

Secretary of Health and Human Services (the Secretary) will determine whether a practitioner is qualified under section 303(g) of the Controlled Substances Act (CSA) (21 U.S.C. 823(g)) to dispense opioid drugs in the treatment of opioid use disorders. The regulations also establish the Secretary's standards regarding the appropriate quantities of opioid drugs that may be provided for unsupervised use by individuals undergoing such treatment (21 U.S.C. 823(g)(1)). Under these regulations, a practitioner who intends to dispense opioid drugs in the treatment of opioid use disorder must first obtain from the Secretary or, by delegation, from the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA), a certification that the practitioner is qualified under the Secretary's standards and will comply with such standards. Eligibility for certification will depend upon the practitioner obtaining accreditation from an accreditation body that has been approved by SAMHSA. These regulations establish the procedures whereby an entity can apply to become an approved accreditation body. This part also establishes requirements and general standards for accreditation bodies to ensure that practitioners are consistently evaluated for compliance with the Secretary's standards for treatment of opioid use disorder with an opioid agonist treatment medication.

(b) The regulations in subpart F of this part establish the procedures and requirements that practitioners who are authorized to treat up to 100 patients pursuant to a waiver obtained under section 303(g)(2) of the CSA (21 U.S.C. 823(g)(2)), must satisfy in order to treat up to 275 patients with medications covered under section 303(g)(2)(C) of the CSA.

[81 FR 44736, July 8, 2016]

§ 8.2 Definitions.

The following definitions apply to this part:

Accreditation body means a body that has been approved by SAMHSA in this part to accredit opioid treatment programs using opioid agonist treatment medications.

Accreditation body application means the application filed with SAMHSA for purposes of obtaining approval as an accreditation body.

Accreditation body application means the application filed with SAMHSA 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 SAMHSA.

Accreditation survey means an onsite review and evaluation of an opioid treatment program by an accreditation body for the purpose of determining compliance with the Federal opioid treatment standards described in § 8.12.

Accredited opioid treatment program means an opioid treatment program that is the subject of a current, valid accreditation from an accreditation body approved by SAMHSA under § 8.3(d).

Additional Credentialing means board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine, the American Board of Medical Specialties, or the American Osteopathic Association or certification by the American Board of Addiction Medicine, or the American Society of Addiction Medicine.

Approval term means the 3 year period in which a practitioner is approved to treat up to 275 patients that commences when a practitioner's Request for Patient Limit Increase is approved in accordance with § 8.625.

Behavioral health services means any non-pharmacological intervention carried out in a therapeutic context at an individual, family, or group level. Interventions may include structured, professionally administered interventions (e.g., cognitive behavior therapy or insight oriented psychotherapy) delivered in person, interventions delivered remotely via telemedicine shown in clinical trials to facilitate medication-assisted treatment (MAT) outcomes, or non-professional interventions.

Certification means the process by which SAMHSA determines that an opioid treatment program is qualified

to provide opioid treatment under the Federal opioid treatment standards.

Certification application means the application filed by an opioid treatment program for purposes of obtaining certification from SAMHSA, as described in § 8.11(b).

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

Comprehensive maintenance treatment is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

Covered medications means the drugs or combinations of drugs that are covered under 21 U.S.C. 823(g)(2)(C).

Detoxification treatment means the dispensing of an opioid agonist treatment medication in decreasing doses to an individual to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of an opioid drug and as a method of bringing the individual to a drug-free state within such period.

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

Diversion control plan means a set of documented procedures that reduce the possibility that controlled substances will be transferred or used illicitly.

Emergency situation means that an existing State, tribal, or local system for substance use disorder services is overwhelmed or unable to meet the existing need for medication-assisted treatment as a direct consequence of a clear precipitating event. This precipitating event must have an abrupt onset, such as practitioner incapacity; natural or human-caused disaster; an outbreak associated with drug use; and result in significant death, injury, exposure to life-threatening circumstances, hardship, suffering, loss of property, or loss of community infrastructure.

Federal opioid treatment standards means the standards established by the Secretary in § 8.12 that are used to determine whether an opioid treatment program is qualified to engage in opioid treatment. The Federal opioid

treatment standards established in § 8.12 also include the standards established by the Secretary regarding the quantities of opioid drugs which may be provided for unsupervised use.

For-cause inspection means an inspection of an opioid treatment program by the Secretary, or by an accreditation body, that may be operating in violation of Federal opioid treatment standards, may be providing substandard treatment, or may be serving as a possible source of diverted medications.

Interim maintenance treatment means maintenance treatment provided in an opioid treatment program in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

Long-term detoxification treatment means detoxification treatment for a period more than 30 days but not in excess of 180 days.

Maintenance treatment means the dispensing of an opioid agonist treatment medication at stable dosage levels for a period in excess of 21 days in the treatment of an individual for opioid use disorder.

Medical director means a physician, licensed to practice medicine in the jurisdiction in which the opioid treatment program is located, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision.

Medical and rehabilitative services means services such as medical evaluations, counseling, and rehabilitative and other social programs (e.g., vocational and educational guidance, employment placement), that are intended to help patients in opioid treatment programs become and/or remain productive members of society.

Medication-Assisted Treatment (MAT) means the use of medication in combination with behavioral health services to provide an individualized approach to the treatment of substance use disorder, including opioid use disorder.

Medication unit means a facility established as part of, but geographically separate from, an opioid treatment program from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

Nationally recognized evidence-based guidelines means 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.

Opioid agonist treatment medication means any opioid agonist drug that is 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 opioid use disorder.

Opioid dependence means repeated self-administration that usually results in opioid tolerance, withdrawal symptoms, and compulsive drug-taking. Dependence may occur with or without the physiological symptoms of tolerance and withdrawal.

Opioid drug means any drug having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability.

Opioid treatment program or “OTP” means a program or practitioner engaged in opioid treatment of individuals with an opioid agonist treatment medication registered under 21 U.S.C. 823(g)(1).

Opioid treatment program certification means the process by which SAMHSA determines that an opioid treatment program is qualified to provide opioid treatment under the Federal opioid treatment standards described in § 8.12.

Opioid use disorder means a cluster of cognitive, behavioral, and physiological symptoms in which the individual continues use of opioids despite significant opioid-induced problems.

Opioid use disorder treatment means the dispensing of an opioid agonist treatment medication, along with a

comprehensive range of medical and rehabilitative services, when clinically necessary, to an individual to alleviate the adverse medical, psychological, or physical effects incident to an opioid use disorder. This term includes a range of services including detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment, and interim maintenance treatment.

Patient for purposes of subparts B through E of this part, means any individual who receives maintenance or detoxification treatment in an opioid treatment program. For purposes of subpart F of this part, patient means any individual who is dispensed or prescribed covered medications by a practitioner.

Patient limit means the maximum number of individual patients that a practitioner may dispense or prescribe covered medications to at any one time.

Practitioner means a physician who is appropriately licensed by the State to dispense covered medications and who possesses a waiver under 21 U.S.C. 823(g)(2).

Practitioner incapacity means the inability of a practitioner as a result of an involuntary event to physically or mentally perform the tasks and duties required to provide medication-assisted treatment in accordance with nationally recognized evidence-based guidelines.

Program sponsor means the person named in the application for certification described in § 8.11(b) as responsible for the operation of the opioid treatment program and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Short-term detoxification treatment means detoxification treatment for a period not in excess of 30 days.

State Authority is the agency designated by the Governor or other appropriate official designated by the Governor to exercise the responsibility and authority within the State or Territory for governing the treatment of opioid use disorder with an opioid drug.

Treatment plan means a plan that outlines for each patient attainable short-term treatment goals that are mutually acceptable to the patient and the opioid treatment program and which specifies the services to be provided and the frequency and schedule for their provision.

[66 FR 4090, Jan. 17, 2001, as amended at 81 FR 44736, July 8, 2016; 81 FR 62404, Sept. 9, 2016]

Subpart B—Accreditation of Opioid Treatment Programs

SOURCE: 81 FR 44738, July 8, 2016, unless otherwise noted.

§ 8.3 Application for approval as an accreditation body.

(a) *Eligibility.* Private nonprofit organizations or State governmental entities, or political subdivisions thereof, 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: <http://buprenorphine.samhsa.gov/pls/bwns/waiver>. 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 governmental entity 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 treatment standards set forth in § 8.12;

(4) A detailed description of the applicant's decisionmaking 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 SAMHSA of deficiencies and for monitoring corrections of deficiencies by OTPs;

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

(vi) Policies and procedures that will ensure processing of applications for accreditation and applications for renewal of accreditation within a time-frame approved by SAMHSA; and

(vii) 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 on the applicant's staff;

(7) A description of the applicant's 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