



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, and 1304

[Docket No. DEA-459]

RIN 1117-AB43

Registration Requirements for Narcotic Treatment Programs with Mobile Components

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to revise the existing regulations for narcotic treatment programs (NTPs) to allow a mobile component associated with the registered program to be considered a coincident activity. The NTP registrants that operate or wish to operate mobile components (in the state that the registrant is registered in) to dispense narcotic drugs in schedules II-V at a remote location for the purpose of maintenance or detoxification treatment would not be required to obtain a separate registration for a mobile component. This proposed rule would waive 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 the proposed rule, once finalized. 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.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal

Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “RIN 1117-AB43/ Docket No. DEA-459” on all correspondence, including any attachments.

- *Electronic comments:* The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on <http://www.regulations.gov>. If you have received a Comment Tracking Number, your comment has been successfully submitted, and there is no need to resubmit the same comment.

- *Paper comments:* Paper comments that duplicate the electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu* of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, Diversion Control Division; Mailing Address: 8701 Morrisette Drive, Springfield, VA 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, Diversion Control Division; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (571) 362-3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “CONFIDENTIAL BUSINESS INFORMATION” in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any

personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this notice of proposed rulemaking are available in their entirety under the tab “Supporting Documents” of the public docket of this action at <http://www.regulations.gov> under FDMS Docket ID: DEA-459 (RIN 1117-AB43/ Docket Number DEA-459) for easy reference.

I. Background and Purpose

A. Legal Authority

The Controlled Substances Act (CSA) generally provides, with certain exceptions, that all persons who are required to register under the Act must obtain a separate registration “at each principal place of business or professional practice” where such persons manufacture, distribute, or dispense a controlled substance. 21 U.S.C. 822(e)(1). However, the CSA authorizes the Administrator of DEA (by delegation from the Attorney General) to issue regulations waiving the requirement of registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety. 21 U.S.C. 822(d).

Pursuant to this latter provision, DEA is hereby proposing a regulation that would waive the requirement of a separate registration for NTPs that utilize mobile components. Specifically, under the proposed rule, an NTP would be permitted to dispense narcotic drugs in 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. Under this proposed rule, regardless of whether the NTP is dispensing narcotic drugs at a remote location on such a regular basis that the location would constitute a principal place of business or professional practice within the meaning of the CSA (see discussion below), the NTP would not need to have a separate registration with DEA at that location as long as it

complies with the requirements of the proposed rule. Such remote dispensing by an NTP would be deemed 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 finds that this proposed waiver of registration is consistent with the public health and safety.

B. Purpose of the Proposed Rule

The impetuses for this notice of proposed rulemaking (NPRM) are the opioid epidemic currently affecting the nation and the desire to design additional ways to curtail this epidemic. During 2017, 70,237 deaths occurred as a result of drug overdoses, including 47,600 deaths (67.8%) that involved an opioid.¹ Further, annual drug overdose deaths have more than tripled since 1999.² From 2015 to 2016, drug overdose deaths increased in all drug categories examined by the Centers for Disease Control and Prevention; the largest increase occurred among deaths involving synthetic opioids other than methadone (synthetic opioids), which includes illicitly manufactured fentanyl. Consequently, the demand for evidence-based medication-assisted treatment for substance use disorders (SUD), including opioid use disorder (OUD), has increased over the years, especially for services provided by NTPs; in some areas, this has resulted in long waiting lists and high service fees. Additionally, in rural and other underserved communities, the distance to the nearest NTP or the lack of consistent access to transportation may prevent or substantially impede access to these critical services.

¹ "Opioid Overdose." *Drug Overdose Deaths*. June 27, 2019. Accessed November 15, 2019. <https://www.cdc.gov/drugoverdose/data/statedeaths.html>.

² Scholl L, Seth P, Kariisa M, Wilson N, & Baldwin G, *Drug and Opioid-Involved Overdose Deaths — United States, 2013–2017*, 67 *MMWR Morbidity Mortality Weekly Report* 1419–1427 (2019). Accessed September 12, 2019. DOI: <http://dx.doi.org/10.15585/mmwr.mm675152e1>

In April of 2000, DEA, in association with the American Methadone Treatment Association (now the American Association for the Treatment of Opioid Dependence), developed guidelines for NTPs to follow to ensure greater stability in the treatment process by using the same standard throughout the United States.³ As the nature of the opioid epidemic evolves, new methods and guidelines to further increase accessibility for persons with OUD also need to evolve. Alternative methods, such as mobile components of NTPs, can be used to bring treatment to those in rural or other areas where NTPs are not accessible, or to allow people who concurrently are unable to travel to an NTP to receive care. This has prompted some NTPs to purchase vehicles (in this NPRM, the word “conveyance” will be used interchangeably with “mobile component” to describe such vehicles) for the purposes of dispensing controlled substances outside of their registered location, but within states in which they are registered. Under the proposed rule, mobile components of NTPs would not be authorized to function as hospitals, long-term care facilities, or emergency medical service vehicles, and would not be authorized to transport patients.

There are more than 1,700 NTPs registered with DEA, including opioid treatment programs, detoxification treatment services that utilize methadone, and compounders. Prior to 2007, DEA authorized mobile NTPs on an ad hoc basis. Since then, it has placed a moratorium on further such authorizations, resulting in a gradual decline in the number of mobile NTPs. During the past five years, 19 NTPs have operated a mobile component. Currently, eight NTPs operate mobile units under those agreements.⁴ The vast majority of authorized mobile NTP components complied with the CSA and its implementing regulations. This NPRM builds on the existing experience and provides additional flexibility

³ Drug Enforcement Administration, *Narcotic Treatment Programs Best Practice Guideline* (2000).

⁴ Data collected from DEA field offices in June 2019.

for NTPs in operating mobile components subject to the regulatory restrictions put into place to prevent the diversion of controlled substances. This NPRM is thus aimed at helping to alleviate the opioid crisis in the United States by formalizing the requirements for operating a mobile NTP and thereby allowing for greater access to OUD treatment while maintaining appropriate controls to reduce the likelihood of diversion.

C. Why this Proposed Rule Is Legally Necessary

As indicated above, the CSA generally requires all persons who dispense controlled substances – including NTPs – to be registered at each “principal place of business or professional practice” where they dispense controlled substances. This requirement is reiterated in DEA regulations. 21 CFR 1301.12. While the CSA and DEA regulations do not define the term “principal place of business or professional practice,” in one case, a federal court looked to 21 CFR 1301.12(b)(3) in evaluating this question and focused on whether the practitioner “regularly engaged in the dispensing or administering of controlled substances” at a particular location as determinative of whether a separate registration is required at such location. *United States v. Clinical Leasing*, 930 F.3d 394, 395-396 (5th Cir. 1991). That court stated: “If a physician intends to dispense controlled substances from a particular location several times a week or month, he must first [obtain] a separate registration for the location.” *Id.* In another case (a DEA administrative proceeding), the agency explained that where a practitioner travels to numerous locations to administer controlled substances on an “as-needed and random basis” and under other circumstances that were not indicative of maintaining a principal place of professional practice at such locations, the practitioner was not required to be separately registered at such locations. *Jeffrey J. Becker, DDS*, 77 FR 72387, 72388 (Dec. 5, 2012).

It is not necessary for purposes of this proposed rule to attempt to define precisely the meaning of the term “principal place of business or professional practice” or to attempt to examine the various scenarios in which that term might apply to a mobile NTP. It is sufficient to note that there may be circumstances in which a mobile NTP would operate in such a manner that it would be considered to have a “principal place of business or professional practice” at one or more consistent remote locations and, therefore, would need to obtain a separate registration at such remote locations under 21 U.S.C. 822(e)(1). Because DEA has concluded that it is consistent with the public health and safety to allow mobile NTPs to operate without obtaining such separate registrations at remote locations, the agency is hereby proposing to waive this requirement through the promulgation of the proposed rule. *See* 21 U.S.C. 822(d). DEA is proposing that the regulations would be amended to specify that operating a mobile NTP will be a coincident activity of a registered NTP.

It should be noted that DEA has always required, with limited exceptions, practitioners to have separate registrations in each state in which they dispense controlled substances. *See, e.g.,* Clarification of Registration Requirements for Individual Practitioners, 71 FR 69478, 69478 (Dec. 1, 2006) (explaining that a practitioner must maintain a DEA registration for each state in which he or she dispenses controlled substances because DEA registrations are based on state licenses to dispense controlled substances). Thus, under the proposed rule, a mobile NTP would be able to only dispense controlled substances in states in which the NTP is registered with DEA to dispense controlled substances.

D. Why the Proposed Waiver of Registration Is Consistent with the Public Health and Safety

As indicated, the CSA allows DEA to issue a regulation waiving the requirement of registration for certain categories of registrants where the Administrator finds it consistent with the public health and safety. For the reasons discussed above, DEA concludes that allowing for the use of mobile NTPs under the conditions specified in this proposed rule would increase access to OUD treatment, which will be beneficial to the public health and safety. This conclusion is further supported by DEA's belief that under the conditions specified in the proposed rule, there would be minimal risk of diversion. DEA bases this view about the minimal diversion risk on historical information gathered from mobile components that have operated or are currently operating.

A review of theft and loss reports from 2005 to 2017 shows that NTPs did not distinguish thefts and losses occurring at the registered location from those occurring at mobile facilities. There was only one report that concluded theft or loss occurred at a mobile NTP. However, this mobile NTP is no longer operational as the registrant voluntarily surrendered DEA registration. Furthermore, since 2017, there have not been any additional mobile NTP reports of thefts or losses of controlled substances submitted to DEA.

E. Summary of Costs and Benefits

DEA conducted an analysis of the costs and benefits of this proposed rule, and concludes that its promulgation will result in a net cost savings between \$1,297,670 and \$1,482,272 over a five-year period. This proposed rule would enable NTPs to expand their treatment availability to patients via mobile units rather than being limited to registering and opening additional brick-and-mortar locations only. DEA's comparative analysis shows that the cost of operating a mobile unit is less than the cost of operating a physical location, yielding the

aforementioned savings. A complete discussion of the costs and benefits of this proposed rule can be found in the Regulatory Analyses below.

II. Scope of the Proposed Rule

This proposed rule describes 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 rule also sets forth proposed requirements for security, recordkeeping, reporting, and inventory for those mobile components that wish to transport controlled substances away from a registered location for dispensing at a mobile NTP.

It is important to note that these mobile components would not be permitted to share or transfer controlled substances from one mobile component to another while deployed outside of the registered location. Nor would mobile components be permitted to act as reverse distributors.⁵ Likewise, stationary NTPs with mobile components would not be allowed to modify their registrations to authorize their mobile components to act as collectors⁶ under 21 CFR 1301.51 and 1317.40. Finally, as stated above, these proposed mobile components of NTPs would not be authorized to function as hospitals, long-term care facilities, or emergency medical service vehicles, and may not transport patients.

A. Part 1300: Definitions

⁵ 21 CFR 1300.01 defines a *reverse distributor* as a person registered with the Administration as a reverse distributor. To reverse distribute means to acquire controlled substances from another registrant or law enforcement for the purpose of: (1) return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or (2) destruction.

⁶ 21 CFR 1300.01 defines *collector* as a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user that resides or has resided at that facility.

In section 1300.01, DEA is proposing to add a definition for mobile narcotic treatment programs (mobile NTPs). This definition reflects that a mobile NTP is a motor vehicle that serves as a mobile component of an NTP, which engages in maintenance and/or detoxification treatment with narcotic drugs in schedules II-V, at a location remote from, but within the same state as, the registered NTP, and which operates under the registration of the NTP. Because the proposed mobile NTP definition references a motor vehicle, DEA also proposes to separately define “motor vehicle” 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; a motor vehicle does not include a trailer in this context. Therefore, under DEA’s proposed rule, a trailer could not serve as a mobile NTP.

B. Part 1301: Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

DEA regulations have always required that all registrants maintain effective security to guard against theft and diversion of controlled substances. *See* 21 CFR 1301.71-77. The need for such security applies equally in the mobile NTP context. Thus, this NPRM contains provisions (described below) that would require NTPs to secure controlled substances while operating a mobile component away from the registered location.

Also, as indicated, DEA proposes to revise 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 lessen the regulatory burden on NTPs by waiving the separate DEA registration requirement, as discussed above, 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 an NTP would not have to apply for a separate registration, as it would be considered coincident activity. Furthermore, DEA proposes to specify in the regulations that the records generated during the operations of a mobile component of an NTP shall be maintained at the location of the registered NTP, rather than requiring such records to be stored at the location of the mobile component. This is discussed in part 1304 of the proposed rule, which is titled Records and Reports of Registrants.

DEA is proposing to revise section 1301.72 to ensure controlled substances in a mobile component of an NTP are protected against theft and diversion. To achieve this end, DEA is proposing that the security requirements under 21 CFR 1301.72(a)(1) and 21 CFR 1301.72(d) become applicable to the mobile components of an NTP. The storage area for controlled substances in a mobile component of a NTP must not be accessible from outside the vehicle. The proposed requirement to secure the controlled substances in a securely locked safe in the conveyance will assist in adequately securing the controlled substances. Since small quantities of controlled substances will be present in the mobile component, DEA is proposing that the safe used by these mobile components have safeguards against forced entry, lock manipulation, and radiological attacks. The safe must also be bolted or cemented to the floor or wall in such a way that it cannot be readily moved. DEA is also proposing that the safe be equipped with an alarm system that transmits a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve if there is an attempted unauthorized entry into the safe.

Upon completion of the operation of the conveyance on a given day, the conveyance would need to be immediately returned to the registered location, and all controlled

substances removed from the conveyance and secured within the registered location. If the mobile component is disabled for any reason (mechanical failure, accident, fire, etc.), the registrant would be required to have a protocol in place to ensure that the controlled substances on the conveyance are secure and accounted for. If the conveyance is taken to an automotive repair shop, all controlled substances would need to be removed and secured at the registered location.

Under the proposed rule, registrants would not be required to obtain a separate registration for conveyances (mobile components) utilized by the registrant to transport controlled substances away from registered locations for dispensing within the same state at unregistered locations. Vehicles must possess valid county/city and state information (*e.g.*, a vehicle information number (VIN) or license plate number) on file in the fixed NTP. Registrants will also be required to provide proper city/county and state licensing and registration to DEA at the time of inspection and prior to transporting controlled substances away from their registered location.

DEA takes this opportunity to remind authorized persons transporting controlled substances to dispense at an unregistered location that the DEA-approved conveyance they utilize to transport these controlled substances is a controlled premise subject to administrative inspection pursuant to 21 U.S.C. 880. The CSA includes in its definition of controlled premises “conveyances, where persons registered under [21 U.S.C. 823] (or exempt from registration under [21 U.S.C. 822(d)] or by regulation of the Attorney General) . . . may lawfully hold . . . distribute, dispense, administer, or otherwise dispose of controlled substances.” 21 U.S.C. 880(a)(2). Included within this section’s scope of inspection for controlled premises, the CSA grants DEA inspectors the right, “[e]xcept as may otherwise be

indicated in an applicable inspection warrant . . . to inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished drugs . . . and other substances or materials, containers, and labeling found therein.” 21 U.S.C. 880(b)(3).

DEA is aware that state and federal security requirements for controlled substances may vary. However, it is the responsibility of the registrant to be aware of these requirements and follow both state and federal regulations, or whichever has the stricter requirements. Registrants and practitioners should continue to consult with their State Opioid Treatment Authority or equivalent office to ensure compliance, as referenced in DEA April 2000 Narcotic Treatment Program Best Practice Guide.

DEA is proposing to revise 21 CFR 1301.74 to include mobile components of DEA-registered NTPs, since the existing regulations do not contain such a provision. As described in the proposed revisions to section 1301.74, personnel who are authorized to dispense controlled substances for narcotic treatment must ensure proper security measures and patient dosage. For example, DEA is proposing that persons enrolled in any NTP, including those who received treatment at a mobile NTP, would be required to wait in an area that is physically separated from the narcotic storage and dispensing area by a physical entrance such as a door or other entryway.

Under the proposed revisions, the distribution and delivery of narcotic drugs in schedules II-V to mobile NTPs would only be permitted by the registrant at the registrant’s registered location. Persons who are permitted to deliver narcotic drugs in schedules II-V to mobile NTPs will not be able to: receive narcotic drugs in schedules II-V from other mobile NTPs or any other entity; deliver narcotic drugs in schedules II-V to other mobile NTPs or any

other entity; or conduct reverse distribution of controlled substances on a mobile NTP. Any controlled substances being transported for disposal from the dispensing location of the mobile component shall be secured and disposed of in compliance with part 1317 and all other applicable federal, state, tribal, and local laws and regulations.

Finally, the proposed physical security controls of mobile components would need to be implemented by the NTP pursuant to 21 CFR 1301.72 and 1301.74. In the event of a security breach in which controlled substances are lost or stolen, the registrant must determine the significance of the loss and look to the theft and loss reporting requirements in 21 CFR 1301.74(c).

C. Part 1304: Records and Reports of Registrants

Under the proposed rule, the recordkeeping requirements of 21 CFR 1304 would apply to mobile components of NTPs. DEA is proposing revisions to sections 1304.04 and 1304.24 to include mobile components. As with brick and mortar NTPs, the records of the mobile components would be stored at the registered location of the NTP in a manner that meets all applicable security and confidentiality requirements, and must be readily retrievable.

Currently 21 CFR 1304.24(b) requires that a brick and mortar NTP maintain the records, required by 21 CFR 1304.24(a), in a dispensing log at the NTP site. It is understood that this log is in paper form. As an alternative to maintaining a paper dispensing log, DEA is proposing that an NTP or its mobile component may also use an automated/computerized data processing system for the storage and retrieval of the program's dispensing records, if a number of conditions are met: the automated system maintains the same information required in 21 CFR 1304.24(a) for paper records; the automated system has the capability of producing a hard copy printout of the program's dispensing records; the NTP or its mobile

component prints a hard copy of each day's dispensing log, which is then initialed appropriately by each person who dispensed medication to the program's patients; and the automated system is approved by DEA.⁷

DEA also is proposing that the NTP's computer software program be required to be capable of producing accurate summary reports for the brick and mortar location and its mobile component, for any time-frame selected by DEA personnel during an investigation. Further, if these summary reports are maintained in hard copy form, DEA proposes that they should be kept in a systematically organized file located at the registered site of the NTP. Additionally, DEA is also proposing that the NTP or its mobile component be required to maintain an off-site back-up of all computer generated program information.

Finally, DEA is proposing that NTPs be required to retain all records for the brick and mortar NTP as well as the mobile component two years from the date of execution. This time period is the same period as that required by 21 CFR 1304.04(a). However, because some states require that records be retained for longer than two years, the NTP should contact its State Opioid Treatment Authority for information about state requirements.

Regulatory Analyses

Summary of Costs and Benefits

DEA examined each of the provisions of the proposed rule to estimate its economic impact. DEA's analytic approach focuses on comparing the costs and/or cost-savings of a "no action" baseline regulatory environment with the costs and/or cost-savings of the regulatory environment that would result from the promulgation of this proposed rule. This

⁷ This is not a new alternative. DEA has previously informed NTPs that they could use an automated/computerized data processing system meeting these requirements for the storage and retrieval of their dispensing records. See *Narcotic Treatment Programs Best Practice Guideline* (April 2000), <https://www.deadiversion.usdoj.gov/pubs/manuals/narcotic/narcotic.pdf> pp. 14, 20, and 21.

is the standard analytic framework codified in the OMB Circular A-4, published on September 17, 2003. This proposed rule is an enabling rule designed to expand access to medication-assisted treatment (MAT) offered by NTPs in underserved communities. Previously, DEA had only authorized mobile NTPs on an ad hoc basis, and had placed a moratorium on further such authorizations in 2007. Thus, DEA compared the costs of delivering MAT services in a baseline regulatory environment in which no new mobile NTPs are authorized, to the costs of delivering an equivalent level of MAT services in the proposed regulatory environment in which a registered NTP may begin to operate a mobile component as a coincident activity. This analysis, detailed below, finds that this proposed rule will result in a cost savings for DEA registered NTPs in the form of reduced startup, labor, and operating costs of MAT services delivered via a mobile component. DEA also recognizes that this proposed rule is likely to result in benefits in the form of economic burden reductions (health care costs, criminal justice costs, and lost productivity costs), as access to treatment for underserved communities is expected to expand. However, DEA does not have a good basis to estimate the totality of this benefit with any accuracy since data on the number of patients treated via existing mobile components are not available. Thus, while these benefits are not quantified, DEA expects that this proposed rule will result in a net benefit to society.

MAT has been shown to be an effective opioid treatment option—a 2014 meta-analysis concluded that MAT has significantly increased treatment retention and decreased illicit opioid use.⁸ While it is estimated that 2 million Americans have an OUD involving medications, and another 526,000 had an OUD involving heroin, in 2018, only 19.7% of

⁸ Thomas CP, Fullerton CA, Kim M, et al. Medication-Assisted Treatment with Buprenorphine: Assessing the Evidence. *Psychiatry Serv.* 2014;65(2):158-170. doi:10.1176/appi.ps.201300256.

Americans with an OUD received any specialty treatment.⁹ A review of private insurance data found that, following an opioid-related hospitalization, fewer than 11 % of covered patients received MAT in combination with psychosocial services. An additional 6% received MAT without psychosocial services, and 43% received psychosocial services only.¹⁰ As of 2016, over 90% of NTPs were located in urban areas, forcing rural patients to travel great distances to receive their doses of medication.¹¹ Some rural patients report that the burden of traveling daily to receive their medication effectively prevents them from working,¹² further increasing the risk that they will discontinue treatment.¹³

Because DEA is not currently authorizing new mobile NTPs, for an NTP registrant to provide MAT services to patient populations with little or no access to an NTP, the registrant would be required to register and open another brick-and-mortar location in the underserved geographic area. The many fixed capital and operating expenses associated with the startup and ongoing operation of a new facility discourage providers from doing this. For example, registrants would be required to obtain another NTP registration at \$244 per year and incur the cost of renting additional office space, and ensuring that the new location meets DEA requirements, that it is appropriately licensed by the state, and that it is accredited by an accrediting organization approved by the Substance Abuse and Mental Health Services

⁹ Substance Abuse and Mental Health Services Administration. (2019). Key substance use and mental health indicators in the United States: Results from the 2018 National Survey on Drug Use and Health (HHS Publication No. PEP19-5068, NSDUH Series H-54). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration.

¹⁰ Ali, M. M., Mutter, R. (2016). The CBHSQ Report: Patients Who Are Privately Insured Receive Limited Follow-up Services After Opioid-Related Hospitalizations. Rockville, MD: Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Retrieved by ONDCP on August 18, 2017 at http://www.samhsa.gov/data/sites/default/files/report_2117/ShortReport-2117.pdf.

¹¹ Leonardson J, Gale JA. Distribution of Substance Abuse Treatment Facilities Across the Rural – Urban Continuum. 2016. <https://muskie.usm.maine.edu/Publications/rural/pb35bSubstAbuseTreatmentFacilities.pdf>.

¹² Sigmon SC. Access to Treatment for Opioid Dependence in Rural America: Challenges and Future Directions. *JAMA Psychiatry*. 2014;71(4):359-360. doi:10.1001/jamapsychiatry.2013.4450.

¹³ Leonardson J, Gale JA. Distribution of Substance Abuse Treatment Facilities Across the Rural – Urban Continuum. 2016. <https://muskie.usm.maine.edu/Publications/rural/pb35bSubstAbuseTreatmentFacilities.pdf>.

Administration (SAMHSA). Additionally, opening a new location would entail additional staffing and facilities costs. Under the proposed regulatory environment, registrants would be able to operate a mobile component as a coincident activity of their existing facility, foregoing the expenses of a brick-and-mortar expansion in favor of the comparatively lower cost of operating a mobile component.

DEA believes it is reasonable to assume that in any given geographic region, the fixed capital expenses of opening a new brick-and-mortar location (most significantly office rent) will always exceed the capital expenses of operating a mobile component (most significantly the purchase price of a conveyance to be converted to a mobile NTP). These major capital expenses are discussed and compared in detail in the following paragraph; however, it is important to first set boundaries for this analysis by discussing what costs will not be included and why. DEA assumes that two significant expenses are the same for both activities, and therefore, are excluded from the analysis: the labor required to dispense narcotic drugs in schedules II-V, and the cost to outfit an NTP office or mobile conveyance with sufficient medical and office equipment. Labor costs are considered to be equal for both activities as the proposed rule does not change the requirements for the types of personnel that are authorized to dispense controlled substances. Whether an NTP expands via a brick-and-mortar location or mobile component, DEA assumes that the registrant would need to expand the quantity and type of labor required to dispense narcotic drugs in schedules II-V, at the same rate for both. However, it is likely that brick and mortar locations would be required to employ a medical administrative assistant to handle records management, billing, and reception; functions that a mobile component of an existing NTP would outsource to the labor provided by the parent brick and mortar NTP. DEA assumes that a new brick and

mortar NTP requires one medical assistant, and calculates that the total annual compensation for this medical assistant to be \$48,994.¹⁴

DEA also recognizes that there are startup costs that will be the same for both activities. This includes the purchase of medical equipment and basic office supplies, and the installation of a section 1301.72(a)(1)(iii)-compliant alarm system. Such startup costs are accordingly also omitted from this analysis. Whether MAT services are being rendered via a mobile conveyance or traditional office environment, the same type and quantity of labor, medical equipment, and security equipment is assumed needed to deliver the same amount of treatment while adhering to DEA regulations.

According to the National Association of Realtors, the average annual price per square foot for office space throughout the United States was \$46 in the first quarter of 2017.¹⁵ Based on DEA's knowledge of registrant operations, NTPs require a minimum of 1,000 square feet of office space, which equates to a conservative estimate of yearly rent for NTPs of \$46,000. Assuming the NTP agrees to a five-year lease, the present value of the cost of five years of office rent is \$188,609.08 at a 7% discount rate and \$210,666.53 at a 3% discount rate. In comparison, commercial vehicles suitable for service as a mobile NTP

¹⁴ The total annual cost of compensation is based on the median annual wage for Occupation Code 31-9092 Medical Assistants (\$33,610). May 2018 National Occupational Employment and Wage Estimates, United States, BUREAU OF LABOR STATISTICS, https://www.bls.gov/oes/current/oes_nat.htm#31-9092 (last visited November 11, 2019). Average benefits for employees in private industry is 31.4% of total compensation. Employer Costs for Employee Compensation – June, 2019, BUREAU OF LABOR STATISTICS, <https://www.bls.gov/news.release/pdf/ecec.pdf> (last visited November 11, 2019). The 31.4% of total compensation equates to 45.8% (31.4% / 68.6%) load on wages and salaries. $\$33,610 \times (1 + 0.4577) = \$48,994.17$.

¹⁵ “2017 Q1 Commercial Real Estate Market Survey.” www.nar.realtor, 2017, www.nar.realtor/research-and-statistics/research-reports/commercial-real-estate-market-survey/2017-q1-commercial-real-estate-market-survey.

range in price from \$30,000 to \$40,000.¹⁶ Furthermore, the proposed rule would not require an NTP to obtain a separate registration for the mobile component at a cost of \$244 per year, which is a cost that a new brick-and-mortar location would be forced to incur. The present value of registration costs per registrant over a five-year period is \$1,000.45 at a 7% discount rate and \$1,117.45 at a 3% discount rate.

There are also several operating expenses that are unique to a mobile conveyance that should be factored into this analysis. The first is the cost of the narcotic safe and associated installation costs. DEA recognizes that while both a mobile conveyance and a traditional NTP office require a safe, the confined space of a mobile conveyance likely requires some amount of customization in the installation process in order to meet the requirements of 21 CFR 1301.72(a)(1). To account for this unique installation cost, DEA doubled the highest quoted price of the safe¹⁷ and attributed that full amount to the mobile conveyance, while attributing only the purchase price of the safe to the cost of a brick-and-mortar NTP. The second set of costs unique to the operation of a mobile component are maintenance and transportation expenses such as fuel, repair, insurance, permits, licenses, tires, tolls, and driver wages and benefits. The American Transportation Research Institute estimates that the average marginal cost per mile of operating a straight truck in 2016 (the most recent year in which this figure was updated) was \$1.63. This figure is inclusive of all previously listed

¹⁶ Price range gathered by searching commercialtrucktrader.com for class 1, 2, and 3 light duty box trucks and class 4, 5, and 6 medium duty box trucks. These vehicle classes were used based on DEA's knowledge of the types of vehicles currently used by registrants for mobile components.

¹⁷ Quotes for safes meeting DEA's regulatory specifications were sourced online from three leading manufacturers: Healthcare Logistics, Medicus Health and Harloff. The highest price quoted was \$899.00. Doubling the price to account for installation yields a total cost of \$1,798.00.

expenses.¹⁸ Based on DEA’s knowledge of the operations of existing mobile NTPs, DEA estimates that a mobile NTP operating under the proposed rule would travel no greater than 5,000 miles per year (roughly 100 miles per week). This equates to an annual transportation and maintenance expense of \$8,150.00 per year. DEA requests input concerning these assumptions especially in light of the needs for this service in rural locations where clients may be located far from one another.

Comparing the present value of the costs associated with operating a mobile NTP over a five-year period with the present value of the costs associated with opening a brick-and-mortar NTP over a five-year period yields a net present value of cost savings between \$318,855 (at a 7% discount rate) and \$359,131 (at a 3% discount rate) for the operation of a mobile NTP. The comparison of costs between the baseline and proposed regulatory environment are summarized in the tables below:

Baseline Regulatory Environment – Total Brick-and-Mortar NTP Expansion Costs*

Office rent per year	\$46,000.00				
Cost of safe ¹⁹	\$899.00				
Labor Cost	\$48,994.00				
Registration fee	\$244.00				
NPV 3%	Year 1	Year 2	Year 3	Year 4	Year 5
\$437,036	\$96,137.00	\$95,238.00	\$95,238.00	\$95,238.00	\$95,238.00
NPV 7%	Year 1	Year 2	Year 3	Year 4	Year 5
\$391,335	\$96,137.00	\$95,238.00	\$95,238.00	\$95,238.00	\$95,238.00

*All figures rounded to the nearest whole dollar.

Proposed Regulatory Environment – Total Mobile NTP Costs*

Vehicle purchase price	\$40,000.00				
Cost to install DEA compliant safe	\$1,798.00				

¹⁸ Hooper, Alan, and Dan Murray. An Analysis of the Operational Costs of Trucking: 2017 Update. ATRI, American Transportation Research Institute, 2017, atri-online.org/wp-content/uploads/2017/10/ATRI-Operational-Costs-of-Trucking-2017-10-2017.pdf.

¹⁹ The cost of a safe is a one-time expense incurred in the first year of operation.

Maintenance cost per year	\$8,150.00				
NPV 3%	Year 1	Year 2	Year 3	Year 4	Year 5
\$77,905	\$49,948.00	\$8,150.00	\$8,150.00	\$8,150.00	\$8,150.00
NPV 7%	Year 1	Year 2	Year 3	Year 4	Year 5
\$72,480	\$49,948.00	\$8,150.00	\$8,150.00	\$8,150.00	\$8,150.00

*All figures rounded to the nearest whole dollar.

DEA does not have a systematic method for estimating how many NTP registrants that are currently deterred or prevented from opening additional brick-and-mortar sites due to costs might take advantage of this enabling rule to begin operating a mobile NTP. DEA also recognizes that, because of their fixed locations, brick-and-mortar sites are more limited in the geographic area they can reasonably serve than are mobile units. DEA conservatively estimates, however, that this number would at least equal the number of NTP registrants that operated mobile components at some point in the previous five years under ad hoc agreements with DEA field offices. There have been 19 such NTP registrants, and there are currently eight with mobile components still in operation. Therefore, DEA considers it a reasonable assumption that at least 11 additional NTP registrants would begin operating a mobile NTP after the promulgation of this rule, bringing the total number of mobile NTPs to at least the previous total of 19. This yields a total cost savings for all of those NTPs over a five-year period of \$3,507,405²⁰ (at a 7% discount rate) to \$3,950,441²¹ (at a 3% discount rate).

For the reasons outlined in the comparative analysis discussed above, DEA concludes that moving from the baseline regulatory environment to the regulatory environment of the proposed rule results in a cost reduction for NTP registrants that wish to expand their

²⁰ The proposed regulatory environment yields a five-year cost savings (discounted at 7%) of \$318,855 over the current regulatory environment. $\$318,855 \times 11 = \$3,507,405$.

²¹ The proposed regulatory environment yields a five-year cost savings (discounted at 3%) of \$359,131 over the current regulatory environment. $\$359,131 \times 11 = \$3,950,441$.

services to new geographic areas, and will spur an increase in the number of mobile NTPs. Therefore, this proposed rule is a deregulatory action that will result in a net cost savings between \$3,507,405 and \$3,950,441.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This proposed rule was developed in accordance with the principles of Executive Orders 12866, 13563, and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. DEA expects that this proposed rule will not have an annual effect on the economy of \$100 million or more in at least one year and therefore is not an economically significant regulatory action. DEA examined each of the provisions of the proposed rule to estimate its economic impact, comparing the costs and/or cost-savings of a “no action” baseline regulatory environment with the costs and/or cost-savings of the regulatory environment that would result from the promulgation of this proposed rule. This proposed rule is an enabling rule designed to expand the supply of medication-assisted treatment (MAT) providers, and DEA currently has only authorized mobile NTPs on an ad hoc basis, with a present moratorium on further such authorizations. Thus, DEA compared the costs of delivering MAT services in a baseline regulatory environment in which no new mobile NTPs are authorized, to the costs of

delivering an equivalent level of MAT services in the proposed regulatory environment in which a registered NTP may begin to operate a mobile component as a coincident activity, subject to the provisions of this proposed rule. DEA's analysis, summarized in the preceding section, finds that this proposed rule will result in a net cost-savings between \$3,507,405 and \$3,950,441, and is therefore below the \$100 million threshold.

For a number of years, DEA has allowed registered NTPs to utilize mobile units as part of their programs through special arrangements with local DEA field offices. The use of these mobile units was in response to the opioid epidemic that is currently affecting the nation. With the number of deaths attributed to overdoses increasing, the demand for access to medication-assisted treatment increased. In many areas, this has resulted in long wait lists and high service fees for services provided by NTPs. Alternative guidelines and methods were sought to increase accessibility to treatment for people with SUD including OUD, especially in rural areas or areas where NTPs are not accessible, or to allow those who have health conditions that prevent them from traveling long distances to receive maintenance or detoxification treatment. Mobile units associated with the registered NTP were seen as an alternative because they increased accessibility to treatment in the areas that needed it.

This NPRM builds on the existing experience and provides additional flexibility for NTPs in operating mobile units, subject to regulatory restrictions put into place to prevent the diversion of controlled substances. DEA is proposing to revise 21 CFR 1301.13 to make operating a mobile component of an NTP a coincident activity of an existing NTP registration, and intends to lessen the regulatory burden on NTPs by waiving the separate DEA registration requirement. These mobile units would be required to maintain effective security to guard against theft and diversion of controlled substances in accordance with 21

CFR 1301.72. The mobile NTPs would also be subject to the recordkeeping requirements in 21 CFR 1304.04 and 1304.24. Many of the current mobile units are already following these regulatory requirements. This proposed rule, once finalized, will ensure that these regulatory requirements can be enforced consistently over any current or future NTP wishing to operate a mobile unit.

Thus, this proposed rule, once promulgated, would enable any NTP registered with DEA to engage in an activity that was previously authorized through special arrangements with DEA field offices. Furthermore, DEA's purpose for allowing registered NTPs to operate a mobile unit as a coincident activity is to expand the availability of MAT in accordance with the priorities outlined in The President's Commission on Combating Drug Addiction and The Opioid Crisis, published on November 1, 2017.

The Office of Information and Regulatory Affairs (OIRA) has determined that the proposed rule is a "significant regulatory action" under Executive Order 12866. Accordingly, this rule has been reviewed by OIRA.

Executive Order 13771 was issued on January 30, 2017, and published in the Federal Register on February 3, 2017. 82 FR 9339. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Guidance from OMB, issued on April 5, 2017, explains that the above requirements only apply to each new "significant regulatory action that . . . imposes costs."

Although this proposed rule is a significant regulatory action under Executive Order 12866, this proposed rule is expected to be an Executive Order 13771 “deregulatory action,” as defined by OMB—that is, a regulatory action with total costs less than zero. The result of DEA’s analysis shows that moving from the baseline regulatory environment to the regulatory environment of the proposed rule results in a cost reduction for NTP registrants that wish to serve new geographic areas, and will increase the number of mobile NTP units. Therefore, this proposed rule is expected to be a deregulatory action that will result in a net cost savings between \$3,507,405 and \$3,950,441.

Executive Order 12988, Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This proposed rule does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (RFA), DEA evaluated the impact of this rule on small entities. DEA's evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of these small entities.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities and discussions of its findings are below.

Description and estimate of the number of small entities

To determine the proposed rule's effect on small entities, DEA must first calculate the total number of affected entities. To do this, DEA must determine the total number of NTP entities in the United States, as those are the entities that are able to take advantage of this enabling rule.

DEA begins with the number of relevant DEA registrations—that is, NTP registrations. The number of NTP entities differs from the number of NTP registrations, however, because NTP entities often hold more than one DEA registration, such as where a registrant handles controlled substances at multiple locations, requiring the entity to hold registrations for each of these locations. DEA does not, in the general course of business, collect or otherwise maintain information regarding associated or parent organizations holding multiple registrations. Therefore, to derive the total number of NTP entities from the number of NTP registrations, DEA needs to develop a relationship, or ratio, between the total number of NTP registrations and the number of entities possessing those registrations.

To do so, DEA first determined the North American Industry Classification System (NAICS)²² classification codes that most closely represent the affected business activity—namely, NTP activity. The business activity and its corresponding representative NAICS codes are listed in the table below.

Business Activity and Representative NAICS Codes

Business Activity	NAICS Codes
Narcotic Treatment Program	622210 - Psychiatric and Substance Abuse Hospitals
	621420 - Outpatient Mental Health and Substance Abuse Centers

DEA then gathered economic data for those codes using the U.S. Census Bureau, Statistics of U.S. Businesses (SUSB). Specifically, DEA used the SUSB data to determine the number of “firms” and the number of “establishments” in the United States that correspond to each relevant NAICS code. (For the purposes of this analysis, the term “firm” as defined in the SUSB is used interchangeably with “entity” as defined in the RFA.) From this, DEA calculated a firm-to-establishment ratio—*i.e.*, the average number of organizations for each establishment engaged in these activities. DEA calculated this ratio to be 0.53, as listed in the table below. In other words, each organization engaged in activities covered by these NAICS codes operated, on average, slightly fewer than two establishments.

Firm-to-Establishment Ratio by NAICS Code

NAICS Code	Number of firms	Number of establishments	Firm to establishment ratio
Total Narcotic Treatment Program	5,889	11,109	0.53
622210 - Psychiatric and Substance Abuse Hospitals	417	635	.66

²² The North American Industry Classification System (NAICS) is the standard used by the Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. <https://www.census.gov/eos/www/naics/> (last accessed: 1/10/2019).

621420 - Outpatient Mental Health and Substance Abuse Centers	5,472	10,474	.52
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Source: SUSB.²³ (Accessed 5/1/2017)

Because an entity generally must obtain a separate registration “at each principal place of business or professional practice” where it manufactures, distributes, or dispenses a controlled substance, *see* 21 U.S.C. 822(e)(1), the number of NTP establishments should be roughly equivalent to the number of DEA registrations for NTPs. Thus, DEA applied the calculated firm-to-establishment ratio of 0.53 to the 1,605 NTP registrations in DEA’s database to estimate the number of NTP entities, resulting in an estimate of 851 NTP entities in the United States. The table below summarizes this calculation.

Number of Entities by Business Activity

Business Activity	NAICS Code	Number of registrations/ establishment	Entity to establishment ratio	Number of entities
Narcotic Treatment Program	622210 621420	1,605	0.53	851
Grand Total		1,605		851

Thus, based on these calculations, DEA estimates that 851 entities could currently make use of the proposed rule, including the eight NTP entities that currently operate mobile NTP components. Of these, DEA estimates that at least an additional 11 entities will choose to operate a mobile NTP as a coincident activity in response to the proposed rule, matching the previous total of 19 mobile NTPs that were in operation over the previous five years.

Because the proposed rule is an enabling rule and thus does not affect entities that choose not to change their behavior in response to it, only NTP entities that choose to establish mobile

²³ Data for NAICS codes related to NTPs are based on the 2014 SUSB Annual Datasets by Establishment Industry, December 2016. SUSB annual or static data includes: number of firms, number of establishments, employment, and annual payroll for most U.S. business establishments. The data are tabulated by geographic area, industry, and employment size of the enterprise. The industry classification is based on 2012 North American Industry Classification System (NAICS) codes.

NTP units would be affected by the rule. Therefore, DEA estimates that 1.29% (11 of 851) of total NTP entities in the United States would be affected by this proposed rule.

To estimate the number of NTP entities that are small entities for RFA purposes, DEA used a process similar to that used to estimate the total number of NTP entities. As described above, U.S. Small Business Administration (SBA)²⁴ size standards—based on the number of employees or annual receipts, depending on the industry—determine what constitutes a “small entity” under the RFA. The SBA has established these size standards for business activities corresponding to each NAICS code. The SBA size standards for each of the NAICS codes that best correspond to NTPs are listed below: firms below this SBA size standard (based on annual receipts for these codes) are small firms—and thus small entities under the RFA.

SBA Size Standards

NAICS Codes	Description	Size Standards (\$ million in annual receipts)	Size Standards (number of employees)
622210	Psychiatric and Substance Abuse Hospitals	38.5	
621420	Outpatient Mental Health and Substance Abuse Centers	15	

Source: SBA, February 26, 2016. (Accessed 5/1/2017)

DEA used SUSB data to estimate the number of small firms for each of these NAICS codes. In 2012, the last year for which the SUSB has published the necessary receipts data,²⁵ 180 of 411 (43.78%) firms within code 622210 fell below the SBA size standard and thus

²⁴ The SBA is an independent agency of the Federal Government to aid, counsel, assist, and protect the interests of small business concerns, to preserve free competitive enterprise, and to maintain and strengthen the overall economy of the nation. <https://www.sba.gov/about-sba> (last accessed: 1/10/2019).

²⁵ SUSB receipts data are available only for Economic Census years (years ending in 2 and 7). Thus, DEA used SUSB data from 2012, the most recent available annual receipt data.

were small firms.²⁶ 4,369 of 4,987 (87.61%) firms within code 621420 fell below the standard. DEA assumes that these percentages of small firms for each code have remained constant in recent years. DEA then applied these percentages to the updated totals found in the 2014 SUSB Annual Datasets by Establishment Industry, resulting in approximately 183 firms (43.78% of the total 417) within code 622210 and 4,794 firms (87.61% of the total 5,472) within code 621420 classified as small firms. Combining these values indicates that, for these codes, 4,977 of 5,889 firms, or 84.51%, are small firms. Thus, since these are the NAICS codes that most closely correspond to NTP entities, DEA estimates that 84.51% of NTP entities are small firms. As described above, DEA has concluded that there are roughly 851 total NTP entities in the United States. Accordingly, DEA estimates that 719 (84.51%) of the total 851 NTP entities are small entities. The analysis is summarized in the table below.

Summary of Registration, Establishment, Entity, and Small Entity

Business Activity	Number of Registrations/ Establishments	Entity to establishment ratio	Number of Entities	Percent Small Entities	Number of Small Entities
Narcotic Treatment Program	1,605	0.53	851	84.51%	719
Percent Small Entity					84.51%

In consultation with the SBA’s Office of Advocacy, DEA has adopted the SBA standard that the amount of small entities affected by a proposed rule is “substantial” if 30% or more of the relevant group of small entities will be affected by the rule. As described in the

²⁶ SUSB data gives the number of firms for each NAICS code within a series of ranges of annual receipts. Thus, to determine the number of firms falling below the SBA size standard, DEA added together the number of firms in each range falling completely below the SBA standard. Because the SBA size standard for code 622210 falls within the middle of a range, DEA’s calculations may slightly underestimate the number of small firms for this code.

Summary of Costs and Benefits section, this proposed rule is an enabling rule and a deregulatory action resulting in a total cost savings of at least \$3,507,405 over a five-year period. The proposed rule allows NTP registrants another option for expanding the reach of their services, if they so choose, without requiring that current or future NTP registrants change their business practices or incur any costs. DEA estimates that only an additional 11 entities will choose to operate a mobile NTP as a coincident activity in response to the proposed rule. Because the proposed rule is an enabling rule and thus does not affect entities that do not change their behavior in response to it, only these 11 NTP entities and the 8 NTPs currently operating units under ad hoc agreements are affected by the rule. Therefore, DEA estimates that 2.23% (19 of 851) of total NTP entities in the United States are affected by this proposed rule. DEA estimates that 11 NTPs not already operating a mobile NTP (or 1.29% of all NTPs) will choose to operate a mobile unit. DEA has no reason to conclude that the percentage of small NTP entities that begin operating mobile components in response to the rule will differ from the percentage of total NTPs (11 of 851, or 1.29%), especially since most NTP entities are small. Thus, DEA estimates that 1.29% (9 of the 719²⁷) of small NTP entities will choose to begin operating a mobile NTP as a coincident activity in response to the rule.

Estimating impact on small entities

The 9 affected small entities are estimated to realize the same cost savings as other affected entities, as calculated above: between \$318,855 (at a 7% discount rate) and \$359,131 (at a 3% discount rate) per entity over a five-year period. DEA generally considers impacts that are greater than 3% of yearly revenue to be a “significant economic impact” on

²⁷ $0.0129 \times 719 = 9.2751$. Rounding down to the nearest whole number yields 9.

an entity, and recognizes that this amount of cost savings rises above that threshold for those small entities. However, since the percent of affected small entities is less than 30% (1.29%), this proposed rule does not impact a substantial number of small entities.

Therefore, this proposed rule does not rise to the level of certification as economically significant.

The table below summarizes the analysis.

Summary of Analysis

Business Activity	Estimated Number of Small Entities (Establishments)	Estimated Number of Affected Small Entities	Percentage of Small Entities Affected	Economic Impact of Compliance
Narcotic Treatment Program	719	9	1.29% (Not Substantial)	Not significant

DEA examined the economic impact of the proposed rule for each affected industry for various size ranges. Based on the analysis above, and because of these facts, DEA certifies this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action would not result in any Federal mandate that may result “in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995. 44 U.S.C. 3501–3521. This action would not impose new recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. Although the proposed rule revises certain recordkeeping and reporting provisions to explicitly apply them to mobile NTPs, these provisions already apply to NTPs in general and thus do not impose any new collection of information requirement.

List of Subjects

21 CFR Part 1300

Chemicals, traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, DEA proposes to amend 21 CFR parts 1300, 1301, and 1304 as follows:

PART 1300—DEFINITIONS

1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

2. In § 1300.01(b), add in alphabetical order the definition of “Mobile Narcotic Treatment Program” and “Motor vehicle” to read as follows:

§ 1300.01 Definitions relating to controlled substances.

* * * * *

(b) * * *

Mobile Narcotic Treatment Program means a motor vehicle, as defined in this section, that serves as a mobile component (conveyance) that is operating under the registration of a narcotic treatment program, and engages in maintenance and/or detoxification treatment with narcotic drugs in schedules II-V, at a location remote from, but within the same State as, its registered location. Operating a mobile narcotic treatment program is a coincident activity of an existing narcotic treatment program listed in 21 CFR 1301.13(e).

Motor vehicle means 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

3. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965 unless otherwise noted.

4. In § 1301.13, revise paragraph (e)(1)(vii) in the table, and add paragraph (e)(4) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(1) * * *

Business	Controlled	DEA	Application	Registration	Coincident
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(ii) A mobile narcotic treatment program is not permitted to reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed outside of the registered location. Stationary narcotic treatment programs with mobile components are not allowed to modify their registrations to authorize their mobile components to act as collectors under 21 CFR 1301.51 and 1317.40. These mobile components of narcotic treatment programs may not function as hospitals, long-term care facilities, or emergency medical service vehicles, and will not transport patients.

* * * * *

5. In § 1301.72, revise the section heading and add paragraph (e) to read as follows:

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; mobile narcotic treatment programs; storage areas.

* * * * *

(e) *Mobile Narcotic Treatment Programs.* For any conveyance operated as a mobile narcotic treatment program (NTP), a securely locked safe must be installed and used to store narcotic drugs in schedules II-V for the purpose of maintenance or detoxification treatment, when not located at the registrant's registered location. The safe must conform to the requirements set forth in paragraph (a)(1) of this section. The mobile component must also be equipped with an alarm system that conforms to the requirements set forth paragraph (a)(1)(iii) of this section. The storage area of the mobile component must conform to the accessibility requirements in paragraph (d) of this section. The storage area for controlled substances in a mobile component of an NTP must not be accessible from outside of the vehicle. The person transporting the controlled substances on behalf of the mobile NTP is

required to retain control over the controlled substances when transferring controlled substances between the registered location and the conveyance, from the conveyance to the dispensing location, and when dispensing at the dispensing location. At all other times during transportation, all controlled substances must be properly secured in the safe. Upon completion of the operation of the conveyance on a given day, the conveyance must be immediately returned to the registered location, and all controlled substances must be removed from the conveyance and secured within the registered location. All registrants of NTPs with mobile components shall be required to establish a standard operating procedure to ensure, if the mobile component becomes inoperable (mechanical failure, accidents, fire, etc.), that the controlled substances on the inoperable conveyance are accounted for, removed from the inoperable conveyance, and secured at the registered location.

* * * * *

6. In § 1301.74:

- a. Revise the section heading;
- b. Revise paragraphs (j) through (l);
- c. Redesignate paragraph (m) as paragraph (o).
- d. Add new paragraphs (m) and (n); and

The revisions and additions are to read as follows:

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; mobile narcotic treatment programs.

* * * * *

(j) Persons enrolled in any narcotic treatment program, including those receiving treatment at a mobile narcotic treatment program, will be required to wait in an area that is physically separated from the narcotic storage and dispensing area by a physical entrance such as a door or other entryway. Patients will need to wait outside of a mobile NTP if that unit does not have seating or a reception area that is separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.

(k) All narcotic treatment programs, including mobile narcotic treatment programs, must comply with standards established by the Secretary of Health and Human Services (after consultation with the Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program or mobile narcotic treatment program, for unsupervised use (*e.g.*, take home or non-directly observed therapy).

(l) 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 a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Personnel that are authorized to dispense controlled substances for narcotic treatment must ensure proper security measures and patient dosage. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program or mobile narcotic treatment program.

(m) Any controlled substances being transported for disposal from the dispensing location of a mobile narcotic treatment program shall be secured and disposed of in

compliance with part 1317, and all other applicable federal, state, tribal, and local laws and regulations.

(n) A conveyance used as part of a mobile NTP may only be supplied with narcotic drugs by the registered NTP that operates such conveyance. 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.

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PART 1304—RECORDS AND REPORTS OF REGISTRANTS

7. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 831, 871(b), 958(e)-(g), and 965, unless otherwise noted.

§ 1304.04 [Amended]

8. In § 1304.04, amend paragraph (f) by adding “mobile narcotic treatment program,” after “exporter,”.

9. In § 1304.24, revise the section heading and paragraphs (a) and (b) to read as follows:

§ 1304.24 Records for maintenance treatment programs, mobile narcotic treatment programs, and detoxification treatment programs.

(a) Each person registered or authorized (by § 1301.22 of this chapter) to maintain and/or detoxify controlled substance users in a narcotic treatment program, including a mobile

narcotic treatment program, shall maintain records with the following information for each narcotic controlled substance:

- (1) Name of substance;
- (2) Strength of substance;
- (3) Dosage form;
- (4) Date dispensed;
- (5) Adequate identification of patient (consumer);
- (6) Amount consumed;
- (7) Amount and dosage form taken home by patient; and
- (8) Dispenser's initials.

(b) The records required by paragraph (a) of this section will be maintained in a dispensing log at the NTP site, or in the case of a mobile NTP, at the registered site of the NTP, and will be maintained in compliance with § 1304.22 without reference to § 1304.03.

(1) As an alternative to maintaining a paper dispensing log, an NTP or its mobile component may also use an automated/computerized data processing system for the storage and retrieval of the program's dispensing records, if the following conditions are met:

- (i) The automated system maintains the information required in paragraph (a);
- (ii) The automated system has the capability of producing a hard copy printout of the program's dispensing records;
- (iii) The NTP or its mobile component prints a hard copy of each day's dispensing log, which is then initialed appropriately by each person who dispensed medication to the program's patients;
- (iv) The automated system is approved by DEA;

(v) The NTP or its mobile component maintains an off-site back-up of all computer generated program information; and

(vi) The automated system is capable of producing accurate summary reports for both the registered site of the NTP and any mobile component, for any time-frame selected by DEA personnel during an investigation. If these summary reports are maintained in hard copy form, they must be kept in a systematically organized file located at the registered site of the NTP.

(2) The NTP must retain all records for the NTP as well as any mobile component two years from the date of execution, in accordance with § 1304.04(a). However, if the State in which the NTP is located requires that records be retained longer than two years, the NTP should contact its State Opioid Treatment Authority for information about state requirements.

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Date: February 14, 2020

Uttam Dhillon,
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[FR Doc. 2020-03627 Filed: 2/25/2020 8:45 am; Publication Date: 2/26/2020]