I. PURPOSE

This Policy applies to Opioid Treatment Programs (OTPs) requirements related to established legislation and coordination with the State Opioid Treatment Authority (SOTA).

II. DEFINITIONS

| CENTER FOR SUBSTANCE ABUSE TREATMENT (CSAT) | Substance Abuse and Mental Health Services Administration’s (SAMHSA’s) center to promote community-based substance abuse treatment and recovery services for individuals and families in every community. CSAT provides national leadership to improve access, reduce barriers, and promote high quality, effective treatment, and recovery services. |
| DISPENSE | 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, as specified in 42 CFR 8.2. |
| MEDICATION ASSISTED TREATMENT (MAT) | The use of medications in combination with counseling and behavioral therapies for the treatment of substance use disorders. |
| MID-LEVEL EXEMPTION REQUEST | An exemption process as specified in 42 CFR Part 8.11 for Opioid Treatment Programs (OTPs) to request the Single State Authority (SSA) and the Substance Abuse and Mental Health Services Administration’s (SAMHSA) Center for Substance Abuse Treatment (CSAT) to provide approval to allow Mid-Level Practitioners to treat opioid-related withdrawal symptoms. |
An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of mid-level practitioners include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the State in which they practice, pursuant to 21 CFR 1300.01.

Licensed and accredited Programs also referred to as Medication Assisted Treatment (MAT) Programs, authorized to dispense medications for the treatment of opioid use disorder through highly structured protocols defined by Federal and State regulations.

The individual responsible for administrative and clinical oversight of certified Opioid Treatment Programs (OTPs), including, but not limited to planning, developing, educating, and implementing policies and procedures to ensure that opioid dependency treatment is provided at an optimal level.

A public agency within the U.S. Department of Health and Human Services (HHS established by Congress in 1992 to make substance use and mental disorder information, services, and research more accessible).

III. Policy

A. Opioid Treatment Program Mid-Level Exemption Process

OTPs that employ Mid-Level Practitioners are required to complete the Mid-Level Exemption Request Process, as specified below, in order to allow those practitioners to dispense opioids within a MAT setting for individuals with opioid use disorder. It is the responsibility of the practitioner to continuously monitor and abide by the Federal Guidelines for OTPs. Federal Guidelines for OTPs can be found on the SAMHSA website at www.samhsa.gov. OTPs are responsible to maintain appropriate policies and procedures guiding the practice and supervision of Mid-Level Practitioners.

1. Mid-Level Exemption Request Process
   a. OTPs shall complete and submit all required information through the SAMHS/A/CSAT OTP Extranet at https://otp-extranet.samhsa.gov/login.aspx,
b. The Arizona SOTA shall coordinate a team of Subject Matter Experts (SMEs) to review the submitted request and supporting documentation,

c. The Arizona SOTA shall approve, deny, and/or return requests for further clarification based on the information provided. Requests are reviewed to ensure the exemption does not:
   i. Violate an existing federal or state law,
   ii. Violate an existing tribal law,
   iii. Jeopardize the safety, health, treatment of patients, and/or
   iv. Impede fair competition of another service provider.

d. Approved requests are submitted by the Arizona SOTA to CSAT for final approval. Mid-Level Exemption Requests that receive final approval from CSAT require renewal as indicated by CSAT,

e. Additional Mid-Level Exemption Requests are also required when an OTP intends to hire additional Mid-Level Practitioners prior to renewal of the existing approved Exemption,

f. Documentation of Mid-Level Practitioner qualifications and training is necessary when an OTP intends to hire replacement Mid-Level Practitioners prior to renewal of the existing approved Exemption, and

g. The Renewal process shall be submitted 60 days prior to the expiration date for an approval process to begin.

B. OPIOID TREATMENT PROGRAM REPORTING REQUIREMENTS

Pursuant to A.R.S. §36-2907.14, in addition to all State or Federal licensing and registration requirements, any OTP (including New and Existing OTP sites) receiving reimbursement from AHCCCS or its Contractors must 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, and
   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.

C. **Opioid Treatment Program Notifications To The State Opioid Treatment Authority**

OTP s shall notify the SOTA of their intent to open new locations within the State, in addition to their notification to SAMHSA. OTPs shall send formal communication via email to AHCCCS/Division of Grants Administration (AHCCCS/DGA), 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 contracted Health Plans.

2. Any new OTP location receiving Medicaid funding shall complete and submit the required reporting as specified in this Policy.