

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.

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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,