660 - OPIOID TREATMENT PROGRAM

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

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

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).

II. DEFINITIONS

Refer to the AHCCCS Contract and Policy Dictionary for common terms found in this Policy including:

CENTER FOR SUBSTANCE ABUSE TREATMENT (CSAT)	**CONTRACTOR**	**DISPENSE**
MEDICATIONS FOR OPIOID USE DISORDER (MOUD)	**OPIOID TREATMENT PROGRAMS (OTPS)**	**STATE OPIOID TREATMENT AUTHORITY (SOTA)**
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)		

III. POLICY

Any OTP providing Medications for Opioid Use Disorder (MOUD) 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 Final Rule Part 8. OTPs are certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) and are contingent upon State and the United States Drug Enforcement Administration (DEA). State approval is the responsibility of the SOTA, for information on SOTA approval please review the Opioid Treatment Program Requirements page of the AHCCCS website. Behavioral health services shall be provided as specified in AMPM Policy 310-B and in compliance with this Policy.

A. OPIOID TREATMENT PROGRAM CERTIFICATION

In accordance with 42 CFR Part 8.11 Final Rule: Opioid Treatment Program Certification, published on February 2, 2024, OTPs shall comply with the following:

1. General
   a. An OTP must be the subject of a current, valid certification from SAMHSA to be considered qualified by the Secretary under section 303(g)(1) of the Controlled Substances Act (21 USC 823(h)(1)) to dispense MOUD in the treatment of OUD,
   b. To obtain certification from the Secretary, an OTP must meet the Federal Opioid Use Disorder treatment standards in 42 CFR Part 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,
   c. All 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 42 CFR Part 8.11 (a)(4),
   d. Any 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 42 CFR Part 8.11(b). 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 42 CFR Part 8.11 (e),
   e. All 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 42 CFR Part 8.4, 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 42 CFR Part 8.11 (a)(3), 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, and
   f. All 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 42 CFR Part 8.11 (a) 6.

2. Application for initial or renewal certifications and re-certification. Applications for certification must be submitted by the OTP using form SMA– 162 found on the SAMHSA Certification of Opioid Treatment Programs webpage. The application for initial or renewal of certification shall include, as determined by the Secretary:
   a. A description of the current accreditation status of the OTP,
   b. A description of the organizational structure of the OTP,
   c. The names of the persons responsible for the OTP,

d. The addresses of the OTP and of each medication unit or other facility under the of the OTP,
e. The sources of funding for the OTP and the name and address of each governmental entity that provides such funding,
f. A statement that the OTP will comply with the conditions of certification set forth in paragraph (g) of this section, and
g. The application shall be signed by the program sponsor who shall certify that the information submitted in the application is truthful and accurate.

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.

3. Action on application
   a. 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,
   b. 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 OUD treatment standards established under 42 CFR Part 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.

   Within five 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.

4. Provisional certification. New OTPs that have not received the Secretary's certification previously, except as provided in paragraph (a)(6) of Part 8.11, 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 one year. To receive provisional certification, an OTP shall submit the information required by paragraph (b) Part 8.11 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) of Part 8.11, unless the Secretary determines that patient health would be adversely affected by the granting of provisional certification.

5. Requirements for certification.
   a. The 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 Arizona State law, or the submission of applications or reports required by the Single State Authority (AHCCCS), 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,
   b. The 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,
   c. 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 USC 321 *et seq.*). Federally sponsored treatment programs are subject to applicable Federal confidentiality statutes,
   d. 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,
   e. The OTPs shall notify the Secretary in writing within three weeks of any replacement or other change in the status of the program sponsor or medical director,
   f. The 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, and
   g. The OTPs must operate in accordance with Federal Opioid Use Disorder treatment standards and approved accreditation elements.

6. Conditions for interim treatment program approval.
   a. Before an OTP may provide interim treatment, the OTP must receive the approval of both the Secretary and the SOTA for Arizona in which the OTP operates, and
   b. Before the Secretary may grant such approval, the OTP must provide the Secretary with documentation from the SOTA for Arizona in which the OTP operates demonstrating that:
      i. The SOTA for Arizona does not object to the providing of interim treatment in Arizona,
      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. The 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.

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.

7. Exemptions:
   a. 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 42 CFR 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 SOTA for Arizona prior to taking action on an exemption request.

8. Medication units, long-term care facilities and hospitals.
   b. 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 Arizona State laws and regulations. Medication units include both mobile and brick and mortar facilities,
   c. 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, and
   d. 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.

9. The term ‘‘long-term care facility’’ is defined in 42 CFR Part 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.

B. OPIOID USE DISORDER TREATMENT STANDARDS

In accordance with the 42 CFR part 8.12 Final Rule: Opioid Use Disorder Treatment Standards, published on February 2, 2024, OTPs operating in Arizona, under the approval of the SOTA shall comply with the following:

1. Patient admission criteria:
   a. 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,
   b. Comprehensive treatment for persons under age 18. No person under 18 years of age may be admitted to OTP treatment unless a parent, legal guardian, or responsible adult designated by the State of Arizona consents in writing to such treatment, and
   c. 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.

2. Required services:
   a. 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,

b. Initial medical examination. OTPs shall require each patient to undergo an initial medical examination. The initial medical examination is comprised of two parts:
   i. A screening examination to ensure that the patient meets criteria for admission and that there are no contraindications to treatment with MOUD,
   ii. 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,
   iii. 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,
   iv. 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,
   v. 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,
   vi. 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,
   vii. 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:
      1) 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, and
      2) 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.

c. Special services for pregnant patients. OTPs must, adhere to AMPM Policy 410, and 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,

d. Initial and periodic physical and behavioral health assessment services.
Each patient admitted to an OTP shall be given a physical examination and a behavioral health assessment, as outlined in AMPM Policy 320-O and 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,

   i. 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 (SUD) 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.

e. Counseling and psychoeducational services,
   i. OTPs 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. 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. Refer to AMPM Exhibit 300-3 for BHP and BHT qualifications and service provision guidance. Patient refusal of counseling shall not preclude them from receiving MOUD, and
   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, as outlined in AMPM Policy 410 and AMPM Policy 420.

f. 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.

2. 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.

3. Recordkeeping and patient confidentiality.
   a. The 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 the treatment of OUD. All records are required to be kept confidential in accordance with all applicable Federal and State requirements, and

b. 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. 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.

4. Medication administration, dispensing, and use
   a. OTPs must ensure that MOUD are administered or dispensed only by a practitioner licensed and registered under Arizona State and the appropriate 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 Arizona State law,
   b. 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 USC 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.
   c. The 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, and
      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 Arizona State law and registered under the appropriate Arizona 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.

d. The 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 Federal and State holidays, no matter their length of time in treatment.
      2) The 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:
         a) 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,
         b) Regularity of attendance for supervised medication administration,
         c) Absence of serious behavioral problems that endanger the patient, the public or others,
         d) Absence of known recent diversion activity,
         e) Whether take-home medication can be safely transported and stored, and
         f) 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.
         a) During the first 14 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to seven days. It remains within the OTP practitioner's discretion to determine the number of take-home doses up to seven 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,

b) 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, and

c) 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) The 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 USC 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.

5. Interim treatment.
   a. 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. <u>At least two drug tests shall be obtained from patients during the maximum of 180 days permitted for interim treatment.</u> 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 USC 300x–23, 300x–27(a), and 300y–11),
   b. The program shall notify the SOTA for Arizona 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,

c. 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),
d. 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.

C. OPIOID TREATMENT PROGRAM REPORTING REQUIREMENTS

Pursuant to ARS 36-2907.14, in addition to all Federal or State licensing and registration requirements, any OTP (including new and existing OTP sites) receiving reimbursement from AHCCCS or its Contractor shall develop and submit Plans as specified in statute, and any relevant documentation, for review and approval by AHCCCS. Existing OTP sites are also required to submit an annual report no later than November 15 of each year. The submitted Plans will be posted to the AHCCCS website for public comment for 30 days. AHCCCS will make a determination on the sufficiency of the submitted documentation within 30 days of the close of the public comment period. If AHCCCS determines that there is a deficiency in any of the submitted documentation, the OTP will be provided 30 days, from day of notification, to correct the deficiency or AHCCCS will suspend reimbursement for OTP providers until deficiency is remediated. The Contractor is required to suspend payment to OTPs who do not receive AHCCCS approval.

1. Plans required for submission from the OTPs include:
    a. Detailed security plan,
    b. Neighborhood engagement plan,
    c. Comprehensive plan to demonstrate how the OTP ensures that appropriate medication-assisted standards of care are met,
    d. Community relations and education plan, including evidence of the program's current provider profile on the AHCCCS Opioid Treatment Services Locator, linked here: https://opioidservicelocator.azahcccs.gov/,
    e. Current diversion control plan.

Refer to the AHCCCS website for detailed information regarding expectations and submission requirements. Hospitals, jails, and OTPs on tribal lands are exempt from the above reporting requirements.

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

OTPs shall notify the SOTA for Arizona of their intent to open any new location within the State, in addition to their notification to SAMSHA. OTPs shall send formal communication via email to AHCCCS at: grantsmanagement@azahcccs.gov.

1. 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 will receive Medicaid funding, and
   d. Confirmation of coordination with designated AHCCCS Contractors.

2. Any new OTP location receiving any reimbursement from AHCCCS, or any Contractor, shall complete and submit the required reporting as specified in this Policy under the Opioid Treatment Program Reporting Requirements section.

3. In accordance with the 42 CFR 8.12 Final Rule, before an OTP may provide interim treatment including inducting new patients onto methadone treatment, or dispensing methadone from a mobile medication unit, the OTP must receive the approval of both SAMHSA and the SOTA for Arizona. The OTP shall send formal communication via email to the SOTA for Arizona within AHCCCS at: grantsmanagement@azahcccs.gov.
   The communication shall include the following:
   a. Demonstrate that 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,
   b. 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,
   c. The 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, and
   d. SAMHSA 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 SAMHSA.

E. OPIOID TREATMENT LOCATOR REGISTRATION

1. The OTP must create provider profiles for each of their program locations on the AHCCCS Opioid Treatment Services Locator, linked here: https://opioidservicelocator.azahcccs.gov/.
   a. The OTP must ensure that each clinic's details are current in the locator, to include at minimum:
      i. Populations served,
      ii. National Treatment Locator (NTL) number for each clinic,
      iii. Naloxone availability and criteria, and
      iv. Medications available for the treatment of opioid use disorder.