

§ 6.3

other officer or employee of the Department of Justice to whom the authority involved has been delegated.

Covered entity means an entity described in § 6.3 which has been deemed by the Secretary, in accordance with § 6.5, to be covered by this part.

Covered individual means an individual described in § 6.4.

Effective date as used in § 6.5 and § 6.6 refers to the date of the Secretary's determination that an entity is a covered entity.

Secretary means the Secretary of Health and Human Services (HHS) and any other officer or employee of the Department of HHS to whom the authority involved has been delegated.

Subrecipient means an entity which receives a grant or a contract from a covered entity to provide a full range of health services on behalf of the covered entity.

§ 6.3 Eligible entities.

(a) *Grantees.* Entities eligible for coverage under this part are public and nonprofit private entities receiving Federal funds under any of the following grant programs:

(1) Section 329 of the Act (relating to grants for migrant health centers);

(2) Section 330 of the Act (relating to grants for community health centers);

(3) Section 340 of the Act (relating to grants for health services for the homeless); and

(4) Section 340A of the Act (relating to grants for health services for residents of public housing).

(b) *Subrecipients.* Entities that are subrecipients of grant funds described in paragraph (a) of this section are eligible for coverage only if they provide a full range of health care services on behalf of an eligible grantee and only for those services carried out under the grant funded project.

§ 6.4 Covered individuals.

(a) Officers and employees of a covered entity are eligible for coverage under this part.

(b) Contractors of a covered entity who are physicians or other licensed or certified health care practitioners are eligible for coverage under this part if they meet the requirements of section 224(g)(5) of the Act.

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(c) An individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of a covered entity will not be covered for acts or omissions occurring after receipt by the entity employing such individual of notice of a final determination by the Attorney General that he or she is no longer covered by this part, in accordance with section 224(i) of the Act.

§ 6.5 Deeming process for eligible entities.

Eligible entities will be covered by this part only on and after the effective date of a determination by the Secretary that they meet the requirements of section 224(h) of the Act. In making such determination, the Secretary will receive such assurances and conduct such investigations as he or she deems necessary.

§ 6.6 Covered acts and omissions.

(a) Only acts and omissions occurring on and after the effective date of the Secretary's determination under § 6.5 and before the later date specified in section 224(g)(3) of the Act are covered by this part.

(b) Only claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions are covered by this part.

(c) With respect to covered individuals, only acts and omissions within the scope of their employment (or contract for services) are covered. If a covered individual is providing services which are not on behalf of the covered entity, such as on a volunteer basis or on behalf of a third-party (except as described in paragraph (d) of this section), whether for pay or otherwise, acts and omissions which are related to such services are not covered.

(d) Only acts and omissions related to the grant-supported activity of entities are covered. Acts and omissions related to services provided to individuals who are not patients of a covered entity will be covered only if the Secretary determines that:

(1) The provision of the services to such individuals benefits patients of the entity and general populations that could be served by the entity through

community-wide intervention efforts within the communities served by such entity;

(2) The provision of the services to such individuals facilitates the provision of services to patients of the entity; or

(3) Such services are otherwise required to be provided to such individuals under an employment contract or similar arrangement between the entity and the covered individual.

(e) *Examples.* The following are examples of situations within the scope of paragraph (d) of this section:

(1) A community health center deemed to be a covered entity establishes a school-based or school-linked health program as part of its grant supported activity. Even though the students treated are not necessarily registered patients of the center, the center and its health care practitioners will be covered for services provided, if the Secretary makes the determination in paragraph (d)(1) of this section.

(2) A migrant health center requires its physicians to obtain staff privileges at a community hospital. As a condition of obtaining such privileges, and thus being able to admit the center's patients to the hospital, the physicians must agree to provide occasional coverage of the hospital's emergency room. The Secretary would be authorized to determine that this coverage is necessary to facilitate the provision of services to the grantee's patients, and that it would therefore be covered by paragraph (d)(2) of this section.

(3) A homeless health services grantee makes arrangements with local community providers for after-hours coverage of its patients. The grantee's physicians are required by their employment contracts to provide periodic cross-coverage for patients of these providers, in order to make this arrangement feasible. The Secretary may determine that the arrangement is within the scope of paragraph (d)(3) of this section.

[60 FR 22532, May. 8, 1995; 60 FR 36073, July 13, 1995]

PART 7—DISTRIBUTION OF REFERENCE BIOLOGICAL STANDARDS AND BIOLOGICAL PREPARATIONS

Sec.

- 7.1 Applicability.
- 7.2 Establishment of a user charge.
- 7.3 Definitions.
- 7.4 Schedule of charges.
- 7.5 Payment procedures.
- 7.6 Exemptions.

AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); title V of the Independent Offices Appropriation Act of 1952 (31 U.S.C. 9701); and sec. 352 of the Public Health Service Act, as amended (42 U.S.C. 263).

SOURCE: 52 FR 11073, Apr. 7, 1987, unless otherwise noted.

§ 7.1 Applicability.

The provisions of this part are applicable to private entities requesting from the Centers for Disease Control (CDC) reference biological standards and biological preparations for use in their laboratories.

§ 7.2 Establishment of a user charge.

Except as otherwise provided in § 7.6, a user charge shall be imposed to cover the cost to CDC of producing and distributing reference biological standards and biological preparations.

§ 7.3 Definitions.

Biological standards means a uniform and stable reference biological substance which allows measurements of relative potency to be made and described in a common currency of international and national units of activity.

Biological preparations means a reference biological substance which may be used for a purpose similar to that of a standard, but which has been established without a full collaborative study, or where a collaborative study has shown that it is not appropriate to establish the preparation as an international standard.

§ 7.4 Schedule of charges.

The charges imposed in § 7.2 are based on the amount published in CDC's price list of available products. These charges will reflect direct costs (such as salaries and equipment), indirect costs (such as rent, telephone service,