Standards Revisions for Opioid Treatment Programs

**Applicable to Behavioral Health Care**

**Effective July 1, 2016**

Care, Treatment, and Services (CTS)

**Standard CTS.01.01.01**
The organization accepts for care, treatment, or services only those individuals whose identified care, treatment, or service needs it can meet.

**Note 1:** For opioid treatment programs: If an individual eligible for treatment applies for admission to a comprehensive maintenance treatment program but cannot be placed within 14 days in a program that is within a reasonable geographic area, an opioid treatment program’s program sponsor may place the individual in interim maintenance treatment.

**Note 2:** For opioid treatment programs: There may be individuals in special populations who have a history of opioid use but are not currently physiologically dependent. Federal regulations waive the one-year history of addiction for these special populations, because these individuals are susceptible to relapse to opioid addiction, leading to high-risk behaviors with potentially life-threatening consequences. These populations include the following:
- Persons recently released from a penal institution
- Persons recently discharged from a chronic care facility
- Pregnant women
- Previously treated patients

**Element of Performance for CTS.01.01.01**

**C 25.** For opioid treatment programs: To receive interim maintenance, the patient must be fully eligible for admission to comprehensive maintenance.

**Standard CTS.02.01.07**
The organization completes a physical health assessment, including a medical history and physical examination.

**Note:** This standard does not apply to foster care and therapeutic foster care. (Refer to CTS.02.04.01, EP 1 for more information)

**Element of Performance for CTS.02.01.07**

**A 9.** For opioid treatment programs: The program does not use telemedicine to substitute for a physical examination when one is needed. Telemedicine may be used to support the decision making of a physician, when a provider qualified to conduct physical examinations and make diagnoses is physically located with the patient.

**Standard CTS.02.02.09**
For opioid treatment programs: The organization has a process to provide medical histories, physical examinations, and diagnostic and laboratory tests.

**Element of Performance for CTS.02.02.09**

**A 12.** For opioid treatment programs: The program includes confirmation testing such as gas chromatography-mass spectrometry (GC-MS) or liquid chromatography-mass spectrometry (LC-MS) as part of its established procedures for addressing potentially false-positive and false-negative urine or other toxicology test results.

Please note that EP numbering for Standard CTS.02.02.09 reflects relocation of various requirements.

Key:
- **A** indicates scoring category A;
- **C** indicates scoring category C;
- **D** indicates that documentation is required;
- **M** indicates Measure of Success is needed;
- **I** indicates an Immediate Threat to Health or Safety;
- **S** indicates situational decision rules apply;
- **D** indicates direct impact requirements apply;
- **R** indicates an identified risk area.
Standard CTS.02.03.03
For organizations providing care, treatment, or services to a child or youth: The organization assesses the needs of children or youth.

Element of Performance for CTS.02.03.03
A 3. For opioid treatment programs: The program’s screenings and assessments tailored to adolescents make certain that medication-assisted treatment is the most appropriate treatment for these patients.

Standard CTS.03.01.01
The organization bases the planned care, treatment, or services on the needs, strengths, preferences, and goals of the individual served.

Note: For opioid treatment programs: Methadone has well-documented effects on several systems, including the respiratory, nervous, and cardiac systems, and the liver. Additionally, many medications including methadone can act to increase the QT interval on an electrocardiogram and potentially lead to torsades de pointes, a potentially life-threatening cardiac arrhythmia. Therefore, it is important for the program physician to consider all of the medications the patient is currently taking (including actual versus prescribed doses, illicit drugs, medically active adulterants potentially present in illicit substances, and medically active over-the-counter or natural remedies). Given consideration of this information, the program physician can determine whether the treatment drug will be methadone, buprenorphine, or another medication and whether the treatment indicated for the patient is induction, detoxification, or maintenance.

Element of Performance for CTS.03.01.01
A 7. For opioid treatment programs: The program establishes strategies to prevent or limit patients from acquiring and abusing prescriptions for controlled substances or other psychotropics from prescribers with whom the patients have ongoing relationships.

Please note that EP numbering for Standard CTS.03.01.01 reflects relocation of various requirements.

Standard CTS.03.01.03
The organization has a plan for care, treatment, or services that reflects the assessed needs, strengths, preferences, and goals of the individual served.

Elements of Performance for CTS.03.01.03
C 7. For opioid treatment programs: The program includes recovery support services in patients’ treatment plans according to patients' needs. Examples of such services include follow-up phone calls; face-to-face meetings; e-mails; and connecting patients to peer-to-peer services, 12-step or faith-based programs, and community groups.

C 13. For opioid treatment programs: The program advises patients of the risks of relapse following withdrawal and offers a relapse prevention program that includes counseling, naloxone, and opioid antagonist therapy. 

A 14. For opioid treatment programs: The program provides medically supervised withdrawal after pregnancy only when clinically indicated or requested by the patient.

Please note that EP numbering for Standard CTS.03.01.03 reflects relocation of various requirements.

Standard CTS.03.01.07
When individuals served need additional care, treatment, or services not offered by the organization, referrals are made and documented in the clinical/case record. (For more information, refer to Standard CTS.04.01.01.)

Element of Performance for CTS.03.01.07
C 5. For opioid treatment programs: The program educates mothers about neonatal abstinence syndrome, its symptoms, its potential effect on their infants, and the need for treatment should it occur.

Please note that EP numbering for Standard CTS.03.01.07 reflects relocation of various requirements.

Standard CTS.04.01.01
The organization coordinates the care, treatment, or services provided to an individual served as part of the plan for care, treatment, or services and in a manner consistent with the organization’s scope of care, treatment, or services. (For more information, refer to Standard CTS.03.01.07.)

Elements of Performance for CTS.04.01.01
C 14. For opioid treatment programs: The program provides medication-assisted treatment for alcohol use disorders, when appropriate, as well as counseling interventions for patients with a need for treatment.

A 17. For opioid treatment programs: The program’s telemedicine services are conducted via an interactive audio and video telecommunications system that permits real-time communication between the health care provider at the distant site and the patient at the originating site.

C 18. For opioid treatment programs: The program periodically queries the prescription drug monitoring program (PDMP) throughout the course of each patient’s treatment (for example, quarterly) and, in particular, before ordering take-home doses as well as at other important clinical decision points.

Please note that EP numbering for Standard CTS.04.01.01 reflects relocation of various requirements.
Standard CTS.04.01.03
The individual served receives education and training specific to the individual's needs and abilities consistent with the care, treatment, or services provided.

Note: This standard does not apply to academic education.

Element of Performance for CTS.04.01.03
C 17. For opioid treatment programs: The program counsels patients known to be using benzodiazepines, even by prescription, as to their risk and provides them with overdose prevention education and naloxone.  


Please note that EP numbering for Standard CTS.06.02.01 reflects relocation of various requirements.

Standard CTS.04.03.35
The organization responds to medical emergencies according to organization policy and procedures.

Elements of Performance for CTS.04.03.35
A 6. For opioid treatment programs: The program provides patients with a mechanism to address medical or psychiatric emergencies occurring outside of program hours of operation.  

C 7. For opioid treatment programs: The program provides each patient with an identification card that identifies the opioid use disorder pharmacotherapy being administered through the program, and the emergency contact information so that appropriate clinical information and dosing information can be obtained in an emergency.

Standard CTS.06.02.01
When an individual served is transferred or discharged, the continuity of care, treatment, or services is maintained.

Element of Performance for CTS.06.02.01
C 11. For opioid treatment programs: If practical under the circumstances and with due regard for patient and staff safety, before administrative discharge, the program conducts a crisis assessment to address suicide risk, danger to self or others, risk of relapse or overdose, urgent or critical medical conditions, and immediate threats.

Please note that EP numbering for Standard CTS.06.02.01 reflects relocation of various requirements.

Emergency Management (EM)

Standard EM.02.01.01
The organization has an Emergency Management Plan.

Note: The organization’s Emergency Management Plan (EMP) is designed to coordinate its communications, resources and assets, safety and security, staff responsibilities, utilities, and clinical and support activities during an emergency (refer to Standards EM.02.02.01, EM.02.02.03, EM.02.02.05, EM.02.02.07, and EM.02.02.11). Although emergencies have many causes, the effects on these areas of the organization and the required response effort may be similar. This "all hazards" approach supports a general response capability that is sufficiently nimble to address a range of emergencies of different duration, scale, and cause. For this reason, the Plan’s response procedures address the prioritized emergencies but are also adaptable to other emergencies that the organization may experience.

Element of Performance for EM.02.01.01
A 9. For opioid treatment programs: The program identifies an alternative dosing location to be used in the event of an emergency, and registers the location with the DEA if it is not already an opioid treatment program.

Human Resources Management (HRM)

Standard HRM.01.01.01
The organization develops written job descriptions.

Elements of Performance for HRM.01.01.01
A 3. For opioid treatment programs: The program physician(s) has experience in addiction medicine or psychiatry, including medication-assisted treatment, and has completed an accredited residency training program.

Note: Board certification in his or her primary medical specialty and in addiction psychiatry or addiction medicine is preferred.

A 4. For opioid treatment programs: The program's medical director has completed an accredited residency training program and has at least one year of experience in addiction medicine or addiction psychiatry.

Note: Board certification in his or her primary medical specialty and in addiction psychiatry or addiction medicine is preferred.

A 5. For opioid treatment programs: In states that permit non-licensed addictions counselors, programs develop job descriptions in accordance with standards put forward by a formal body such as those published by the National Certification Commission for Addiction Professionals.
Standard HRM.01.01.03
The organization determines how staff function within the organization.

Elements of Performance for HRM.01.01.03
A 2. Staff practice within the scope of their license, certification, or registration and as required by law and regulation and organization policy.

Note: For opioid treatment programs: The organization will have a federal exemption in place to allow mid-level medical practitioners to write medication orders in opioid treatment programs.

A 4. For opioid treatment programs: The program’s telemedicine services do not expand the scope of practice of a health care provider or permit practice in a jurisdiction (the location of the patient) where the provider is not licensed.

A 5. For opioid treatment programs: The program reviews the individual licensing, scope of practice, and supervision requirements of its state with regard to the duties of authorized health care professionals within the program, such as advanced practice nurses, physician assistants, and advanced practice pharmacists.

Standard HRM.01.06.03
Staff who assess individuals with substance abuse, dependence, and other addictive behaviors and who plan services for and deliver services to these individuals have specific competencies.

Element of Performance for HRM.01.06.03
A 7. For opioid treatment programs: The staff members responsible for establishing referrals with other health care organizations and practitioners are knowledgeable about pharmacotherapy treatment (drug interactions, acute withdrawal, and overdose), actively seek patient consent to talk with other providers, and check their state’s prescription drug monitoring program (PDMP).

Leadership (LD)

Standard LD.01.01.01
The organization has a leadership structure.

Element of Performance for LD.01.01.01
A 7. For opioid treatment programs: The program’s administrative organization is comprised of, at a minimum, a program sponsor, program director or manager, and medical director.

Standard LD.04.01.01
The organization complies with law and regulation.

Element of Performance for LD.01.01.01
A 14. For opioid treatment programs: The program complies with Occupational Safety and Health Administration (OSHA) workplace health and safety standards.

Standard LD.04.01.05
The organization effectively manages its programs or services.

Elements of Performance for LD.04.01.05
A 16. For opioid treatment programs: Physicians have authority over the medical and nursing aspects of medication-assisted treatment and retain autonomy so as to ensure ongoing medical decisions are individualized according to the needs of each patient, the clinical course of treatment, and the standards of medical practice.

A 17. For opioid treatment programs: In programs where either could occur, the program clearly distinguishes between patients who are cared for by a physician in accordance with the rules under DATA 2000 and those who are cared for in an OTP facility in accordance with 42 CFR 8.12.

C 18. For opioid treatment programs: The program’s medical director is responsible for assuring all medical, psychiatric, nursing, pharmacy, toxicology, and other services offered by the program are conducted in compliance with federal regulations at all times.

A 19. For opioid treatment programs: The medical director is present at the program a sufficient number of hours to assure regulatory compliance and carry out those duties specifically assigned to the medical director by law and regulation.

A 20. For opioid treatment programs: The medical director either directly provides the required services to the program’s patients or assures that the needed services are provided by appropriately trained and licensed providers in compliance with federal and state regulation.

A 21. For opioid treatment programs: The day-to-day management of the program is assigned to the program director or manager who assumes the duties assigned by the program sponsor.

Note: In some programs, the program sponsor may also serve as the program director or manager.

Standard LD.04.01.09
Policies and procedures guide the provision of program services and define the goals and scope of services offered.
Elements of Performance for LD.04.01.09

A 10. For opioid treatment programs: Programs providing treatment with multiple medications using both the OTP and office-based opioid treatment (OBOT) models of service delivery develop clear written policies and procedures for assigning patients to a specific model and establish criteria for determining a specific pharmacotherapy.

A 11. For opioid treatment programs: If the program offers inpatient detoxification services, it develops written policies and procedures to provide the service so that treatment can be matched to the individual needs and preferences of the patient. These include careful review of the risks and benefits of detoxification; obtaining thorough informed consent from patients choosing this treatment option; and providing accompanying relapse prevention counseling, overdose prevention education (may include an FDA-approved naloxone kit), and aftercare plans that include a strategy to transition to medication-assisted treatment if needed.

Please note that EP numbering for Standard LD.04.01.09 reflects relocation of various requirements.

Standard MM.01.01.03
The organization safely manages high-alert medications.

Note: This standard is applicable to organizations that engage in any of the medication management processes.

Elements of Performance for MM.01.01.03

A 12. For opioid treatment programs: The program obtains patient input on the program’s policies and procedures regarding its diversion control plan (DCP), and how those policies and procedures are implemented.

A 13. For opioid treatment programs: The program develops written policies and procedures to govern the use of and response to prescription drug monitoring program (PDMP) information for diversion control.

Standard MM.03.01.01
The organization safely stores medications.

Note: This standard is applicable to organizations that store medications at their sites.

Element of Performance for MM.03.01.01

A 25. For opioid treatment programs: The program stores methadone and buprenorphine separately from other medications.

Note: Methadone and buprenorphine may be stored together in the same safe, with each product documented in a separate inventory.

Standard MM.04.01.01
Medication orders are clear and accurate.

Note: This standard is applicable only to organizations that prescribe medications. The elements of performance in this standard do not apply to prescriptions written by a prescriber who is not affiliated with the organization.

Elements of Performance for MM.04.01.01

C 18. For opioid treatment programs: When the patient requires a medication that is not provided by the program, the program makes a referral that meets the needs and preferences of the patient.

C 24. For opioid treatment programs: A physician assesses the patient and adjusts the medication dosage as needed when the program switches from one generic formulation to another and differences in the effective dose cause clinically relevant complaints.

Note: Caution should also be exercised when a patient has missed several doses of medication because his or her tolerance may have changed.

A 26. For opioid treatment programs: The program prohibits the use of standing orders regarding the dose, schedule, or re-administration of methadone because of the unique pharmacologic properties, the well-established potential for fatalities in the induction period, and the risk of relapse during medically supervised withdrawal.

C 26. For opioid treatment programs: A physician may write a very short cascading order incorporating a clinical opiate withdrawal scale (COWS) score or other objective measure in order to titrate the dose of a specific individual only if appropriately trained and qualified staff (as determined by licensing criteria or credentialing) are available to evaluate the ongoing appropriateness of the physician’s treatment plan and recognize the need for the patient to be re-evaluated prior to completion of the full course of the order.

C 27. For opioid treatment programs: The program’s physicians and other health care providers, as permitted, register to use their state’s prescription drug monitoring program (PDMP) and query it for each newly admitted patient prior to initiating dosing.

Please note that EP numbering for Standard MM.04.01.01 reflects relocation of various requirements.

Standard MM.05.01.11
The organization safely dispenses medications.

Note: This standard is applicable only to organizations that operate a pharmacy.

Element of Performance for MM.05.01.11

A 9. For opioid treatment programs: The program authorizes appropriate staff members to dispense methadone and buprenorphine to patients admitted for treatment.
Prepublication Requirements continued

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Please note that EP numbering for Standard MM.05.01.11 reflects relocation of various requirements.

Standard MM.06.01.03
Self-administered medications are administered safely and accurately.

Note: The term self-administered medication(s) may refer to medications administered by a family member.

Elements of Performance for MM.06.01.03

A 13. For opioid treatment programs: The medical director makes certain that the program's policies for the approval of take-home medication do not create barriers to patients continuing in treatment.

C 19. For opioid treatment programs: The program has a written policy regarding random call-backs.

A1820. For opioid treatment programs: Take-home medications are packaged in individual, child-proof containers.

C 22. For opioid treatment programs: The program educates patients receiving unsupervised (take-home) medication about using a locked container to inconspicuously and safely transport take-home medication and store the medication at home.

A 25. For opioid treatment programs: The program develops a standard process to record chain-of-custody of dispensed take-home doses not dispensed directly to the patient.

C 26. For opioid treatment programs: The program determines whether patients who need to travel but do not meet criteria for take-home medications can receive guest dosing.

A 27. For opioid treatment programs: For alcohol use disorders, the program is able to assess patients' recent use of alcohol via toxicology tests and Breathalyzer results as a means of establishing safety for dosing and take-homes.

Please note that EP numbering for Standard MM.06.01.03 reflects relocation of various requirements.

Rights and Responsibilities of the Individual (RI)

Standard RI.01.03.01
The organization honors the right of the individual served to give or withhold informed consent.