and

(*4*) *Medications.* The standard specified in § 170.207(d).

(2) Enable a user to create an electronic copy of a patient's discharge summary in human readable format and on electronic media or through some other electronic means.

(e) *Electronic copy of discharge instructions.* Enable a user to create an electronic copy of the discharge instructions for a patient, in human readable format, at the time of discharge on electronic media or through some other electronic means.

(f) *Exchange clinical information and patient summary record*—(1) *Electronically receive and display.* Electronically receive and display a patient's summary record from other providers and organizations including, at a minimum, diagnostic test results, problem list, medication list, medication allergy list, and procedures in accordance with the standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2). Upon receipt of a patient summary record formatted according to the alternative standard, display it in human readable format.

(2) *Electronically transmit.* Enable a user to electronically transmit a patient's summary record to other providers and organizations including, at a minimum, diagnostic results, problem list, medication list, medication allergy list, and procedures in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(a)(1) or § 170.205(a)(2); and

(ii) For the following data elements the applicable standard must be used:

(A) *Problems.* The standard specified in § 170.207(a)(1) or, at a minimum, the version of the standard specified in § 170.207(a)(2);

(B) *Procedures.* The standard specified in § 170.207(b)(1) or § 170.207(b)(2);

(C) *Laboratory test results.* At a minimum, the version of the standard specified in § 170.207(c); and

(D) *Medications.* The standard specified in § 170.207(d).

(g) *Reportable lab results.* Electronically record, modify, retrieve, and submit reportable clinical lab results in accordance with the standard (and applicable implementation specifications) specified in § 170.205(c) and, at a minimum, the version of the standard specified in § 170.207(c).

(h) *Advance directives.* Enable a user to electronically record whether a patient has an advance directive.

(i) *Calculate and submit clinical quality measures*—(1) *Calculate.* Electronically calculate all of the clinical quality measures specified by CMS for eligible hospitals and critical access hospitals.

(2) *Submission.* Enable a user to electronically submit calculated clinical quality measures in accordance with the standard and implementation specifications specified in § 170.205(f).

§ 170.314 2014 Edition electronic health record certification criteria.

The Secretary adopts the following certification criteria for Complete EHRs or EHR Modules. Complete EHRs or EHR Modules must include the capability to perform the following functions electronically, unless designated as optional, and in accordance with all

applicable standards and implementation specifications adopted in this part:

(a) *Clinical.* (1) *Computerized provider order entry.* Enable a user to electronically record, change, and access the following order types, at a minimum:

(i) Medications;

(ii) Laboratory; and

(iii) Radiology/imaging.

(2) *Drug-drug, drug-allergy interaction checks. (i) Interventions.* Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.

(ii) Adjustments. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.

(B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.

(3) *Demographics.* (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.

(A) Enable race and ethnicity to be recorded in accordance with the standard specified in § 170.207(f) and whether a patient declines to specify race and/or ethnicity.

(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g) and whether a patient declines to specify a preferred language.

(ii) Inpatient setting only. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality.

(4) *Vital signs, body mass index, and growth charts.* (i) *Vital signs.* Enable a user to electronically record, change, and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only.

(ii) *Calculate body mass index.* Automatically calculate and electronically display body mass index based on a patient's height and weight.

(iii) *Optional—Plot and display growth charts.* Plot and electronically display, upon request, growth charts for patients.

(5) *Problem list.* Enable a user to electronically record, change, and access a patient's active problem list:

(i) *Ambulatory setting.* Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3); or

(ii) Inpatient setting. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(3).

(6) *Medication list.* Enable a user to electronically record, change, and access a patient's active medication list as well as medication history:

(i) *Ambulatory setting.* Over multiple encounters; or

(ii) *Inpatient setting.* For the duration of an entire hospitalization.

(7) *Medication allergy list.* Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy history:

(i) *Ambulatory setting.* Over multiple encounters; or

(ii) *Inpatient setting.* For the duration of an entire hospitalization.

(8) *Clinical decision support. (i) Evidence-based decision support interventions.* Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

(A) Problem list;

(B) Medication list;

(C) Medication allergy list;

(D) Demographics;

(E) Laboratory tests and values/results; and

(F) Vital signs.

(ii) Linked referential clinical decision support. (A) EHR technology must be able to:

(*1*) Electronically identify for a user diagnostic and therapeutic reference information; or

(*2*) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the

standard specified at § 170.204(b) and the implementation specifications at § 170.204 (b)(1) or (2).

(B) For paragraph (a)(8)(ii)(A) of this section, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.

(iii) *Clinical decision support configuration*. (A) Enable interventions and reference resources specified in paragraphs (a)(8)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) EHR technology must enable interventions to be electronically triggered:

(*1*) Based on the data referenced in paragraphs (a)(8)(i)(A) through (F) of this section.

(*2*) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to paragraph (b)(1)(iii) of this section.

(*3*) *Ambulatory setting only*. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(5)(i)(A)(*1*) of this section.

(iv) Automatically and electronically interact. Interventions triggered in accordance with paragraphs (a)(8)(i) through (iii) of this section must automatically and electronically occur when a user is interacting with EHR technology.

(v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:

(A) For evidence-based decision support interventions under paragraph (a)(8)(i) of this section:

(*1*) Bibliographic citation of the intervention (clinical research/guideline);

(*2*) Developer of the intervention (translation from clinical research/guideline);

(*3*) Funding source of the intervention development technical implementation; and

(*4*) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential clinical decision support in paragraph (a)(8)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph(a)(2) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(9) *Electronic notes*. Enable a user to electronically record, change, access, and search electronic notes.

(10) *Drug-formulary checks*. EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.

(11) *Smoking status*. Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the standard specified at § 170.207(h).

(12) *Image results*. Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

(13) *Family health history*. Enable a user to electronically record, change, and access a patient's family health history according to:

(i) At a minimum, the version of the standard specified in § 170.207(a)(3); or

(ii) The standard specified in § 170.207(j).

(14) *Patient list creation*. Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data:

(i) Problems;

(ii) Medications;

(iii) Medication allergies;

(iv) Demographics;

(v) Laboratory tests and values/results; and

(vi) *Ambulatory setting only*. Patient communication preferences.

(15) *Patient-specific education resources*. EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests and values/results:

(i) In accordance with the standard specified at §170.204(b) and the implementation specifications at §170.204(b)(1) or (2); and

(ii) By any means other than the method specified in paragraph (a)(15)(i) of this section.

(16) *Inpatient setting only—electronic medication administration record.* (i) In combination with an assistive technology that provides automated information on the ''rights'' specified in paragraphs (a)(16)(i)(A) through (E) of this section, enable a user to electronically verify the following before administering medication(s):

(A) *Right patient.* The patient to whom the medication is to be administered matches the medication to be administered.

(B) *Right medication.* The medication to be administered matches the medication ordered for the patient.

(C) *Right dose.* The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) *Right route.* The route of medication delivery matches the route specified in the medication order.

(E) *Right time.* The time that the medication was ordered to be administered compared to the current time.

(ii) *Right documentation.* Electronically record the time and date in accordance with the standard specified in §170.210(g), and user identification when a medication is administered.

(17) *Inpatient setting only—advance directives.* Enable a user to electronically record whether a patient has an advance directive.

(b) Care coordination. (1) *Transitions of care—receive, display, and incorporate transition of care/referral summaries.* (i) *Receive.* EHR technology must be able to electronically receive transition of care/referral summaries in accordance with:

(A) The standard specified in §170.202(a).

(B) *Optional.* The standards specified in §170.202(a) and (b).

(C) *Optional.* The standards specified in §170.202(b) and (c).

(ii) *Display.* EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: §170.205(a)(1), §170.205(a)(2), and §170.205(a)(3).

(iii) *Incorporate.* Upon receipt of a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(3), EHR technology must be able to:

(A) Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(B) Data incorporation. Electronically incorporate the following data expressed according to the specified standard(s):

(*1*) *Medications.* At a minimum, the version of the standard specified in §170.207(d)(2);

(*2*) *Problems.* At a minimum, the version of the standard specified in §170.207(a)(3);

(*3*) *Medication allergies.* At a minimum, the version of the standard specified in §170.207(d)(2).

(C) *Section views.* Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at §170.205(a)(3).

(2) *Transitions of care—create and transmit transition of care/referral summaries.* (i) *Create.* Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at §170.205(a)(3) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(A) *Encounter diagnoses.* The standard specified in §170.207(i) or, at a minimum, the version of the standard specified §170.207(a)(3);

(B) *Immunizations.* The standard specified in §170.207(e)(2);

(C) Cognitive status;

(D) Functional status; and

(E) *Ambulatory setting only.* The reason for referral; and referring or transitioning provider's name and office contact information.

(F) *Inpatient setting only*. Discharge instructions.

(ii) *Transmit*. Enable a user to electronically transmit the transition of care/referral summary created in paragraph (b)(2)(i) of this section in accordance with:

(A) The standard specified in § 170.202(a).

(B) *Optional*. The standards specified in § 170.202(a) and (b).

(C) *Optional*. The standards specified in § 170.202(b) and (c).

(3) *Electronic prescribing*. Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:

(i) The standard specified in § 170.205(b)(2); and

(ii) At a minimum, the version of the standard specified in § 170.207(d)(2).

(4) *Clinical information reconciliation*. Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:

(i) Electronically and simultaneously display (i.e., in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.

(ii) Enable a user to create a single reconciled list of medications, medication allergies, or problems.

(iii) Enable a user to review and validate the accuracy of a final set of data and, upon a user's confirmation, automatically update the list.

(5) *Incorporate laboratory tests and values/results*. (i) *Receive results*. (A) *Ambulatory setting only*. (*1*) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the standard specified in § 170.205(j) and, at a minimum, the version of the standard specified in § 170.207(c)(2).

(*2*) Electronically display the tests and values/results received in human readable format.

(B) *Inpatient setting only*. Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7).

(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

(6) *Inpatient setting only—transmission of electronic laboratory tests and values/results to ambulatory providers*. EHR technology must be able to electronically create laboratory test reports for electronic transmission in accordance with the standard specified in § 170.205(j) and with laboratory tests expressed in accordance with, at a minimum, the version of the standard specified in § 170.207(c)(2).

(7) *Data portability*. Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) *Encounter diagnoses*. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

(ii) *Immunizations*. The standard specified in § 170.207(e)(2);

(iii) Cognitive status;

(iv) Functional status; and

(v) *Ambulatory setting only*. The reason for referral; and referring or transitioning provider's name and office contact information.

(vi) *Inpatient setting only*. Discharge instructions.

(c) Clinical quality measures. (1) *Clinical Quality Measures—capture and export*. (i) *Capture*. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the standard specified at § 170.204(c) that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include

codified expressions of ''patient reason,'' ''system reason,'' or ''medical reason.''

(ii) *Export.* EHR technology must be able to electronically export a data file formatted in accordance with the standards specified at §170.205(h) that includes all of the data captured for each and every CQM to which EHR technology was certified under paragraph (c)(1)(i) of this section.

(2) *Clinical quality measures—import and calculate.* (i) *Import.* EHR technology must be able to electronically import a data file formatted in accordance with the standard specified at §170.205(h) and use such data to perform the capability specified in paragraph (c)(2)(ii) of this section. EHR technology presented for certification to all three of the certification criteria adopted in paragraphs (c)(1) through (3) of this section is not required to meet paragraph (c)(2)(i).

(ii) *Calculate.* EHR technology must be able to electronically calculate each and every clinical quality measure for which it is presented for certification.

(3) *Clinical quality measures—electronic submission.* Enable a user to electronically create a data file for transmission of clinical quality measurement data:

(i) In accordance with the standards specified at §170.205(h) and (k); and

(ii) That can be electronically accepted by CMS.

(d) Privacy and security. (1) *Authentication, access control, and authorization.* (i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and

(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in paragraph (d)(1)(i) of this section, and the actions the user is permitted to perform with the EHR technology.

(2) *Auditable events and tamper-resistance.* (i) *Record actions.* EHR technology must be able to:

(A) Record actions related to electronic health information in accordance with the standard specified in §170.210(e)(1);

(B) Record the audit log status (enabled or disabled) in accordance with the standard specified in §170.210(e)(2) unless it cannot be disabled by any user; and

(C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the standard specified in §170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see 170.314(d)(7) of this section).

(ii) *Default setting.* EHR technology must be set by default to perform the capabilities specified in paragraph (d)(2)(i)(A) of this section and, where applicable, paragraphs (d)(2)(i)(B) or (C), or both paragraphs (d)(2)(i)(B) and (C).

(iii) *When disabling the audit log is permitted.* For each capability specified in paragraphs (d)(2)(i)(A) through (C) of this section that EHR technology permits to be disabled, the ability to do so must be restricted to a limited set of identified users.

(iv) *Audit log protection.* Actions and statuses recorded in accordance with paragraph (d)(2)(i) of this section must not be capable of being changed, overwritten, or deleted by the EHR technology.

(v) *Detection.* EHR technology must be able to detect whether the audit log has been altered.

(3) *Audit report(s).* Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the standards at §170.210(e).

(4) *Amendments.* Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in paragraphs (d)(4)(i) or (ii) of this section.

(i) *Accepted amendment.* For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location.

(ii) *Denied amendment.* For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.

(5) *Automatic log-off.* Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.

(6) *Emergency access.* Permit an identified set of users to access electronic health information during an emergency.

(7) *End-user device encryption.* Paragraph (d)(7)(i) or (ii) of this section must be met to satisfy this certification criterion.

(i) EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.

(A) Electronic health information that is stored must be encrypted in accordance with the standard specified in § 170.210(a)(1).

(B) *Default setting.* EHR technology must be set by default to perform this capability and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.

(ii) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.

(8) *Integrity.* (i) Create a message digest in accordance with the standard specified in § 170.210(c).

(ii) Verify in accordance with the standard specified in § 170.210(c) upon receipt of electronically exchanged health information that such information has not been altered.

(9) *Optional—accounting of disclosures.* Record disclosures made for treatment, payment, and health care operations in accordance with the standard specified in § 170.210(d).

(e) *Patient engagement.* (1) *View, download, and transmit to 3rd party.* (i) EHR technology must provide patients (and their authorized representatives) with an online means to view, download, and transmit to a 3rd party the data specified below. Access to these capabilities must be through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) *View.* Electronically view in accordance with the standard adopted at § 170.204(a), at a minimum, the following data:

(*1*) The Common MU Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

(*2*) *Ambulatory setting only.* Provider's name and office contact information.

(*3*) *Inpatient setting only.* Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(B) *Download.* (*1*) Electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in human readable format or formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

(*i*) *Ambulatory setting only.* All of the data specified in paragraph (e)(1)(i)(A)(*1*) and (*2*) of this section.

(*ii*) *Inpatient setting only.* All of the data specified in paragraphs (e)(1)(i)(A)(*1*) and (*3*) of this section.

(*2*) *Inpatient setting only.* Electronically download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(2) of this section).

(C) *Transmit to third party.* (*1*) Electronically transmit the ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(*1*) of this section in accordance with the standard specified in § 170.202(a).

(*2*) *Inpatient setting only.* Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with the standard specified in § 170.202(a).

(ii) *Activity history log.* (A) When electronic health information is viewed, downloaded, or transmitted to a third-

party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section, the following information must be recorded and made accessible to the patient:

(*1*) The action(s) (i.e., view, download, transmission) that occurred;

(*2*) The date and time each action occurred in accordance with the standard specified at § 170.210(g); and

(*3*) The user who took the action.

(B) EHR technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at § 170.314(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

(2) *Ambulatory setting only—clinical summary*. (i) *Create*. Enable a user to create a clinical summary for a patient in human readable format and formatted according to the standards adopted at § 170.205(a)(3).

(ii) *Customization*. Enable a user to customize the data included in the clinical summary.

(iii) *Minimum data from which to select*. EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:

(A) Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set)

(B) The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids.

(3) *Ambulatory setting only—secure messaging*. Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:

(i) Both the patient (or authorized representative) and EHR technology user are authenticated; and

(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(f) *Public health*. (1) *Immunization information*. Enable a user to electronically record, change, and access immunization information.

(2) *Transmission to immunization registries*. EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:

(i) The standard and applicable implementation specifications specified in § 170.205(e)(3); and

(ii) At a minimum, the version of the standard specified in § 170.207(e)(2).

(3) *Transmission to public health agencies—syndromic surveillance*. EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) *Ambulatory setting only*. (A) The standard specified in § 170.205(d)(2). (B) *Optional*. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

(ii) *Inpatient setting only*. The standard (and applicable implementation specifications) specified in § 170.205(d)(3).

(4) *Inpatient setting only—transmission of reportable laboratory tests and values/results*. EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(g); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

(5) *Optional—ambulatory setting only—cancer case information*. Enable a user to electronically record, change, and access cancer case information.

(6) *Optional—ambulatory setting only—transmission to cancer registries*. EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

(i) The standard (and applicable implementation specifications) specified in § 170.205(i); and

(ii) At a minimum, the versions of the standards specified in § 170.207(a)(3) and (c)(2).

(g) *Utilization.* (1) *Automated numerator recording.* For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

(2) *Automated measure calculation.* For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

(3) *Safety-enhanced design.* User-centered design processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria: § 170.314(a)(1), (2), (6) through (8), and (16) and (b)(3) and (4).

(4) *Quality management system.* For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single QMS was used for applicable capabilities, it would only need to be identified once.

(ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others.

(iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

EFFECTIVE DATE NOTE: At 77 FR 54287, Sept. 4, 2012, § 170.341 was added, effective Oct. 4, 2012.

Subpart D—Temporary Certification Program for HIT

SOURCE: 75 FR 36203, June 24, 2010, unless otherwise noted.

§ 170.400 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act, and sets forth the rules and procedures related to the temporary certification program for health information technology administered by the National Coordinator for Health Information Technology.

§ 170.401 Applicability.

This subpart establishes the processes that applicants for ONC–ATCB status must follow to be granted ONC–ATCB status by the National Coordinator, the processes the National Coordinator will follow when assessing applicants and granting ONC–ATCB status, the requirements that ONC–ATCBs must follow to remain in good standing, and the requirements of ONC–ATCBs for testing and certifying Complete EHRs and/or EHR Modules in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part.

§ 170.402 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC–ATCB by requesting and subsequently submitting an application for ONC–ATCB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR or EHR Module resides or is being or has been implemented.

Development site means the physical location where a Complete EHR or EHR Module was developed.

ONC–ATCB or ONC–Authorized Testing and Certification Body means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the testing and certification of Complete EHRs and/or EHR Modules under the temporary certification program.

Remote testing and certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC–ATCB to be physically present at the development or deployment site to conduct testing and certification.

§ 170.405 Correspondence.

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless otherwise necessary. The official date of receipt of any e-mail between the National Coordinator and an applicant for ONC–ATCB status or an ONC–ATCB is the day the e-mail was sent.

(b) In circumstances where it is necessary for an applicant for ONC–ATCB status or an ONC–ATCB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

§ 170.410 Types of testing and certification.

Applicants may seek authorization from the National Coordinator to perform the following types of testing and certification:

(a) Complete EHR testing and certification; and/or

(b) EHR Module testing and certification.

§ 170.415 Application prerequisite.

Applicants must request in writing an application for ONC–ATCB status from the National Coordinator. Applicants must indicate:

(a) The type of authorization sought pursuant to § 170.410; and

(b) If seeking authorization to perform EHR Module testing and certification, the specific type(s) of EHR Module(s) they seek authorization to test and certify. If qualified, applicants will only be granted authorization to test and certify the types of EHR Modules for which they seek authorization.

§ 170.420 Application.

The application for ONC–ATCB status consists of two parts. Applicants must complete both parts of the application in their entirety and submit them to the National Coordinator for the application to be considered complete.

(a) *Part 1.* An applicant must provide all of the following:

(1) General identifying information including:

(i) Name, address, city, state, zip code, and Web site of applicant; and

(ii) Designation of an authorized representative, including name, title, phone number, and e-mail address of the person who will serve as the applicant's point of contact.

(2) Documentation of the completion and results of a self-audit against all sections of ISO/IEC Guide 65:1996 (incorporated by reference in § 170.499), and the following:

(i) A description of the applicant's management structure according to section 4.2 of ISO/IEC Guide 65:1996;

(ii) A copy of the applicant's quality manual that has been developed according to section 4.5.3 of ISO/IEC Guide 65:1996;

(iii) A copy of the applicant's policies and approach to confidentiality according to section 4.10 of ISO/IEC Guide 65:1996;

(iv) A copy of the qualifications of each of the applicant's personnel who oversee or perform certification according to section 5.2 of ISO/IEC Guide 65:1996;

(v) A copy of the applicant's evaluation reporting procedures according to section 11 of ISO/IEC Guide 65:1996; and

(vi) A copy of the applicant's policies for use and display of certificates according to section 14 of ISO/IEC Guide 65:1996.

(3) Documentation of the completion and results of a self-audit against all sections of ISO/IEC 17025:2005 (incorporated by reference in § 170.499), and the following:

(i) A copy of the applicant's quality system document according to section 4.2.2 of ISO/IEC 17025:2005;

(ii) A copy of the applicant's policies and procedures for handling testing nonconformities according to section 4.9.1 of ISO/IEC 17025:2005; and

(iii) The qualifications of each of the applicant's personnel who oversee or conduct testing according to section 5.2 of ISO/IEC 17025:2005.

(4) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC–ATCBs.

(b) *Part 2.* An applicant must submit a completed proficiency examination.

§ 170.423 Principles of proper conduct for ONC–ATCBs.

An ONC–ATCB shall:

(a) Operate its certification program in accordance with ISO/IEC Guide 65:1996 (incorporated by reference in § 170.499) and testing program in accordance with ISO/IEC 17025:2005 (incorporated by reference in § 170.499);

(b) Maintain an effective quality management system which addresses all requirements of ISO/IEC 17025:2005 (incorporated by reference in § 170.499);

(c) Attend all mandatory ONC training and program update sessions;

(d) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to test and certify Complete EHRs and/or EHR Modules;

(e) Use test tools and test procedures approved by the National Coordinator for the purposes of assessing Complete EHRs and/or EHR Modules compliance with the certification criteria adopted by the Secretary;

(f) Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management, including key testing and certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to test and certify Complete EHRs and/or EHR Modules;

(g) Allow ONC, or its authorized agents(s), to periodically observe on site (unannounced or scheduled) during normal business hours, any testing and/or certification performed to demonstrate compliance with the requirements of the temporary certification program;

(h) Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified which includes, at a minimum:

(1) The vendor name (if applicable);

(2) The date certified;

(3) The product version;

(4) The unique certification number or other specific product identification;

(5) The clinical quality measures to which a Complete EHR or EHR Module has been tested and certified;

(6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and

(7) Where applicable, the certification criterion or criteria to which each EHR Module has been tested and certified.

(i) Retain all records related to tests and certifications according to ISO/IEC Guide 65:1996 (incorporated by reference in § 170.499) and ISO/IEC 17025:2005 (incorporated by reference in § 170.499) for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program;

(j) Promptly refund any and all fees received for:

(1) Requests for testing and certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Testing and certification that will not be completed as a result of its conduct; and

(3) Previous testing and certification that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Modules;

(k) Ensure adherence to the following requirements when issuing a certification to Complete EHRs and/or EHR Modules:

(1) All certifications must require that a Complete EHR or EHR Module developer conspicuously include the following text on its Web site and in all marketing materials, communications

statements, and other assertions related to the Complete EHR or EHR Module's certification:

(i) ''This [Complete EHR or EHR Module] is 201[X]/201[X] compliant and has been certified by an ONC–ATCB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments.''; and

(ii) The information an ONC–ATCB is required to report to the National Coordinator under paragraph (h) of this section for the specific Complete EHR or EHR Module at issue;

(2) A certification issued to an integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section except that it must also indicate each EHR Module that comprises the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based on applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

§ 170.425 Application submission.

(a) An applicant for ONC–ATCB status must submit its application either electronically via e-mail (or web submission if available), or by regular or express mail.

(b) An application for ONC–ATCB status may be submitted to the National Coordinator at any time during the existence of the temporary certification program.

§ 170.430 Review of application.

(a) *Method of review and review timeframe.* (1) Applications will be reviewed in the order they are received.

(2) The National Coordinator will review Part 1 of the application in its entirety and determine whether Part 1 of the application is complete and satisfactory before proceeding to review Part 2 of the application in its entirety.

(3) The National Coordinator is permitted up to 30 days to review an application (submitted for the first time) upon receipt.

(b) *Application deficiencies.*

(1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the applicant may be issued a deficiency notice specifying the error, omission, or deficient statement.

(2) If the National Coordinator determines that deficiencies in either part of the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) *Revised application.*

(1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request an extension for good cause from the National Coordinator of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order to continue to be considered for ONC–ATCB status, an applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

(4) If the National Coordinator determines that a revised application still

contains deficiencies, the applicant will be issued a denial notice indicating that the applicant will no longer be considered for authorization under the temporary certification program. An applicant may request reconsideration of a denial in accordance with § 170.435.

(d) *Satisfactory application.* (1) An application will be deemed satisfactory if it meets all application requirements, including a passing score on the proficiency examination.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC–ATCB status.

(3) Once notified by the National Coordinator of its successful achievement of ONC–ATCB status, the applicant may represent itself as an ONC–ATCB and begin testing and certifying Complete EHRs and/or EHR Modules consistent with its authorization.

§ 170.435 ONC–ATCB application reconsideration.

(a) An applicant may request that the National Coordinator reconsider a denial notice issued for each part of an application only if the applicant can demonstrate that clear, factual errors were made in the review of the applicable part of the application and that the errors' correction could lead to the applicant obtaining ONC–ATCB status.

(b) *Submission requirement.* An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual errors it believes can account for the denial. If the National Coordinator does not receive the applicant's submission within the specified timeframe, its reconsideration request may be rejected.

(c) *Reconsideration request review.* If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) *Decision.* (1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's decision to reverse the previous decision(s) not to approve part of the applicant's application or the entire application.

(i) If the National Coordinator's decision to reverse the previous decision(s) affected part 1 of an application, the National Coordinator will subsequently review part 2 of the application.

(ii) If the National Coordinator's decision to reverse the previous decision(s) affected part 2 of an application, the applicant's authorized representative will be notified of the National Coordinator's decision as well as the applicant's successful achievement of ONC–ATCB status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify any factual errors or that correction of those factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§ 170.440 ONC–ATCB status.

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available the names of ONC–ATCBs, including the date each was authorized and the type(s) of testing and certification each has been authorized to perform.

(b) *Representation.* Each ONC–ATCB must prominently and unambiguously identify the scope of its authorization on its Web site, and in all marketing and communications statements (written and oral) pertaining to its activities under the temporary certification program.

(c) *Renewal.* ONC–ATCB status does not need to be renewed during the temporary certification program.

(d) *Expiration.* The status of all ONC–ATCBs will expire upon the sunset of the temporary certification program in accordance with § 170.490.

§ 170.445 Complete EHR testing and certification.

(a) An ONC–ATCB must test and certify Complete EHRs to all applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC–ATCB must provide the option for a Complete EHR to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Inherited certified status.* An ONC–ATCB must accept requests for a newer version of a previously certified Complete EHR to inherit the previously certified Complete EHR's certified status without requiring the newer version to be retested and recertified.

(1) Before granting certified status to a newer version of a previously certified Complete EHR, an ONC–ATCB must review an attestation submitted by the developer of the Complete EHR to determine whether the newer version has adversely affected any previously certified capabilities.

(2) An ONC–ATCB may grant certified status to a newer version of a previously certified Complete EHR if it determines that previously certified capabilities have not been adversely affected.

(d) An ONC–ATCB that has been authorized to test and certify Complete EHRs is also authorized to test and certify all EHR Modules under the temporary certification program.

§ 170.450 EHR module testing and certification.

(a) When testing and certifying EHR Modules, an ONC–ATCB must test and certify in accordance with the applicable certification criterion or certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC–ATCB must provide the option for an EHR Module or a bundle of EHR Modules to be tested and certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Privacy and security testing and certification.* EHR Modules shall be tested and certified to all privacy and security certification criteria adopted by the Secretary unless the EHR Module(s) is/are presented for testing and certification in one of the following manners:

(1) The EHR Module(s) is/are presented for testing and certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR (as defined in 45 CFR 170.102), and one or more of the constituent EHR Modules is/are demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Module(s); or

(2) An EHR Module is presented for testing and certification, and the presenter can demonstrate and provide documentation to the ONC–ATCB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be tested and certified in accordance with such certification criterion.

(d) *Inherited certified status.* An ONC–ATCB must accept requests for a newer version of a previously certified EHR Module or bundle of EHR Modules to inherit the previously certified EHR Module's or bundle of EHR Modules certified status without requiring the newer version to be retested and recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module or bundle of EHR Modules, an ONC–ATCB must review an attestation submitted by the developer of the EHR Module or presenter of the bundle of EHR Modules to determine whether the newer version has adversely affected any previously certified capabilities.

(2) An ONC–ATCB may grant certified status to a newer version of a previously certified EHR Module or bundle of EHR Modules if it determines that previously certified capabilities have not been adversely affected.

§ 170.455 Testing and certification to newer versions of certain standards.

(a) ONC–ATCBs may test and certify Complete EHRs and EHR Module to a newer version of certain identified minimum standards specified at subpart B of this part if the Secretary has

accepted a newer version of an adopted minimum standard.

(b) Applicability of an accepted new version of an adopted minimum standard.

(1) ONC–ATCBs are not required to test and certify Complete EHRs and/or EHR Modules according to newer versions of an adopted minimum standard accepted by the Secretary until the incorporation by reference provision of the adopted version is updated in the FEDERAL REGISTER with a newer version.

(2) Certified EHR Technology may be upgraded to comply with newer versions of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology.

§ 170.457 Authorized testing and certification methods.

An ONC–ATCB must provide remote testing and certification for both development and deployment sites.

§ 170.460 Good standing as an ONC–ATCB.

An ONC–ATCB must maintain good standing by:

(a) Adhering to the Principles of Proper Conduct for ONC–ATCBs;

(b) Refraining from engaging in other types of inappropriate behavior, including an ONC–ATCB misrepresenting the scope of its authorization as well as an ONC–ATCB testing and certifying Complete EHRs and/or EHR Modules for which it does not have authorization; and

(c) Following all other applicable Federal and state laws.

§ 170.465 Revocation of authorized testing and certification body status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC–ATCB's status for committing a Type-1 violation. Type-1 violations include violations of law or temporary certification program policies that threaten or significantly undermine the integrity of the temporary certification program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the temporary certification program, a program administered by HHS or any program administered by the Federal government.

(b) *Type-2 violations.* The National Coordinator may revoke an ONC–ATCB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute noncompliance with § 170.460.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC–ATCB may no longer be in compliance with § 170.460, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC–ATCB requesting that the ONC–ATCB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC–ATCB is permitted up to 30 days to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC–ATCB submits a response, the National Coordinator is permitted up to 30 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC–ATCB during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC–ATCB confirming this determination.

(iii) If the National Coordinator determines that the ONC–ATCB failed to demonstrate that no violation occurred or to correct the area(s) of non-compliance identified under paragraph (b)(1) of this section within 30 days of receipt of the noncompliance notification, then the National Coordinator may propose to revoke the ONC–ATCB's status.

(c) *Proposed revocation.* (1) The National Coordinator may propose to revoke an ONC–ATCB's status if the National Coordinator has reliable evidence that the ONC–ATCB committed a Type-1 violation; or

(2) The National Coordinator may propose to revoke an ONC–ATCB's status if, after the ONC–ATCB has been notified of a Type-2 violation, the ONC–ATCB fails to:

(i) To rebut the finding of a violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the noncompliance notification within the specified timeframe under paragraph (b)(2).

(d) *Suspension of an ONC–ATCB's operations.* (1) The National Coordinator may suspend the operations of an ONC–ATCB under the temporary certification program based on reliable evidence indicating that:

(i) The ONC–ATCB committed a Type-1 or Type-2 violation; and

(ii) The continued testing and certification of Complete EHRs and/or EHR Modules by the ONC–ATCB could have an adverse impact on the health or safety of patients.

(2) If the National Coordinator determines that the conditions of paragraph (d)(1) have been met, an ONC–ATCB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC–ATCB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended.

(4) The National Coordinator is permitted up to 5 days from receipt of an ONC–ATCB's written response to a notice of proposed suspension to review the response and make a determination.

(5) The National Coordinator may make one of the following determinations in response to the ONC–ATCB's written response or if the ONC–ATCB fails to submit a written response within the timeframe specified in paragraph (d)(3):

(i) Rescind the proposed suspension; or

(ii) Suspend the ONC–ATCB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with §170.465(c) and suspend the ONC–ATCB's operations for the duration of the revocation process.

(6) A suspension will become effective upon an ONC–ATCB's receipt of a notice of suspension.

(e) *Opportunity to respond to a proposed revocation notice.* (1) An ONC–ATCB may respond to a proposed revocation notice, but must do so within 10 days of receiving the proposed revocation notice and include appropriate documentation explaining in writing why its status should not be revoked.

(2) Upon receipt of an ONC–ATCB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC–ATCB and reach a decision.

(3) Unless suspended, an ONC–ATCB will be permitted to continue its operations under the temporary certification program during the time period provided for the ONC–ATCB to respond to the proposed revocation notice and the National Coordinator to review the response.

(f) *Good standing determination.* If the National Coordinator determines that an ONC–ATCB's status should not be revoked, the National Coordinator will notify the ONC–ATCB's authorized representative in writing of this determination.

(g) *Revocation.* (1) The National Coordinator may revoke an ONC–ATCB's status if:

(i) A determination is made that revocation is appropriate after considering the information provided by the ONC–ATCB in response to the proposed revocation notice; or

(ii) The ONC–ATCB does not respond to a proposed revocation notice within the specified timeframe in paragraph (d)(1) of this section.

(2) A decision to revoke an ONC–ATCB's status is final and not subject to further review unless the National Coordinator chooses to reconsider the revocation.

(h) *Extent and duration of revocation.* (1) The revocation of an ONC–ATCB is effective as soon as the ONC–ATCB receives the revocation notice.

(2) A testing and certification body that has had its ONC–ATCB status revoked is prohibited from accepting new requests for testing and certification

and must cease its current testing and certification operations under the temporary certification program.

(3) A testing and certification body that has had its ONC–ATCB status revoked for a Type-1 violation is prohibited from reapplying for ONC–ATCB status under the temporary certification program for one year. If the temporary certification program sunsets during this time, the testing and certification body is prohibited from applying for ONC–ACB status under the permanent certification program for the time that remains within the one year prohibition.

(4) The failure of a testing and certification body that has had its ONC–ATCB status revoked, to promptly refund any and all fees for tests and/or certifications of Complete EHRs and EHR Modules not completed will be considered a violation of the Principles of Proper Conduct for ONC–ATCBs and will be taken into account by the National Coordinator if the testing and certification body reapplies for ONC–ATCB status under the temporary certification program or applies for ONC–ACB status under the permanent certification program.

§ 170.470 Effect of revocation on the certifications issued to complete EHRs and EHR Modules.

(a) The certified status of Complete EHRs and/or EHR Modules certified by an ONC–ATCB that had it status revoked will remain intact unless a Type-1 violation was committed that calls into question the legitimacy of the certifications issued by the former ONC–ATCB.

(b) If the National Coordinator determines that a Type-1 violation occurred that called into question the legitimacy of certifications conducted by the former ONC–ATCB, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC–ATCB's status; and

(2) Publish a notice on ONC's Web site if the National Coordinator believes that Complete EHRs and/or EHR Modules were improperly certified by the former ONC–ATCB.

(c) If the National Coordinator determines that Complete EHRs and/or EHR Modules were improperly certified, the certification status of affected Complete EHRs and/or EHR Modules would only remain intact for 120 days after the National Coordinator publishes the notice. The certification status of the Complete EHR and/or EHR Module can only be maintained thereafter by being re-certified by an ONC–ATCB in good standing.

§ 170.490 Sunset of the temporary certification program.

(a) The temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. On and after the temporary certification program sunset date, ONC–ATCBs will be prohibited from accepting new requests to test and certify Complete EHRs or EHR Modules.

(b) ONC–ATCBs are permitted up to six months after the sunset date to complete all testing and certification activities associated with requests for testing and certification of Complete EHRs and/or EHR Modules received prior to the sunset date.

§ 170.499 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave, SW., Washington, DC

20201, call ahead to arrange for inspection at 202–690–7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56, CH·1211, Geneve 20, Switzerland, telephone +41–22–749–01–11, *http://www.iso.org*.

(1) ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories (Second Edition), May 15, 2005, IBR approved for § 170.420 and § 170.423.

(2) ISO/IEC GUIDE 65 General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for § 170.420 and § 170.423.

(3) [Reserved]

Subpart E—Permanent Certification Program for HIT

SOURCE: 76 FR 1325, Dec. 7, 2011, unless otherwise noted.

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, subpart E was amended by removing the phrases ''permanent certification program for HIT'' and ''permanent certification program'' and add in their place ''ONC HIT Certification Program'' wherever they may occur, effective Oct. 4, 2012.

§ 170.500 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act and sets forth the rules and procedures related to the permanent certification program for health information technology (HIT) administered by the National Coordinator for Health Information Technology.

§ 170.501 Applicability.

This subpart establishes the processes that applicants for ONC–ACB status must follow to be granted ONC–ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC–ACB status; the requirements that ONC–ACBs must follow to maintain ONC–ACB status; and the requirements of ONC–ACBs for certifying Complete EHRs, EHR Module(s), and other types of HIT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. It also establishes the processes accreditation organizations must follow to request approval from the National Coordinator and that the National Coordinator in turn will follow to approve an accreditation organization under the permanent certification program as well as certain ongoing responsibilities for an ONC–AA.

§ 170.502 Definitions.

For the purposes of this subpart:

Applicant means a single organization or a consortium of organizations that seeks to become an ONC–ACB by submitting an application for ONC–ACB status to the National Coordinator.

Deployment site means the physical location where a Complete EHR, EHR Module(s) or other type of HIT resides or is being or has been implemented.

Development site means the physical location where a Complete EHR, EHR Module(s) or other type of HIT was developed.

Gap certification means the certification of a previously certified Complete EHR or EHR Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or EHR Module(s).

ONC–Approved Accreditor or ONC–AA means an accreditation organization that the National Coordinator has approved to accredit certification bodies under the permanent certification program.

ONC–Authorized Certification Body or ONC–ACB means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the certification of Complete EHRs, EHR Module(s), and/or other types of HIT under the permanent certification program.

Providing or provide an updated certification means the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB

has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module(s).

Remote certification means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC–ACB to be physically present at the development or deployment site to conduct certification.

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, § 170.502 was amended by revising the definition of ''providing or provide an updated certification'', effective Oct. 4, 2012. For the convenience of the user, the revised text is set forth as follows:

§ 170.502 Definitions.

* * * * *

Providing or provide an updated certification means the action taken by an ONC–ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by § 170.523(k)(1)(i), after the ONC–ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria are applicable to the EHR Module(s).

* * * * *

§ 170.503 Requests for ONC–AA status and ONC–AA ongoing responsibilities.

(a) The National Coordinator may approve only one ONC–AA at a time.

(b) *Submission*. The National Coordinator will publish a notice in the FEDERAL REGISTER to announce the 30-day period during which requests for ONC–AA status may be submitted. In order to be considered for ONC–AA status, an accreditation organization must submit a timely request in writing to the National Coordinator along with the following information to demonstrate its ability to serve as an ONC–AA:

(1) A detailed description of the accreditation organization's conformance to ISO/IEC17011:2004 (incorporated by reference in § 170.599) and experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599);

(2) A detailed description of the accreditation organization's accreditation, requirements as well as how those requirements would complement the Principles of Proper Conduct for ONC–ACBs and ensure the surveillance approaches used by ONC–ACBs include the use of consistent, objective, valid, and reliable methods;

(3) Detailed information on the accreditation organization's procedures that would be used to monitor ONC–ACBs;

(4) Detailed information, including education and experience, about the key personnel who review organizations for accreditation; and

(5) Procedures for responding to, and investigating, complaints against ONC–ACBs.

(c) *Preliminary selection*.

(1) The National Coordinator is permitted up to 60 days from the end of the submission period to review all timely submissions that were received and determine which accreditation organization is best qualified to serve as the ONC–AA.

(2) The National Coordinator's determination will be based on the information provided, the completeness of an accreditation organization's description of the elements listed in paragraph (b) of this section, and each accreditation organization's overall accreditation experience.

(3) The accreditation organization that is determined to be the best qualified will be notified that it has been selected as the ONC–AA on a preliminary basis, subject to the resolution of the reconsideration process in § 170.504. All other accreditation organizations will be notified that their requests for ONC–AA status have been denied. The accreditation organization that is selected on a preliminary basis shall not represent itself as the ONC–AA or perform accreditation(s) under the permanent certification program unless and until it receives written notice from the National Coordinator that it has been approved as the ONC–AA on a final basis pursuant to paragraph (d) of this section.

(4) Any accreditation organization that submits a timely request for ONC–AA status and is denied may request

reconsideration in accordance with § 170.504.

(d) *Final approval.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in § 170.504(b), then that organization will be approved as the ONC–AA on a final basis. The accreditation organization that was selected as the ONC–AA on a preliminary basis pursuant to paragraph (c) of this section will be notified of this final decision and cannot request reconsideration or further review.

(2) If the National Coordinator determines that no accreditation organization has met the standard specified in § 170.504(b), then the organization that was selected as the ONC–AA on a preliminary basis pursuant to paragraph (c) of this section will be approved as the ONC–AA on a final basis.

(e) *ONC–AA ongoing responsibilities.* An ONC–AA must:

(1) Maintain conformance with ISO/IEC 17011:2004 (incorporated by reference in § 170.599);

(2) Verify that the certification bodies it accredits and ONC–ACBs conform to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in § 170.599);

(3) Ensure the surveillance approaches used by ONC–ACBs include the use of consistent, objective, valid, and reliable methods;

(4) Verify that ONC–ACBs are performing surveillance in accordance with their respective annual plans; and

(5) Review ONC–ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC–ACBs with the conditions of their respective accreditations.

(f) *ONC–AA status.*

(1) An accreditation organization has not been granted ONC–AA status unless and until it is notified by the National Coordinator that it has been approved as the ONC–AA on a final basis pursuant to paragraph (d) of this section.

(2) An ONC–AA's status will expire not later than 3 years from the date its status was granted by the National Coordinator.

(3) The National Coordinator will accept requests for ONC–AA status, in accordance with paragraph (b) of this section, at least 180 days before the current ONC–AA's status is set to expire.

[76 FR 1325, Dec. 7, 2011, as amended at 76 FR 72642, Nov. 25, 2011]

§ 170.504 Reconsideration process for requests for ONC–AA status.

(a) An accreditation organization that submits a timely request for ONC–AA status in accordance with § 170.503 and is denied may request reconsideration of the decision to deny its request for ONC–AA status.

(b) *Submission requirement.* To request reconsideration, an accreditation organization is required to submit to the National Coordinator, within 15 days of receipt of a denial notice, a written statement with supporting documentation contesting the decision to deny its request for ONC–AA status. The submission must demonstrate that clear, factual errors were made in the review of its request for ONC–AA status and that the accreditation organization would have been selected as the ONC–AA pursuant to § 170.503(c) if those errors had been corrected. If the National Coordinator does not receive an accreditation organization's submission within the specified timeframe, then its request for reconsideration may be denied.

(c) *Review of submissions.* The National Coordinator is permitted up to 30 days to review all timely submissions that were received and determine whether an accreditation organization has met the standard specified in paragraph (b) of this section.

(d) *Decision.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in paragraph (b) of this section, then that organization will be approved as the ONC–AA on a final basis. All other accreditation organizations will be notified that their requests for reconsideration have been denied.

(2) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§ 170.505 Correspondence.

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless

otherwise necessary. The official date of receipt of any e-mail between the National Coordinator and an accreditation organization requesting ONC–AA status, the ONC–AA, an applicant for ONC–ACB status, or an ONC–ACB is the date on which the e-mail was sent.

(b) In circumstances where it is necessary for an accreditation organization requesting ONC–AA status, the ONC–AA, an applicant for ONC–ACB status, or an ONC–ACB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

§ 170.510 Types of certification.

Applicants may seek authorization from the National Coordinator to perform the following types of certification:

(a) Complete EHR certification; and/or

(b) EHR Module certification; and/or

(c) Certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

§ 170.520 Application.

Applicants must include the following information in an application for ONC–ACB status and submit it to the National Coordinator for the application to be considered complete.

(a) The type of authorization sought pursuant to § 170.510. For authorization to perform EHR Module certification, applicants must indicate the specific type(s) of EHR Module(s) they seek authorization to certify. If qualified, applicants will only be granted authorization to certify the type(s) of EHR Module(s) for which they seek authorization.

(b) General identifying, information including:

(1) Name, address, city, state, zip code, and Web site of applicant; and

(2) Designation of an authorized representative, including name, title, phone number, and e-mail address of the person who will serve as the applicant's point of contact.

(c) Documentation that confirms that the applicant has been accredited by the ONC–AA.

(d) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC–ACBs.

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

(a) Maintain its accreditation, or if a new ONC–AA is approved by the National Coordinator, obtain accreditation from the new ONC–AA within 12 months or a reasonable period specified by the National Coordinator and maintain such accreditation;

(b) Attend all mandatory ONC training and program update sessions;

(c) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to certify HIT;

(d) Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management including key certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Personnel, facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to certify HIT.

(e) Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any certifications performed to demonstrate compliance with the requirements of the permanent certification program;

(f) Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified, which includes, at a minimum:

(1) The Complete EHR or EHR Module developer name (if applicable);

(2) The date certified;

(3) The product version;

(4) The unique certification number or other specific product identification;

(5) The clinical quality measures to which a Complete EHR or EHR Module has been certified;

(6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and

(7) Where applicable, the certification criterion or criteria to which each EHR Module has been certified.

(g) Retain all records related to the certification of Complete EHRs and/or EHR Module(s) for a minimum of 5 years;

(h) Only certify HIT, including Complete EHRs and/or EHR Module(s), that has been tested, using test tools and test procedures approved by the National Coordinator, by a/an:

(1) NVLAP-accredited testing laboratory; or

(2) ONC–ATCB when:

(i) Certifying previously certified EHR Module(s) if the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and no new certification criteria are applicable to the EHR Module(s); or

(ii) Performing gap certification.

(i) Submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results; and

(j) Promptly refund any and all fees received for:

(1) Requests for certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Certifications that will not be completed as a result of its conduct; and

(3) Previous certifications that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Module(s);

(k) Ensure adherence to the following requirements when issuing a certification to a Complete EHR and/or EHR Module(s):

(1) A Complete EHR or EHR Module developer must conspicuously include the following on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:

(i) ''This [Complete EHR or EHR Module] is 20[XX]/20[XX] compliant and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments.''; and

(ii) The information an ONC–ACB is required to report to the National Coordinator under paragraph (f) of this section for the specific Complete EHR or EHR Module at issue;

(2) A certification issued to a pre-coordinated, integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section, except that the certification must also indicate each EHR Module that is included in the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

[76 FR 1325, Dec. 7, 2011, as amended at 76 FR 72642, Nov. 25, 2011]

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, § 170.523 was amended by adding paragraph (f)(8), revising paragraphs (k)(1)(i) and (ii), and adding paragraph (k)(1)(iii), effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.523 Principles of proper conduct for ONC–ACBs.

An ONC–ACB shall:

* * * * *

(f) * * *

(8) A hyperlink to the test results used to certify the Complete EHRs and/or EHR Modules that can be accessed by the public.

* * * * *

(k) * * *

(1) * * *

(i) ''This [Complete EHR or EHR Module] is [specify Edition of EHR certification criteria] compliant and has been certified by an ONC–ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This

certification does not represent an endorsement by the U.S. Department of Health and Human Services'';

(ii) The information an ONC–ACB is required to report to the National Coordinator under paragraph (f) of this section for the specific Complete EHR or EHR Module at issue; and

(iii) Any additional types of costs that an EP, EH, or CAH would pay to implement the Complete EHR's or EHR Module's capabilities in order to attempt to meet meaningful use objectives and measures. EHR technology self-developers are excluded from this requirement.

* * * * *

§ 170.525 Application submission.

(a) An applicant for ONC–ACB status must submit its application either electronically via e-mail (or web submission if available), or by regular or express mail.

(b) An application for ONC–ACB status may be submitted to the National Coordinator at any time.

§ 170.530 Review of application.

(a) *Method of review and review timeframe.*

(1) Applications will be reviewed in the order they are received.

(2) The National Coordinator is permitted up to 30 days from receipt to review an application that is submitted for the first time.

(b) *Application deficiencies.*

(1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the National Coordinator may issue a deficiency notice to the applicant.

(2) If the National Coordinator determines that deficiencies in the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) *Revised application.*

(1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request from the National Coordinator an extension for good cause of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order for an applicant to continue to be considered for ONC–ACB status, the applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice, unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant cannot reapply for ONC–ACB status for a period of six months from the date of the denial notice. An applicant may request reconsideration of this decision in accordance with § 170.535.

(d) *Satisfactory application.*

(1) An application will be deemed satisfactory if it meets all the application requirements, as determined by the National Coordinator.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC–ACB status.

(3) Once notified by the National Coordinator of its successful achievement of ONC–ACB status, the applicant may represent itself as an ONC–ACB and begin certifying health information technology consistent with its authorization.

§ 170.535 ONC–ACB application reconsideration.

(a) An applicant may request that the National Coordinator reconsider a denial notice only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC–ACB status.

(b) *Submission requirement.* An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual error(s) it believes can account for the denial. If the National Coordinator does not receive the applicant's reconsideration request within the specified timeframe, its reconsideration request may be rejected.

(c) *Reconsideration request review.* If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) *Decision.*

(1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's determination and the applicant's successful achievement of ONC–ACB status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify factual errors or that the correction of the factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

§ 170.540 ONC–ACB status.

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available the names of ONC–ACBs, including the date each was authorized and the type(s) of certification each has been authorized to perform.

(b) *Representation.* Each ONC–ACB must prominently and unambiguously identify the scope of its authorization on its Web site and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program.

(c) *Renewal.* An ONC–ACB is required to renew its status every three years. An ONC–ACB is required to submit a renewal request, containing any updates to the information requested in § 170.520, to the National Coordinator 60 days prior to the expiration of its status.

(d) *Expiration.* An ONC–ACB's status will expire three years from the date it was granted by the National Coordinator unless it is renewed in accordance with paragraph (c) of this section.

§ 170.545 Complete EHR certification.

(a) When certifying Complete EHRs, an ONC–ACB must certify in accordance with all applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC–ACB must provide the option for a Complete EHR to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC–ACB may provide the option for and perform gap certification of previously certified Complete EHRs.

(d) *Inherited certified status.* An ONC–ACB must accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified Complete EHR, an ONC–ACB must review an attestation submitted by the developer of the Complete EHR to determine whether any change in the newer version has adversely affected the Complete EHR's capabilities for which certification criteria have been adopted.

(2) An ONC–ACB may grant certified status to a newer version of a previously certified Complete EHR if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

(e) An ONC–ACB that has been authorized to certify Complete EHRs is also authorized to certify all EHR Modules under the permanent certification program.

§ 170.550 EHR Module certification.

(a) When certifying EHR Module(s), an ONC–ACB must certify in accordance with the applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC–ACB must provide the option for an EHR Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC–ACB may provide the option for and perform gap certification of previously certified EHR Module(s).

(d) An ONC–ACB may provide an updated certification to a previously certified EHR Module(s).

(e) *Privacy and security certification.* EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC–ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) *Inherited certified status.* An ONC–ACB must accept requests for a newer version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module(s), an ONC–ACB must review an attestation submitted by the developer(s) of the EHR Module(s) to determine whether any change in the newer version has adversely affected the EHR Module(s)' capabilities for which certification criteria have been adopted.

(2) An ONC–ACB may grant certified status to a newer version of a previously certified EHR Module(s) if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, § 170.550 was amended by revising paragraph (e), redesignating paragraph (f) as paragraph (g), and adding a new paragraph (f), effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.550 EHR Module certification.

* * * * *

(e) *Privacy and security certification.* For certification to the 2011 Edition EHR certification criteria, EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC–ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) When certifying an EHR Module to the 2014 Edition EHR certification criteria, an ONC–ACB must certify the EHR Module in accordance with the certification criteria at:

(1) Section 170.314(g)(1) if the EHR Module has capabilities presented for certification

that would support a meaningful use objective with a percentage-based measure;

(2) Section 170.314(g)(3) if the EHR Module is presented for certification to one or more listed certification criteria in §170.314(g)(3); and

(3) Section 170.314(g)(4).

* * * * *

§ 170.553 Certification of health information technology other than Complete EHRs and EHR Modules.

An ONC–ACB authorized to certify health information technology other than Complete EHRs and/or EHR Modules must certify such health information technology in accordance with the applicable certification criterion or certification criteria adopted by the Secretary at subpart C of this part.

§ 170.555 Certification to newer versions of certain standards.

(a) ONC–ACBs may certify Complete EHRs and/or EHR Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part if the Secretary has accepted a newer version of an adopted minimum standard.

(b) *Applicability of an accepted newer version of an adopted minimum standard.*

(1) ONC–ACBs are not required to certify Complete EHRs and/or EHR Module(s) according to newer versions of an adopted minimum standard accepted by the Secretary until the incorporation by reference provision of the adopted version is updated in the FEDERAL REGISTER with a newer version.

(2) Certified EHR Technology may be upgraded to comply with newer versions of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology.

EFFECTIVE DATE NOTE: At 77 FR 54291, Sept. 4, 2012, §170.555 was revised, effective Oct. 4, 2012. For the convenience of the user, the added and revised text is set forth as follows:

§ 170.555 Certification to newer versions of certain standards.

(a) ONC–ACBs may certify Complete EHRs and/or EHR Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part, unless the Secretary prohibits the use of a newer version for certification.

(b) *Applicability of a newer version of a minimum standard.* (1) ONC–ACBs are not required to certify Complete EHRs and/or EHR Module(s) according to newer versions of standards identified as minimum standards in subpart B of this part, unless and until the incorporation by reference of a standard is updated in the FEDERAL REGISTER with a newer version.

(2) A certified Complete EHR or certified EHR Module may be upgraded to comply with newer versions of standards identified as minimum standards in subpart B of this part without adversely affecting its certification status, unless the Secretary prohibits the use of a newer version for certification.

§ 170.557 Authorized certification methods.

An ONC–ACB must provide remote certification for both development and deployment sites.

§ 170.560 Good standing as an ONC–ACB.

An ONC–ACB must maintain good standing by:

(a) Adhering to the Principles of Proper Conduct for ONC–ACBs;

(b) Refraining from engaging in other types of inappropriate behavior, including an ONC–ACB misrepresenting the scope of its authorization, as well as an ONC–ACB certifying Complete EHRs and/or EHR Module(s) for which it does not have authorization; and

(c) Following all other applicable Federal and State laws.

§ 170.565 Revocation of ONC–ACB status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC–ACB's status for committing a Type-1 violation. Type-1 violations include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the permanent certification program, a program administered by HHS or any program administered by the Federal government.

(b) *Type-2 violations.* The National Coordinator may revoke an ONC–ACB's

status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute noncompliance with § 170.560.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC–ACB may no longer be in compliance with § 170.560, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC–ACB requesting that the ONC–ACB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC–ACB is permitted up to 30 days to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC–ACB submits a response, the National Coordinator is permitted up to 30 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC–ACB during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC–ACB confirming this determination.

(iii) If the National Coordinator determines that the ONC–ACB failed to demonstrate that no violation occurred or to correct the area(s) of non-compliance identified under paragraph (b)(1) of this section within 30 days of receipt of the noncompliance notification, then the National Coordinator may propose to revoke the ONC–ACB's status.

(c) *Proposed revocation.*

(1) The National Coordinator may propose to revoke an ONC–ACB's status if the National Coordinator has reliable evidence that the ONC–ACB has committed a Type-1 violation; or

(2) The National Coordinator may propose to revoke an ONC–ACB's status if, after the ONC–ACB has been notified of a Type-2 violation, the ONC–ACB fails to:

(i) To rebut the finding of a violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the noncompliance notification within the specified timeframe under paragraph (b)(2) of this section.

(d) *Suspension of an ONC–ACB's operations.*

(1) The National Coordinator may suspend the operations of an ONC–ACB under the permanent certification program based on reliable evidence indicating that:

(i) The ONC–ACB committed a Type-1 or Type-2 violation; and

(ii) The continued certification of Complete EHRs, EHR Module(s), and/or other types of HIT by the ONC–ACB could have an adverse impact on the health or safety of patients.

(2) If the National Coordinator determines that the conditions of paragraph (d)(1) of this section have been met, an ONC–ACB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC–ACB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended.

(4) The National Coordinator is permitted up to 5 days from receipt of an ONC–ACB's written response to a notice of proposed suspension to review the response and make a determination.

(5) The National Coordinator may make one of the following determinations in response to the ONC–ACB's written response or if the ONC–ACB fails to submit a written response within the timeframe specified in paragraph (d)(3) of this section:

(i) Rescind the proposed suspension; or

(ii) Suspend the ONC–ACB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with § 170.565(c) and suspend the ONC–ACB's operations for the duration of the revocation process.

(6) A suspension will become effective upon an ONC–ACB's receipt of a notice of suspension.

(e) *Opportunity to respond to a proposed revocation notice.*

(1) An ONC–ACB may respond to a proposed revocation notice, but must do so within 10 days of receiving the proposed revocation notice and include appropriate documentation explaining in writing why its status should not be revoked.

(2) Upon receipt of an ONC–ACB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC–ACB and reach a decision.

(f) *Good standing determination.* If the National Coordinator determines that an ONC–ACB's status should not be revoked, the National Coordinator will notify the ONC–ACB's authorized representative in writing of this determination.

(g) *Revocation.*

(1) The National Coordinator may revoke an ONC–ACB's status if:

(i) A determination is made that revocation is appropriate after considering the information provided by the ONC–ACB in response to the proposed revocation notice; or

(ii) The ONC–ACB does not respond to a proposed revocation notice within the specified timeframe in paragraph (e)(1) of this section.

(2) A decision to revoke an ONC–ACB's status is final and not subject to further review unless the National Coordinator chooses to reconsider the revocation.

(h) *Extent and duration of revocation.*

(1) The revocation of an ONC–ACB is effective as soon as the ONC–ACB receives the revocation notice.

(2) A certification body that has had its ONC–ACB status revoked is prohibited from accepting new requests for certification and must cease its current certification operations under the permanent certification program.

(3) A certification body that has had its ONC–ACB has its status revoked for a Type-1 violation, is not permitted to reapply for ONC–ACB status under the permanent certification program for a period of 1 year.

(4) The failure of a certification body that has had its ONC–ACB status revoked to promptly refund any and all fees for certifications of Complete EHRs and EHR Module(s) not completed will be considered a violation of the Principles of Proper Conduct for ONC–ACBs and will be taken into account by the National Coordinator if the certification body reapplies for ONC–ACB status under the permanent certification program.

§ 170.570 Effect of revocation on the certifications issued to Complete EHRs and EHR Module(s).

(a) The certified status of Complete EHRs and/or EHR Module(s) certified by an ONC–ACB that had its status revoked will remain intact unless a Type-1 violation was committed that calls into question the legitimacy of the certifications issued by the former ONC–ACB.

(b) If the National Coordinator determines that a Type-1 violation occurred that called into question the legitimacy of certifications conducted by the former ONC–ACB, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC–ACB's status; and

(2) Publish a notice on ONC's Web site if the National Coordinator believes that Complete EHRs and/or EHR Module(s) were improperly certified by the former ONC–ACB.

(c) If the National Coordinator determines that Complete EHRs and/or EHR Module(s) were improperly certified, the certification status of affected Complete EHRs and/or EHR Module(s) would only remain intact for 120 days after the National Coordinator publishes the notice. The certification status of affected Complete EHRs and/or EHR Module(s) can only be maintained thereafter by being re-certified by an ONC–ACB in good standing.

§ 170.575 Removal of the ONC–AA.

(a) *Conduct violations.* The National Coordinator may remove the ONC–AA for committing a conduct violation. Conduct violations include violations of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program. These violations include, but are not limited to: false, fraudulent, or abusive activities that affect the permanent

certification program, a program administered by HHS, or any program administered by the Federal government.

(b) *Performance violations.* The National Coordinator may remove the ONC–AA for failing to timely or adequately correct a performance violation. Performance violations constitute a failure to adequately perform the ONC–AA's responsibilities as specified in §170.503(e).

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that the ONC–AA may no longer be adequately performing its responsibilities specified in §170.503(e), the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC–AA requesting that the ONC–AA respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* The ONC–AA is permitted up to 30 days from receipt of a noncompliance notification to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC–AA submits a response, the National Coordinator is permitted up to 60 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC–AA during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC–AA confirming this determination. Otherwise, the National Coordinator may propose to remove the ONC–AA in accordance with paragraph (c) of this section.

(c) *Proposed removal.*

(1) The National Coordinator may propose to remove the ONC–AA if the National Coordinator has reliable evidence that the ONC–AA has committed a conduct violation; or

(2) The National Coordinator may propose to remove the ONC–AA if, after the ONC–AA has been notified of an alleged performance violation, the ONC–AA fails to:

(i) Rebut the alleged violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the noncompliance notification within the specified timeframe under paragraph (b)(2) of this section.

(d) *Opportunity to respond to a proposed removal notice.*

(1) The ONC–AA may respond to a proposed removal notice, but must do so within 20 days of receiving the proposed removal notice and include appropriate documentation explaining in writing why it should not be removed as the ONC–AA.

(2) Upon receipt of the ONC–AA's response to a proposed removal notice, the National Coordinator is permitted up to 60 days to review the information submitted by the ONC–AA and reach a decision.

(e) *Retention of ONC–AA status.* If the National Coordinator determines that the ONC–AA should not be removed, the National Coordinator will notify the ONC–AA in writing of this determination.

(f) *Removal.*

(1) The National Coordinator may remove the ONC–AA if:

(i) A determination is made that removal is appropriate after considering the information provided by the ONC–AA in response to the proposed removal notice; or

(ii) The ONC–AA does not respond to a proposed removal notice within the specified timeframe in paragraph (d)(1) of this section.

(2) A decision to remove the ONC–AA is final and not subject to further review unless the National Coordinator chooses to reconsider the removal.

(g) *Extent and duration of removal.*

(1) The removal of the ONC–AA is effective upon the date specified in the removal notice provided to the ONC–AA.

(2) An accreditation organization that is removed as the ONC–AA must cease all activities under the permanent certification program, including accepting new requests for accreditation under the permanent certification program.

(3) An accreditation organization that is removed as the ONC–AA is prohibited from being considered for ONC–AA status for a period of 1 year from the effective date of its removal as the ONC–AA.

[76 FR 72643, Nov. 25, 2011]

§ 170.599 Incorporation by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201, call ahead to arrange for inspection at 202–690–7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56, CH·1211, Geneve 20, Switzerland, telephone +41–22–749–01–11, *http://www.iso.org*.

(1) ISO/IEC 17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005, IBR approved for § 170.503.

(2) ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for § 170.503.

(3) [Reserved]

PARTS 171–199 [RESERVED]