660 - OPIOID TREATMENT PROGRAM

EFFECTIVE DATES: 10/01/18, 01/08/20, 08/14/20, 04/01/21, 10/01/24, 10/01/26

APPROVAL DATES: 06/07/18, 10/03/19, 08/11/20, 03/03/21, 05/14/24, 04/21/26

I. PURPOSE

AHCCCS serves as Arizona's State Treatment Authority pursuant to ARS 36-2907.14 and is the entity responsible for providing administrative and clinical oversight to the certified Opioid Treatment Providers (OTPs) including planning, development, educating and implementing policies and procedures to ensure that opioid dependency treatment is provided at an optimal level. This Policy establishes requirements for the provision of care and services provided by OTPs in compliance with established legislation and coordination with the State Opioid Treatment Authority (SOTA). Opioid Treatment Programs (OTPs) operating in Arizona shall comply with all applicable requirements of 42 CFR Part 8, including 8.11 and 8.12, as amended.

All OTPs providing Medications for Opioid Use Disorder (MOUD) in Arizona shall be licensed by the Arizona Department of Health Services (ADHS) as specified in AAC Title 9, Chapter 10, in alignment with AAC R9-10-120, and 42 CFR Part 8. The OTPs are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and are contingent upon State and United States Drug Enforcement Administration (DEA) approval. State approval is the responsibility of the SOTA, for information on SOTA approval please review the Innovative Solutions for Opioid Use Disorder in Arizona of the AHCCCS website.

This Policy applies to ACC, ACC-RBHA, ALTCS E/PD, DCS CHP (CHP), and DES DDD (DDD) Contractors; Fee-For-Service (FFS) Programs including American Indian Health Program (AIHP), Tribal ALTCS, TRBHA, and all FFS populations, excluding Federal Emergency Services Program (FESP). This Policy describes Title XIX/XXI behavioral health services provided within Opioid Treatment Programs. For additional information regarding behavioral health services, please refer to AMPM 310-B, AMPM Policy 320-T1, AMPM Policy 320-T2. Please refer to the AHCCCS Covered Behavioral Health Services Guide for applicable billing and coding guidance.

II. DEFINITIONS

Refer to the AHCCCS ACOM and AMPM Dictionary for common terms found in this Policy.

III. POLICY

A. OPIOID TREATMENT PROGRAM CERTIFICATION

In accordance with 42 CFR Part 8.11, the OTP shall comply with the following:

1. General Requirements:

   An OTP shall hold a current, valid certification from SAMHSA and be determined to be qualified by the Attorney General to be registered under section 303(h)(1) of the Controlled Substances Act (21 U.S.C. 823(h)(1)) to dispense MOUD for the treatment of Opioid Use Disorder (OUD). To operate in Arizona, an OTP shall also have, hold, or maintain a current license issued by the Arizona Department of Health Services, a current DEA registration to dispense methadone for the treatment of OUD, and shall current accreditation by an Accreditation Body as provided under 42 CFR Part 8.11.

2. Exemptions**:**

   An OTP shall submit an exemption request through the SAMHSA Extranet in the following scenarios:
   a. The OTPs that are delivering prepared, patient-specific doses of methadone to any location outside of the OTP (e.g., jails, prisons, residential treatment facilities, Skilled Nursing Facilities (SNFs), the patient's home, or other locations) shall include the following documentation within the patient-specific exemption request for the delivery of methadone doses to the off-site location:
      i. Written agreement between the OTP and the receiving agency documenting responsibility for the safe storage of the methadone doses delivered,
      ii. A chain of custody form documenting the transfer of, and responsibility to ensure the safety and security of, the prepared methadone doses from the OTP to the receiving program or other identified responsible person, and
      iii. A signed dosing log shall be retained in the patient's chart.
   b. Take home medication requests for periods of time longer than what is allowed in 42 CFR Part 8.12,
   c. Temporary, single-day, OTP clinic closures:
      i. It is expected that OTP clinics are open for patient dosing of methadone 6 days per week (it is expected that Saturday hours are less than the number of hours the dosing window is open Monday through Friday, with a minimum of 2 hours open on each Saturday), unless they have communicated with the SOTA, all contracted health plans, and SAMHSA Center for Substance Abuse Treatment (CSAT) the specific reasons for the requested closure and have obtained approval,

ii. For all OTP clinic closures that are not Federal or State holidays, or a single weekend day that the OTP is typically closed (typically Sundays), the OTP must first notify by email their contracted RBHA and MCO health plans, and the Arizona SOTA at grantsmanagement@azahcccs.gov, of the OTP's plan to ensure patient continuity of access to their medication and other components of OTP care during the clinic's closure, and
iii. The exemption request submitted for review to SAMHSA must include this plan to ensure continued patient care.

d. Any other aspect of OTP routine practice that is governed by this Policy.

The OTP shall obtain approval from both the SAMHSA CSAT and the Arizona SOTA, before the exemption request can be considered approved, and the requested action taken.

B. OPIOID USE DISORDER TREATMENT STANDARDS

All OTPs operating in Arizona must comply with 42 CFR part 8.12: Opioid Use Disorder Treatment Standards as amended. In alignment with the federal regulations, all treatment decisions made by OTP providers are clinical, and are therefore the sole responsibility of the OTP Medical Director currently associated with the OTP to review and approve.

1. Patient Admission Criteria:
   a. Comprehensive treatment
      An OTP shall 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; the individual has an OUD in remission; or the individual is at high risk for recurrence or overdose. A health care practitioner shall ensure that each patient:
      i. Is clearly informed of all relevant facts concerning the use of MOUD,
      ii. Voluntarily chooses treatment with MOUD, and
      iii. Provides informed consent to treatment,
   b. Comprehensive treatment for persons under age 18
      No person under 18 years of age may be admitted to OTP treatment without Health Care Decision Maker (HCDM) consent,
   c. Withdrawal management:
      An OTP shall 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, and
   d. All treatment decisions and patient consent must be documented in the clinical record by the treating health care practitioner.

2. Required Services, Including:
   a. General:
      The OTP shall provide adequate medical, counseling, vocational, educational, and other screening, assessment, and treatment services with the combination and frequency of services tailored to each individual patient. An individualized assessment and patient care plan shall be created using shared decision making between the patient and the clinical team, and it shall drive the services offered. Services must be available at the primary OTP facility or through a documented agreement with an external community-based private or public agency, organization, or health care provider, that is able to provide the services identified within the treatment plan.

      Refer to AMPM Exhibit 300-3 for a description of the AHCCCS Integrated System of Care Structure, Values, and Principles that underlie respectful, patient-centered treatment.

   b. Initial Screening and Physical Examination:
      The OTP shall conduct an initial screening to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD. Each patient must receive a full history and physical examination to determine the patient's broader health status. The physical examination shall include lab testing as clinically indicated and required by an appropriately licensed health care practitioner.

      A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to methadone treatment, provided such refusal does not have potential to negatively impact treatment with medications.

      Assuming no contraindications, a patient may commence treatment with MOUD after the screening examination has been completed.

      The initial screening, full history, and physical examination must be completed by an appropriately licensed health care practitioner.

      Behavioral health services shall be provided as specified in AMPM Policy 310-B and in compliance with this Policy.

   c. Initial and periodic physical and behavioral health assessment services:
      Each patient admitted to an OTP shall be given a physical examination and an initial behavioral health assessment.

      A full, initial psychosocial assessment must be completed within 14 calendar days of admission into the OTP and must include preparation of a comprehensive, patient-centered care plan.

d. Subsequent physical examinations shall occur not less than one time each year and shall be conducted by an OTP practitioner,
e. Special services for pregnant patients:
The OTP must adhere to AMPM Policies 410 and 420 and shall 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 by the OTP medical provider and documented in the patient's chart. Evidence-based treatment protocols for pregnant patients, 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 health care 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 health care practitioners,
f. Counseling and psychoeducational services:
The OTP must provide adequate SUD counseling and psychoeducation to each patient as clinically necessary and mutually agreed-upon, including harm-reduction education and recovery-oriented counseling. Refer to AMPM 300-3 for Integrated System of Care structure, Values and Principles. Refer to AMPM 610 for BHP and BHT qualifications and service provision guidance. Patient refusal of counseling shall not preclude them from receiving MOUD, and
g. The OTP must provide patient education on preventing exposure to, and the transmission of, Human Immunodeficiency Virus (HIV), viral hepatitis, and Sexually Transmitted Infections (STIs). The OTP shall either directly provide clinically appropriate medical services and treatment or connect all patients who have received positive test results for these conditions to treatment.

3. Drug testing services:
The OTP must conduct no fewer than eight random drug tests per year, per patient. Additional drug tests may be conducted based on the clinical judgement and rationale of the OTP medical provider.

4. Recordkeeping and patient confidentiality:
The OTP shall establish and maintain a recordkeeping system that is adequate to document and monitor patient care related to MOUD treatment for each patient enrolled in the OTP.

The 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.

5. Medication administration, dispensing, and use, including:
   a. The OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed and registered under Arizona state laws and appropriate Federal laws to administer or dispense MOUD,
   b. The OTPs shall only prescribe and provide those MOUD that are approved by the Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 USC 355) for use in the treatment of OUD: a. Methadone, Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of OUD, and
   c. Naltrexone.

6. Methadone initial dose criteria:
   a. Methadone shall be administered or dispensed only in oral form, and
   b. For each new patient enrolled in an OTP, the initial dose of methadone should not exceed 50 milligrams unless the OTP practitioner finds sufficient medical rationale, including but not limited to:
      i. If the patient is transferring from another OTP on a higher dose that has been verified, and
      ii. Documents in the patient's record that a higher dose was clinically indicated.

7. Unsupervised or "take-home" doses of methadone decision making:
   "Take-home" doses of methadone may only be provided under the following circumstances:
   a. 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 Federal and State holidays, no matter their length of time in treatment,
   b. The OTP decisions on dispensing additional take-home doses to patients beyond the days that the OTP clinic is regularly closed shall be determined by an appropriately licensed OTP medical practitioner or the medical director of the OTP. The OTP medical director or OTP program medical practitioner shall consider the following factors, among others, to determine if the therapeutic benefits of take-home doses outweigh the risks of not providing them:
      i. Absence of active SUD, 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 any recent diversion activity engaged in by the patient,
      v. Whether take-home medication can be safely transported and stored, and
      vi. Any other criteria that the OTP medical director or OTP medical practitioner considers relevant to the patient's safety and the public's health.

The clinical rationale underlying the decision to provide individualized take-home doses of methadone is the OTP medical director's responsibility and must be documented in each patient's clinical record.

8. Take-home doses "time in treatment" criteria:
   It is within the OTP practitioner's discretion to determine the number of take-home doses. The number of take-home doses shall not exceed the following parameters:
   a. During the first 14 days of treatment, the number of take-home doses cannot exceed 7 days of medication,
   b. After the first 15 days of treatment, the take-home doses cannot exceed 14 days of medication,
   c. After the first 31 days of treatment, the take-home doses cannot exceed 28 days of medication, and
   d. The clinical rationale underlying the decision to provide take-home doses of methadone must be documented in the patient's clinical record.

9. Diversion control measures and patient education to maintain safety:
   a. The OTPs must maintain current procedures adequate to identify the theft or diversion of methadone, including labeling take-home containers with the OTP's name, address, and telephone number. The OTPs 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 USC 1471 *et seq.*)), and
   b. The OTPs must provide education to each patient on safely transporting medication from the OTP to the patient's place of residence and safe storage of take-home doses at the patient's place of residence, including child and household safety precautions. The provision of this education should be documented in the patient's clinical record.

C. OPIOID TREATMENT PROGRAM REPORTING REQUIREMENTS

All AHCCCS-registered OTP providers, pursuant to ARS 36-2907.14, must comply with all applicable Federal or State licensing and registration requirements. All new and existing OTP sites receiving reimbursement from AHCCCS or AHCCCS's Contractor is required to develop and submit the plans as specified in statute, along with all relevant documentation, for review and approval by AHCCCS. Refer to Attachment A for required components.

Hospitals, jails, prisons, and OTPs on tribal lands are exempt from the above reporting requirements.

D. OPIOID TREATMENT PROGRAM NOTIFICATIONS TO THE STATE OPIOID TREATMENT AUTHORITY

1. This section applies to all OTPs operating in Arizona, as required by 42 CFR Part 8.12.

2. The OTPs shall notify the SOTA of Arizona of their intent to open any new location within the State in addition to their notification to SAMSHA, the DEA, the Arizona Department of Health Services Licensing Bureau, and the SAMHSA-approved Accrediting Body they will use. The OTPs shall send this information through formal communication via email to AHCCCS at grantsmanagement@azahcccs.gov.

   The communication shall include the following information:
   a. Address of the new location,
   b. Status of submission for licensure,
   c. Information on whether the location intends to receive Medicaid funding, and
   d. Confirmation of coordination with designated AHCCCS Contractors.

3. If an OTP is considering voluntary decertification of their OTP program or reducing the level of services offered, the OTP must communicate via formal email communication to the SOTA at grantsmanagement@azahcccs.gov.

   The communication shall include the following information:
   a. Address of the OTP to be closed,
   b. The OTP's rationale for closure,
   c. The end date of OTP services,
   d. Patient communication plan notifying of the OTP closure and care transition support available,
   e. Status of communication with all contracted health plans, the Arizona Department of Health Services, Drug Enforcement Agency, the Accrediting Body the OTP uses, and SAMHSA, and
   f. Status of patient transitions to ongoing OTP treatment at other locations.

E. OPIOID TREATMENT LOCATOR REGISTRATION

1. This Policy applies to all AHCCCS-registered OTP providers.

2. The OTP must create provider profiles for each of their program locations on the AHCCCS Opioid Treatment Services Locator:
   The OTP must ensure that each clinic's details are current in the AHCCCS Opioid Treatment Services Locator and to include but not limited to:
   a. Populations served,
   b. National Treatment Locator (NTL) number for each clinic,
   c. Naloxone availability and criteria, and
   d. Medications available for the treatment of opioid use disorder.