DEA Initiates Rule making to Waive Separate Registration for Mobile NTP

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On February 26, 2020, the US Drug Enforcement Administration (DEA) issued a <u>Notice of Proposed</u> <u>Rule Making</u> (NPRM), which proposes waiving the requirement of a separate DEA registration at each principal place of business or professional practice where controlled substances are dispensed for narcotic treatment programs (NTP) that utilize a mobile component in the state in which the DEA registrant is registered. The DEA noted that its intent was to make maintenance and detoxification treatments more widely available, especially in rural and underserved communities.

Under the federal Controlled Substances Act (CSA), a DEA registration is required for each principle place of business or professional practice where controlled substances are manufactured, distributed or dispensed. 21 U.S.C. 822(e)(1). This requirement has posed a challenge to providers such as mobile narcotic treatment programs, whose services—including administering and dispensing controlled substances—logically take place in locations other than the principle place of business.

Under the proposed rule, an NTP would be allowed to dispense controlled substances is schedules II–V at a location remote from, but within the same state as, the NTP's registered location for the purpose of maintenance or detoxification treatment regardless of whether dispensing occurred on such a regular basis that the location would constitute a principal place or business or professional practice.

Although the proposed rule would make operating a mobile component of an NTP a coincident activity of an existing NTP registration, in order to operate the mobile component, the NTP must obtain prior explicit written approval from its local DEA office. The proposed rule also sets forth requirements for security and recordkeeping. Some of these proposed requirements include the following:

- Persons receiving treatment at a mobile NTP must wait in an area physically separated from the narcotic storage and dispensing area either by a physical entrance (*i.e.*, door or other entryway). If the NTP does not have a separate seating or reception area, patient will need to wait outside of the mobile NTP.
- When not in use, controlled substances must be stored in a securely locked safe that is bolted

or cemented to the floor or wall, equipped with an alarm and not accessible from outside of the mobile NTP.

- At the end of each day, the mobile NTP must return to the DEA registrant's location, and all controlled substances must removed from the mobile NTP and secured within the DEA registrant's location.
- Records generated during the operations of the mobile component of an NTP must be maintained at the location of the registered NTP and retained for two years.

In issuing the NPRM, the DEA noted allowing for the operation of mobile NTPs under the conditions specified in the proposed rule would increase access to opioid use treatment with minimal risk of diversion.

DEA is accepting public comments on the proposed rule until April 27, 2020.

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