

hospital as a condition for obtaining hospital admitting privileges. There must also be documentation for the particular health care provider that this coverage is a condition of employment at the health center.

(iii) *Coverage-Related Activities.* As part of a health center's arrangement with local community providers for after-hours coverage of its patients, the health center's providers are required by their employment contract to provide periodic or occasional cross-coverage for patients of these providers.

(iv) *Coverage in Certain Individual Emergencies.* A health center provider is providing or undertaking to provide covered services to a health center patient within the approved scope of project of the center, or to an individual who is not a patient of the health center under the conditions set forth in this rule, when the provider is then asked, called upon, or undertakes, at or near that location and as the result of a non-health center patient's emergency situation, to temporarily treat or assist in treating that non-health center patient. In addition to any other documentation required for the original services, the health center must have documentation (such as employee manual provisions, health center bylaws, or an employee contract) that the provision of individual emergency treatment, when the practitioner is already providing or undertaking to provide covered services, is a condition of employment at the health center.

[60 FR 22532, May 8, 1995; 60 FR 36073, July 13, 1995; 78 FR 58204, Sept. 23, 2013]

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 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,

Public Health Service, HHS

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1600 Clifton Road NE., MS C-17, Atlanta, Georgia, 30333 or 404-639-3466.

[78 FR 43820, July 22, 2013]

§ 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.

[78 FR 43820, July 22, 2013]

§ 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—CERTIFICATION OF OPIOID TREATMENT PROGRAMS

Subpart A—Accreditation

Sec.

- 8.1 Scope.
- 8.2 Definitions.
- 8.3 Application for approval as an accreditation body.
- 8.4 Accreditation body responsibilities.
- 8.5 Periodic evaluation of accreditation bodies.
- 8.6 Withdrawal of approval of accreditation bodies.

Subpart B—Certification and Treatment Standards

- 8.11 Opioid treatment program certification.
- 8.12 Federal opioid treatment standards.
- 8.13 Revocation of accreditation and accreditation body approval.
- 8.14 Suspension or revocation of certification.

- 8.15 Forms.

Subpart C—Procedures for Review of Suspension or Proposed Revocation of OTP Certification, and of Adverse Action Regarding Withdrawal of Approval of an Accreditation Body

- 8.21 Applicability.
- 8.22 Definitions.
- 8.23 Limitation on issues subject to review.
- 8.24 Specifying who represents the parties.
- 8.25 Informal review and the reviewing official's response.
- 8.26 Preparation of the review file and written arguments.
- 8.27 Opportunity for oral presentation.
- 8.28 Expedited procedures for review of immediate suspension.
- 8.29 Ex parte communications.
- 8.30 Transmission of written communications by reviewing official and calculation of deadlines.
- 8.31 Authority and responsibilities of the reviewing official.
- 8.32 Administrative record.
- 8.33 Written decision.
- 8.34 Court review of final administrative action; exhaustion of administrative remedies.

AUTHORITY: 21 U.S.C. 823; 42 U.S.C. 257a, 290aa(d), 290dd-2, 300x-23, 300x-27(a), 300y-11.

SOURCE: 66 FR 4090, Jan. 17, 2001, unless otherwise noted.

Subpart A—Accreditation

§ 8.1 Scope.

The regulations in this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid addiction. These regulations also establish the Secretary's standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner who intends to dispense opioid drugs in the treatment of opioid addiction must first obtain from the Secretary or by delegation, from the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is