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Public Interest Comment¹ on
The Drug Enforcement Administration's Proposed Rule

Registration Requirements for Narcotic Treatment Programs with Mobile Components

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The George Washington University Regulatory Studies Center

The George Washington University Regulatory Studies Center improves regulatory policy through research, education, and outreach. As part of its mission, the Center conducts careful and independent analyses to assess rulemaking proposals from the perspective of the public interest. This comment on the Drug Enforcement Administration's (DEA) Proposed Rule, "Registration Requirements for Narcotic Treatment Programs with Mobile Components," does not represent the views of any particular affected party or special interest, but is designed to evaluate the effect of the proposal on overall consumer welfare.

Introduction

The abuse of prescription pharmaceuticals, in particular opioids, is a fast-growing problem in the United States. In 2017, more than 47,000 Americans died from an opioid overdose, and that same year the U.S. Department of Health and Human Services (HHS) declared the opioid epidemic a public health emergency.³ Methadone and buprenorphine, both DEA controlled substances, are the mainstay of treatment for opioid use disorder.⁴

¹ This comment reflects the views of the author and does not represent an official position of the GW Regulatory Studies Center or the George Washington University. The Center's policy on research integrity is available at <http://regulatorystudies.columbian.gwu.edu/policy-research-integrity>.

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³ DEP'T OF HEALTH & HUMAN SERV., WHAT IS THE OPIOID [EPIDEMIC?](#) (2019).

⁴ See Shahid Ali et al., *Methadone Treatment of Opiate Addiction: A Systematic Review of Comparative Studies*, 14 INNOVATIONS IN CLINICAL NEUROSCIENCE 8 (2017).

Practitioners who want to administer methadone, a schedule II controlled substance, to treat opioid use disorder must first obtain a registration from DEA to operate as a Narcotic Treatment Program (NTP). The Controlled Substances Act (CSA) requires that each person registered with the DEA to dispense controlled substances must obtain a separate registration “at each principal place of business or professional practice.”⁵ This requirement generally extends to NTPs. However, the statute also gives DEA the authority to waive this requirement if “consistent with the public health and safety.”⁶

There is impetus for expanding NTPs to treat opioid use disorder. In particular, practitioners want to operate mobile NTPs, sometimes referred to as “methadone vans,” to expand access to rural locations and underserved urban neighborhoods.⁷ However, DEA placed a moratorium on approving mobile NTPs in 2007. Under this 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.

Background

There are approximately 1,700 NTPs at brick-and-mortar locations registered with DEA.⁸ DEA previously authorized mobile components on an ad hoc basis, but in 2007 placed a moratorium on approving new mobile components. DEA provides no evidence that there was an increased risk of diversion associated with operating mobile components that led to this moratorium. DEA points out in the preamble that “the vast majority of authorized mobile NTP components complied with the CSA and its implementing regulations” and that there has been only one instance of theft or loss at a mobile component (the reporting does not distinguish between theft and loss).⁹

DEA’s 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.¹⁰ Rural 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.¹¹

DEA has received pressure from local, state, and federal agencies working to combat the opioid epidemic, as well as members of Congress, to lift the moratorium so practitioners can deploy

⁵ 21 U.S.C. § 822(e)(1) (2018).

⁶ 21 U.S.C. § 822(d).

⁷ Christine Vestal, *Federal Ban on Methadone Vans Seen as Barrier to Treatment*, PEW CHARITABLE TR. (Mar. 23, 2018), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2018/03/23/federal-ban-on-methadone-vans-seen-as-barrier-to-treatment>.

⁸ Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11008, 11009 (proposed Feb. 26, 2020).

⁹ *Id.*

¹⁰ *Id.* at 11012.

¹¹ Sigmon S.C., *Access to Treatment for Opioid Dependence in Rural America: Challenges and Future Directions*, 71 JAMA PSYCHIATRY 359 (2014).

methadone vans and provide critical treatment.¹² 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.¹³ The Substance Abuse and Mental Health Services Administration has also urged DEA to lift the moratorium.¹⁴

The Proposed Rule

Under the proposed rule, DEA would repeal its moratorium and waive the requirement that a mobile NTP must have a separate registration, provided the mobile component follows certain conditions laid out in the proposal. Under the proposed rule framework, only NTPs that are already registered with DEA would have the ability to start a mobile component. DEA would not approve a standalone mobile NTP. 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.¹⁵

To minimize diversion of controlled substances in the mobile NTPs, DEA proposes to place the following conditions on mobile NTP operations:

- Registered NTPs must notify the local DEA office and receive explicit written approval prior to operating a mobile component.
- Mobile components cannot dispense in states other than the state where the registered NTP is located.
- Each day, the mobile component must return to the registered NTP location and remove and secure the controlled substances inside the registered location.
- 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.
- Mobile components must keep a log with information on dispensed controlled substances (dose dispensed, patient, etc.). The log must be stored at the registered NTP 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 must preapprove the electronic system.

¹² See, e.g., Letter from Patty Murray, U.S. Sen., et al. to Uttam Dhillon, Acting Admin., DEA (Jan. 17, 2020), <https://kuster.house.gov/media-center/press-releases/congresswoman-kuster-senators-murray-and-warren-press-drug-enforcement>.

¹³ Vestal, *supra* note 7.

¹⁴ *Id.*

¹⁵ Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. 11008 (proposed Feb. 26, 2020).

Recommendations

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 NTPs to meet some conditions for mobile components that will not evidently reduce diversion risks but will increase the burden and cost of expansion.

This public interest comment assesses the proposed rule and offers four sets of recommendations: a) DEA should immediately begin approving mobile components in response to the coronavirus crisis, while the agency works towards finalizing the proposed rule, b) DEA should revise or remove conditions in the proposed rule that do not decrease the risk of diversion but do increase the burden of expanding mobile components, c) DEA should issue an updated economic analysis, and d) DEA should commit to conducting an evaluation of the mobile NTP program.

- a. **DEA should take immediate steps to increase access to treatment while moving expeditiously to finalize the proposed rule.**

Recommendation 1: DEA should immediately begin approving mobile components in response to the public health emergency resulting from COVID-19.

It will take significant resources and time for DEA to finalize this rule. In light of the current public health emergency, DEA should follow a tiered approach and immediately begin approving mobile components while devoting resources to finalizing this rule. As mentioned, the CSA gives DEA the authority to waive the requirement for separate registrations if it is "consistent with the public health and safety."¹⁶ 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. DEA should start using the flexibility immediately, prior to issuance of a final rule.

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.¹⁷ The public health emergency may also limit treatment capacity at brick-and-mortar NTPs. This reduction in treatment capacity indicates how critical it is to immediately approve additional mobile components to fill this gap. Additionally, although many stay-at-home orders exempt essential medical services, patients in rural areas and underserved urban communities might not be willing to travel far distances to receive their daily dose of methadone because they want to minimize their exposure to the virus.

¹⁶ 21 U.S.C. § 822(d) (2018).

¹⁷ Dialynn Dwyer, *Those Struggling with Addiction Face Double Risk During COVID-19 Pandemic*, BOSTON.COM (Mar. 31, 2020), <https://www.boston.com/news/health/2020/03/31/opioid-epidemic-recovery-services-covid-19-outbreak>.

Recommendation 2: DEA should devote resources to finalizing the rule as quickly as possible.

It is critical that DEA devote resources to finalizing this rule quickly. Although this public comment recommends that DEA 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. It will provide registered NTPs with consistent expectations about the requirements for mobile components, making it easier for them to plan and allocate resources towards methadone van projects. This will also reduce the likelihood that DEA officials will abuse their discretion by placing arbitrary or unexpected requirements on registered NTPs attempting to get approval for mobile components.

b. DEA should revise and remove conditions in the proposed rule that do not decrease the risk of diversion and increase the burden of expanding mobile components.

DEA proposed to place multiple conditions on mobile components that should be revised or removed because the agency does not provide sufficient evidence that these conditions decrease the risk of diversion. Although these conditions might seem like small hurdles, they add up and increase the cost to registered NTPs to operate mobile components.

Recommendation 3: DEA should not require NTPs to get pre-approval from the local DEA field office before operating a mobile component.

Rather, DEA should only require registered NTPs to notify the local DEA field office that they will begin operating a mobile component. This will prevent a situation where a registered NTP seeking to expand access with a mobile component will be required to wait for approval, missing out on critical days and weeks that could be spent providing access to patients. The other conditions in this proposed rule, in combination with DEA's regular inspections, are sufficient to ensure diversion is not occurring at mobile components. Since only NTPs that are already registered with DEA will be able to operate a mobile component, the providers will be familiar with the DEA diversion regulations and capable of complying with the conditions for mobile components.

Recommendation 4: DEA should allow mobile components to dispense in a different state than the registered NTP location if the provider can obtain the requisite state license.

For an NTP to dispense controlled substances in a state, it must be authorized or licensed by the state methadone authority. If state methadone authorities are hesitant to license a mobile component with a brick-and-mortar location in another state, or states place a more onerous licensing process on mobile components from another state, it is possible NTPs will choose to only operate within their own state. However, DEA should not prohibit this at the federal level. If states are willing to approve mobile components that are based out of another state to promote access for their own citizens, DEA should defer to the states and not prohibit this practice.

Recommendation 5: Absent evidence of abuse, DEA should not require the mobile component to return to the registered NTP location daily or store the controlled substances in the registered location at the end of each day.

The proposed rule includes multiple safety measures and procedures that are adequate to protect controlled substances. For example, DEA requires the controlled substances to be locked in a safe that is secure and triggers an alarm to a protection company or law enforcement. These measures act as a significant check against theft and diversion, and it is not clear that moving the mobile component back to the registered location and removing the controlled substances decreases the risk of diversion. DEA does not provide evidence or reasoning to explain how these requirements reduce the risk of diversion. One can imagine that DEA fears a thief would be able to more easily break into a motor vehicle and drive away than break into a brick-and-mortar location, but the secured safe that alerts a protection company or law enforcement about a break in might be sufficient to impede a theft. Pending the development of better information regarding the risks of diversion, DEA should not place these restrictions on mobile NTPs.

Mobile components have also proved valuable when providers administer regular treatment in the same location, but it is too costly to build a brick-and-mortar-facility. For example, mobile components are particularly valuable to patients who cannot travel to a registered NTP location due to incarceration. The American Society of Addiction Medicine points out in their comment on the proposed rule that the logistics of transporting patients from a correctional facility to an NTP location can be challenging, and it is easier to bring the NTP to the correctional facility.¹⁸ In these instances, mobile components intend to be stationed primarily at the correctional facility. If the registered NTP location is far from the correctional facility, it will be onerous and costly to require the mobile component to return to that location daily and store the controlled substances inside. Additionally, this requirement might reduce accessibility since mobile components will only be able to reach areas within a one-day driving distance. Rather, DEA should not specify when the mobile component must return to the registered NTP location. As an alternative, DEA should consider increasing the intervals and only requiring the mobile component to return to the registered NTP location on a weekly basis.

Recommendation 6: DEA should not finalize the regulatory provision that gives it the discretion to determine if additional security protections should be required for mobile components.

DEA proposed to alter the regulation text at 21 C.F.R. § 1301.74 to add mobile NTPs as follows:

DEA may exercise discretion regarding the degree of security required in narcotic treatment programs, *including mobile narcotic treatment programs*, based on such factors as the location of the program, the number of patients enrolled in a program and the number of physicians and staff members...¹⁹

¹⁸ Comment from Paul Earley, President, Am. Soc’y of Addiction Med. to Scott Brinks, DEA (Apr. 27, 2020), <https://www.regulations.gov/document?D=DEA-2020-0005-0016>.

¹⁹ Registration Requirements for Narcotic Treatment Programs with Mobile Components, 85 Fed. Reg. at 11019.

Under the existing regulations for NTPs, DEA already retains the discretion to require additional security measures for NTPs seeking registration. However, I was unable to locate any DEA guidance that elaborates on how the factors listed in the regulations (e.g., location of the program) affect an NTP's need for additional security measures. In the proposed rule, DEA does not provide any information on how these factors might be used to evaluate security measures for mobile components. DEA does not provide a single example of the security measures it might require for a mobile component if the factors are relevant.

This regulation is not clear, not transparent, and could lead to rules and policies being applied unevenly. DEA provides a registered NTP planning to open a mobile component minimal information on how these factors could affect the cost of the project. The registered NTP would likely have to reach out to the local DEA field office early in the planning phase before raising money for the project to ensure it can cover the costs of any additional security measures. Although it may be a best practice to engage with the local DEA office at the early planning phases of a methadone van project, the administrative burdens associated with a project of this scale are significant, and DEA should not add this burden. Additionally, this regulation could lead to an uneven application of rules for different NTPs because it gives DEA field officers enormous discretion to place arbitrary or unexpected requirements on registered NTPs seeking approval for mobile components. If DEA decides to finalize this provision, at a minimum, the agency should provide clarity in the preamble surrounding the application of the factors and the security measures that might be required.

Recommendation 7: DEA should allow recordkeeping to be done completely electronically and should not require pre-approval of the electronic recordkeeping system.

Although DEA allows mobile components to keep electronic dispensing logs, the proposed rule would require them to print a hard copy of each day's log and ensure the person who dispensed the controlled substances signs his or her initial beside the relevant entry. DEA should allow mobile components to record each person's initials electronically. There is no reason why DEA cannot allow digital signatures; these electronic processes are readily available and widely used. Although this might seem like a small hurdle, reducing unnecessary paperwork for physicians who are already overwhelmed with paperwork burdens is a worthwhile goal.²⁰ Physicians already experience what some scholars refer to as "sludge," or excessive burdens, that make their professions difficult to navigate.²¹ This sludge can have harmful effects, particularly if it discourages physicians from providing critical treatment.

Also, DEA should not require the mobile component to get pre-approval of the electronic recordkeeping system it will use for the dispensing log because this could create unnecessary delays in the transition to electronic recordkeeping. The other performance-based requirements for recordkeeping are sufficient. If DEA finalizes this requirement, it should clarify that if DEA has already approved an electronic recordkeeping system for a registered NTP location, that this is sufficient for the mobile component.

²⁰ See generally Shelagh McRae & Robert Hamilton, *The Burden of Paperwork*, 52(5) CANADIAN FAMILY PHYSICIAN 586 (2006).

²¹ See Cass R. Sunstein, *Sludge Audits*, BEHAVIOURAL PUB. POLICY 1 (2019).

c. DEA should issue a revised economic analysis.

Section 1(b)(6) of Executive Order 12866 instructs agencies to assess the costs and benefits of a regulation:

Each agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, proposed or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.²²

DEA should be commended for conducting a prospective benefit-cost analysis of the proposed rule. Benefit-cost analysis can provide insight into the scope of the problem created by DEA's moratorium on mobile NTPs and assesses whether the agency's proposal addresses this problem.

DEA qualitatively describes benefits and cost-savings that cannot be quantified, including reduced health care costs, criminal justice costs, and lost productivity costs that will be reduced as a result of increased access to treatment.

Recommendation 8: DEA should include a qualitative discussion of other important benefits that cannot be quantified, like improved quality of life and improved dignity for patients who can access treatment.

The major benefit of this proposed rule is that it is expected to reduce the cost per patient for treatment for opioid use disorder, increasing the number of patients who have access to treatment. This will improve the quality of life and dignity for patients who can access this critical treatment, and DEA should acknowledge these benefits in the analysis.

DEA also conducts a quantitative benefit-cost analysis that compares the cost of renting and operating a brick-and-mortar NTP with the cost of purchasing and operating a mobile component.

Recommendation 9: DEA should clarify that the benefit-cost analysis framework applied in the proposed rule is best used to analyze the reduced marginal cost of treatment.

DEA is unable to determine how many existing NTP registrants would like to operate a mobile component and are prohibited by DEA but are also deterred from opening an additional brick-and-mortar location because of the costs. This suggests there are NTP registrants that are currently deterred from opening an additional brick-and-mortar location but would operate a mobile component under this rule. Rather than compare the status quo (which is that NTPs are not incurring costs to expand brick-and-mortar locations) with the proposed rule environment (which is that NTPs will incur costs for expanding mobile components), DEA assumes the status quo is that NTPs *are* incurring costs to expand brick-and-mortar locations.

The approach is not an unreasonable way to analyze the impacts of the rule. This analysis helps to determine how the rule will reduce the marginal and average costs of treatment. In other words, the analysis DEA conducted for the proposed rule is best used to identify the reduction in the

²² Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993).

marginal cost of treating patients for opioid use disorder. Physicians may actually incur more costs to deploy mobile components under this rule, assuming they would have never put resources towards building more brick-and-mortar NTPs. However, if this rule reduces the *marginal cost* of treating additional patients, this will facilitate an expansion of output. In this case, the social benefit is the benefit created by the expansion of output rather than the cost reduction.

d. DEA should commit to evaluating the mobile NTP program.

The information garnered from program evaluation is critical because it tells the agency and the public if the estimated impacts of a program were accurate and provides insight into designing future standards. Retrospective review of regulation is a form of program evaluation. Although regulation is a distinct type of public policy that must be evaluated differently from other types of policies, the evidence-based tools applied in program evaluation can be used to examine regulatory impacts and inform future decisions.²³

Recommendation 10: DEA should commit to conducting an evaluation of the mobile program established under this rule.

In the preamble to the final rule, DEA should commit to conducting retrospective review and collecting data to assess the impact of the rule on treatment accessibility and the risk of diversion. If this rule succeeds at expanding treatment for opioid use disorder to patients while simultaneously minimizing diversion risks, DEA should further expand the program. For example, DEA could allow mobile NTPs to obtain a registration without requiring them to be connected to a separate registered NTP location. This would benefit rural areas, and other areas that have minimal infrastructure and health care facilities (e.g., Puerto Rico after Hurricane Maria).

As described in the previous section, the social benefit of this final rule will likely be the benefit created by the expansion of output. Once DEA has approved mobile components, DEA can collect data to estimate the elasticity of demand and associated expansion in output due to the reduced marginal cost. DEA can use this information to assess the social benefits and social costs of the rule. If DEA articulates what counts as a social benefit and social cost in the economic analysis accompanying the final rule, as recommended in the previous section, DEA will be better equipped to conduct this retrospective review.

Conclusion

This public interest comment assesses the proposed rule in four main sections: a) DEA should immediately begin approving mobile NTPs in response to the coronavirus crisis while the agency works expeditiously towards finalizing the proposed rule, b) DEA should revise or remove conditions in the proposed rule that do not decrease the risk of diversion but do increase the burden

²³ Marcus C. Peacock, Sofie E. Miller, and Daniel R. Pérez, *A Proposed Framework for Evidence-Based Regulation* (Feb. 2018) (working paper), <https://regulatorystudies.columbian.gwu.edu/sites/g/files/zaxdzs3306/f/downloads/WorkingPapers/GW%20Reg%20Studies%20-%20Evidence%20Based%20Regulation%20-%20MPeacock%20SMiller%20and%20DPerez.pdf>.

of expanding mobile components, c) DEA should issue an updated economic analysis, and d) DEA should commit to conducting an evaluation of the mobile NTP program.

Below I summarize my recommendations:

1. DEA should immediately begin approving mobile components in response to the public health emergency resulting from COVID-19.
2. DEA should devote resources to finalizing the rule as quickly as possible.
3. DEA should not require NTPs to get pre-approval from the local DEA field office before operating a mobile component.
4. DEA should allow mobile components to dispense in a different state than the registered NTP location if the provider can obtain the requisite state license.
5. DEA should not require the mobile component to return to the registered NTP location daily or store the controlled substances in the registered location at the end of each day.
6. DEA should not finalize the regulatory provision that gives it the discretion to determine which security protections should be required.
7. DEA should allow recordkeeping to be done completely electronically and should not require pre-approval of the electronic recordkeeping system.
8. In the economic analysis, DEA should include a qualitative discussion of other important benefits that cannot be quantified, like improved quality of life and improved dignity for patients who can seek treatment.
9. DEA should clarify that the benefit-cost analysis framework applied in the proposed rule is best used to analyze the reduced marginal cost of treatment.
10. DEA should commit to conducting an evaluation of the mobile program.