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DEA Lifts Moratorium on Methadone Vans

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In brief…

The Drug Enforcement Administration released a final rule that lifts a ban on new methadone vans. The rule is expected to increase access to methadone, an effective treatment for opioid use disorder, in rural and underserved urban areas.

The Drug Enforcement Administration (DEA) released a final rule that repeals a longstanding moratorium on new mobile methadone clinics. Methadone, along with buprenorphine, is much more effective at treating opioid use disorder than approaches that do not use medication. The rule is expected to expand the number of mobile methadone clinics, otherwise known as "methadone vans," and increase access to the medication in rural and underserved urban areas.

The opioid crisis is worsening. Preliminary data suggests over 90,000 people died of overdoses in the United States last year, up from roughly 70,000 the year before. DEA should be commended for lifting the moratorium on new methadone vans. Moving forward, DEA should learn from the experience of the program, and in the absence of any evidence of increased diversion (i.e., the movement of controlled substances "from their lawful purposes into illicit drug traffic"), it should provide even more flexibilities for methadone vans.

Regulation of Methadone Limits Patient Access

Patients can only receive methadone, a schedule II controlled substance, at clinics that have been registered with DEA and certified by the Substance Abuse and Mental Health Services Administration. These clinics are highly regulated by both agencies. Clinics must provide counseling services and conduct patient drug tests, and they can only provide patients with a take-home supply of methadone after they meet time-in-treatment requirements. The limits on taking home additional doses of methadone force many patients must make a daily trip to a clinic. This creates a logistical challenge, particularly for rural patients. Over 90 percent of methadone clinics are located in urban areas, and rural patients report that traveling long distances each day to a clinic makes them less likely to continue treatment.

DEA's New Rule is a Step Forward

DEA previously allowed brick-and-mortar methadone clinics to operate a mobile component, but in 2007, it halted the approval of any new methadone vans. This final rule lifts that moratorium and allows any clinic that is already registered with DEA to add a mobile component to their program without obtaining a separate registration. The Controlled Substances Act generally requires practitioners to obtain a separate DEA registration at each "principal place of business or professional practice" where they dispense or distribute a controlled substance, but it also gives DEA authority to waive registration requirements.

Under DEA's final rule, brick-and-mortar clinics that are already registered with DEA can begin a mobile component. Although they do not need a separate registration, DEA still requires them to get pre-approval from a local DEA field office before operating the mobile component.

Although DEA has no good way to predict how many methadone vans will begin operating under the final rule, it estimates that operating one costs roughly $320,000 to $360,000 less than operating a brick-and-mortar clinic over a five-year period. DEA did not estimate the difference in patient capacity between clinics and vans, but methadone vans may be a cost-effective way to increase patient capacity.

Under the final rule, methadone vans must follow requirements that are intended to minimize the diversion of controlled substances. For example, DEA requires the vans to return to the registered location each day, and the controlled substances must be removed and stored inside the registered location. In a public comment filed on the proposed rule, I suggested that DEA not require the mobile components to return to the registered location because DEA already requires clinics to take sufficient safety measures, such as locking controlled substances in a safe that triggers an alarm, that act as a significant check against theft and diversion. DEA maintained the requirement that vans return to the clinic each day, arguing that the security risks "become unwieldy" when vans are left unattended. However, in light of the many public comments received on this issue, DEA clarified that methadone vans can apply for an exception to this requirement.

The final rule also prohibits methadone vans from operating in states other than the state where the registered clinic is located. DEA generally requires practitioners to have separate registrations in each state where they dispense controlled substances. Since the rule permits methadone clinics to operate mobile components without a separate registration, the program is not designed to allow the mobile components to seek a standalone registration in another state. Although DEA could authorize a single methadone van to partner with multiple registered clinics in different states, DEA argued that this would diminish oversight authority and complicate recordkeeping, increasing the risks of diversion.

DEA finalized various other requirements aimed at reducing diversion, such as requiring the vans to lock controlled substances in a safe that is bolted or cemented to the floor and protected from manipulation or radiological attacks. This rule also requires methadone vans to keep hard copy records with information on dispensed controlled substances.

Conclusion

DEA's rule is a positive step that should increase access to lifesaving treatment. Moving forward, in the absence of any evidence of increased diversion, DEA should consider providing additional flexibilities for methadone vans, such as allowing them to partner with multiple clinics in different states or allowing them to remain away from the registered clinics overnight. Absent issues with theft, DEA should even consider registering standalone methadone vans that are not associated a brick-and-mortar clinic.