

660 OPIOID TREATMENT PROGRAM MID-LEVEL EXEMPTION

EFFECTIVE DATES: 10/01/18, XX/XX/XX¹

~~REVISION~~

~~APPROVAL DATES:~~ 06/07/18, 10/03/19²

I. PURPOSE

This Policy applies to Opioid Treatment Programs (OTPs) that employ Mid-Level Practitioner providers. ~~This Policy~~ and describes the process that ~~the Opioid Treatment Programs (OTPs)~~ shall follow to request ~~for~~ Mid-Level Practitioners to provide medication services for opioid use disorder treatment within an OTP setting.

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 Pursuant to 42 CFR 8.2 Dispense means 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.³

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 authorized under 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.

¹ Post APC Change: Policy Effective Date will be the date the policy is published to the AMPM Web Page

² Date presented at APC Meeting or without APC review, the date Policy is published

³ Dispense definition included

**MID-LEVEL
PPRACTITIONER**

Pursuant to ~~Title 21 CFR, Code of Federal Regulations, Section 1300.01(b28),⁴ the term mid-level practitioner means a Nurse Practitioner or Physician Assistant, 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.~~

Mid-level practitioner means 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.⁵

OPIOID TREATMENT PROGRAMS (OTPs)

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

STATE OPIOID TREATMENT AUTHORITY (SOTA)

The individual responsible for administrative and clinical oversight ~~to~~ 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.

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)

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 described below, in order to allow those

⁴ [Revised structure of reference to align with formatting](#)

⁵ [Deleted mid-level practitioner definition and added the updated mid-level practitioner definition.](#)

~~practitioners~~ practitioners to ~~treat~~ dispense⁶ opioids within an MAT setting for individuals with opioid use disorder ~~with MAT~~⁷. It is the responsibility of the practitioner to continuously monitor and abide by the Federal Guidelines for OTPs. Federal Guidelines for Opioid Treatment Programs. ~~Standards for operation~~⁸ 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 Attachment A with all required supporting documentation,
- 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 ~~will be~~ 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.⁵
- 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.⁹
- 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.

2. Mid-Level Exemption Renewal Process:

- ~~¹⁰ OTPs shall complete and submit Attachment B with all required supporting documentation for renewal of Mid Level Exemptions,~~
- ~~e. Additional Mid Level Exemption Requests are required when an OTP intends to hire additional Mid Level Practitioners prior to renewal of the existing approved Exemption,~~
- a. OTPs shall complete and submit Attachment B with all required supporting documentation,
- b. If the renewal application is not submitted and approved 60 days prior to expiration date the OTP is no longer authorized to have the assigned mid-level

⁶ Replaced with 'dispense' to align with definition of Mid-level Practitioner

⁷ Language was corrected

⁸ Standards for operations was deleted and Federal Guidelines for OTP's was added

⁹ Language was moved from below

¹⁰ Moved to beginning of sentence for ease of distinguishing between Attachment A and Attachment B.

- practitioner dispense any medication(s), and a Request Application – Attachment A will need to be submitted,
- c. Renewal applications shall include a listing of the current Mid-Level Practitioners employed by the OTP,
 - d. The Arizona SOTA shall coordinate a team of Subject Matter Experts (SMEs) to review the submitted renewal and supporting documentation
 - e. The Arizona SOTA shall approve, deny, and/or return renewals for further clarification based on the information provided. Renewals 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, and
 - f. Approved renewals will be submitted by the Arizona SOTA to CSAT for final approval. Mid-Level Exemption Renewals that receive final approval from CSAT require renewal as indicated by CSAT.
 - ~~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. Renewal applications shall include the current Mid Level Practioners employed by the OTP, and~~
 - ~~g. A denied request for exemption will be provided to the OTP in writing from Arizona SOTA or CSAT.¹¹~~

¹¹ Moved this section above; information is retained.