



# Prescription Drug Monitoring Program

## 21 Code of Federal Regulations (CFR) Parts 1300, 1301, and 1304: Registration Requirements for Narcotic Treatment Programs

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In its continuing effort to keep prescription drug monitoring programs (PDMPs) and other stakeholders apprised of new and changing practices, current research, and new laws and regulations, the Prescription Drug Monitoring Program Technical Training and Assistance Center (PDMP TTAC) has compiled the following information on new regulations that have become effective regarding Narcotic Treatment Programs (NTPs), which are now allowed to have mobile sites. According to the U.S. Drug Enforcement Administration (DEA), these “revisions to the regulations are intended to make maintenance or detoxification treatments more widely available, while ensuring that safeguards are in place to reduce the likelihood of diversion.” The regulations detail under what circumstances mobile components of NTPs would be able to transport and dispense controlled substances away from their registered locations within the same state as the registered NTP. The regulations also set forth requirements for security, recordkeeping, reporting, and inventory for those mobile components. This will undoubtedly enhance the ability for NTPs to provide an expanded resource to those seeking and in need of substance use disorder treatment. This becomes even more critical at a time when the Centers for Disease Control and Prevention (CDC) reports that between 1999 and 2019, more than 495,881 people died from overdoses involving opioids (prescription and illicit). Data from CDC’s Wide-ranging Online Data for Epidemiologic Research (WONDER) database revealed that the greatest number of opioid involved deaths in the U.S. occurred in 2019 (49,860).

*Note: This report and other resources, training, technical assistance, or any other information provided by TTAC do not constitute legal advice. TTAC encourages all PDMPs to seek advice from their own legal offices or their state’s Attorney General Office.*

The summary information for this report is based on the following:

A full version of the rule can be found starting on page 33861 of the following link:  
<https://www.govinfo.gov/content/pkg/FR-2021-06-28/pdf/FR-2021-06-28.pdf>

The DEA’s published rule summary can be found at the following link:  
[https://www.deadiversion.usdoj.gov/fed\\_regs/rules/2021/fr0628\\_3.pdf](https://www.deadiversion.usdoj.gov/fed_regs/rules/2021/fr0628_3.pdf)

## **21 Code of Federal Regulations (CFR) Parts 1300, 1301, and 1304 – Registration Requirements for Narcotic Treatment Programs With Mobile Components**

### **U.S. Drug Enforcement Administration’s Published Rule Summary:**

As stated in the U.S. Drug Enforcement Administration’s (DEA) published rule summary (linked above), this final rule revises “existing regulations for narcotic treatment programs (NTPs) to allow the operation of a mobile component associated with a DEA-registered NTP to be considered coincident activity permitted under the NTP’s registration. Based on these revisions, NTP registrants that operate or wish to operate mobile components (in the State in which the registrant is registered) to dispense narcotic drugs in schedules II–V at remote location(s) for the purpose of maintenance or detoxification treatment do not need a separate registration for such mobile component. This final rule waives the requirement of a separate registration at each principal place of business or professional practice where controlled substances are dispensed

for those NTPs with mobile components that fully comply with the requirements of this rule. These revisions to the regulations are intended to make maintenance or detoxification treatments more widely available, while ensuring that safeguards are in place to reduce the likelihood of diversion.”

#### **Legal Authority and Background and Basis for Waiver:**

The Controlled Substances Act (CSA) provides at 21 U.S.C. 822(e)(1) that “a separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.” However, 21 U.S.C. 822(d) allows for the Attorney General, through regulation, to waive the requirement if consistent with the public health and safety. The Attorney General delegated this authority to the Administrator of DEA, and pursuant to that authority, the DEA finalized this rule to waive the requirement of a separate registration for NTPs that use mobile components under certain conditions. The summary to the rule provides that “specifically, under this final rule, an NTP is permitted to dispense narcotic drugs in schedules II–V from a mobile component at location(s) remote from, but within the same State as, the NTP’s registered location, for the purpose of maintenance or detoxification treatment. Under this final rule, the NTP does not need to obtain a separate DEA registration for dispensing from the mobile component at a separate location as long as it complies with the requirements of the final rule. Such remote dispensing from an NTP’s mobile component is deemed under the final rule to be a coincident activity permitted under the NTP’s registration. In the interest of helping to alleviate the ongoing opioid epidemic in the United States, the Acting Administrator of DEA (Acting Administrator) finds that this waiver of registration is consistent with the public health and safety.”

#### **Section-by-Section Analysis of the Final Rule:**

##### ***Part 1300: Definitions***

The definition of mobile NTP found at section 1300.01(b) was revised to clarify that the operation of the mobile NTP is the coincident activity that allows for the activity to be permitted under the NTP’s registration and not the actual vehicle itself. **Mobile NTP** is defined in section 1300.01 as “a narcotic treatment program (NTP) operating from a motor vehicle, as defined in this section, that serves as a mobile component (conveyance) and is operating under the registration of the NTP, and engages in maintenance and/or detoxification treatment with narcotic drugs in schedules II–V, at a location or locations remote from, but within the same State as, its registered location. Operating a mobile NTP is a coincident activity of an existing NTP, as listed in § 1301.13(e) of this chapter.” **Motor vehicle** is defined as “a vehicle propelled under its own motive power and lawfully used on public streets, roads, or highways with more than three wheels in contact with the ground. This term does not include a trailer.”

##### ***Part 1301: Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances***

As stated in the final rule summary, “this final rule contains provisions. . . that require NTPs to secure controlled substances while operating a mobile component away from the registered location.”

**Relationship to Existing NTP Registration:**

As explained in the final rule summary, security concerns are addressed by revising section 1301.13 “to make operating a mobile component of an NTP a coincident activity of an existing NTP registration, provided the NTP has obtained prior approval from the local DEA office. DEA intends to reduce the regulatory burden on NTPs by waiving the separate DEA registration requirement . . . and allowing them to operate a mobile component of an NTP in the same State as the registered NTP, under its existing registration. As a result, the mobile component of a registered NTP will not have to apply for a separate registration, as its operation is considered coincident activity. In addition, DEA specifies in the regulations that the records generated during the operations of a mobile component of an NTP shall be maintained at the NTP’s registered location, rather than requiring such records to be stored in the mobile component.”

The rule revises section 1301.13(e)(4) by adding a subparagraph (iii). This third subparagraph clarifies “that a mobile NTP may operate at a location or locations, *including correctional facilities*, away from, but within the same State as, the NTP’s registered location (emphasis added).” Previously, the rule did not address correctional facilities. In addition, the rule clarifies that a mobile NTP can operate at more than one remote location under appropriate circumstances.

**Securing a Mobile NTP and Substances When an NTP Is Not in Use or Disabled:**

The rule also revises section 1301.72(e) to address security concerns, especially regarding theft and diversion of controlled substances. Security requirements under 21 CFR 1301.72(a)(1) and (d) apply to the mobile component of an NTP, and subsection (e) describes security requirements for the mobile NTPs. As stated in the rule’s published summary, section 1301.72(e) allows “the mobile component to be parked at the registered location or any secure, fenced-in area when the mobile component is not in use. Prior to parking the conveyance at a secure, fenced-in location, all controlled substances must be removed from the conveyance and returned to the registered location and, the local DEA office must be notified of the location of the secure, fenced-in area.” The rule addresses protocols for situations wherein the mobile component becomes disabled or needs to be taken to an automotive repair shop. This rule also adds a provision in section 1301.72(e) that allows the NTP to apply for an exception to the requirement that the mobile NTP return daily to the registered location and store the controlled substances at the registered location. The detailed process is outlined in 21 CFR 1307.03. Section 1301.72(e) provides additional specifics that need to be met to qualify for the exception and indicates that the waiver will be reviewed on a case-by-case basis to determine if exceptional circumstances warrant such a waiver.

**Dispensing Protocols:**

Section 1301.74 is also revised to include mobile NTPs. Section 1301.74 discusses personnel who are authorized to dispense controlled substances for narcotic treatment and security measures that must be in place and patient dosage. This section also describes the protocol for handling theft or significant loss of controlled substances. Section 1301.74 (m) specifically addresses mobile NTPs and states that “any controlled substance being transported for disposal from the dispensing location of a mobile NTP shall be secured and disposed of in compliance with

part 1317, and all other applicable Federal, State, tribal, and local laws and regulations.” Subsection (n) states that a mobile NTP “may only be supplied with narcotic drugs by the registered NTP that operates such conveyance.” It also states that “persons permitted to dispense controlled substances to mobile NTPs shall not (1) receive controlled substances from other mobile NTPs or any other entity; (2) deliver controlled substances to other mobile NTPs or any other entity; or (3) conduct reverse distribution of controlled substances on a mobile NTP.”

***Part 1304: Records and Reports of Registrants***

The recordkeeping requirements of 21 CFR Part 1304 apply to mobile components of NTPs (sections 1304.04 and 1304.24 are revised to include mobile components).

**Records to Be Stored at Registered Location:**

The records of the mobile NTP will be stored at the registered location of the NTP meeting applicable requirements and being readily retrievable.

**NTP May Use Automated Data if Conditions Are Met:**

21 CFR 1304.24(b) requires the NTP to maintain the records required by subsection (a) in a dispensing log at the registered location in paper form; however, DEA is allowing an NTP or its mobile component to use an automated/computerized data processing system for storage and retrieval of records if a number of conditions are met (see rule for a list of conditions), if the NTP's computer software program is capable of producing accurate summary dispensing reports, and a backup of all computer-generated records of dispensing by the NTP and its mobile component must be maintained off site. The time period for retention is outlined in the rule.

This rule was made final after it was proposed, and public comments were received. It is effective on July 28, 2021.