pennsylvania
DEPARTMENT OF DRUG AND ALCOHOL PROGRAMS

LICENSING ALERT 02-22

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Deputy Secretary
Department of Drug and Alcohol Programs

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Effective: Immediately
Subject: Mobile Narcotic Treatment Programs (NTPs)
Purpose: To provide the process for establishing mobile NTPs.

Background: Effective June 28, 2021, the U.S. Drug Enforcement Administration (DEA) issued a final rule authorizing registered Narcotic Treatment Programs (NTPs) to add mobile components for dispensing controlled substances for maintenance or detoxification treatment without obtaining a separate registration. See 2021-13519.pdf (govinfo.gov). This rule is designed to increase access to treatment, particularly in rural and underserved areas, while maintaining protections to public health and safety. NTPs must obtain prior approval from the DEA before operating a mobile component and must comply with record keeping and security requirements specified by the DEA.

In addition, the Substance Abuse and Mental Health Services Administration (SAMHSA), which certifies Opioid Treatment Programs (OTPs) to administer and dispense medication to treat opioid use disorder, has issued guidance regarding the range of services that these mobile components may provide. See Letter to OTP Directors, SOTAs and State Directors on Mobile Component (samhsa.gov). Under the SAMHSA guidance, the following services may be provided in mobile units compliant with applicable federal, state, and local laws:

- Administering and dispensing medications for opioid use disorder treatment.
- Collecting samples for drug testing or analysis.
- Dispensing of take-home medications.
- Completing initial psychosocial and medical assessments, in units with appropriate privacy and adequate space.
- Initiating methadone or buprenorphine following an appropriate medical assessment.
- Providing counseling in units with appropriate privacy and adequate space.

State Licensing Requirements: Federally registered and authorized NTPs must also follow state licensing requirements. Any NTP that is interested in establishing a mobile component must request an exception to 28 Pa. Code § 715.25, Prohibition of medication units. See 28 Pa. Code § 715.25. Prohibition of medication units. (pacodeandbulletin.gov). NTPs that request an exception to the prohibition on medication units must submit the exception request in writing to RA-licensuredivision@pa.gov. DDAP will consider exception requests submitted by NTPs that hold full licenses.

The exception request must include:

- Updated policies and procedures for the mobile NTP relating to
  - § 715.17. Medication control.
  - § 715.26. Security.
- Other new or revised policies and procedures relating to the mobile component.
- Photographs of the mobile component.
- Documentation of insurance and state inspection for the mobile component.
- Written agreements or documentation of permission to use identified location.
- Contingency plans for weather related events, scheduled and unscheduled mobile component maintenance, and travel related issues, such as motor vehicle accident or travel delay.

An NTP that operates a mobile component must also:

- Maintain the active physical location that is licensed by DDAP, certified by SAMHSA, and registered by the DEA.
- Return the mobile component to the registered NTP site upon completion of operation every day and secure all controlled substances inside the registered NTP.
- Store records securely in accordance with 28 Pa. Code § 709.28.
- Follow all Federal, State, Local and Municipal laws, including zoning approval, at all service locations.
- Adhere to Fire Safety requirements in § 705.28.
- Obtain the appropriate Pennsylvania Department of Health Lab Permit and Clinical Laboratory Improvement Amendments (CLIA) waiver if performing diagnostic testing, including instant tests.

After the exception request is approved by DDAP, NTPs that seek to operate mobile components must also obtain approvals from DEA and SAMHSA.

DEA Requirements: The NTP must submit an application to and receive approval from the facility's local DEA before commencing operation of a mobile NTP. For additional information regarding the DEA requirements related to mobile medication units, refer to the eCFR :: 21 CFR Part 1301 - Registration.

SAMHSA Requirements: The OTP must notify SAMHSA via submission of an online SMA-162 form. Please note that OTPs must secure state approval from DDAP, the State Opioid Treatment Authority (SOTA) prior to submitting an online SMA-162 form. For additional information regarding SAMHSA requirements, refer to Certification of Opioid Treatment Programs (OTPs) | SAMHSA.

Mobile components must follow the rules and guidelines for NTPs as outlined by SAMHSA and the state in which they reside and must apply and renew the certification. For additional information see OTP Guidance.

Please submit all questions regarding this Licensing Alert to the Bureau of Program Licensure at RA-licensuredivision@pa.gov.