

PART 7—DISTRIBUTION OF REFERENCE BIOLOGICAL STANDARDS AND BIOLOGICAL PREPARATIONS

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); title V of the Independent Offices Appropriations Act of 1952 (31 U.S.C. 9701); and secs. 301(a) and 352 of the Public Health Service Act, as amended (42 U.S.C. 241(a) and 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 and Prevention (CDC) reference biological Standards and Biological preparations for use in their laboratories.

[78 FR 43820, July 22, 2013]

§ 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 changes will reflect direct costs (such

as salaries and equipment), indirect costs (such as rent, telephone service, and a proportionate share of management and administrative costs), and the cost of particular ingredients. Charges may vary over time and between different biological standards or biological preparations, depending upon the cost of ingredients and the complexity of production. An up-to-date schedule of charges is available from the Division of Scientific Resources, Centers for Disease Control, 1600 Clifton Road NE., MS C-17, Atlanta, Georgia, 30333 or 404-639-3466.

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§ 7.5 Payment procedures.

An up-to-date fee schedule and instructions for terms of payment are available from the Division of Scientific Resources, Centers for Disease Control and Prevention, 1600 Clifton Road, MS C-17, Atlanta, Georgia 30333 or 404-639-3466. Any changes in the fee schedule will be published in the FEDERAL REGISTER. The fee must be paid in U.S. dollars at the time that the requester requests the biological reference standard or biological preparation.

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§ 7.6 Exemptions.

State and local health departments, governmental institutions (e.g., State hospitals and universities), the World Health Organization, and ministries of health of foreign governments may be exempted from paying user charges, when using biological standards or biological preparations for public health purposes.

PART 8—MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER

Subpart A—General Provisions

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- 8.3 Application for approval as an Accreditation Body.