

42 C.F.R. § 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
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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.

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