

**Department of Health and Human Services****§ 2.2**

“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.

## § 2.3

*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

## 45 CFR Subtitle A (10-1-14 Edition)

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]