

SUBCHAPTER A—GENERAL ADMINISTRATION

PART 1—HHS'S REGULATIONS

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- 1.1 Location of HHS regulations.
- 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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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 a Department of Health and Human Services employee, 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 the employee's official capacity. This part also sets forth procedures for the handling of subpoenas duces tecum and other requests for any document in the possession of the Department of Health and Human Services other than the Food and Drug Administration, and to requests for certification of copies of documents. Separate regulations, 21 CFR part 20 and 20 CFR part 401, govern the Food and Drug Administration and requests for certain information maintained by the Social Security Administration, and those regulations are not affected by this part.

(b) It is the policy of the Department of Health and Human Services to provide information, data, and records to

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non-federal litigants to the same extent and in the same manner that they are available to the general public. The availability of Department of Health and Human Services' employees to testify in litigation not involving Federal parties is governed by the Department of Health and Human Services' policy on maintaining strict impartiality with respect to private litigants and to minimize the disruption of official duties.

(c) This part applies to state and local court, administrative, and legislative proceedings and Federal court 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 45 CFR 73.735-704 and 73.735-708. (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 Department of Health and Human Services.)

(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, and 20 CFR part 401, involving the Social Security Administration.

(7) Any civil or criminal proceedings in State court brought on behalf of the

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Department of Health and Human Services.

[52 FR 37146, Oct. 5, 1987, as amended at 55 FR 4611, Feb. 9, 1990]

§2.2 Definitions.

Agency Head refers to the head of the relevant operating division or other major component of the Department of Health and Human Services, or his or her delegates. For each component of the Department, the Agency Head for the purposes of this part is as follows:

(1) Office of the Secretary—Assistant Secretary for Management and Budget;

(2) Office of Human Development Services—Assistant Secretary for Human Development Services;

(3) Public Health Service—Assistant Secretary for Health;

(4) Health Care Financing Administration—Administrator;

(5) Family Support Administration—Assistant Secretary for Family Support;

(6) Social Security Administration—Commissioner; and

(7) Office of the Inspector General—Inspector General.

Employee includes commissioned officers in the Public Health Service Commissioned Corps, as well as regular and special Department of Health and Human Services employees (except employees of the Food and Drug Administration), and any employees of health insurance intermediaries and carriers performing functions under agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act, 42 U.S.C. 1395h, 1395u.

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.

[52 FR 37146, Oct. 5, 1987, as amended at 55 FR 4611, Feb. 9, 1990]

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

(a) No Department of Health and Human Services employee 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 employee's official relationship with the Department of Health and Human Services 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 of Health and Human Services.

(b) The Office of the General Counsel will request the assistance of the Department of Justice where necessary to represent the interests of the Department of Health and Human Services and its employees under this part.

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

(a) All requests for testimony by a Department of Health and Human Services employee in his or her official capacity and not subject to the exceptions set forth in §2.1(d), of this part, must be 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 interests of the Department of Health and Human Services 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 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.

§2.5 Subpoenas duces tecum.

(a) Subpoenas duces tecum for records of the Department of Health and Human Services shall be deemed a request for records under the Freedom of Information Act and shall be han-

dled pursuant to the rules governing public disclosure established in 45 CFR Part 5.

(b) Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon a Department of Health and Human Services' employee commanding the production of any record, such employee, after consultation with the Office of the General Counsel, shall appear in response thereto, respectfully decline to produce the record(s) on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures and disclosure rules established in 45 CFR Part 5.

§2.6 Certification and authentication of records.

Upon request, Department of Health and Human Services' agencies will certify the authenticity of copies of records that are to be disclosed pursuant to 45 CFR Part 5 and will authenticate copies of records previously disclosed. Fees for such certification are set forth in 45 CFR 5.43(e).

[52 FR 37146, Oct. 5, 1987, as amended at 55 FR 4611, Feb. 9, 1990]

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