

§ 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.

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