



Substance Abuse and Mental Health
Services Administration

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Dear OTP Directors, SOTAs and State Directors:

As of July 28, 2021, the Drug Enforcement Administration (DEA) authorized Opioid Treatment Programs (OTPs) to add a “mobile component” to their existing registration, eliminating a separate registration requirement for mobile medication units of OTPs. This is an opportunity to expand access to medications for treatment of Opioid Use Disorders (OUD), especially in remote or underserved areas. 42 C.F.R. § 8.11(i) provides that OTPs certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) may establish medication units (as defined under 42 C.F.R. § 8.2) that are authorized to dispense opioid agonist treatment medications.

Federal regulations under 42 C.F.R. § 8.12(b) require that OTP facilities “shall be adequate to ensure quality patient care and to meet the requirements of all pertinent Federal, State, and local laws and regulations.” Consistent with this requirement, this document revises and supersedes related portions of SAMHSA’s 2015 Federal Guidelines for Opioid Treatment Programs (Guidelines) by clarifying the range of services that can be provided in both mobile and non-mobile medication units.

Specifically, the following services may be provided in mobile medication units, assuming compliance with all applicable federal, state, and local law:

- Administering and dispensing medications for opioid use disorder treatment
- Collecting samples for drug testing or analysis
- Dispensing of take-home medications
- In units that provide appropriate privacy and adequate space, intake/initial psychosocial and appropriate medical assessments (with a full physical examination to be completed or provided within 14-days of admission)
- Initiating methadone or buprenorphine after an appropriate medical assessment has been performed
- In units that provide appropriate privacy and have adequate space, other OTP services, such as counseling, may be provided directly or when permissible through use of telehealth services

This document also clarifies that non-mobile medication units may also offer the above services where space allows for quality patient care and are consistent with state and local laws and regulations. It is expected that any required services not provided in mobile and non-mobile medication units must be conducted at the OTP, including medical, counseling, vocational, educational, and other assessment and treatment services [42 CFR § 8.12(f)(1)].

SAMHSA is working with the Accrediting Bodies to assure their standards incorporate this revised guidance. It should be noted that both mobile and non-mobile medication units will be reviewed by the respective SAMHSA-approved Accrediting Body as part of the OTP's accreditation process, and the scope of reviews will be based on the accreditation standards for the services provided.

For OTPs interested in establishing a mobile or non-mobile medication unit, notification to SAMHSA should be completed by the OTP sponsor via submission of an on-line SMA-162 form (<http://otp-extranet.samhsa.gov>). Please note that OTPs must secure state approval from the respective State Opioid Treatment Authority (SOTA) prior to submitting an on-line SMA-162 form.

SAMHSA is committed to addressing the opioid and substance misuse epidemic through expansion and use of mobile and non-mobile medication units. We thank you for your efforts in mitigating the opioid epidemic.

Sincerely,

/Kimberly Nelson/

Kimberly Nelson, LAC, MPA Acting
Director
Center for Substance Abuse Treatment