

## DEA Proposes to Lift Ban on Mobile Methadone Vans

By: Laura Stanley | April 29, 2020

The abuse of prescription pharmaceuticals, in particular opioids, is a crisis in the United States. In 2018, more than 46,000 Americans [died](#) from an opioid overdose. Methadone and buprenorphine, both Drug Enforcement Administration (DEA) controlled substances, are the [mainstay](#) of treatment for opioid use disorder.

There is impetus for expanding mobile narcotic treatment programs (NTP), sometimes referred to as “methadone vans,” to increase access to rural locations and underserved urban neighborhoods.

However, DEA placed a moratorium on approving new mobile NTPs in 2007. Under a recently [proposed rule](#), DEA would repeal the moratorium and waive the requirement that a mobile NTP must have a separate registration, provided the mobile component follows the conditions in the proposal.

### DEA Regulation of Narcotic Treatment Programs

Practitioners who want to administer methadone, a schedule II controlled substance, to treat opioid use disorder generally must obtain a registration (i.e., a license) from DEA to operate as an NTP. However, DEA has the [authority](#) to waive this requirement if that decision is “consistent with the public health and safety.”

There are approximately 1,700 NTPs at brick-and-mortar locations [registered](#) with DEA. DEA previously allowed brick-and-mortar NTPs to operate a mobile component, but in 2007 placed a moratorium on approving new mobile components. In the proposed rule, DEA provides no evidence that there was an increased risk of diversion associated with operating mobile components. DEA [writes](#) that “the vast majority of authorized mobile NTP components complied with the [Controlled Substances Act] and its implementing regulations” and that there has been only one instance of theft or loss at a mobile component.

DEA’s current moratorium on approving mobile components limits access to opioid use disorder treatment for patients in rural areas. Over 90% of the registered NTPs are [located](#) in urban areas, which forces rural patients to travel long distances to receive their daily doses of methadone. Rural

### In brief...

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patients have [reported](#) that the burden of traveling long distances on a daily basis impedes their ability to work and increases the chances they discontinue treatment.

Local, state, and federal agencies working to combat the opioid epidemic, as well as members of Congress, have [pressured](#) DEA to lift the moratorium so practitioners can deploy methadone vans and provide critical treatment. In Seattle, for example, federal grant money has been [allocated](#) to deploy methadone vans in underserved communities, but the project is on hold until DEA lifts the moratorium.

## **The Proposed Rule**

Under the proposed rule, DEA would repeal its moratorium and waive the requirement that a mobile component must have a separate registration from the brick-and-mortar NTP, provided the mobile component follows certain conditions. Under the proposed rule framework, only NTPs that are already registered with DEA would have the ability to start a mobile component. DEA [concludes](#) that waiving the registration requirement for mobile components is “consistent with the public health and safety” because it will increase access to treatment for opioid use disorder while posing minimal diversion risk.

To minimize diversion of controlled substances, DEA proposes to place a number of conditions on mobile components. For example, mobile components will not be allowed to dispense in states other than the state where the registered NTP is located. Each day, the mobile component must return to the registered location and remove and secure the controlled substances inside. Additionally, the controlled substances in the mobile component must be locked in a safe that is protected from manipulation and radiological attacks, bolted or cemented to the floor, and equipped with an alarm system that transmits to a protection company or law enforcement. The mobile components must also keep a log with information on dispensed controlled substances (dose dispensed, patient, etc.). The log must be stored at the registered location, and if a mobile component uses an electronic log, it must print a hard copy each day and ensure each entry is initialed by the physician who dispensed the controlled substance.

## **DEA’s Proposal is a Step in the Right Direction**

DEA’s proposed rule represents a significant improvement over the status quo. Allowing NTPs to operate a mobile component will likely reduce the cost of expanding treatment for opioid use disorder, increasing access to critical treatment. However, the proposed rule requires mobile components to meet conditions that will not evidently reduce diversion risks and could increase the burden and cost of expansion.

In a [public comment](#) filed on the proposed rule, I recommend that DEA revise or remove conditions that do not evidently decrease the risk of diversion but could increase the cost of expanding mobile components. For example, absent evidence of abuse, DEA should not require the mobile component to return to the registered location daily or store the controlled substances inside. Mobile components have proved valuable when providers administer regular treatment in the same location, but it is too costly to build a brick-and mortar-facility. If the registered location is far from where the provider wants to administer treatment, it will be onerous and costly to require

the mobile component to return to that location daily. Rather, DEA should not specify when the mobile component must return to the registered NTP location. As an alternative, DEA could consider increasing the intervals and only requiring the mobile component to return to the registered NTP location on a weekly basis.

In light of the COVID-19 public health emergency, I also recommend DEA follow a tiered approach and immediately begin approving mobile components while devoting resources to finalizing this rule. It will take significant resources and time for DEA to finalize this rule, and the potential [reduction](#) in capacity to treat patients due to the emergency indicates how critical it is to immediately approve additional mobile components to fill this gap.

The COVID-19 public health emergency has strained resources for medical providers treating opioid use disorder. Medical providers operating vans have reported that they have adjusted their services out of concern for COVID-19. For example, some providers [report](#) that instead of allowing three to four people in a van at a time, only one person is allowed into the van with the provider. The public health emergency may also limit treatment capacity at brick-and-mortar NTPs. Additionally, even though many stay-at-home orders exempt essential medical services, patients might be unwilling to travel to clinics to receive their daily dose of methadone because they want to minimize their exposure to the virus. Although DEA and the Substance Abuse and Mental Health Services Administration [relaxed](#) restrictions so that clinics can provide stable patients with 14-day or 28-day take-home supplies, many patients do not get to take advantage of this [privilege](#).

As mentioned, the [Controlled Substances Act](#) gives DEA the authority to waive the requirement for separate registrations if it is “consistent with the public health and safety.” DEA used this discretion to [approve](#) mobile components on an ad hoc basis prior to 2007; there is no legal constraint on DEA to finalize this rule before beginning to approve mobile components on an ad hoc basis again.

Although DEA should immediately begin approving mobile components on an ad hoc basis, this is only a short-term solution. DEA should finalize this rule to provide a formal program for licensed NTPs seeking to operate a mobile component. By establishing a formal program that is transparent and codifies the requirements for mobile components, this rule will increase certainty for the regulated community.

## **Conclusion**

DEA should be commended for proposing to lift the ban on approving mobile methadone vans. Once finalized, this action could reduce the cost of expanding treatment for opioid use disorder, increasing access to this critical treatment. However, DEA should revise or remove certain proposed conditions that will not evidently reduce diversion risks and could increase the cost of expansion. Additionally, DEA should immediately begin approving mobile components in light of the COVID-19 public health emergency.

For additional recommendations and analysis of the proposed rule, see my [public comment](#).