

## 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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- 2.1 Scope, purpose, and applicability.
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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 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

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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.

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*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

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“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 func-

tions 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.

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

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

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

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

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

[68 FR 25839, May 14, 2003]

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

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

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

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

[68 FR 25840, May 14, 2003]

#### **§ 2.5 Subpoenas duces tecum.**

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

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

[68 FR 25840, May 14, 2003]

#### **§ 2.6 Certification and authentication of records.**

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

[68 FR 25840, May 14, 2003]

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

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- AUTHORITY: 40 U.S.C. 318–318d. 486; Delegation of Authority, 33 FR 604.
- SOURCE: 55 FR 2068, Jan. 22, 1990, unless otherwise noted.

**Subpart A—General**

**§ 3.1 Definitions.**

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

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

*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