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PART 7—DISTRIBUTION OF REFERENCE BIOLOGICAL STANDARDS AND BIOLOGICAL PREPARATIONS

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7.1 Applicability.
7.2 Establishment of a user charge.
7.3 Definitions.
7.4 Schedule of charges.
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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, 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—MEDICATIONS FOR THE TREATMENT OF OPIOID USE DISORDER

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

SOURCE: 89 FR 7549, Feb. 2, 2024, unless otherwise noted.

Subpart A—General Provisions

§ 8.1 Scope.

(a) *Scope*. This subpart and subparts B through D of this part establish the procedures by which the Secretary of Health and Human Services (the Secretary) will determine whether an applicant seeking to become an Opioid Treatment Program (OTP) is qualified under section 303(h) of the Controlled Substances Act (CSA) (21 U.S.C. 823(h)) to dispense Medications for Opioid Use Disorder (MOUD) in the treatment of Opioid Use Disorder (OUD), and establishes the Secretary's standards regarding the appropriate quantities of MOUD that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(h)). Under this subpart and subparts B through D, an applicant seeking to become an OTP must first obtain from the Secretary or, by delegation, from the Assistant Secretary for Mental Health and Substance Use, a certification that the applicant is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the applicant obtaining accreditation from an Accreditation Body that has been approved by the Secretary. This subpart and subparts B through D also establish the procedures whereby an entity can apply to become an approved Accreditation Body, and the requirements and general standards for Accreditation Bodies to ensure that OTPs are consistently evaluated for compliance with the Secretary's standards for treatment of OUD with MOUD.

(b) *Severability*. Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, shall be construed so as to give it the maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§thnsp;8.2 Definitions.

The following definitions apply to this part:

Accreditation Body or *''the Body''* means an organization that has been approved by the Secretary in this part to accredit OTPs dispensing MOUD.

Accreditation Body application means the application filed with the Secretary for purposes of obtaining approval as an Accreditation Body, as described in §8.3(b).

Accreditation elements mean the elements or standards that are developed and adopted by an Accreditation Body and approved by the Secretary.

Accreditation survey means an onsite or virtual review and evaluation of an OTP by an Accreditation Body for the purpose of determining compliance with the Federal opioid use disorder treatment standards described in §8.12.

Accredited OTP means an OTP that is the subject of a current, valid accreditation from an Accreditation Body approved by the Secretary under §8.3(d).

Behavioral health services means any intervention carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered clinical interventions (*e.g.*, cognitive behavior therapy or insight-oriented psychotherapy) delivered in-person, or remotely via telehealth or telemedicine, which has been shown to facilitate treatment outcomes, or nonclinical interventions.

Care plan means an individualized treatment and/or recovery plan that outlines attainable treatment goals that have been identified and agreed upon between the patient and the OTP clinical team, and which specifies the services to be provided, as well as the proposed frequency and schedule for their provision.

Certification means the process by which the Secretary determines that an OTP is qualified to provide OUD treatment under the Federal Opioid Use Disorder treatment standards.

Certification application means the application filed by an OTP for purposes of obtaining certification from the Secretary, as described in §8.11(b).

Certified opioid treatment program means an OTP that is the subject of a current, valid certification under §8.11.

Comprehensive treatment is treatment that includes the continued use of MOUD provided in conjunction with an individualized range of appropriate harm reduction, medical, behavioral health, and recovery support services.

Conditional certification is a type of temporary certification granted to an OTP that has requested renewal of its certification and that has received temporary accreditation for one year by an approved Accreditation Body. The one-year accreditation period is to allow the OTP to address areas of significant non-conformance with accreditation standards that do not involve immediate, high-risk health and/or safety concerns.

Continuous medication treatment means the uninterrupted treatment for OUD involving the dispensing and administration of MOUD at stable dosage levels for a period in excess of 21 days.

Dispense means to deliver a controlled medication to an ultimate user by, or pursuant to, the lawful order of, a practitioner, including the prescribing and administering of a controlled medication.

Diversion control plan means a set of documented procedures that reduce the possibility that controlled medications will be transferred or otherwise shared with others to whom the medication was not prescribed or dispensed.

Federal Opioid Use Disorder treatment standards means the standards established by the Secretary in §8.12 that are used to determine whether an OTP is qualified to engage in OUD treatment. The Federal Opioid Use Disorder treatment standards established in §8.12 also include the standards established by the Secretary regarding the quantities of MOUD which may be provided for unsupervised, take-home use.

For-cause inspection means an inspection, by the Secretary, an Accreditation Body, or a State authority, of an OTP that may be operating in violation of Federal Opioid Use Disorder treatment standards, may be providing substandard treatment, may be serving as a possible source of diverted medications, or where patient well-being is at risk.

Harm reduction refers to practical and legal evidence-based strategies, including: overdose education; testing and intervention for infectious diseases, including counseling and risk mitigation activities forming part of a comprehensive, integrated approach to address human immunodeficiency virus (HIV), viral hepatitis, sexually transmitted

infections, and bacterial and fungal infections; distribution of opioid overdose reversal medications; linkage to other public health services; and connecting those who have expressed interest in additional support to peer services.

Individualized dose means the dose of a medication for opioid use disorder, ordered by an OTP practitioner and dispensed to a patient, that sufficiently suppresses opioid withdrawal symptoms. Individualized doses may also include split doses of a medication for opioid use disorder, where such dosing regimens are indicated.

Interim treatment means that on a temporary basis, a patient may receive some services from an OTP, while awaiting access to more comprehensive treatment services. The duration of interim treatment is limited to 180 days.

Long-term care facilities mean those facilities that provide rehabilitative, restorative, and/or ongoing services to those in need of assistance with activities of daily living. Long-term care facilities include: extended acute care facilities; rehabilitation centers; skilled nursing facilities; permanent supportive housing; assisted living facilities; and chronic care hospitals.

Medical director means a physician, licensed to practice medicine in the jurisdiction in which the OTP is located, who assumes responsibility for all medical and behavioral health services provided by the program, including their administration. A medical director may delegate specific responsibilities to authorized program physicians, appropriately licensed non-physician practitioners with prescriptive authority functioning under the medical director's supervision, or appropriately licensed and/or credentialed non-physician healthcare professionals providing services in the OTP, in compliance with applicable Federal and State laws. Such delegations will not eliminate the medical director's responsibility for all medical and behavioral health services provided by the OTP.

Medication for Opioid Use Disorder or *MOUD* means medications, including opioid agonist medications, approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), for use in the treatment of OUD. As used in this part, ''continuous medication treatment'' is intended to be synonymous with the term ''maintenance'' treatment as used in 21 U.S.C. 823(h)(1), and the term ''withdrawal management'' is intended to be synonymous with the term ''detoxification'' as used in 21 U.S.C. 823(h)(1).

Medication unit means an entity that is established as part of, but geographically separate from, an OTP from which appropriately licensed OTP practitioners, contractors working on behalf of the OTP, or community pharmacists may dispense or administer MOUD, collect samples for drug testing or analysis, or provide other OTP services. Medication units can be a brick-and-mortar location or mobile unit.

Nationally recognized evidence-based guidelines mean a document produced by a national or international medical professional association, public health agency, such as the World Health Organization, or governmental body with the aim of assuring the appropriate use of evidence to guide individual diagnostic and therapeutic clinical decisions for the management of OUD and other health conditions that are widely recognized within the United States.

Opioid Treatment Program or *OTP* means a program engaged in OUD treatment of individuals with MOUD registered under 21 U.S.C. 823(h)(1).

Opioid Treatment Program certification means the process by which the Secretary determines that an OTP applicant is qualified to provide Opioid Use Disorder treatment under the Federal Opioid Use Disorder treatment standards described in §8.12.

Opioid Use Disorder means a cluster of cognitive, behavioral, and physiological symptoms associated with a problematic pattern of opioid use that continues despite clinically significant impairment or distress within a 12-month period.

Opioid Use Disorder treatment means the dispensing of MOUD, along with the provision of a range of medical and behavioral health services, as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan, to an individual to alleviate the combination of adverse

medical, psychological, or physical effects associated with an OUD.

Patient, for purposes of this part, means any individual who receives continuous treatment or withdrawal management in an OTP.

Physical and behavioral health services include services such as medical and psychiatric screening, assessments, evaluations, examinations, and interventions, counseling, health education, peer support services, and social services (*e.g.*, vocational and educational guidance, employment training), that are intended to help patients receiving care in OTPs achieve and sustain remission and recovery.

Practitioner, for purposes of this part, means a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP.

Program sponsor means the person named in the application for certification described in §8.11(b) as responsible for the operation of the OTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, behavioral health, or social services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall ensure that an actively licensed physician occupies the position of medical director within an OTP.

Recovery support services means:

(1) *Recovery* is the process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential.

(2) *Recovery support services* can include, but are not limited to, community-based recovery housing, peer recovery support services, social support, linkage to and coordination among allied service providers and a full range of human services that facilitate recovery and wellness contributing to an improved quality of life. The services extend the continuum of care by strengthening and complementing substance use disorder (SUD) treatment interventions in different settings and stages.

Split dosing means dispensing of a single dose of MOUD as separate portions to be taken within a 24-hour period. Split dosing is indicated among, but not limited to, those patients who: possess a genetic variant which increases methadone metabolism; concurrently take other medications or drink alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent pain indication in addition to the diagnosis of OUD. This leads to more stable, steady-state medication levels.

State Opioid Treatment Authority (SOTA) is the agency designated by the Governor of a State, or other appropriate official designated by the Governor, to exercise the responsibility and authority within the State or Territory for governing the treatment of OUD with MOUD in OTPs.

Telehealth or *telemedicine*, *for purposes of this part*, is the delivery and facilitation of health and health-related services including medical care, counseling, practitioner, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies. This includes Health Insurance Portability and Accountability Act (HIPAA)-compliant video and audio-only communication platforms.

Withdrawal management means the dispensing of a MOUD in decreasing doses to an individual to alleviate adverse physical effects incident to withdrawal from the continuous or sustained use of an opioid and as a method of bringing the individual to an opioid-free state within such period. Long-term withdrawal management refers to the process of medication tapering that exceeds 30 days.

Subpart B—Accreditation of Opioid Treatment Programs

§ 8.3 Application for approval as an Accreditation Body.

(a) *Eligibility.* Private nonprofit organizations, State or territorial governmental entities, or political subdivisions thereof, and Indian Tribes as defined by the Federally Recognized Indian Tribe List Act of 1994, that are capable of meeting the requirements of this part may apply for approval as an Accreditation Body.

(b) *Application for initial approval.* Electronic copies of an Accreditation Body application form [SMA–167] shall be submitted to: *https://dpt2.samhsa.gov/sma163/.* Accreditation Body applications shall include the following information and supporting documentation:

(1) Name, address, and telephone number of the applicant and a responsible official for the Accreditation Body. The application shall be signed by the responsible official;

(2) Evidence of the nonprofit status of the applicant (*i.e.*, of fulfilling Internal Revenue Service requirements as a nonprofit organization) if the applicant is not a State or territorial governmental entity, Indian Tribe, or political subdivision;

(3) A set of the accreditation elements or standards and a detailed discussion showing how the proposed accreditation elements or standards will ensure that each OTP surveyed by the applicant is qualified to meet or is meeting each of the Federal opioid use disorder treatment standards set forth in § 8.12;

(4) A detailed description of the applicant's decision-making process, including:

(i) Procedures for initiating and performing onsite accreditation surveys of OTPs;

(ii) Procedures for assessing OTP personnel qualifications;

(iii) Copies of an application for accreditation, guidelines, instructions, and other materials the applicant will send to OTPs during the accreditation process, including a request for a complete history of prior accreditation activities and a statement that all information and data submitted in the application for accreditation is true and accurate, and that no material fact has been omitted;

(iv) Policies and procedures for notifying OTPs and the Secretary of deficiencies, for monitoring corrections of deficiencies by OTPs and for reporting corrections to the Secretary;

(v) Policies and procedures for determining OTPs level of adherence to this part and Accrediting Body standards and level of accreditation;

(vi) Policies and procedures for suspending or revoking an OTP's accreditation;

(vii) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a timeframe approved by the Secretary; and

(viii) A description of the applicant's appeals process to allow OTPs to contest adverse accreditation decisions;

(5) Policies and procedures established by the Accreditation Body to avoid conflicts of interest, or the appearance of conflicts of interest, by the applicant's board members, commissioners, professional personnel, consultants, administrative personnel, and other representatives;

(6) A description of the education, experience, and training requirements for the applicant's professional staff, accreditation survey team membership, and the identification of at least one licensed physician with experience treating OUD with MOUD on the applicant's staff;

(7) A description of the applicant's survey team training policies;

(8) Fee schedules, with supporting cost data;

(9) Satisfactory assurances that the Body will comply with the requirements of § 8.4, including a contingency plan for investigating complaints under § 8.4(e);

(10) Policies and procedures established to protect confidential information the applicant will collect or receive in its role as an Accreditation Body; and

(11) Any other supporting information the Secretary may require.

(c) *Application for renewal of approval.* An Accreditation Body that intends to continue to serve as an Accreditation Body beyond its current term shall apply to the Secretary for renewal, or

notify the Secretary of its intention not to apply for renewal, in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of an Accreditation Body's term of approval, the Body shall inform the Secretary in writing of its intent to seek renewal.

(2) The Secretary will notify the applicant of the relevant information, materials, and supporting documentation required under paragraph (b) of this section that the applicant shall submit as part of the renewal procedure.

(3) At least 3 months before the date of expiration of the Accreditation Body's term of approval, the applicant shall send to the Secretary electronically a renewal application containing the information, materials, and supporting documentation requested by the Secretary under paragraph (c)(2) of this section.

(4) An Accreditation Body that does not intend to renew its approval shall so notify the Secretary at least 9 months before the expiration of the Body's term of approval.

(d) *Rulings on applications for initial approval or renewal of approval.* (1) The Secretary will grant an application for initial approval or an application for renewal of approval if it determines the applicant substantially meets the Accreditation Body requirements of this subpart.

(2) If the Secretary determines that the applicant does not substantially meet the requirements set forth in this subpart, the Secretary will notify the applicant of the deficiencies in the application and request that the applicant resolve such deficiencies within 90 days of receipt of the notice. If the deficiencies are resolved to the satisfaction of the Secretary within the 90-day time period, the Body will be approved as an Accreditation Body. If the deficiencies have not been resolved to the satisfaction of the Secretary within the 90-day time period, the application for approval as an Accreditation Body will be denied.

(3) If the Secretary does not reach a final decision on a renewal application before the expiration of an Accreditation Body's term of approval, the approval will be deemed extended until the Secretary reaches a final decision, unless an Accreditation Body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of approval.* An Accreditation Body that intends to relinquish its accreditation approval before expiration of the Body's term of approval shall submit a letter of such intent to the Secretary, at the address in paragraph (b) of this section, at least 9 months before relinquishing such approval.

(f) *Notification.* An Accreditation Body that does not apply for renewal of approval, or is denied such approval by the Secretary, relinquishes its accreditation approval before expiration of its term of approval, or has its approval withdrawn, shall:

(1) Transfer copies of records and other related information as required by the Secretary to a location, including another Accreditation Body, and according to a schedule approved by the Secretary; and

(2) Notify, in a manner and time period approved by the Secretary, all OTPs accredited or seeking accreditation by the Body that the Body will no longer have approval to provide accreditation services.

(g) *Term of approval.* An Accreditation Body's term of approval is for a period not to exceed 5 years.

(h) *State, territorial, or Indian Tribe Accreditation Bodies.* State, territorial, and Indian Tribe entities, including political subdivisions thereof, may establish organizational units that may act as Accreditation Bodies, provided such units meet the requirements of this section, are approved by the Secretary under this section, and have taken appropriate measures to prevent actual or apparent conflicts of interest, including cases in which State or Federal funds are used to support MOUD.

§ 8.4 Accreditation Body responsibilities.

(a) *Accreditation surveys and for cause inspections.* (1) Accreditation Bodies shall conduct routine accreditation surveys for initial accreditation, and

then at least every three years to allow for renewal of certification.

(2) Accreditation Bodies must agree to conduct for-cause inspections upon the request of the Secretary.

(3) Accreditation decisions shall be fully consistent with the policies and procedures submitted as part of the approved Accreditation Body application.

(b) *Response to noncompliant programs.* (1) If an Accreditation Body receives or discovers information that suggests that an OTP is not meeting applicable accreditation or certification standards established or authorized under this part, or if a survey of the OTP by the Accreditation Body demonstrates that such standards are not being met, the Accreditation Body shall, within 60 days following discovery of the non-compliant condition(s) or applicable survey date:

(i) Provide written notice to the OTP that identifies each area of non-compliance, categorizes each non-compliant condition as either ''minor'' or ''significant'' as determined by the Accrediting Body, and requires the OTP to take corrective action to address the area(s) of non-compliance within a schedule, not to exceed 180 days, that the Accrediting Body deems appropriate based on the severity of the non-compliant conditions; and

(ii) Provide the Secretary with a copy of the written notice required under paragraph (b)(1)(i) of this section.

(2) Once an Accreditation Body provides an OTP with the notice described in paragraph (b)(1)(i) of this section, it shall verify the implementation of the corrective measures by the OTP within the specified schedule. Within 30 days following the last day of the specified schedule, the Accreditation Body shall provide written notice to the Secretary regarding whether the OTP has implemented the corrective measures.

(3) OTPs that are meeting the requirements of § 8.12, but are only required to correct minor non-compliant conditions shall be granted a three-year accreditation, beginning from the end date of the current and expiring accreditation period. Minor non-compliant conditions, found at the time of the survey that are not resolved, as determined by the Accreditation Body, within the OTP's three-year accreditation period and that remain areas of non-compliance during the OTP's subsequent three-year accreditation renewal survey, shall automatically be categorized as ''significant'' non-compliant conditions for purposes of the renewal survey and must be corrected in accordance with paragraph (b)(1)(i) of this section.

(4) OTPs that are required to correct significant non-compliant conditions shall be granted a one-year accreditation, beginning from the end date of the current and expiring accreditation period. An OTP's accreditation must be revoked if it fails to correct significant non-compliant conditions within the schedule provided under paragraph (b)(1)(i) of this section. If an Accrediting Body verifies that an OTP has corrected the significant non-compliant conditions identified within the specified schedule, it shall extend the OTP's accreditation period by an additional two years.

(5) In cases of severe non-compliance with the requirements of § 8.12 that pose immediate risks to patient health and safety, the Accreditation Body shall inform the OTP and Secretary within 48 hours and provide a detailed written report of the non-compliance within 5 business days. The Accreditation Body shall give the OTP 30 days from the date of the non-compliance report to correct the non-compliance issue(s). A follow-up survey shall be conducted by the Accreditation Body within 30 days of the expected correction date to ensure successful remediation. Should the OTP not rectify the non-compliance within the 30-day period, the Accreditation Body shall revoke the OTP's accreditation. The Secretary will then make a decision regarding the OTP's certification in accordance with the procedures under § 8.13.

(c) *Recordkeeping.* (1) Accreditation Bodies shall maintain, and make available as requested by the Secretary, records of their accreditation activities for at least 5 years from the creation of the record. Such records must contain sufficient detail to support each accreditation decision made by the Accreditation Body.

(2) Accreditation Bodies shall establish procedures to protect confidential information collected or received in their role as Accreditation Bodies that are consistent with, and that are designed to ensure compliance with, all Federal and State laws, including 42 CFR part 2.

(i) Information collected or received for the purpose of carrying out Accreditation Body responsibilities shall not be used for any other purpose or disclosed, other than to the Secretary or its duly designated representatives, unless otherwise required by law or with the consent of the OTP.

(ii) Nonpublic information that the Secretary shares with the Accreditation Body concerning an OTP shall not be further disclosed except with the written permission of the Secretary.

(d) *Reporting.* (1) Accreditation Bodies shall provide to the Secretary any documents and information requested by the Secretary within 5 days of receipt of the request.

(2) Accreditation Bodies shall submit a summary of the results of each accreditation survey to the Secretary within 90 days following the survey visit. Such summaries shall contain sufficient detail to justify the accreditation action taken.

(3) Accreditation Bodies shall provide the Secretary a list of each OTP surveyed, and the identity of all individuals involved in the conducting and reporting of survey results.

(4) Accreditation Bodies shall submit to the Secretary the name of each OTP for which the Accreditation Body accredits conditionally, denies, suspends, or revokes accreditation, and the basis for the action, within 48 hours of the action.

(5) Notwithstanding any reports made to the Secretary under paragraphs (d)(1) through (4) of this section, each Accreditation Body shall submit to the Secretary semiannually, on January 15 and July 15 of each calendar year, a report consisting of a summary of the results of each accreditation survey conducted in the past year. The summary shall contain sufficient detail to justify each accreditation action taken.

(6) All reporting requirements listed in this section shall be provided to the Secretary at the address specified in §8.3(b).

(e) *Complaint response.* Accreditation Bodies shall have policies and procedures in place to respond to complaints received from the Secretary, patients, facility staff, and others within 5 business days from the receipt of the complaint. Accreditation Bodies shall also agree to notify the Secretary within 5 business days of receipt of a complaint from a patient, facility, staff or others, and to inform the Secretary of their response to the complaint.

(f) *Modifications of accreditation elements.* Accreditation Bodies shall obtain the Secretary's written authorization prior to making any substantive (*i.e.,* noneditorial) change in accreditation elements.

(g) *Conflicts of interest.* The Accreditation Body shall maintain and apply policies and procedures that the Secretary has approved in accordance with §8.3 to reduce the possibility of actual conflict of interest, or the appearance of a conflict of interest, on the part of individuals who act on behalf of the Accreditation Body. Individuals who participate in accreditation surveys or otherwise participate in the accreditation decision or an appeal of the accreditation decision, as well as their spouses and minor children, shall not have a financial interest in the OTP that is the subject of the accreditation survey or decision.

(h) *Accreditation teams.* (1) An Accreditation Body survey team shall consist of healthcare professionals with expertise in OUD treatment. The Accreditation Body shall consider factors such as the size of the OTP, the anticipated number of survey non-compliance issues, and the OTP's accreditation history in determining the composition of the team. At a minimum, survey teams shall consist of at least two healthcare professionals whose combined expertise includes:

(i) The dispensing and administration of medications subject to control under the Controlled Substances Act (21 U.S.C. 801 *et seq.*);

(ii) Medical issues relating to the dosing and administration of MOUD for the treatment of OUD;

(iii) Psychosocial counseling of individuals receiving OUD treatment; and

(iv) Organizational and administrative issues associated with OTPs.

(2) Members of the accreditation team must be able to recuse themselves at any time from any survey in which either they or the OTP believes there is an actual conflict of interest or the appearance of a conflict of interest. Conflict or perceived conflict of interest must be documented by the Accreditation Body and made available to the Secretary.

(i) *Accreditation fees.* Fees charged to OTPs for accreditation shall be reasonable. the Secretary generally will find fees to be reasonable if the fees are limited to recovering costs to the Accreditation Body, including overhead incurred. Accreditation Body activities that are not related to accreditation functions are not recoverable through fees established for accreditation.

(1) The Accreditation Body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different OTPs.

(2) At the Secretary's request, Accreditation Bodies shall provide to the Secretary financial records or other materials, in a manner specified by the Secretary, to assist in assessing the reasonableness of Accreditation Body fees.

§ 8.5 Periodic evaluation of Accreditation Bodies.

The Secretary will periodically evaluate the performance of Accreditation Bodies primarily by inspecting a selected sample of the OTPs accredited by the Accrediting Body, and by evaluating the Accreditation Body's reports of surveys conducted, to determine whether the OTPs surveyed and accredited by the Accreditation Body are in compliance with applicable standards under this part. The evaluation will include a determination of whether there are major deficiencies in the Accreditation Body's performance that, if not corrected, would warrant withdrawal of the approval of the Accreditation Body under § 8.6.

§ 8.6 Withdrawal of approval of Accreditation Bodies.

If the Secretary determines that an Accreditation Body is not in substantial compliance with this subpart, the Secretary shall take appropriate action as follows:

(a) *Major deficiencies.* If the Secretary determines that the Accreditation Body has a major deficiency, such as commission of fraud, material false statement, failure to perform a major accreditation function satisfactorily, or significant noncompliance with the requirements of this subpart, the Secretary shall withdraw approval of that Accreditation Body.

(1) In the event of a major deficiency, the Secretary shall notify the Accreditation Body of the agency's action and the grounds on which the approval was withdrawn.

(2) An Accreditation Body that has lost its approval shall notify each OTP that has been accredited or is seeking accreditation that the Accreditation Body's approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by the Secretary.

(b) *Minor deficiencies.* If the Secretary determines that the Accreditation Body has minor deficiencies in the performance of an accreditation function, that are less serious or more limited than the types of deficiencies described in paragraph (a) of this section, the Secretary will notify the Body that it has 90 days to submit to the Secretary a plan of corrective action. The plan must include a summary of corrective actions and a schedule for their implementation. The Secretary may place the Body on probationary status for a period of time determined by the Secretary, or may withdraw approval of the Body if corrective action is not taken.

(1) If the Secretary places an Accreditation Body on probationary status, the Body shall notify all OTPs that have been accredited, or that are seeking accreditation, of the Accreditation Body's probationary status within a time period and in a manner approved by the Secretary.

(2) Probationary status will remain in effect until such time as the Body can demonstrate to the satisfaction of the Secretary that it has successfully implemented or is implementing the corrective action plan within the established schedule, and the corrective

actions taken have substantially eliminated all identified problems.

(3) If the Secretary determines that an Accreditation Body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, the Secretary may withdraw approval of the Accreditation Body. The Accreditation Body shall notify all OTPs that have been accredited, or are seeking accreditation, of the Accreditation Body's loss of the Secretary's approval within a time period and in a manner approved by the Secretary.

(c) *Reapplication.* (1) An Accreditation Body that has had its approval withdrawn may submit a new application for approval if the Body can provide information to the Secretary to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If the Secretary determines that the new application demonstrates that the Body satisfactorily has addressed the causes of its previous unacceptable performance, the Secretary may reinstate approval of the Accreditation Body.

(3) The Secretary may request additional information or establish additional conditions that must be met before the Secretary approves the reapplication.

(4) The Secretary may refuse to accept an application from a former Accreditation Body whose approval was withdrawn because of fraud, material false statement, or willful disregard of public health.

(d) *Hearings.* An opportunity to challenge an adverse action taken regarding withdrawal of approval of an Accreditation Body shall be addressed through the relevant procedures set forth in subpart C of this part, except that the procedures in § 8.28 for expedited review of an immediate suspension would not apply to an Accreditation Body that has been notified under paragraph (a) or (b) of this section of the withdrawal of its approval.

Subpart C—Certification and Treatment Standards for Opioid Treatment Programs

§ 8.11 Opioid Treatment Program certification.

(a) *General.* (1) An OTP must be the subject of a current, valid certification from the Secretary to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 U.S.C. 823(h)(1)) to dispense MOUD in the treatment of OUD. An OTP must be determined to be qualified under section 303(g)(1) of the Controlled Substances Act, and must be determined to be qualified by the Attorney General under section 303(g)(1), to be registered by the Attorney General to dispense MOUD to individuals for treatment of OUD.

(2) To obtain certification from the Secretary, an OTP must meet the Federal Opioid Use Disorder treatment standards in § 8.12, must be the subject of a current, valid accreditation by an Accreditation Body or other entity designated by the Secretary and must comply with any other conditions for certification established by the Secretary.

(3) OTPs are expected to maintain certification with the Secretary and to comply with any other conditions for certification established by the Secretary. Certification shall be granted for a term not to exceed 3 years, except that certification may be renewed during the final certification year if the OTP applies for certification renewal in accordance with the steps outlined in paragraph (a)(4) of this section.

(4) OTPs which satisfy the criteria for certification under this section may apply for renewal of their certification. OTPs are expected to apply for certification renewal during the final year of the OTP's certification period. OTPs should take steps to ensure that administrative tasks associated with renewal are completed before the OTP's certification expires. OTPs may apply for certification renewal in accordance with the procedures as outlined in paragraph (b) of this section. If an OTP anticipates any delays in routine certification renewal, an extension may be

requested by submitting to the Secretary a statement justifying the extension in accordance with paragraph (e) of this section.

(5) OTPs that are certified and are seeking certification renewal, and who have been granted accreditation for one year by an Accreditation Body as provided under §8.4(b)(1)(iii), may receive a conditional certification for one year unless the Secretary determines that such conditional certification would adversely affect patient health. An OTP must obtain a standard 3-year certification, as described in paragraph (a)(3) of this section, within the 1-year conditional certification period. If standard accreditation is not obtained by the OTP within the 1-year conditional certification period, the OTP's conditional certification will lapse, and the Attorney General will be notified that the OTP's registration should be revoked.

(6) OTPs whose certification has expired, and who seek re-certification, will be considered ''new'' programs and will be required to apply for provisional certification in accordance with paragraph (d) of this section.

(b) *Application for initial or renewal certifications and re-certification.* Applications for certification must be submitted by the OTP using form SMA–162. The application for initial or renewal of certification shall include, as determined by the Secretary:

(1) A description of the current accreditation status of the OTP;

(2) A description of the organizational structure of the OTP;

(3) The names of the persons responsible for the OTP;

(4) The addresses of the OTP and of each medication unit or other facility under the of the OTP;

(5) The sources of funding for the OTP and the name and address of each governmental entity that provides such funding;

(6) A statement that the OTP will comply with the conditions of certification set forth in paragraph (g) of this section; and

(7) The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

(8) Applications for re-certification shall include an explanation of why the OTP's most recent certification expired and information regarding the schedule for an accreditation survey.

(c) *Action on application.* (1) Following the Secretary's receipt of an application for certification of an OTP, and after consultation with the appropriate State authority regarding the qualifications of the applicant, the Secretary may grant the application for certification, or renew an existing certification, if the Secretary determines that the OTP has satisfied the requirements for certification or renewal of certification in this section.

(2) The Secretary may deny the application if the Secretary determines that:

(i) The application for certification is deficient in any respect;

(ii) The OTP will not be operated in accordance with the Federal Opioid Use Disorder treatment standards established under §8.12;

(iii) The OTP will not permit an inspection or a survey to proceed, or will not permit in a timely manner access to relevant records or information; or

(iv) The OTP has made misrepresentations in obtaining accreditation or in applying for certification.

(3) Within 5 days after it reaches a final determination that an OTP meets the requirements for certification in this section, the Secretary will notify the Drug Enforcement Administration (DEA) that the OTP has been determined to be qualified to provide OUD treatment under section 303(g)(1) of the Controlled Substances Act.

(d) *Provisional certification.* New OTPs that have not received the Secretary's certification previously, except as provided in paragraph (a)(6) of this section, who are applying for certification from the Secretary, and who have applied for accreditation with an Accreditation Body, are eligible to receive provisional certification for up to 1 year. To receive provisional certification, an OTP shall submit the information required by paragraph (b) of this section to the Secretary along with a statement identifying the Accreditation Body to which the OTP has applied for accreditation, the date on which the OTP applied for accreditation, the

dates of any accreditation surveys that have taken place or are expected to take place, and the expected schedule for completing the accreditation process. Provisional certification for up to 1 year will be granted, following receipt of the information described in this paragraph (d), unless the Secretary determines that patient health would be adversely affected by the granting of provisional certification.

(e) *Requirements for certification.* (1) OTPs shall comply with all pertinent Federal and State laws and regulations. Nothing in this part is intended to limit the authority of State and, as appropriate, local governmental entities to regulate the use of MOUD in the treatment of OUD. The provisions of this section requiring compliance with requirements imposed by State law, or the submission of applications or reports required by the State authority, do not apply to OTPs operated directly by the Department of Veterans Affairs, the Indian Health Service, or any other department or agency of the United States.

(2) OTPs shall allow, in accordance with Federal controlled substances laws and Federal confidentiality laws, inspections and surveys by duly authorized employees of the Department of Health and Human Services (HHS) or Substance Abuse and Mental Health Services Administration (SAMHSA), by Accreditation Bodies, by the Drug Enforcement Administration (DEA), and by authorized employees of any other Federal governmental entity with legal authority to conduct inspections or surveys on an OTP's premises.

(3) Disclosure of patient records maintained by an OTP is governed by the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164, and every program must comply with these regulations, as applicable. Records on the receipt, storage, and distribution of MOUD are also subject to inspection under Federal controlled substances laws and under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*). Federally sponsored treatment programs are subject to applicable Federal confidentiality statutes.

(4) An OTP or medication unit or any part thereof, including any facility or any individual, shall permit a duly authorized employee of the Department of Health and Human Services or SAMHSA to have access to and to copy all records on the use of MOUD in accordance with the provisions of 42 CFR part 2 and 45 CFR parts 160 and 164.

(5) OTPs shall notify the Secretary in writing within 3 weeks of any replacement or other change in the status of the program sponsor or medical director.

(6) OTPs shall comply with all regulations enforced by the DEA under 21 CFR chapter II and must be registered by the DEA before administering or dispensing MOUD.

(7) OTPs must operate in accordance with Federal Opioid Use Disorder treatment standards and approved accreditation elements.

(f) *Conditions for interim treatment program approval.* (1) Before an OTP may provide interim treatment, the OTP must receive the approval of both the Secretary and the SOTA of the State in which the OTP operates.

(2) Before the Secretary may grant such approval, the OTP must provide the Secretary with documentation from the SOTA of the State in which the OTP operates demonstrating that:

(i) Such officer does not object to the providing of interim treatment in the State;

(ii) The OTP seeking to provide such treatment is unable to provide access for patients in a comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek treatment for OUD;

(iii) The authorization of the OTP to provide interim treatment will not otherwise reduce the capacity of comprehensive treatment programs in the State to admit individuals (relative to the date on which such officer so certifies); and

(iv) OTPs providing interim treatment will arrange for each individual's transfer to a comprehensive treatment program no later than 180 days from the date on which each individual first requested treatment. Individuals enrolled in interim treatment shall not be discharged without the approval of an OTP practitioner, who shall consider on-going and patient-centered treatment needs, which are to be documented in the patient record, while

awaiting transfer to a comprehensive treatment program.

(3) The Secretary will provide notice to the OTP denying or approving the request to provide interim treatment. The OTP shall not provide such treatment until it has received such notice from the Secretary.

(g) *Exemptions.* An OTP may, at the time of application for certification or any time thereafter, request from the Secretary exemption from the regulatory requirements set forth under this section and § 8.12. An example of a case in which an exemption might be granted would be for a private practitioner who wishes to treat a limited number of patients in a non-metropolitan area with few physicians and no OUD treatment services geographically accessible, and requests exemption from some of the staffing and service standards. The OTP shall support the rationale for the exemption with thorough documentation, to be supplied in an appendix to the initial application for certification or in a separate submission. The Secretary will approve or deny such exemptions at the time of application, or any time thereafter, if appropriate. The Secretary shall consult with the appropriate State authority prior to taking action on an exemption request.

(h) *Medication units, long-term care facilities and hospitals.* (1) Certified OTPs may establish medication units that are authorized to dispense MOUD. Before establishing a medication unit, a certified OTP must notify the Secretary by submitting form SMA–162. The OTP must also comply with the provisions of 21 CFR part 1300 before establishing a medication unit. Medication units shall comply with all pertinent State laws and regulations. Medication units include both mobile and brick and mortar facilities.

(2) Specifically, any services that are provided in an OTP may be provided in the medication unit, assuming compliance with all applicable Federal, State, and local law, and the use of units that provide appropriate privacy and have adequate space.

(3) Certification as an OTP under this part is not required for the initiation or continuity of medication treatment or withdrawal management of a patient who is admitted to a hospital, long-term care facility, or correctional facility, that is registered with the Drug Enforcement Administration as a hospital/clinic, for the treatment of medical conditions other than OUD, and who requires treatment of OUD with methadone during their stay, when such treatment is permitted under applicable Federal law.

(i) The term ''long-term care facility'' is defined in § 8.2. Nothing in this section is intended to relieve hospitals, or long-term care facilities and correctional facilities that are registered with the Drug Enforcement Administration as a hospital/clinic, from their obligations to obtain appropriate registration from the Attorney General, under section 303(g) of the Controlled Substances Act. Treatment provided under this section should always comply with applicable Federal laws.

(ii) [Reserved]

§ 8.12 Federal Opioid Use Disorder treatment standards.

(a) *General.* OTPs must provide treatment in accordance with the standards in this section and must comply with these standards as a condition of certification.

(b) *Administrative and organizational structure.* (1) An OTP's organizational structure and facilities shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations. At a minimum, each OTP shall formally designate a program sponsor and medical director. The program sponsor shall agree on behalf of the OTP to adhere to all requirements set forth in this part.

(2) The medical director shall assume responsibility for all medical and behavioral health services performed by the OTP. In addition, the medical director shall be responsible for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations.

(c) *Continuous quality improvement.* (1) An OTP must maintain current quality assurance and quality control plans that include, among other things, annual reviews of program policies and procedures and ongoing assessment of patient outcomes.

(2) An OTP must maintain a current ''Diversion Control Plan'' or ''DCP'' as part of its quality assurance program that contains specific measures to reduce the possibility of diversion of dispensed MOUD, and that assigns specific responsibility to the OTP providers and administrative staff for carrying out the diversion control measures and functions described in the DCP.

(d) *Staff credentials.* Each person engaged in the treatment of OUD must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. All practitioners and other licensed/certified health care providers, including counselors, must comply with the credentialing and maintenance of licensure and/or certification requirements of their respective professions.

(e) *Patient admission criteria*—(1) *Comprehensive treatment.* An OTP shall maintain current procedures designed to ensure that patients are admitted to treatment by qualified personnel who have determined, using accepted medical criteria, that: The person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD, or OUD in remission, or is at high risk for recurrence or overdose. Such decisions must be appropriately documented in the patient's clinical record. In addition, a health care practitioner shall ensure that each patient voluntarily chooses treatment with MOUD and that all relevant facts concerning the use of MOUD are clearly and adequately explained to the patient, and that each patient provides informed consent to treatment.

(2) *Comprehensive treatment for persons under age 18.* Except in States where State law grants persons under 18 years of age the ability to consent to OTP treatment without the consent of another, no person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the relevant State authority consents in writing to such treatment.

(3) *Withdrawal management.* An OTP shall maintain current procedures that are designed to ensure that those patients who choose to taper from MOUD are provided the opportunity to do so with informed consent and at a mutually agreed-upon rate that minimizes taper-related risks. Such consent must be documented in the clinical record by the treating practitioner.

(f) *Required services*—(1) *General.* OTPs shall provide adequate medical, counseling, vocational, educational, and other screening, assessment, and treatment services to meet patient needs, with the combination and frequency of services tailored to each individual patient based on an individualized assessment and the patient's care plan that was created after shared decision making between the patient and the clinical team. These services must be available at the primary facility, except where the program sponsor has entered into a documented agreement with a private or public agency, organization, practitioner, or institution to provide these services to patients enrolled in the OTP. The program sponsor, in any event, must be able to document that these services are fully and reasonably available to patients.

(2) *Initial medical examination.* (i) OTPs shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts:

(A) A screening examination to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD; and

(B) A full history and examination, to determine the patient's broader health status, with lab testing as determined to be required by an appropriately licensed practitioner. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications.

(ii) Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed. Both the screening examination and full examination must be completed by an appropriately licensed practitioner. If the licensed practitioner is not an OTP practitioner, the screening examination must

be completed no more than seven days prior to OTP admission. Where the examination is performed outside of the OTP, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the OTP, and verified by an OTP practitioner.

(iii) A full in-person physical examination, including the results of serology and other tests that are considered to be clinically appropriate, must be completed within 14 calendar days following a patient's admission to the OTP. The full exam can be completed by a non-OTP practitioner, if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws.

(iv) Serology testing and other testing as deemed medically appropriate by the licensed OTP practitioner based on the screening or full history and examination, drawn not more than 30 days prior to admission to the OTP, may form part of the full history and examination.

(v) The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth. When using telehealth, the following caveats apply:

(A) In evaluating patients for treatment with schedule II medications (such as Methadone), audio-visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(B) In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used. The OTP practitioner shall review the examination results and order treatment medications as indicated.

(3) *Special services for pregnant patients.* OTPs must maintain current policies and procedures that reflect the special needs and priority for treatment admission of patients with OUD who are pregnant. Pregnancy should be confirmed. Evidence-based treatment protocols for the pregnant patient, such as split dosing regimens, may be instituted after assessment by an OTP practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocol. Prenatal care and other sex-specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners. Specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the OTP or by referral to appropriate healthcare practitioners.

(4) *Initial and periodic physical and behavioral health assessment services.* (i) Each patient admitted to an OTP shall be given a physical and behavioral health assessment, which includes but is not limited to screening for imminent risk of harm to self or others, within 14 calendar days following admission, and periodically by appropriately licensed/credentialed personnel. These assessments must address the need for and/or response to treatment, adjust treatment interventions, including MOUD, as necessary, and provide a patient-centered plan of care. The full, initial psychosocial assessment must be completed within 14 calendar days of admission and include preparation of a care plan that includes the patient's goals and mutually agreed-upon actions for the patient to meet those goals, including harm reduction interventions; the patient's needs and goals in the areas of education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue. The care plan also must identify the recommended frequency

with which services are to be provided. The plan must be reviewed and updated to reflect responses to treatment and recovery support services, and adjustments made that reflect changes in the context of the person's life, their current needs for and interests in medical, psychiatric, social, and psychological services, and current needs for and interests in education, vocational training, and employment services.

(ii) The periodic physical examination should occur not less than one time each year and be conducted by an OTP practitioner. The periodic physical examination should include review of MOUD dosing, treatment response, other substance use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals. The periodic physical examination should be documented in the patient's clinical record.

(5) *Counseling and psychoeducational services.* (i) OTPs must provide adequate substance use disorder counseling and psychoeducation to each patient as clinically necessary and mutually agreed-upon, including harm reduction education and recovery-oriented counseling. This counseling shall be provided by a program counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, and engage with patients, to contribute to the appropriate care plan for the patient and to monitor and update patient progress. Patient refusal of counseling shall not preclude them from receiving MOUD.

(ii) OTPs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment each patient admitted or readmitted to treatment who has received positive test results for these conditions from initial and/or periodic medical examinations.

(iii) OTPs must provide directly, or through referral to adequate and reasonably accessible community resources, vocational training, education, and employment services for patients who request such services or for whom these needs have been identified and mutually agreed-upon as beneficial by the patient and program staff.

(6) *Drug testing services.* When conducting random drug testing, OTPs must use drug tests that have received the Food and Drug Administration's (FDA) marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment, at a frequency that is in accordance with generally accepted clinical practice and as indicated by a patient's response to and stability in treatment, but no fewer than eight random drug tests per year patient, allowing for extenuating circumstances at the individual patient level. This requirement does not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

(g) *Recordkeeping and patient confidentiality.* (1) OTPs shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care. This system is required to comply with all Federal and State reporting requirements relevant to MOUD approved for use in treatment of OUD. All records are required to be kept confidential in accordance with all applicable Federal and State requirements.

(2) OTPs shall include, as an essential part of the recordkeeping system, documentation in each patient's record that the OTP made a good faith effort to determine whether the patient is enrolled in any other OTP. A patient enrolled in an OTP shall not be permitted to obtain treatment in any other OTP except in circumstances involving an inability to access care at the patient's OTP of record. Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure. If the medical director or program practitioner of the OTP in which the patient is enrolled determines that such circumstances exist, the patient may seek treatment at another OTP,

provided the justification for the particular circumstances are noted in the patient's record both at the OTP in which the patient is enrolled and at the OTP that will provide the MOUD.

(h) *Medication administration, dispensing, and use.* (1) OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner and if consistent with Federal and State law.

(2) OTPs shall use only those MOUD that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of OUD. In addition, OTPs who are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of OUD. Currently the following MOUD will be considered to be approved by the Food and Drug Administration for use in the treatment of OUD:

(i) Methadone;

(ii) Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of OUD; and

(iii) Naltrexone.

(3) OTPs shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosing requirements are met:

(i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral misuse.

(ii) For each new patient enrolled in an OTP, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal. The total dose for the first day should not exceed 50 milligrams unless the OTP practitioner, licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense MOUD, finds sufficient medical rationale, including but not limited to if the patient is transferring from another OTP on a higher dose that has been verified, and documents in the patient's record that a higher dose was clinically indicated.

(4) OTPs shall maintain current procedures adequate to ensure that each MOUD used by the program is administered and dispensed in accordance with its FDA approved product labeling. The program must ensure that any significant deviations from the approved labeling, including deviations with regard to dose, frequency, or the conditions of use described in the approved labeling, are specifically documented in the patient's record.

(i) *Unsupervised or ''take-home'' medication doses.* Unsupervised or ''take-home'' medication doses may be provided under the following circumstances:

(1) Any patient in comprehensive treatment may receive their individualized take-home doses as ordered for days that the clinic is closed for business, including one weekend day (*e.g.*, Sunday) and State and Federal holidays, no matter their length of time in treatment.

(2) OTP decisions on dispensing MOUD to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section shall be determined by an appropriately licensed OTP medical practitioner or the medical director. In determining which patients may receive unsupervised medication doses, the medical director or program medical practitioner shall consider, among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria:

(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;

(ii) Regularity of attendance for supervised medication administration;

(iii) Absence of serious behavioral problems that endanger the patient, the public or others;

(iv) Absence of known recent diversion activity;

(v) Whether take-home medication can be safely transported and stored; and

(vi) Any other criteria that the medical director or medical practitioner considers relevant to the patient's safety and the public's health.

(3) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient's medical record. If it is determined that a patient is safely able to manage unsupervised doses of MOUD, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (iii) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(ii) of this section.

(i) During the first 14 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 7 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 7 days, but decisions must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(ii) From 15 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to 14 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 14 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(iii) From 31 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) provided to a patient is not to exceed 28 days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to 28 days, but this determination must be based on the criteria listed in paragraph (i)(2) of this section. The rationale underlying the decision to provide unsupervised doses of methadone must be documented in the patient's clinical record, consistent with paragraph (g)(2) of this section.

(4) OTPs must maintain current procedures adequate to identify the theft or diversion of take-home medications, including labeling containers with the OTP's name, address, and telephone number. Programs also must ensure that each individual take-home dose is packaged in a manner that is designed to reduce the risk of accidental ingestion, including child-proof containers (see Poison Prevention Packaging Act, Pub. L. 91–601 (15 U.S.C. 1471 *et seq.*)). Programs must provide education to each patient on: Safely transporting medication from the OTP to their place of residence; and the safe storage of take-home doses at the individual's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

(j) *Interim treatment.* (1) The program sponsor of an OTP may admit an individual, who is eligible for admission to comprehensive treatment, into interim treatment if comprehensive services are not readily available within a reasonable geographic area and within 14 days of the individual's seeking treatment. At least two drug tests shall be obtained from patients during the maximum of 180 days permitted for interim treatment. A program shall establish and follow reasonable criteria for establishing priorities for moving patients from interim to comprehensive treatment. These transition criteria shall be in writing and shall include, at a minimum, prioritization of pregnant patients in admitting patients to interim treatment and from interim to comprehensive treatment. Interim treatment shall be provided in a manner consistent with all applicable Federal and State laws, including sections

1923, 1927(a), and 1976 of the Public Health Service Act (21 U.S.C. 300x–23, 300x–27(a), and 300y–11).

(2) The program shall notify the SOTA when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of transfer to comprehensive services, and shall document such notifications.

(3) The Secretary may revoke the interim authorization for programs that fail to comply with the provisions of this paragraph (j). Likewise, the Secretary will consider revoking the interim authorization of a program if the State in which the program operates is not in compliance with the provisions of § 8.11(h).

(4) All requirements for comprehensive treatment apply to interim treatment with the following exceptions:

(i) A primary counselor is not required to be assigned to the patient, but crisis services, including shelter support, should be available;

(ii) Interim treatment cannot be provided for longer than 180 days in any 12-month period;

(iii) By day 120, a plan for continuing treatment beyond 180 days must be created, and documented in the patient's clinical record; and

(iv) Formal counseling, vocational training, employment, economic, legal, educational, and other recovery support services described in paragraphs (f)(4) and (f)(5)(i) and (iii) of this section are not required to be offered to the patient. However, information pertaining to locally available, community-based resources for ancillary services should be made available to individual patients in interim treatment.

§ 8.13 Revocation of accreditation and Accreditation Body approval.

(a) *The Secretary's action following revocation of accreditation.* If an Accreditation Body revokes an OTP's accreditation, the Secretary may conduct an investigation into the reasons for the revocation. Following such investigation, the Secretary may determine that the OTP's certification should no longer be in effect, at which time the Secretary will initiate procedures to revoke the program's certification in accordance with § 8.14. Alternatively, the Secretary may determine that another action or combination of actions would better serve the public health, including the establishment and implementation of a corrective plan of action that will permit the certification to continue in effect while the OTP seeks reaccreditation.

(b) *Accreditation Body approval.* (1) If the Secretary withdraws the approval of an Accreditation Body under § 8.6, the certifications of OTPs accredited by such Body shall remain in effect for a period of 1 year after the date of withdrawal of approval of the Accreditation Body, unless the Secretary determines that to protect public health or safety, or because the Accreditation Body fraudulently accredited treatment programs, the certifications of some or all of the programs should be revoked or suspended or that a shorter time period should be established for the certifications to remain in effect. The Secretary may extend the time in which a certification remains in effect under this paragraph (b)(1) on a case-by-case basis.

(2) Within 1 year from the date of withdrawal of approval of an Accreditation Body, or within any shorter period of time established by the Secretary, OTPs currently accredited by the Accreditation Body must obtain accreditation from another Accreditation Body. The Secretary may extend the time period for obtaining reaccreditation on a case-by-case basis.

§ 8.14 Suspension or revocation of certification.

(a) *Revocation.* Except as provided in paragraph (b) of this section, the Secretary may revoke the certification of an OTP if the Secretary finds, after providing the program sponsor with notice and an opportunity for a hearing in accordance with this subpart, that the program sponsor, or any employee of the OTP:

(1) Has been found to have engaged in misrepresentation in obtaining the certification;

(2) Has failed to comply with the Federal Opioid Use Disorder treatment standards in any respect;

(3) Has failed to comply with reasonable requests from the Secretary or from an Accreditation Body for

records, information, reports, or materials that are necessary to determine the continued eligibility of the OTP for certification or continued compliance with the Federal Opioid Use Disorder treatment standards; or

(4) Has refused a reasonable request of a duly designated inspector, Drug Enforcement Administration (DEA) Inspector, State Inspector, or Accreditation Body representative for permission to inspect the program or the program's operations or its records.

(b) *Suspension.* Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect public health or safety, the Secretary may immediately suspend the certification of an OTP, and notify the Attorney General that the OTP's registration should be suspended, before holding a hearing under this subpart. The Secretary may immediately suspend as well as propose revocation of the certification of an OTP before holding a hearing under this subpart if the Secretary makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with the Federal Opioid Use Disorder treatment standards presents an imminent danger to the public health or safety;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the failure to comply with the Federal Opioid Use Disorder treatment standards was intentional or was associated with fraud.

(c) *Written notification.* In the event that the Secretary suspends the certification of an OTP in accordance with paragraph (b) of this section or proposes to revoke the certification of an OTP in accordance with paragraph (a) of this section, the Secretary shall promptly provide the sponsor of the OTP with written notice of the suspension or proposed revocation by facsimile transmission, personal service, commercial overnight delivery service, or certified mail, return receipt requested. Such notice shall state the reasons for the action, state that the OTP may seek review of the action in accordance with the procedures in this subpart, and identify the reviewing official to whom a written request for review may be submitted.

(d) *Procedure.* (1) If the Secretary suspends certification in accordance with paragraph (b) of this section:

(i) The Secretary will immediately notify DEA that the OTP's registration should be suspended under 21 U.S.C. 824(d); and

(ii) the Secretary will provide an opportunity for a hearing under this subpart.

(2) Suspension of certification under paragraph (b) of this section shall remain in effect until the agency determines that:

(i) The basis for the suspension cannot be substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The OTP's certification shall be revoked.

§ 8.15 Forms.

(a) SMA–162—Application for Certification to Use Medications for Opioid Use Disorder.

(b) SMA–163—Application for Becoming an Accreditation Body under § 8.3.

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

§ 8.21 Applicability.

The procedures in this subpart apply when:

(a) The Secretary has notified an OTP in writing that its certification under the regulations in subpart B of this part has been suspended or that the Secretary proposes to revoke the certification; and

(b) The OTP has, within 30 days of the date of the notification or within 3 days of the date of the notification when seeking an expedited review of a suspension, requested in writing to the reviewing official, an opportunity for an informal review of the suspension or proposed revocation.

(c) The Secretary has notified an Accreditation Body of an adverse action taken regarding withdrawal of approval of the Accreditation Body under the regulations in subpart A of this part; and

(d) The Accreditation Body has, within 30 days of the date of the notification, requested in writing an opportunity for a review of the adverse action.

§ 8.22 Definitions.

The following definitions apply to this subpart:

Appellant means:

(1) The OTP which has been notified of its suspension or proposed revocation of its certification under the regulations of this part and has requested a review of the suspension or proposed revocation; or

(2) The Accreditation Body which has been notified of adverse action regarding withdrawal of approval under the regulations of this subpart and has requested a review of the adverse action.

Respondent means SAMHSA.

Reviewing official means the person or persons designated by the Secretary who will informally review the suspension or proposed revocation. The reviewing official may be assisted by one or more Department of Health and Human Services (HHS) officers or employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

§ 8.23 Limitation on issues subject to review.

The scope of this informal review shall be limited to the facts relevant to any suspension, or proposed revocation, or adverse action, the necessary interpretations of the facts, the regulations in this subpart, and other relevant law.

§ 8.24 Specifying who represents the parties.

The appellant's request for an informal review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

§ 8.25 Informal review and the reviewing official's response.

(a) *Request for review.* Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension, proposed revocation, or adverse action, a brief statement of why the decision to suspend, propose revocation, or take an adverse action is incorrect, and the appellant's request for an oral presentation, if desired.

(b) *Acknowledgment.* Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

§ 8.26 Preparation of the review file and written arguments.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's documents and brief.* Within 30 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification or to take adverse action regarding withdrawal of approval of the Accreditation Body is incorrect (appellant's brief).

(b) *Respondent's documents and brief.* Within 30 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification, or approval as an Accreditation Body, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension, proposed revocation, or adverse action (respondent's brief).

(c) *Reply briefs.* Within 10 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive documentation.* The reviewing official may take any appropriate steps to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

(f) *Discovery.* The use of interrogatories, depositions, and other forms of discovery shall not be allowed.

§ 8.27 Opportunity for oral presentation.

(a) *Electing oral presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding official.* The reviewing official or designee will be the presiding official responsible for managing the oral presentations.

(c) *Preliminary conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: Simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at the presiding official's discretion, produce a written document summarizing the conference or transcribe the conference.

(d) *Time and place of oral presentation.* The presiding official will attempt to schedule the oral presentation within 45 days of the date appellant's request for review is received or within 15 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the oral presentation—*(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more HHS officers or employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of proof/standard of proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend, propose revocation, or take adverse action is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is incorrect.

(3) *Admission of evidence.* The rules of evidence do not apply, and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly

repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the pre-hearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of justice or making of false statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1001 or 1505.

(g) *Post-hearing procedures.* At the presiding official's discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

§ 8.28 Expedited procedures for review of immediate suspension.

(a) *Applicability.* When the Secretary notifies an OTP in writing that its certification has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 10 days of the date the OTP received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is incorrect, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing official's response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review file and briefs.* Within 10 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official in accordance with § 8.27(a), the presiding official will attempt to schedule the oral presentation within 20 to 30 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with § 8.27(c) and will conduct the oral presentation in accordance with the procedures of § 8.27(e), (f), and (g).

(e) *Written decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7 to 10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in § 8.33 apply.

(f) *Transmission of written communications.* Because of the importance of timeliness for the expedited procedures in this section, all written communications between the parties and between either party and the reviewing official shall be sent by facsimile transmission, personal service, or commercial overnight delivery service.

§ 8.29 Ex parte communications.

For the purposes of maintaining the equity of informal review proceedings, except for routine administrative and procedural matters or as described in §§ 8.22(2) and 8.27(e), a party shall not communicate with the reviewing or presiding official without notice to the other party.

§ 8.30 Transmission of written communications by reviewing official and calculation of deadlines.

(a) *Timely review.* Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile transmission, personal service, or commercial overnight delivery service, or certified mail, return receipt requested, in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) *Due date.* In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

§ 8.31 Authority and responsibilities of the reviewing official.

In addition to any other authority specified in this subpart, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify the procedures in this subpart in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of the procedures in this subpart.

§ 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

§ 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the FEDERAL REGISTER. The Secretary will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the FEDERAL REGISTER. The Secretary will notify DEA within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under §8.28(e) or §8.33(a), constitutes final agency action as of the date of the decision.

Subpart E [Reserved]

PART 9—STANDARDS OF CARE FOR CHIMPANZEES HELD IN THE FEDERALLY SUPPORTED SANCTUARY SYSTEM

Sec.

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AUTHORITY: 42 U.S.C. 216, 287a–3a.

SOURCE: 73 FR 60423, Oct. 10, 2008, unless otherwise noted.

§ 9.1 Applicability and purpose.

(a) *General.* The standards of care set forth in this part apply to the chimpanzee sanctuaries that are contracted (or subcontracted) to the Federal Government to operate the federally supported chimpanzee sanctuary system authorized by section 481C of the Public Health Service (PHS) Act, as amended (42 U.S.C. 287a–3a).

(b) *What is the purpose of the federally supported chimpanzee sanctuary system and the authority for establishing these standards of care regulation?* The Chimpanzee Health Improvement, Maintenance, and Protection Act (Pub. L. 106–551, referred to as the ''CHIMP Act'' or ''Chimpanzee Retirement Act'') was enacted by Congress to provide for the establishment and operation of a sanctuary system to provide lifetime care for chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the agencies of the Federal Government, and that are determined to be no longer needed for such research. The CHIMP Act also mandates that standards of care for chimpanzees in the sanctuary shall be developed to ensure the well-being of chimpanzees and the health and safety of the chimpanzees.

(c) *To what chimpanzee sanctuaries do the standards of care in this part apply?* The standards of care set forth in this part apply to only those sanctuaries that are contracted or subcontracted to the Federal Government to operate the federally supported chimpanzee sanctuary system.

§ 9.2 Definitions.

As used in this part:

Adequate veterinary care means a program directed by a veterinarian qualified through training and/or experience to provide professional medical care to the chimpanzees within the Sanctuary and with the appropriate authority to provide this care. The program also provides guidance to all caregivers on all matters relating to the health and well-being of the chimpanzees.

American Zoo and Aquarium Association (AZA) means the professional society composed of individuals with various backgrounds and interests that are devoted to advancing the knowledge and understanding of zoo animals and the management of zoos in the United States.

American Zoo and Aquarium Association (AZA) Accreditation Standards are those standards developed by the AZA