DEPARTMENT OF MENTAL HEALTH AND ADDICTION SERVICES

Mobile Opioid Treatment Program

Request for Proposal

RFP# DMHAS-OSU-Mobile OTP-2024

ADDENDUM #1

The state of Connecticut Department of Mental Health and Addiction Services is issuing Addendum 1 to the Mobile Opioid Treatment Program Request for Proposal.

Addendum 1 contains:

A. Questions and Answers - The following are DMHAS responses to the questions received during and after the Bidder's Conference.

1. **Question:** We are requesting clarification regarding the geographic locations. Our agency meets all the qualifications to submit proposals for multiple regions. If we propose to serve a specific region (Northeast, Northwest, Southeast, or Central CT,) should we also include information about how we would cover other areas?
   Answer: Please only apply for one region and do not include information about covering other regions, only the towns within the region you are applying for.

2. **Question:** How and when will decisions be made about the geographic areas that will be funded? What happens if we propose to serve a specific region, and that region isn't selected to have a Mobile Treatment Van?
   Answer: All proposals will be scored and the 2 highest scoring proposals will be selected. If the two highest scoring proposals are within the same geographic area, then the next highest scoring proposal in a different geographical area will be selected.

3. **Question**: Scope of Service Description on pages 9-11 does not match Required Proposal Submission Outline and Requirements on pages 17-19. Please clarify.
   Answer: **The Scope of Service on pages 9-11 does not mention cultural competence but does ask proposer to provide information on cultural competence on pages 17-19. Please make sure that all RFP questions are answered regardless of where asked in the RFP. The following components are to be addressed:**
   a. Organization expectations
   b. Service expectations
   c. Staffing expectations
   d. Data and technology
   e. Subcontractors
   f. Work plan
   g. Financial expectations
   h. Budget and budget narrative
   i. Cultural competence

4. **Question:** Pg 9 Question 1a, asks us to include an Advisory/Oversight Committee. Can you please clarify what this means? Is this similar to a governing body or Board of Directors?
Answer: Please provide an organizational chart including any oversight committee if applicable. Yes, it could be proposer's governing body or Board of Directors.

5. **Question:** Are we required to include signed MOUs with community organizations that will host the mobile OTP vans?
Answer: This is not required.

6. **Question:** Is the total funding $2 million over the three years or is it $2 million per year?
Answer: The funding is $2 million for three years.

7. **Question:** Are we expected to bill for services while building our footprint?
Answer: Yes, proposers should have a plan in place to bill for services.

8. **Question:** Should we include a billing infrastructure?
Answer: Yes.

9. **Question:** Should we include Harm Reduction materials in our budget?
Answer: This is up to the proposer.

10. **Question:** What are the expectations for medical providers in regard to providing client physicals in the Mobile OTP? Can physicals be performed remotely through telehealth?
Answer: Mobile OTPs are required to adhere to all federal and state regulatory standards. Telehealth for physical examinations is not allowed at this time.

11. **Question**: Pg 15 lists letters of support. This is not listed elsewhere in the proposal. Please clarify exactly what the Department is requesting.
Answer: **It is also mentioned under the proposal checklist on page 38. Please refer to section C.2.i on page 10 for information on references. Letters of support used here interchangeably with letters of reference being required only if the proposer did not provide contracted services for the Department in the last 3 years**.

12. **Question:** Do you want the Org chart as an attachment or as part of the narrative?
Answer: Please include as an attachment.

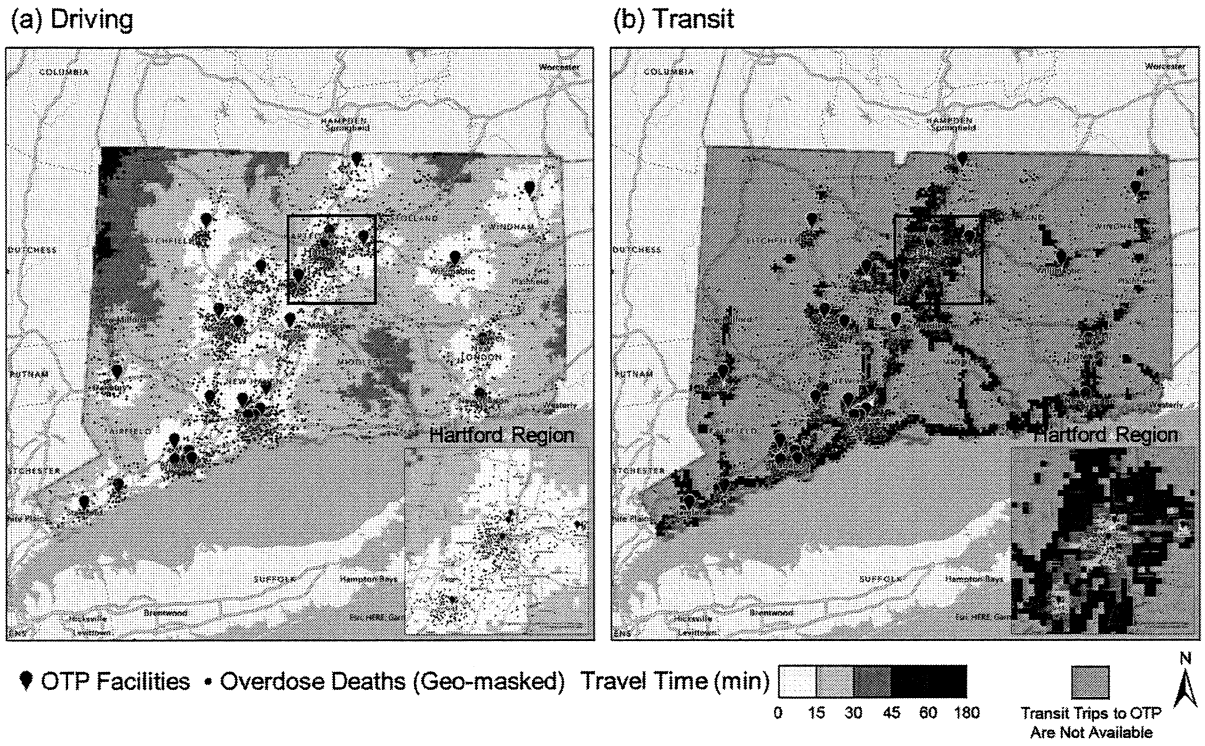
13. **Question:** Page 15 lists resumes, but they are not listed elsewhere in the proposal. Please clarify exactly what the Department is requesting.
Answer: Please include resume of staff described in your staffing plan. If the staff person is to be hired, please include job description.

14. **Question**: On page 4, # 2 – if these documents were uploaded to CT Source within the last year, is it okay to submit those with our proposal or do you need new ones?
Answer: **Yes, we will accept documents uploaded within the last year to be submitted with your proposal.**

15. **Question**: The RFP states on page 3 that the Mobile OTPs will operate in the "Northeast, Northwest, Southeast, or Central, CT." Can you further define these areas by the municipalities in each area? In particular, what municipalities comprise the "Central, CT" area?
Answer: Please use the map from travel assessment on access to OTP: Based on analysis performed by Yale/Virginia Tech team (Dr. Howell, Dr. Kim et al) on drive time and access

to current OTPs, this proposal is to establish units in these geographical areas: Northeast, Northwest, Southeast, and Central CT:

Figure 1: Map of travel time from all points in Connecticut to nearest Opioid Treatment Program (OTP) providing methadone for the treatment of Opioid Use Disorder (OUD) by (a) drive time (e.g., personal car) and (b) public transit travel time (e.g., bus).



Note. 2019-2021 overdose deaths data. The location of overdose deaths on the map is geo-masked and does not represent the true location to maximize the geoprivacy.

16. **Question**: Does DMHAS intend to release a separate RFP for Mobile OTPs that will operate in the Southwest and/or South Central, CT areas?
    Answer: Not at this time.

17. **Question:** The RFP states on page 3 that the Mobile OTPs are intended to serve "individuals in remote locations of the state". Is the phrase "remote locations" intended to be used interchangeably with "rural locations"? If not, how are "remote locations" defined for this funding opportunity?
    Answer: Remote locations should be understood as those where travel to an OTP is a barrier.

18. **Question:** The RFP states on page 5 that each of the two contracts awarded will be up to $2 million dollars over a period of three years. Is that intended to mean that the contracts will be up to $2 million a year for three years? Or will the contracts be up to $2 million total over the three-year period (about $666,667 a year for three years)?
Answer: The total contract award will be up to $2 million, and the duration of the contract will be three years.

19. **Question:** The RFP states on page 8 that the Mobile OTP is supposed to supplement an existing SAMHSA certified brick and mortar OTP. What do you mean by a "SAMHSA certified" brick and mortar OTP? Do you mean a SAMHSA "Certified Community Behavioral Health Clinic (CCBHC)"?
Answer: SAMHSA certified means that the provider is currently certified to provide OTP services, specifically methadone maintenance.

20. **Question:** The RFP states on page 9 that the Mobile OTP must be staffed by a team of a "licensed prescriber, registered nurse (RN), recovery coaches, and clinical staff." Since the Mobile OTP is intended to operate 5 days a week for 8 hours a day, are all of these team members expected to be 1.0 FTEs?
Answer: The proposers are asked to provide a staffing pattern that they believe will fit within their scope of work and meet Department of Public Health regulatory expectations.

21. **Question:** Within how many months from the contract start date is the Mobile OTP supposed to be operational?
Answer: January 2025.

22. **Question:** Is there an indirect rate cap associated with this funding? Are organizations with a federally negotiated indirect rate able to request that rate?
Answer: Organizations with a federally negotiated indirect rate are able to request the rate. If an organization does not have a federally negotiated indirect rate, then 10% de minimis rate should be used.

23. **Question:** The RFP states on page 15 that the Staffing Plan include a "Description of Program Evaluation and/or resumes of evaluators." Are grantees recommended or required to have an external evaluator to conduct the program evaluation?
Answer: The proposers should have an evaluation plan that includes either internal or external process for evaluating. Resumes of evaluators should be included.

24. **Question:** Will the slides be available to attendees?
Answer: Yes. If you would like a copy of the slide deck from the Bidder's Conference, please forward an email to DMHAS.FiscalContracts@ct.gov to request a copy.

25. **Question:** The two sections that reference staffing on Page 9 and Page 10 are inconsistent. Page 9 states of clinicians required and Page 10 does not have a clinician required. Can you please clarify?
Answer: Please provide a staffing pattern in the proposal that includes access to clinical services. Clinician time does not have to be paid by this funding.

26. **Question:** The RFP stats on Page 3 that the mobile OTP's will operate in Northeast, Northwest, SE or Central Connecticut. Can you further define these areas by the municipalities in each area? In particular, what municipalities comprise the Central Connecticut area?
Answer: Please use the map from travel assessment on access to OTP: Based on analysis performed by Yale/Virginia Tech team (Dr. Howell, Dr. Kim et al) on drive time and access to current OTPs, this proposal is to establish units in these geographical areas: Northeast, Northwest, Southeast, and Central CT. The map is included under question #15 in this document.

27. **Question:** Will the DDAP system be the standardized method of data collection?
Answer: Contracted providers will need to input data into DDAP in addition to reports on progress.

28. **Question:** Just to clarify, a clinician is defined differently than the prescriber, correct?
Answer: Yes.

29. **Question:** When the RFP states that the vans will serve people in "remote areas", is it fair to interpret that to mean the vans are supposed to serve "rural areas"?
Answer: The vans should serve areas in need of such services with identified gaps as determined by the OTP access map included in question #15.

30. **Question:** To clarify, qualified applicants must have a federal designation as an OTP?
Answer: Correct.

31. **Question:** Will you provide written answers to today's questions?
Answer: Yes, answers will be posted to CTSource and the DMHAS website as an addendum on September 13, 2024 by 3:00 PM EST.

32. **Question:** Regarding the need for in-person physicals for clients: Can you offer any guidance for how these should be conducted? Can we propose that we will arrange for in-person physicals at one of our locations and/or send a provider on the van once a week? Or can we let the RN collect and report any vitals and scales to the provider and then the provider could complete the physical virtually?
Answer: Please provide a plan in the proposal that will meet the standard. The CT State Opioid Treatment Authority (SOTA) will be available to provide guidance to contracted providers.

33. **Question:** Would you like year over year budgets, or a multi-year budget?
Answer: Please provide an annualized budget.

34. **Question:** The Scope of Services questions end with number 8 on Page 11 but on Page 19, there is a #9 which asks about Cultural Competence. Which are we supposed to follow?
Answer: Please refer to Question #3 above.

35. **Question:** Does DMHAS intend to standardize a set of outcomes and measures for all applicants?
Answer: This will be addressed with proposers during contract negotiations.

36. **Question:** Do all brick-and-mortar OTP regulations apply to the mobile unit?
Answer: Yes.

37. **Question:** Are there other providers currently contracted with DMHAS to provide this service?
Answer: No.

38. **Question:** The minimum qualifications (page 5) do not indicate the requirement of SAMHSA OTP certification and accreditation. Are OTP certification and accreditation considered minimum qualifications for applicants?
Answer: Yes.

39. **Question:** Can you provide the link to DEA regulations that specifically govern Mobile OTP specifications?
Answer: DPH regulations are finalized and link available here: https://eregulations.ct.gov/eRegsPortal/Search/getDocument?guid={D0A40E91-0000-CE11-97B7-5E54B037470C}
DEA regulations are attached to this document.

40. **Question:** What is the DMHAS expectation for the medications available through the mobile OTP? Will the OTP be required to offer all MOUD's? Is methadone specifically required? Is buprenorphine specifically required?
Answer: All three FDA medications should be offered: methadone, buprenorphine, and naltrexone.

Accordingly, to ensure consumers can realize the full benefits of Order No. 2222 and the wholesale market services demand response resources can provide, I urge the Commission to press forward to eliminate the Order No. 719 opt-out once and for all.

For these reasons, I respectfully concur.

Neil Chatterjee,
Commissioner.

Department of Energy

Federal Energy Regulatory Commission

Participation of Distributed Energy Resource Aggregations in Markets Operated by Regional Transmission Organizations and Independent System Operators

Docket No. RM18–9–003

DANLY, Commissioner, *concurring:*

1. I agree with the Commission's order today granting rehearing to extend the states' existing rights to opt-out of wholesale demand response programs [1] including demand response resources that participate in "heterogeneous distributed energy resource aggregations." [2] In other words, states can choose to prohibit demand response resources within their boundaries from participating in multi-state, wholesale distributed energy resource programs. This order represents the correct division of authority between state and federal jurisdiction.

2. I write separately to highlight that even if the Commission is correct that it has jurisdiction over distributed energy resource aggregations—including those "aggregations" comprised of a single resource [3]—the Commission still should have chosen not to exercise such jurisdiction in Order No. 2222.[4] This order on rehearing returns authority over demand response resources—which often are included in distributed energy resource aggregations—to the states, letting the states choose whether demand response resources can participate in wholesale distributed energy resource aggregations. This correctly preserves the traditional allocation of authority between the individual states and the federal government.

For these reasons, I respectfully concur.

James P. Danly,
Commissioner.

Department of Energy

Federal Energy Regulatory Commission

Participation of Distributed Energy Resource Aggregations in Markets Operated by Regional Transmission Organizations and Independent System Operators

Docket No. RM18–9–003

CHRISTIE, Commissioner, *concurring in part and dissenting in part:*

1. I concur with the first sentence of Paragraph 26 and other provisions of the order which set "aside our prior decision [in Order No. 2222–A] not to extend the Order No. 719 opt-out to demand response resources that participate in heterogeneous distributed energy resource aggregations . . . ." [1]

2. As the second sentence in Paragraph 26 and other provisions in today's order indicate, however, there is no decision affirmatively to preserve those Order No. 719 opt-out provisions; [2] on the contrary, the prospect of ultimately removing even these opt-out provisions is very much alive as a result of the NOI proceeding in Docket No. RM21–14–000.[3]

3. Beyond the parts of this order that restore, at least temporarily, those opt-out provisions, I dissent from the remainder of the order, because I would have voted against Order No. 2222 had I been a member of the Commission at that time and I did vote against Order No. 2222–A. As I said in my dissent to the latter:

Today the majority . . . sides against the consumers who for years to come will almost surely pay billions of dollars for grid expenditures likely to be rate-based in the name of "Order 2222 compliance."

. . .

Sadly, instead of making the states, municipal and public-power authorities and electric co-operatives truly equal partners in managing the timing and conditions of deployment of behind-the-meter DERs in ways that are sensitive to local needs and challenges—both *technical* and *economic*—today's order denies them any meaningful control by prohibiting any opt-out or opt-in options except in relatively tiny circumstances. This order—and its predecessor—intentionally seize from the states and other authorities their historic authority to balance the competing interests of deploying new technologies while maintaining grid reliability *and* protecting consumers from unaffordable costs . . . .[4]

4. To ameliorate at least some of the damaging effects caused by Order Nos. 2222 and 2222–A, I would authorize states and other RERRAs the right to exercise an opt-out from the requirements of those orders, if not permanently then at least for some period of years to enable them better to prepare for the impacts on retail customers and distribution grids they now face.

For these reasons, I respectfully concur in part and dissent in part.

Mark C. Christie,
Commissioner.

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BILLING CODE 6717–01–P

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: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is publishing this final rule to revise existing regulations for narcotic treatment programs (NTPs) to allow the operation of a mobile

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[1] *See Wholesale Competition in Regions with Organized Electric Markets,* Order No. 719, 125 FERC ¶ 61,071, at P 155 (2008), *order on reh'g,* Order No. 719–A, 128 FERC ¶ 61,059, *order on reh'g,* Order No. 719–B, 129 FERC ¶ 61,252 (2009).

[2] *Participation of Distributed Energy Res. Aggregations in Mkts. Operated by Reg'l Transmission Orgs. & Indep. Sys. Operators,* 175 FERC ¶ 61,227, at P 26 (2021) (Order).

[3] *See Participation of Distributed Energy Res. Aggregations in Mkts. Operated by Reg'l Transmission Orgs. & Indep. Sys. Operators,* Order No. 2222, 85 FR 67,094 (Oct. 21, 2020), 172 FERC ¶ 61,247, at P 1 n.1 (2020), *corrected,* 85 FR 68,450 (Oct. 29, 2020), *order on reh'g,* Order No. 2222–A, 174 FERC ¶ 61,197 (2021) (Danly, Comm'r, *dissenting*) (discussing single resource "aggregations"); 18 CFR 35.28(b)(10) (2020).

[4] *See* Order, 175 FERC ¶ 61,227 at P 27 (discussing case law on jurisdiction).

[1] *Participation of Distributed Energy Resource Aggregations in Markets Operated by Regional Transmission Organizations and Independent System Operators,* Order No. 2222, 85 FR 67094 (Oct. 1, 2020), 172 FERC ¶ 61,247 (2020), *corrected,* 85 FR 68450 (Oct. 29, 2020), *order on reh'g,* Order No. 2222–A, 174 FERC 61,197 (2021), *order on reh'g and clarification,* Order No. 2222–B, 175 FERC ¶ 61,227, at P 26 (2021).

[2] Order No. 2222–B at P 26.

[3] *Participation of Aggregators of Retail Demand Response Customers in Markets Operated by Regional Transmission Organizations and Independent System Operators,* Notice of Inquiry, 174 FERC ¶ 61,198 (2021) (NOI); *see also* Order No. 2222–B at P 28.

[4] Order No. 2222–A (Christie, Comm'r, dissenting at PP 1, 3 (emphasis in original) (footnotes omitted) (available at *https://www.ferc.gov/news-events/news/item-e-1-commissioner-mark-c-christie-dissent-regarding-participation-distributed*)).

component associated with a DEA-registered NTP to be considered a coincident activity permitted under the NTP's registration. Based on these revisions, NTP registrants that operate or wish to operate mobile components (in the State in which the registrant is registered) to dispense narcotic drugs in schedules II–V at remote location(s) for the purpose of maintenance or detoxification treatment do not need a separate registration for such mobile component. This final rule waives 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 this rule. 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: This final rule is effective July 28, 2021.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, Diversion Control Division; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 776–2265.

SUPPLEMENTARY INFORMATION:

Legal Authority and Background

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 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). The Attorney General has delegated this authority to the Administrator of the Drug Enforcement Administration (Administrator of DEA or Administrator). Pursuant to this authority, DEA is hereby finalizing a regulation that would waive the requirement of a separate registration for narcotic treatment programs (NTPs) that utilize mobile components under certain conditions. Specifically, under this final rule, an NTP is permitted to dispense narcotic drugs in schedules II–V from a mobile component at location(s) remote from, but within the same State as, the NTP's registered location, for the purpose of maintenance or detoxification treatment. Under this final rule, the NTP does not need to obtain a separate DEA registration for dispensing from the mobile component at a separate location as long as it complies with the requirements of the final rule. Such remote dispensing from an NTP's mobile component is deemed under the final rule to be 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 of DEA (Acting Administrator) finds that this waiver of registration is consistent with the public health and safety.

The final rule also contains additional requirements specified in the proposed rule to reduce the likelihood of diversion. Certain aspects of these additional requirements, which were raised by the commenters, are addressed below in the discussion of the comments. In addition, a section-by-section analysis of the final rule is provided following the discussion of the comments.

Notice of Proposed Rulemaking

On February 26, 2020, DEA published a notice of proposed rulemaking (NPRM) in the **Federal Register**, which provided an opportunity for comment on the proposed rule. 85 FR 11008. The comment period closed on April 27, 2020. Through this final rule, DEA is responding to these comments and finalizing the proposed rule with certain modifications discussed below.

Discussion of Comments

DEA received a total of 114 comments on the NPRM, copies of which are available online at *www.regulations.gov*. The commenters included: Researchers, practitioners, universities, non-profit organizations, addiction treatment programs, State and city boards of behavioral health and human services, associations, manufacturers, a law enforcement office, and other individual or anonymous commenters. DEA thanks all commenters for their thoughtful questions and suggestions, and appreciates their input during the rulemaking process.

One comment was a general statement of support for the rule, with no discussion of the proposed regulatory changes. Some commenters sought clarification of certain provisions in the proposed rule or recommended additional changes. The majority of commenters expressed support for various provisions in the proposed rule. That said, some commenters offered only partial support for the rule, agreeing with its general purpose but disagreeing with particular provisions; some of these commenters offered suggestions and proposed amendments to the rule that they thought would help DEA achieve its purpose. Three comments were outside of the scope of the rule. One comment—a general complaint about the government's COVID–19 response, unrelated to DEA—was outside the scope of the rulemaking and will therefore not be addressed. Another commenter suggested lengthening the five-year term for nurse anesthetists to treat patients with substance use disorder, which is a matter beyond the scope of this rule and will not be addressed. A third commenter suggested future rule changes DEA should consider to reduce patient access burdens, including: Reducing adherence requirements for take-home dosing, allowing community pharmacies to dispense methadone treatment, and allowing physicians outside of NTPs to prescribe methadone treatment for patients with opioid use disorders (OUDs). These issues are outside the scope of the rule and will not be addressed.

After a review of the comments, DEA noted that there were thirteen main issues that commenters raised, and many commenters raised multiple issues in their comments. Each issue is summarized below, along with DEA's responses. DEA has also summarized the remainder of the comments that did not fit into one of the thirteen main issues.

Expanding the Rule's Scope Beyond Mobile NTPs

Comment: One commenter recommended that the scope of the proposed rule be expanded to allow mobile components to carry controlled substances used for sedation (general anesthesia). The commenter stated that many specialty doctors (such as oral surgeons) work in multiple locations each week and are required to obtain separate permits (*i.e.*, separate DEA registrations) for each office in which they operate, and as such, cannot fill in for another doctor in the case of an emergency.

DEA Response: DEA understands that many specialty doctors (such as oral surgeons) may work in multiple locations each week and are therefore required under 21 U.S.C. 822(e)(1) and 21 CFR 1301.12(a) to obtain separate registrations for each office in which they operate, and as such are unable to fill in for another doctor in the case of an emergency.

This CSA requirement of separate registrations for each principal place of business or professional practice where the practitioner dispenses controlled substances allows DEA to monitor the dispensing of controlled substances. This requirement thereby reduces the potential for diversion of those substances. Accordingly, the CSA only authorizes the Administrator (by delegation from the Attorney General) to issue regulations waiving this requirement if he finds doing so to be consistent with the public health and safety. 21 U.S.C. 822(d).

As explained in the NPRM and above, DEA has concluded that allowing NTPs to operate mobile NTPs under the conditions specified in this rule is consistent with the public health and safety. *See* NPRM, 85 FR 11008, 11010. This conclusion, however, only extends to mobile NTP components used for maintenance and detoxification treatment; any other use is beyond the scope of this rule.

In this rulemaking, DEA has not considered whether waiving the separate registration requirement in any other circumstances would be consistent with the public health and safety, because such a determination was not necessary for this rulemaking. It is, in other words, beyond the scope of this rule. This final rule, therefore, does not change the requirement for separate registrations at each principal place of business or professional practice for any other registrants (including specialty doctors) that dispense controlled substances. To the degree interested parties believe that the separate registration requirement should be waived in other circumstances, they may petition DEA to do so by regulation.

Setting a Mileage Limit for Mobile NTP Dispensing

Comments: One commenter suggested that the proposed rule clarify the radius outside of the "dispensary" (*i.e.*, the NTP's registered location) within which the "dispenser" (*i.e.*, the mobile NTP) can deliver. Another commenter was concerned that the proposed rule suggested a mileage limit which might not be realistic, especially when applied to larger States. The commenter stated that there may be value in allowing each individual State to set and adjust the mileage limit that would be most appropriate for mobile NTPs operating in their State. Several other commenters (discussed in more detail below) suggested that DEA allow mobile NTPs to operate within a 200-mile radius of the NTP's registered location, even if that radius included areas in neighboring states.

DEA Response: DEA will not define an exact distance that the mobile component can travel from its registered location. As further explained below, DEA has concluded that mobile NTPs must be required to return to their registered locations upon the completion of their operations each day and that such a requirement can be met while still increasing access to maintenance or detoxification treatment in rural and underserved areas. A specified mileage limit, however, is not necessary to ensure that mobile NTPs will return to their registered locations daily. NTPs are better positioned than DEA to determine how far from their registered location the mobile components can travel while still allowing adequate time to return to their registered location at the end of the day, especially given that this distance is likely to vary between different geographic regions given differences in roads, traffic, and other conditions.

Mobile Components Crossing State Lines

Comments: Several organizations, practitioners, and non-profit organizations; a university policy think tank and researcher; and members of the general public were opposed to the proposed rule's requirement that mobile NTP components only operate in the same State as their registered NTP location. Multiple commenters voiced concern that this requirement would hinder the effectiveness of the proposed rule in providing services to underserved communities. One commenter noted that for many rural communities, the closest NTP may be across state lines. Five commenters cited studies that provided statistics on the number of NTP patients that traveled across state lines to access services, and calculated the mean driving distance to a methadone clinic in five rural states. These studies noted that many of these patients lived in areas that have been hit hardest by the opioid epidemic, and would benefit greatly from mobile medication delivery. Another commenter provided a citation to an article that showed the ineffectiveness of limiting mobile NTPs to intrastate in rural and underserved communities. These commenters urged DEA to allow NTPs located in one State to provide services to underserved areas in neighboring States. Commenters suggested that one way of allowing the mobile components to cross State lines would be to authorize an NTP's mobile component to operate across State lines so long as it remains within a 200-mile radius of the NTP's registered location, which would increase access to remote areas that otherwise might remain underserved. Commenters went on to say that as long as the NTP abided by the applicable State laws and secured approval from local DEA field offices, the mobile component should be allowed to cross State lines. Finally, one commenter suggested making requirements based on distance and population, and creating regulations built on collaboration. The commenter stated this approach would allow an NTP with mobile capabilities in one state to collaborate with an NTP that seeks to provide those services in a different state if the two NTPs share a patient base within a certain geographic area.

Another commenter expressed concern that NTPs would choose to only operate within their own State if (1) State methadone authorities hesitated to license a mobile component with a registered location in another State, or (2) States placed more onerous licensing processes on mobile components from another State. The commenter suggested that DEA should not prohibit this at the Federal level. The commenter further suggested that if States are willing to approve mobile components that are based in another State to promote access for their own citizens, DEA should defer to the States and permit mobile NTPs to operate in a different State than that of the NTP's registered location if the provider can obtain the requisite license from the State methadone authority.

Finally, one organization and an anonymous commenter supported the requirement that a mobile NTP only operate in the same State in which the NTP is registered with DEA. The organization noted that State regulations can vary greatly, and the organization was aware of the immediate regulatory crisis that would exist if DEA promulgated Federal regulations around mobile NTPs that permitted the mobile NTPs to dispense controlled substances in States in which they are not registered. The organization expressed concern that any potential for conflict within the treatment delivery system could put patient care in jeopardy and foster confusion that may fuel additional stigma against an already overly stigmatized medical treatment. The organization also noted that mobile NTPs are governed by State regulations in addition to the Federal regulations promulgated by DEA and the Substance Abuse and Mental Health Services Administration (SAMHSA). The organization further noted that operating a mobile NTP across State lines would call into question which

State has oversight and how the originating State could enforce their rules on a mobile NTP that is not located within their borders. The anonymous commenter also supported limiting the mobile NTP to the same State in which the NTP is registered, stating the restriction would prevent the mobile NTP from breaking the laws of the surrounding states it would be operating in, which might be different than the laws of the State in which the NTP is registered.

DEA Response: DEA appreciates the concerns raised by commenters that the proposed requirement that mobile NTPs only operate in the same State as their associated NTP's registered location may hinder the effectiveness of the rule in providing services to underserved communities. The intent of the rule is to increase access to these rural and underserved communities, while ensuring that certain recordkeeping and security requirements are met to prevent the diversion of controlled substances.

As stated in the preamble to the proposed rule, however, the CSA and DEA regulations have always required, with limited exceptions, practitioners to have separate registrations in each State in which they dispense controlled substances. *See* NPRM, 85 FR 11008, 11010. A practitioner, including an NTP, must maintain a DEA registration in each State in which it dispenses controlled substances because DEA registrations are based on State licenses to dispense controlled substances. *See, e.g.,* Clarification of Registration Requirements for Individual Practitioners, 71 FR 69478, 69478 (Dec. 1, 2006). DEA relies on State licensing bodies to determine that NTPs are qualified to dispense controlled substances for detoxification and maintenance purposes. State authority to conduct these activities only confers rights and privileges within the issuing State; consequently, a DEA registration based on a State license cannot authorize controlled substance dispensing outside of the State. This aspect of the CSA and DEA regulations also helps to ensure that each State retains the primary authority to regulate the practice of medicine within its borders. Therefore, DEA can only authorize an NTP and, as a coincident activity, its mobile component, to dispense controlled substances in the same State in which its brick-and-mortar NTP is registered with DEA to dispense controlled substances. Restricting a mobile NTP to a 200-mile radius of the DEA-registered site would not address this requirement, as the State authority to operate an NTP is limited to the borders of the State, regardless of distance.

DEA also cannot authorize NTPs to avoid this requirement by allowing a single mobile NTP to partner with multiple NTPs with registered locations in different States. This rule authorizes a registered NTP to operate a mobile component away from its registered location as a coincident activity of its DEA registration, which, as stated above, is predicated on state authorization. Moreover, this arrangement is critical to ensuring that a registered NTP maintains effective security and recordkeeping oversight of its mobile NTP operations to safeguard against diversion of the mobile NTP's controlled substances. Allowing multiple registered NTPs to share the same mobile component would diminish any individual location's perceived authority and responsibility for the controlled substances contained on the mobile NTP. For example, it would complicate the NTP's task of reconciling the dispensing logs from both the mobile component and the NTP's registered location to ensure that only the NTP's enrolled patients are receiving controlled substances. Furthermore, the task of recording (and investigators' task of tracing) the movement of controlled substances received at the NTP's registered location and transferred to the mobile NTP components would also be complicated. Thus, as reflected in the rule, DEA has concluded that each mobile NTP component may only operate under the DEA registration of a single NTP location—and may only operate in the State in which that registered NTP is licensed.

Comment: One commenter noted that although the proposed rule limited mobile components to the same State as the existing registration, it did not enumerate explicit measures for physically monitoring unauthorized out-of-State dispensations. The commenter stated that a lack of monitoring requirements in the proposed rule seemingly undermined effective DEA enforcement of its standards, thus enabling unauthorized medical practice to go undetected, and, accordingly, impeding States' rights to authorize practitioners.

DEA Response: The risk of a mobile NTP engaging in unauthorized out-of-State dispensing is not appreciably greater than any other practitioner engaging in such dispensing. Thus, DEA has concluded that the various regulatory requirements and monitoring activities that DEA uses to combat unauthorized dispensing in general should be adequate to combat any unauthorized dispensing by mobile NTPs. Moreover, this final rule already provides for certain measures designed to enhance DEA's ability to monitor the activities of mobile NTPs, such as the requirement that NTPs notify their local DEA office before using a mobile component to dispense controlled substances.

Mobile Components Facilitate Expanded Access in Rural Areas

Comments: A majority of commenters voiced support for the proposed rule saying that it would expand access to treatment for those who needed it. Multiple commenters stated that the proposed regulation was a step in the right direction because it reversed outdated regulations that have inhibited access to treatment. Several commenters stated that the proposed rule would greatly improve health outcomes for people with substance use disorder living in both rural and urban areas. These commenters noted that rural or geographically remote areas that were lacking in opioid replacement medication services faced a treatment gap because of issues like poverty, lack of access to care, and premature deaths; these mobile components could bridge these gaps, and allow more individuals to have access to treatment programs, which would help improve the odds of long-term recovery. Other commenters mentioned that the use of these mobile components could have positive outcomes outside of treatment for OUD, stating they could help with human immunodeficiency virus prevention, overdoses, and relapses. Other commenters also noted how the mobile components would allow many underrepresented groups like those suffering from mobility issues, mental health issues, incarceration, and homelessness to access treatment. Several commenters also stated that these mobile components, while expanding access, would reduce costs because there would not be as great of a need to build more brick-and-mortar NTPs.

Two associations, one representing NTPs and the other representing the interests of individuals in medication-assisted treatment (MAT), noted a potential funding source available through the U.S. Department of Agriculture (USDA). Both associations mentioned that the funding is available to assist NTPs with the purchase of mobile vans, if the NTPs meet USDA criteria in serving rural communities as defined by a population of 50,000 or less. Both associations also stated that they would advise NTPs to actively pursue this funding, working in

coordination with State opioid treatment authorities as well as SAMHSA and DEA, once the proposed rule had been finalized.

Several commenters also pointed out the advantages of allowing practitioners to dispense controlled substances at multiple locations, as the rule would facilitate. One commenter provided her personal experiences that she currently can only treat patients with opioid addiction at the DEA-registered location, where the injectable buprenorphine is delivered. The commenter believed that allowing providers to have more than one location is essential for good health care, because this would greatly increase access and treatment options for those suffering from opioid addiction.

Finally, several commenters mentioned how the current COVID–19 public health emergency would have negative effects on individuals who were suffering from OUD, because of State-mandated stay-at-home orders, social distancing requirements, and severe limitations on some of the transportation options on which these individuals rely. Commenters further noted that these negative consequences of the public health emergency could cause increases in isolation and an inability to reach treatment clinics, which could result in an increase in overdoses or even deaths. These commenters said that the use of mobile components would ensure that these individuals would be able to continue treatment.

DEA Response: As stated in the NPRM, DEA concluded that waiving the requirement for separate registration for mobile NTPs is consistent with the public health and safety, as it will increase access to treatment for those suffering from OUD in rural and underserved communities. *See* NPRM, 85 FR 11008, 11011. DEA re-affirms that position in the final rule. Specifically, DEA will waive the requirement of separate registration only for an NTP operating a mobile component at location(s) remote from, but within the same State as, the NTP's registered location for the purpose of maintenance or detoxification treatment.

The intent of the rule is to ensure that there is greater access to treatment for those who are suffering from OUD, and who are unable to access treatment because of rural or geographic limitations, mobility issues, etc. Furthermore, DEA has no objection to NTPs seeking grants or funding from government programs, or partnering with other organizations in order to defray the costs of purchasing and outfitting a mobile component. Regarding the COVID–19 public health emergency, this is an unprecedented event that has resulted in many agencies and organizations changing the way they operate. As a result of the public health emergency, DEA has worked closely with SAMHSA to provide guidance and support to opioid treatment programs to ensure that any individual who relies on MAT is able to continue treatment without disruption. It is DEA's hope that these mobile NTPs will be able to ensure greater access in in the future, especially when public health emergencies like this arise.

The Mobile Component Returning to Its Registered Location on a Daily Basis

Comments: Multiple commenters expressed concern regarding the requirement in proposed 21 CFR 1301.72(e) to return the mobile component and the controlled substances on board to the NTP's registered location daily. One commenter asserted that the daily return trip to prevent diversion is unnecessary since the mobile NTPs would be required to keep a record of all controlled substances removed from the safe on any given day. Several other commenters were concerned that the proposal would reduce the effectiveness of the mobile NTPs. Two commenters specifically stated this requirement would significantly limit the geographical reach of the mobile component. Multiple commenters argued that travel times could negatively affect the amount of time the component could operate, as many of the communities being served by mobile NTPs were far from the nearest DEA-registered NTP location. In fact, some commenters contended that many of these communities were hundreds of miles, with some specifying 100 to 200 miles and some simply stating over one hundred miles, from the NTP's registered location. One commenter further stated that the time required to travel such large distances could deter NTPs from offering regular services in the most remote areas. The commenter indicated that there are communities with significant rates of OUD located as far as 195 miles from the nearest NTP, which would require the mobile component to travel six hours round trip daily to reach these communities. The commenter recommended that DEA allow NTPs to enter into DEA-approved agreements with local or State law enforcement entities closer to the remote service area to secure the controlled substances in their facility while the mobile NTP is not in operation. The commenter stated that DEA already requires controlled substances in the possession of law enforcement be stored in a manner consistent with DEA's standard procedures for storing illicit controlled substances, and referenced DEA's disposal final rule regulation at 21 CFR 1317.35(c) (Collection by law enforcement).[1] Accordingly, the commenter pointed out that, if a law enforcement entity in closer proximity to the mobile component's service area than the NTP's registered location has secure storage procedures that meet DEA standards, the medications could be stored at this location for easier day-to-day access.

Another commenter expressed concerns that the security requirements DEA proposed were administratively burdensome, and specifically mentioned the requirement that the mobile component return to the NTP's registered location on a daily basis. The commenter stated that this requirement would increase the amount of time spent traveling, which would result in additional wear and tear on the vehicles and less time to work with patients who need care and rely on the mobile component. The commenter thus indicated that this requirement would detract from the increased access to treatment and reduced costs of expanded access that this regulation aims to achieve.

Likewise, a number of commenters also noted that requiring the mobile components to return to the NTP's registered location every day would be costly when factoring in staff time, travel costs, and the wear and tear on the vehicles. Several commenters postulated that these expenses could easily rival the cost of opening a new brick-and-mortar NTP. Two commenters estimated the cost for a mobile NTP, with at least one nurse and one medical assistant, traveling 100 miles round trip, six times per week for a year, as approaching $62,000. Both commenters stated this this amount could be more expensive than renting space for a new registered NTP location in some areas. Several commenters suggested that this requirement might hinder the effectiveness of the rule, particularly in rural areas, due to the extra costs and travel time associated with traveling back and forth daily. One commenter further stated that although DEA asserted that the proposed rule would benefit rural areas, this assertion was incorrect due to the scarcity of registered NTP locations near rural areas, and the costs that would be incurred if a mobile NTP attempted to

[1] 79 FR 53520 (Sept. 9, 2014).

travel to a rural area each day from an urban area.

Many commenters suggested that DEA allow these mobile components to stay in the field for longer periods of time. The commenters indicated that costs would be reduced significantly and there would be more time for providing care to patients, thus making the mobile components more effective, if the components were allowed to return to the registered location less frequently. The majority of commenters proposed only requiring the mobile NTPs to return to the registered location once a week, while another commenter suggested a 72-hour turnaround time, and another commenter simply requested that the mobile NTP be allowed to remain in the field for "multiple days." One of the commenters who suggested returning once a week, alternatively recommended the mobile NTPs not be required to return more frequently than every other day. Another commenter stated that DEA should not specify when the mobile component must return or, as an alternative, suggested that DEA should consider increasing the intervals between returns and only requiring weekly returns.

Most commenters believed that requiring the mobile components to return to the registered location less frequently would increase access to treatment while still maintaining appropriate safeguards against potential theft and diversion. Indeed, several commenters asserted that these longer turnaround times were feasible given that DEA was proposing to apply existing security protocols to mobile components. One commenter similarly stated that the security measures required by the proposed rule were adequate to prevent diversion while the mobile component is in the field. However, one commenter suggested that if the mobile components are allowed to stay in the field for longer periods of time, additional security measures should be taken. The commenter suggested requiring an armed guard outside the mobile component or requiring the mobile component to be locked in a secure, fenced-in location.

Finally, one commenter stated that in the absence of 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 commenter stated that the proposed rule includes multiple safety measures and procedures that are adequate to protect controlled substances, which the commenter felt acted as a significant check against theft and diversion. The commenter further contended that it is not clear that moving the mobile component back to the registered location and removing the controlled substances daily decreases the risk of diversion. Furthermore, the commenter asserted that DEA does not provide evidence or reasoning to explain how these requirements reduce the risk of diversion. The commenter insisted that pending the development of better information regarding the risks of diversion, DEA should not specify when the mobile component must return to the NTP's registered location.

DEA Response: DEA appreciates commenters' concerns over the proposed requirement that the mobile component and the controlled substances it carries return to the NTP's registered location daily. As stated before, the intent of the rule is to ensure that more individuals have access to treatment despite geographical limitations. The need to ensure that individuals in these remote locations can access the care that they need has to be balanced against security and recordkeeping requirements to ensure that the controlled substances on board the mobile component are not diverted for illicit use.

Several concerns drive DEA's conclusion that, upon the completion of their daily operations, mobile NTPs generally must return to their registered locations and secure all controlled substances within their registered location.

The first and most important concern is the danger associated with controlled substances that mobile NTPs will be carrying, should those substances be diverted. Of course, mobile NTPs will primarily be storing and distributing methadone, and methadone is an extremely dangerous drug if abused. More specifically, methadone is a potent schedule II opioid with a relatively long elimination half-life of 8–59 hours with an average of 24 hours depending on the individual.[2] As such, methadone can accumulate in an individual's body if taken more frequently than prescribed or in doses that exceed an individual's tolerance for the medication.[3] Methadone has been associated with adverse events and opioid overdose deaths in those lacking experience with the drug as well as in experienced users who overuse the drug or combine it with other illicit drugs or with other prescribed medications that have adverse drug-drug interactions with methadone.[4]

Methadone is also a demonstrated diversion risk.[5] It has significant street value, and its misuse and abuse has been documented.[6] And mobile NTPs, especially if they were allowed to remain away from their registered locations for multiple days, are likely to be carrying methadone in substantial quantities, enough to be of great street value and to impose a significant risk to an entire community should a fully stocked mobile NTP have its methadone diverted.[7]

So long as methadone remains in a mobile component, it is at an elevated risk of theft both because the mobile conveyance itself could be stolen, and because security measures in a mobile NTP will generally be less robust than those at the NTP's registered location. This risk is manageable when the mobile NTP is in operation and thus secured by staff to guard against theft. However, the risk becomes unwieldy—especially given that dangers posed by such quantities of methadone—when the mobile NTP is not in use and is unattended, generally at night, and the likelihood of theft is greater. Thus, by requiring NTPs to secure their controlled substances within their registered NTP location after operation each day, DEA decreases the risk that those controlled substances will be stolen—and thereby decreases the risk

[2] Substance Abuse and Mental Health Services Administration, Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63, Publication No. PEP20–02–01–006, Rockville, MD: Substance Abuse and Mental Health Services Administration (2020).

[3] Roxane Laboratories, Dolophine hydrochloride package insert, *Fda.gov/media/76020/download* (accessed May 10, 2021).

[4] Food and Drug Administration, Public health advisory: Methadone use for pain control may result in death and life-threatening changes in breathing and heartbeat, Silver Spring, MD: U.S. Department of Health and Human Services, 2006, *https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm12346.htm* (accessed May 10, 2021); Modesto-Lowe V, Brooks D, Petry N., Methadone deaths: Risk factors in pain and addicted populations, J Gen Intern Med 25: 305–309 (2010); Madden ME, Shapiro SL, The methadone epidemic: Methadone-related deaths on the rise in Vermont, Am J Forensic Med Pathol. 32(2): 131–135, 2011.

[5] McCance-Katz EF. The National Survey on Drug Use and Health: 2019. Slide 14. *SAMHSA.gov/data/release/2019-national-survey-on-drug-use-and-health-nsduh-releases* (accessed May 10, 2021).

[6] National Drug Intelligence Center. Methadone diversion, abuse and misuse: Deaths increasing at alarming rate. *Justice.gov/archive/ndic/pubs25/25930/index.htm#Diversion* (2007) (accessed May 10, 2021); Wright N, D'Agnone O, Krajci P, et al. Addressing misuse and diversion of opioid substitution medication: Guidance based on systematic evidence review and real-world experience. J Public Health. 38 (3): e368–e374, 2016.

[7] For example, an average dose range for an individual on methadone maintenance is 60–120 mg daily, which would be multiplied by the number of individuals for whom the mobile NTP conveyance carries doses. *See* SAMSHA TIP 63, *supra* note 2.

that the communities served by mobile NTPs will be harmed by diverted methadone.

Requiring the mobile NTP and its controlled substances to return to the registered location of the NTP also reduces the likelihood that controlled substances will be lost or mishandled. Requiring an NTP's mobile component to return nightly better enables the NTP to monitor its mobile component's dispensing, and thus become more readily aware of any problems—such as the "double-dipping" discussed below (under Recordkeeping Requirements for Mobile Components)—or other discrepancies that may signal that the mobile NTP's controlled substances are being diverted or otherwise improperly dispensed.[8] For similar reasons, DEA will not allow NTPs to enter into agreements with local or State law enforcement entities closer to the remote service area to secure the controlled substances in their facility while the mobile NTP is not in operation. Even assuming that these law enforcement entities are equipped to securely store the controlled substances, the regular transfer of these substances back and forth between mobile NTPs and the law enforcement entities would inhibit the NTP's (and ultimately DEA's) ability to monitor the controlled substances and unnecessarily create opportunities for the substances to be stolen, mislaid, or otherwise mishandled.

Additionally, allowing mobile NTPs to remain in operation for multiple days without returning to their registered locations not only presents an elevated risk of diversion, there are alternative options that make it generally unnecessary. For example, nothing in this rule impacts the ability of an NTP to register at an additional physical location. Thus, if an NTP wishes to treat patients with methadone at a remote correctional facility or similar rural location, that NTP could simply register a physical location in the area to which to return its mobile component and where to secure its controlled substances. Indeed, a correctional facility can itself register with DEA as an NTP. While some correctional facilities have obtained an NTP registration, DEA wishes to emphasize this option for those who may be unaware of it. Moreover, many OUD patients may be successfully treated with alternative medications such as buprenorphine or naltrexone. Buprenorphine is a schedule III narcotic drug approved by the U.S. Food and Drug Administration (FDA) for the treatment of OUD, and, as such, may be dispensed for such purpose without the dispenser being registered as an NTP.[9] Naltrexone is a non-controlled substance and, as such, may be dispensed without a DEA registration. Accordingly, OUD treatment involving the use of either buprenorphine or naltrexone does not require the use of a mobile NTP.

In sum, DEA has concluded, for the reasons stated above, that it is necessary and appropriate to maintain in the final rule the requirement that a mobile NTP return to its registered location each day. However, in view of the comments DEA received on this issue, DEA wishes to emphasize that it has decided to add to the text of the final rule a provision that expressly allows NTPs to apply for an exception to this requirement. The process for applying for such an exception will be as set forth in 21 CFR 1307.03, which allows any person to apply for an exception to any provision of the DEA regulations. As with all applications for an exception to any provision of the regulations submitted pursuant to section 1307.03, each application for an exception to the requirement that a mobile NTP return each day will be evaluated by DEA on a case-by-case basis in determining whether the applicant has demonstrated exceptional circumstances that warrant a waiver of the regulation. In making this determination, DEA will consider the applicant's security and recordkeeping as well as other factors relevant to determining whether effective controls against diversion will be maintained. DEA is revising 21 CFR 1301.72(e) (from that proposed in the NPRM) to reflect this change to the regulatory text.

In addition, DEA will continue to evaluate the risk of diversion that might result from eliminating, in some circumstances, the requirement that a mobile NTP return to its registered location each day. DEA will closely monitor applications seeking an exception to that requirement. One year after this rule is finalized, DEA will review whether additional rulemaking is necessary to improve access to treatment via mobile NTPs. In conducting its review, DEA will consult with the Department of Health and Human Services (HHS) and the Office of National Drug Control Policy (ONDCP). If the volume and nature of such applications and an evaluation of the associated risk of diversion warrant it, DEA will further amend the regulations to allow mobile NTPs to be excepted from this requirement—without having to apply for an exception—under certain specified circumstances. If DEA determines that such additional amendment to the regulations is warranted, it will initiate a separate rulemaking proceeding to do so in accordance with the Administrative Procedure Act (APA).

Security Requirements for Mobile Components

Comments: Several commenters addressed the security requirements that were detailed in the proposed rule. Two commenters, who recommended a 72-hour return instead of the proposed same day return requirement for mobile NTPs (see discussion above), suggested that the final rule add additional security requirements during this 72-hour time frame. The commenters suggested either utilizing armed security guards outside the mobile component, or locking the mobile component in a secure fenced-in location and using, possibly, unarmed (rather than armed) security guards. One commenter believed such security measures would not present any additional diversion issues and noted that DEA acknowledged thefts from mobile NTPs in the past had not been an issue.

One commenter pointed out the known criminal activity risks associated with having controlled substances on site, such as theft, and noted that "brick-and-mortar" NTPs often protect their employees and patients through various security measures. The commenter provided two examples of these measures: (1) A panic button that, when activated, triggers law enforcement to immediately respond, and (2) the local law enforcement knows the existence and whereabouts of an NTP and, therefore, can respond quickly and efficiently to an emergency. In contrast, the commenter stated that the proposed rule fails to mention whether mobile NTPs must take any explicit security measures to protect their employees and patients, including installing panic buttons, or making local law enforcement aware of the mobile NTPs' exact locations at any given moment, including during travel. The commenter

[8] DEA appreciates commenters' suggestions that the risk of theft or diversion of controlled substances left in a mobile NTP overnight could be mitigated by increasing the security requirements for mobile NTPs. While such measures could reduce the danger of theft or diversion somewhat, they would not suffice to overcome the inherent enhanced dangers of leaving controlled substances in an unmanned conveyance overnight at an unregistered location. And such enhanced security measures would do nothing to address the reduction in the registered NTP's ability to monitor the mobile component's dispensing that would result if mobile NTPs were not required to return to their registered NTP location nightly.

[9] The CSA requirements governing the dispensing of buprenorphine are set forth in 21 U.S.C. 823(g)(2).

requested that the final rule more fully address how mobile NTPs will implement such security measures to improve the safety of their employees and patients.

DEA Response: DEA appreciates the concerns expressed regarding the security requirements for mobile NTPs. DEA regulations have always required that all registrants maintain effective security to guard against theft and diversion of controlled substances. *See, e.g.,* 21 CFR 1301.71(a). The need for such security applies equally to mobile NTPs. Thus, under this final rule, the security requirements of 21 CFR 1301.72(e) and 1301.74(j)–(n) apply to the mobile components of NTPs to ensure this need for security is met.

Of course, under certain circumstances, mobile NTPs may need additional security measures beyond those specifically required by DEA regulations to effectively protect against theft or diversion of controlled substances. Because the need for such measures is circumstance-specific, DEA is not including them in the final rule, but rather will rely on local DEA personnel, NTPs themselves, and any other relevant laws and regulations to determine what additional measures, if any, are necessary. In particular, DEA will leave the decision on whether armed or unarmed security personnel will be utilized by the mobile component while it is away from its registered location to the NTP, as there are many factors that should be considered when making this decision. For example, the NTP may want to consider the location to which the mobile components will be traveling, the cost of security personnel, and whether or not these security personnel would fit in to any standard operating procedures used by the NTP. Thus, DEA will not mandate that armed or unarmed security personnel be utilized by these mobile components.

The proposed rule stated in proposed 21 CFR 1301.72(e) that the mobile component must be returned to the registered location on a daily basis. *See* NPRM, 85 FR 11008, 11011, 11019. DEA appreciates that some registered NTP locations might not have enough room to park the mobile component overnight; therefore parking the mobile component in a secure fenced-in location would be permissible, as long as all DEA security requirements are met, the controlled substances are removed from the mobile component at the end of the day, and the local DEA office is notified of the location where the mobile component will be parked overnight.

For similar reasons, DEA will leave the decision on what safety measures the NTP would like to take to ensure the safety of the mobile component's staff and patients to the NTP and any relevant government bodies outside of DEA. There are many factors like the location of the NTP, the number of patients it treats, cost, etc., which would affect the NTP's decision when deciding which safety measures would ensure patient and staff safety. Aside from DEA security requirements, there are other Federal, State, local, and tribal laws these NTPs must take into consideration when making their decision. Thus, because the appropriate safety measures for a mobile NTP will vary based on circumstances and legal requirements, DEA will not attempt to specify additional safety requirements for NTPs as part of this rule. If such requirements are necessary, other Federal, State, local, and tribal authorities can create them.

Comment: One commenter stated that the proposed rule was silent on what would happen to the medication if the mobile NTP breaks down, and recommended that DEA include a requirement for a standard operation procedure or contingency plan if the vehicle breaks down while en route to the communities where services are provided remotely, and if the mobile NTP is out of service for an extended period due to repairs. The commenter suggested that at a minimum, the standard operating procedure needs to include plans for dosing patients in the following circumstances: (1) If the mobile NTP breaks down while en route to the community, and (2) when the mobile NTP is out of service for an extended period due to repairs. The commenter expressed concern that if these plans are not in place, patients may encounter barriers to receiving their medication in an alternative manner (*e.g.,* transportation and costs to reach a registered NTP location, waivers by NTP for patients to have "take home" privileges for the medication) and be put at increased risk for overdose. The commenter also noted possible limitations in the responsiveness of a mobile NTP's security system, reliant on Wi-Fi capability, when the mobile NTP has weak or no access to Wi-Fi while in rural communities and is not near the registered NTP location.

DEA Response: DEA has concluded that it is unnecessary for this rule to require NTPs to create a contingency plan for dosing patients served by the mobile NTP if the mobile NTP breaks down or is placed out of service. NTPs may well decide that such plans are appropriate, and other laws, regulations, or governing bodies may require them. The requirements DEA is imposing in this rule, however, are appropriately focused on DEA's duty under the CSA to protect against the diversion of controlled substances. Thus, DEA is requiring a contingency plan for safeguarding the mobile NTP's controlled substances if it breaks down. In the proposed rule, DEA stated that if the mobile component was 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. DEA went on to state that if the conveyance is taken to an automotive repair shop, all controlled substances would need to be removed and secured at the registered location. However, other than those security requirements, DEA will not specify what should be included in the NTP's standard operating procedures, or what plans NTPs should implement regarding dosing patients while the mobile component is out of service. Such matters are beyond the scope of this rule, and properly within the judgment of the NTP and any relevant regulatory bodies outside of DEA.

Comment: Another commenter noted that the proposed amendment to DEA regulations at 21 CFR 1301.74(l) would provide DEA discretion to require additional security measures for mobile NTPs based on certain factors. The commenter acknowledged that DEA currently has this discretion for NTPs but could not locate any DEA guidance on how DEA utilizes the listed factors to determine if an NTP applying for registration warrants additional security measures. The commenter stated that this proposed provision similarly did not provide any information regarding how DEA would use these factors to evaluate security measures for mobile components, nor did DEA provide a single example of the security measures it might require for such a component if the factors were relevant.

As a result, the commenter believed this provision to not be clear or transparent and could lead to DEA field offices unevenly or arbitrarily applying the regulations. The commenter further stated that a registered NTP considering starting a mobile NTP would likely have to reach out to the local DEA field office early in the planning phase which could result in delays getting the mobile component up and running. Therefore, the commenter recommended that DEA not finalize this proposed provision, or at the very minimum, that DEA provide clarity in the final rule preamble regarding the factors and additional security measures.

Another commenter noted that current regulations provide DEA discretion to prescribe security requirements to the NTP based on certain factors. However, this commenter stated that it would seem practically impossible for DEA to fully exercise its discretion under 21 CFR 1301.73(l) and effectively set security standards for mobile components, given the changing locations of mobile components when contrasted with registered NTP locations.

DEA Response: Under the final rule, DEA will review the security systems used on these mobile components and make a determination on which security systems meet DEA requirements on a case-by-case basis before approving the operation of a mobile NTP. DEA appreciates the concern that such case-by-case evaluation of mobile NTPs' security systems may lead to delays and differences in enforcement between local DEA offices. As it is DEA's intent to ensure that there are no delays or unfairness in getting mobile components up and running, DEA will endeavor to prevent such problems from occurring.

DEA, however, cannot forego case-by-case determinations, even if they inevitably bring some risk of delay or enforcement discrepancies. As discussed above, although this final rule and DEA regulations more broadly articulate basic security requirements, they cannot account for all security situations. Some situations may require additional security measures for a mobile NTP to be able to adequately guard against loss through theft or other forms of diversion. Attempting to account for all such scenarios in advance through regulation is ineffective and may impose unnecessary restrictions on other mobile NTPs. DEA can best ensure that mobile NTPs provide adequate security by enabling local DEA offices to conduct case-by-case evaluations as appropriate. That said, DEA is slightly modifying the proposed regulatory language describing how these case-by-case evaluations are conducted in this final rule to clarify that DEA, not any other entity, applies the factors.

DEA has concluded that mobile NTPs' changing locations will not compromise its ability to make such assessments. DEA already evaluates the security arrangements provided by a wide range of registrants under many different circumstances. Although mobile NTPs do present some unique challenges, DEA is confident that it can work with mobile NTPs to ensure that they operate securely.

Comment: Finally, one commenter stated that DEA's security requirements in 21 CFR 1301.72 through 1301.76 are extremely outdated and currently put all registered NTPs, as well all DEA registrants, at high risk for diversion, and that this risk would extend to mobile NTPs. In particular, this commenter claimed that, in today's environment, the controls outlined in 21 CFR 1301.75(a) and (b) are inconsistent with those in 21 CFR 1301.71(a), and stated that securing controlled substances consistent with DEA's non-practitioner requirements in 21 CFR 1301.72(a) can potentially reduce crime by 75–85 percent. This commenter encouraged DEA to strengthen and enhance the schedule I–V physical security requirements for all registrants consistent with 21 CFR 1301.72(a), by utilizing currently available market technologies.

DEA Response: DEA appreciates this comment suggesting in general terms that it broadly update the security requirements of its regulations to better reflect currently available security technologies. DEA recognizes that technologies change, but has concluded that the security regulations in this rule adequately protect against theft and diversion in the use of mobile NTPs given current technologies. The sort of broader changes to DEA security regulations suggested by the commenter are beyond the scope of this rule.

Recordkeeping Requirements for Mobile Components

Comments: One commenter stated that they did not see a reason why all of the records mobile components would be required to keep could not be electronically logged in on a daily basis, while still being in compliance with the proposed amendment to 21 CFR part 1304. Another commenter noted that the proposed rule allows mobile NTPs to maintain electronic dispensing logs; however, the mobile NTP would still need to print out a hard copy of such log daily with the dispenser of each dose initialing each relevant entry. The commenter advocated for allowing these dispensers to use digital signatures in these logs because the processes for digital signatures are readily available and widely used, and using digital signatures would reduce unnecessary paperwork for physicians. In addition, the commenter stated that DEA should not require pre-approval of the mobile NTP's electronic recordkeeping system for the dispensing log because this could create unnecessary delays in the transition to electronic recordkeeping. Further, if DEA permits digital signatures in the final rule, the commenter requested that DEA clarify that DEA's approval of an electronic recordkeeping system for a registered NTP location will be sufficient for the mobile component.

DEA Response: DEA recognizes the concerns expressed by commenters regarding the use of electronic dispensing logs. In the proposed rule, DEA proposed an alternative to maintaining a paper dispensing log, stating 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 were met. The requirement that the NTP or its mobile component print 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, is one of the conditions that must be met. This requirement, along with the others specified in section 1304.24(b)(1), is based on recommendations in the Narcotic Treatment Programs Best Practice Guideline (April 2000).[10] Furthermore, DEA emphasizes that the rule is not adding additional recordkeeping requirements to NTPs. The rule is instead simply applying already-existing recordkeeping requirements of 21 CFR part 1304 to mobile NTPs, as well as providing NTPs and their mobile components the option of using a computerized data processing system, instead of a paper dispensing log. DEA believes the recordkeeping requirements in this rule are necessary to ensure accountability and prevent diversion. Thus, DEA generally agrees that electronic logging of dispensing records is appropriate. These electronic records, however, will still have to be logged on a daily basis, and must comply with the requirements in 21 CFR part 1304. Finally, requiring the NTP employee who dispensed the medication to review and initial the hard copy of the dispensing log at the end of each day is important for maintaining accurate records and ensuring accountability.

DEA also notes the commenter's concerns about the requirement that

[10] The Narcotic Treatment Programs Best Practices Guideline, developed by DEA in collaboration with the American Methadone Treatment Association (now the American Association for the Treatment of Opioid Dependence), provided assistance in understanding the provisions of the CSA and in the implementation of the regulations as they apply to dosage reconciliation practices in NTPs. DEA rescinded the guideline after publication of the NPRM, but the recommendations it contained continue to represent best practices for NTP operation.

DEA must pre-approve any electronic recordkeeping system used in lieu of a paper dispensing log. Prior to granting a registration to an NTP and its mobile component, under § 1301.13(e)(4) of this rule, the local DEA field office must evaluate all of the mobile components' procedures and processes to determine if they provide effective controls against diversion. If the electronic recordkeeping system meets all of the recordkeeping and security requirements under the CSA, DEA will approve the system; this will be done on a case-by-case basis. If a registered NTP has an electronic recordkeeping system that is approved by DEA, this does not necessarily mean the same system will be as useful on the mobile component; this is why the electronic recordkeeping system on the mobile component must be evaluated separately.

Comment: One commenter expressed concern that under the proposed rule, it appeared that patients could engage in "double-dipping" by receiving treatment at a mobile NTP in the morning, and then at a registered NTP location later in the day, for example. The commenter stated that under the proposed revisions to 21 CFR 1304.24 there is a requirement that NTPs must maintain records of patient information including the dosage consumed, but no requirement that the records be maintained in real-time, potentially allowing such "double-dipping" to occur before an NTP could compare dispensing logs and discover it. Therefore, to decrease the likelihood of patient overdoses, the commenter recommended that the final rule require all mobile NTPs to record doses in real time.

DEA Response: NTPs have protocols in place to ensure that their patients cannot engage in "double-dipping" by receiving treatment at a mobile component in the morning, and then at a registered NTP location later in the day; the use of paper or electronic logs should not have a major impact on these protocols. Moreover, regardless of whether NTPs have such a protocol in place, ordinary diligence by NTPs, including periodic comparisons between the dispensing logs of a mobile NTP and its registered NTP, should readily reveal any individuals who are engaged in such "double-dipping" and enable NTPs to take steps to prevent them from doing so in the future. Although the use of "real-time" electronic dispensing logs might allow an NTP to uncover such "double-dipping" more quickly, DEA has concluded that requiring the use of technology could be burdensome and is not necessary to prevent "double-dipping" from becoming a significant source of diversion or significant risk of overdose among patients. Thus, DEA has concluded that NTPs should generally be capable of guarding against "double-dipping" without further regulation. Every NTP has protocols in place to ensure that their patients receive the correct dose, and to ensure that the records containing this information are correct and up-to-date. As stated earlier, DEA has concluded that the use of technology could be burdensome, which goes against the purpose of this rulemaking. For these reasons, DEA will not require all mobile components to record doses in real time; however, if a mobile NTP chooses to do so, that would be permitted.

Advantages of Serving Multiple Locations

Comments: One commenter stated that the proposed rule was ambiguous on whether the mobile component could park at a location, dispense medication, and then move to another location or locations for further dispensing. The commenter suggested that DEA revise the proposed rule to explicitly allow mobile treatment components to serve multiple locations in a single day, because this would enable opioid treatment providers to help patients residing in skilled nursing/long term nursing facilities to receive their medication for opioid use disorder. The commenter did not provide any specific information on how this would help.

DEA Response: DEA will leave the decision of whether a mobile component serves multiple locations in a single day to the NTP. For a mobile component in a more urban area, multiple stops might be more feasible, in comparison to a mobile component that would be serving a more remote area. As long as these mobile components follow all applicable Federal, State, local, and tribal laws, DEA will permit the mobile component to serve multiple locations. Although the proposed rule was not intended to limit mobile NTPs to serving a single location, DEA recognizes that references in the proposed regulatory text to mobile NTPs serving "a location" or "a dispensing location" in proposed 21 CFR 1300.01(b) and 1301.72(e) may have been confusing. Thus, in this final rule, DEA has revised these sections to clarify that a mobile NTP may serve multiple remote locations.

The Use of Past/Current Mobile Components

Comments: Several commenters noted that mobile components have not only been used in the past, but some States are currently using them, and they have had a positive impact on the communities they operate in. One commenter stated that Minnesota benefited from a mobile methadone unit that operated approximately 15 years ago, because it increased compliance with dosing and provided services to geographically remote patients, allowing for better supervision, and faster stabilization of both dose and behavior. Another commenter said many NTPs already operate mobile components and these revisions will allow more flexibility, allowing even more NTPs to provide treatment via mobile components. A commenter who worked at a treatment program mentioned that their organization operated a mobile Suboxone program, and stated that it benefitted the community because the number of overdoses had been greatly reduced, and larger numbers of people were able to initiate treatment who would not otherwise have been able to without such access.

Finally, two commenters mentioned the use of mobile components in emergency situations, such as during Hurricanes Katrina and Sandy. One of these commenters mentioned how mobile methadone components are an important part of the broad continuum of care for individuals with OUD, and stated these mobile components provided essential treatment services during Hurricane Katrina. However, the other commenter noted that mobile components had been largely unavailable to providers responding to emergency situations. That commenter mentioned that during Hurricane Sandy in 2012, affected NTPs employed strategies such as alternative transportation, take-home dosing, and guest dosing at nearby programs (*i.e.,* temporary dosing at another NTP) to ensure continued access to treatment, and stated that these actions had varying degrees of execution and success. The commenter went on to say that mobile NTPs were considered as an option for reaching patients when facilities were destroyed, but one unit was being repaired at the time and the other was not able to operate because there was not a functioning registered NTP location to store the methadone.

DEA Response: DEA appreciates the information provided by the commenters. As stated previously, the intent of this rule is to ensure that there is greater access to treatment for those who are suffering from OUD, and are unable to access treatment because of rural or geographic limitations, mobility issues, etc. The revised regulations will allow NTPs the option to use mobile

components during emergency situations such as those described by the two commenters, as long as all applicable, Federal, State, local, and tribal laws are followed when operating these mobile components. As discussed in the NPRM, prior to this rule, DEA only authorized mobile NTPs on an ad hoc basis and had placed a moratorium on new authorizations in 2007. *See* 85 FR 11008, 11009. This rule will allow the use of mobile NTPs to be expanded more extensively, more consistently, and with greater protections against theft and diversion than was possible before.

The Costs and Benefits Associated With Mobile Components

Comments: Many commenters believed that this proposed rule would give providers a lower cost option for reaching patients where it may not be otherwise financially feasible to establish a new registered NTP location. Several commenters stated that the proposed rule would reduce the costs for NTPs wanting to expand their geographic reach and increase the treatment they are able to provide. Several commenters pointed to benefits that would result from the use of these mobile components that might not be quantifiable. Multiple commenters stated that the proposed rule would save many lives, as well as improve the health and well-being of patients receiving treatment, and allow these patients to live productive and satisfying lives. One commenter mentioned that the use of mobile NTPs could start saving thousands of lives and decrease illicit opioid use.

Other commenters mentioned the savings that would be realized by allowing the mobile components to register only once. One commenter estimated savings between $1,270,670 and $1,482,272 would be possible over five years "simply because operating out of the mobile unit would allow more treatments to be dispensed and operating over multiple locations would bring in more revenue." However, the commenter did not explain the basis for this estimate.

Conversely, one State behavioral health agency expressed general concerns about the startup costs associated with operating a mobile component, and stated that some NTPs may find this expense to be a barrier to establishing a mobile component. The commenter further indicated that as a result, some NTPs may desire to partner with agencies who already own well-equipped mobile components. The commenter recommended that DEA explicitly indicate whether it will allow a registered NTP to partner with an organization who owns a mobile NTP (*e.g.,* hospital or health center).

As discussed in detail above, many commenters were opposed to requiring the mobile component to return to the NTP's registered location on a daily basis; the costs of the daily round trips were chief among the issues raised when voicing their concerns. These commenters generally believed that the costs associated with traveling to and from the communities served by mobile NTPs (*e.g.,* staff time, travel costs, wear and tear on vehicles, etc.) could easily rival the cost of opening a new registered NTP location, especially when the communities are 100 to 200 miles away, as noted by some commenters. Two commenters gave an example of a mobile NTP with at least one nurse and one medical assistant traveling 100 miles round trip six times per week for a year and estimated the yearly cost, based on the proposed rule's estimated per mile operating cost, would be close to $62,000. Similarly, another commenter remarked that in the summary and benefits section of the proposed rule's preamble, the mileage used to estimate operating costs for a mobile NTP, no more than 5,000 miles per year (100 miles per week), was rather low, especially for rural areas in some States.

Three commenters also detailed other expenses that might result from operating the mobile component. One commenter stated that while the proposed rule provided potential safeguards addressing security, theft, and misuse, the rule did not discuss in its cost-benefit analysis the intangible costs associated with detecting any violation of either operating the mobile component as a treatment center or any of the rule's other prohibitions. However, the commenter did not detail any specific cost numbers for these intangible costs. One commenter expressed concerns that the costs associated with paying an entire team of healthcare professionals for their travel time would likely be expensive and possibly even cost prohibitive, particularly if mobile NTPs will provide the same interdisciplinary services offered at registered NTP locations. This commenter further stated that the proposed rule failed to address these costs. Another commenter also mentioned the small, extra expense of hiring security personnel to protect the mobile NTP, which the commenter recommended if the regulations would no longer require the mobile NTPs to return to the DEA-registered location at the end of each day.

Finally, a commenter expressed great appreciation that the proposed rule's economic analysis qualitatively described 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. However, the commenter stated that this analysis omitted other important unquantifiable benefits, such as improved quality of life and improved dignity for patients who can access treatment. The commenter stated that the major benefit of this proposed rule is its expected effect on the cost to treat each patient with OUD and the number of patients who have access to such treatment (*i.e.,* a decrease in costs and an increase in patients), noting that this will improve the quality of life and dignity for patients who can access this critical treatment. Therefore, the commenter suggested that DEA should revise its economic analysis and acknowledge these benefits in the final rule. In addition, this commenter stated that DEA should clarify in the final rule that the benefit-cost analysis framework applied in the proposed rule shows that a reduction in the marginal cost of treating patients for OUD could expand output, which would be a social benefit. The commenter explained that the analysis conducted by DEA in the proposed rule assumes that NTPs are currently incurring costs to expand treatment access by opening additional registered NTP locations. However, the commenter further noted that if DEA's assumption is not true, and NTPs are not currently incurring costs to expand registered NTP locations, then under this rule, NTPs might actually incur more costs, the costs associated with operating a mobile NTP.

DEA Response: DEA appreciates the support from commenters agreeing with the agency's assessment that this rule will provide a less costly avenue for NTP's to expand operations and treat more patients compared with opening a new registered NTP location. As stated earlier, the intent of the proposed rule is to ensure that treatment is made more widely available to those who need it. Although not readily quantifiable, saving lives, preventing overdoses, and ensuring patients receiving treatment are able to live productive lives help further the purpose in the proposed and final rule. Regarding one commenter's view that DEA has not accounted for a potential increase in costs to the agency related to monitoring the security and recordkeeping of mobile components, DEA anticipates that its field offices will conduct any necessary security reviews

as a part of their routine NTP inspection workload, thus there will be no additional costs to DEA.

DEA's estimation of operating costs for a mobile NTP represents the average costs for an NTP choosing to operate a mobile component. As one commenter noted, in certain rural locations throughout the United States, these operating costs may be higher than the average costs presented in the regulatory analysis because NTPs may choose to travel further distances on a more frequent basis in order to reach patients in particularly remote areas. These operating costs may even surpass the costs associated with opening another registered location. Delivering treatment to patients in very remote locations will always carry higher transaction costs than delivering treatment to patients in readily accessible locations such as urban or suburban centers. Absent this rule, however, treating patients in these remote areas would likely require opening not just one more registered location, but many. DEA is confident that the operating costs of a single mobile NTP servicing a wide geographic area will always be less than those of multiple additional registered NTP locations that would be required to treat the patients dispersed throughout the same area.

Additionally, DEA recognizes that some mobile components may indeed travel greater distances than the 100 miles per week estimated in the proposed rule. However, DEA considers this mileage estimate to be a reasonable average of the weekly distance any particular mobile component might travel to treat patients, especially when factoring in mobile components that will operate in more densely-packed urban and suburban settings. As another commenter noted, operating a mobile component may also result in higher cost savings than what is presented in the regulatory analysis due to the possible increased volume of patients treated by a mobile component. Again, DEA's analysis represents average cost savings when comparing the operation of a mobile NTP with a registered location, and therefore, this is factored into the agency's conclusions below.

Regarding one commenter's challenge that the labor costs for the healthcare professionals needed to staff a mobile component would likely be prohibitive, DEA assumes that the labor required to provide MAT services are the same in a mobile component and a registered NTP setting. Therefore, any particular NTP would incur those labor costs when choosing to expand operations, whether via starting a mobile component or opening an additional registered NTP location.

DEA agrees with the commenter stating that this rule is likely to result in an increase in quality of life and personal dignity for previously untreated patients who are able to receive care from a mobile NTP. DEA believes that these benefits are already discussed in the regulatory analysis below, and no further expansion is necessary.

DEA also agrees with the commenter's summation that the framework for the analysis presented in the regulatory impact analysis of this rule is a marginal cost framework, *i.e.,* a comparison of the incremental costs incurred by NTPs choosing to expand operations under the baseline regulatory environment vs. under the rule's regulatory environment. DEA does not see any benefit to the public in explaining this fact further in the regulatory impact analysis.

The Ability of the Mobile Component To Operate as an Emergency Medical Services Vehicle or Hospital

Comments: Several commenters noted that DEA did not address the specific services the mobile component could and could not provide to those individuals who utilize it. Many of these commenters also provided suggestions for the services they believed the mobile components should provide. One commenter suggested that DEA allow the mobile component to operate as an emergency medical services (EMS) vehicle or a hospital. The commenter stated that by not allowing the vehicles to operate as an EMS vehicle (*e.g.,* to transport patients) or a hospital, there was a risk to the communities being served by the mobile component, because many of the rural areas might not have local hospitals or only have access to hospitals that are overcrowded and underfunded. The commenter also noted that some community members utilizing the mobile component may mistakenly assume that the mobile component is able to treat overdose victims or try to seek emergency treatment at a mobile component instead of an EMS vehicle or a hospital.

One commenter suggested that DEA revise the proposed amendment, 21 CFR 1301.13(4)(ii), to state explicitly that mobile NTPs are allowed to conduct the necessary medical and psychosocial services required to induct and maintain MAT/medications for opioid use disorder (MOUD); to utilize a Qualified Service Organization Agreement (QSOA) with an entity or entities that can provide these services; and to provide counseling services electronically (*e.g.,* telehealth) by qualified providers. The commenter also mentioned that allowing these services, which would have to be consistent with applicable State and Federal law, would decrease the risk of discontinuity of care, which could cause the patient to relapse and/overdose.

Another commenter noted that the proposed rule did not include guidance on ancillary requirements for NTP patients such as toxicology and serology, and stated that the NTP registrant should be required to indicate whether physical examinations, toxicology testing, and serology testing would be conducted in the mobile NTP or at the registered NTP location. The commenter also asked if the mobile NTP could conduct these services, and if not, recommended that the rule include clear guidance as to where these services could be provided or if these services could be conducted in coordination with a partner, like a hospital.

Finally, another commenter suggested that the final rule should expressly state that services such as infectious disease screenings and harm reduction interventions are available in mobile NTPs just as they are at the registered NTP locations. As these mobile NTP components are to operate as "coincident," or equivalent, to the registered NTP location, the commenter suggested, a mobile NTP should provide most or all of the same supplemental services that are logistically possible. The commenter stated further that the exclusion of such language could be interpreted as prohibiting these critical public health interventions that are essential to addressing disparate rates of sexually transmitted and other infectious diseases among persons with substance use disorder, especially those who inject drugs.

DEA Response: DEA appreciates commenters' concerns about those individuals in rural communities being served by the mobile component not having local hospitals or access to hospitals that are overcrowded or underfunded. However, as stated in the NPRM, the mobile components will not be configured in a way to allow them to serve as an EMS vehicle or hospital, and will not have the necessary equipment or supplies on board to function as such. *See* NPRM, 85 FR 11008, 11010.

In the preamble of the proposed rule, DEA stated it was proposing to waive the requirement of a separate registration for NTPs that utilize mobile components, and that specifically, an NTP would be permitted to dispense narcotic drugs in schedules II–V at location(s) remote from, but within the

same State as, the NTP's registered location, for the purpose of maintenance or detoxification treatment. *See* NPRM, 85 FR 11008, 11009. DEA did not include guidance on ancillary requirements for NTP patients such as toxicology and serology, infectious disease screenings, and harm reduction interventions, because if and how such services are provided is outside the scope of DEA's authority. Although nothing in the rule prohibits a mobile NTP from providing such services, (if they can be provided in a manner consistent with the rule and other laws), it is similarly outside the scope of DEA's authority to explicitly permit mobile NTPs to conduct the medical and psychosocial services required to induct and maintain MAT/MOUD, to utilize a QSOA with an entity or entities that can provide these services, and to provide counseling services electronically by qualified providers. Further, the registered NTP should decide whether its mobile component will offer these services based on the needs of the community they are servicing, staffing, financial impact to the NTP, etc. As long as the NTP follows all applicable, Federal, State, local, and tribal laws, DEA knows of no reason, at this time, why these activities would be prohibited.

The Mobile Component Servicing Correctional Facilities

Comments: Approximately 20 commenters addressed the benefits of mobile components servicing incarcerated individuals with OUD. All of these commenters asserted that this rule would help in the treatment of incarcerated individuals. Commenters posited that the proposed revisions might allow NTPs to bring their mobile components to correctional facilities, as these facilities might have logistical difficulties arranging the transport of inmates to NTPs. One commenter recommended that DEA collaborate with NTPs and other Federal agencies to maximize opportunities to increase the use of mobile methadone to increase treatment access for these vulnerable populations. Several commenters similarly suggested that NTPs partner with law enforcement and State opioid treatment authorities to expand access to the services provided by the mobile component to correctional facilities. An organization representing individuals in medication-assisted recovery from OUD declared that it would encourage its members to advocate for the use of mobile components in these facilities with their State opioid treatment authorities and local law enforcement agencies.

Some commenters noted that existing mobile NTPs have proven to be helpful in providing treatment for incarcerated individuals; however, no specific examples were provided. Another commenter, a non-profit organization, gave an example where mobile NTPs in Atlantic County, New Jersey provide medication (methadone, buprenorphine, and naltrexone) and counseling to inmates onsite, and link those being released from correctional facilities to community-based NTPs. The non-profit also stated that one NTP that shared that its mobile NTP had treated more than 1,000 inmates in more than two years, and that these inmates subsequently had a lower recidivism rate compared to the general correctional facility population. Other commenters cited studies that showed how access to MAT services would decrease the rates of recidivism and post-release mortality as patients successfully transition from the correctional environment into an outpatient treatment setting. Two commenters both referenced data from a study in Rhode Island; the commenters reported that the data showed that offering MAT during incarceration and upon release resulted in a 60 percent decrease in overdose mortality among people who were recently incarcerated. One of the commenters described the study as "recent," but neither provided a specific citation for the study.

Finally, a pharmaceutical manufacturer sought clarity for itself, and its treatment provider customers, on whether NTPs operating a mobile component as described in the proposed rule would be allowed to regularly use the mobile component to transport and provide NTP services, including methadone treatment, to inmates housed in correctional facilities. The manufacturer believed the plain language of the proposed rule's legal authority, as well as the proposed changes to 21 CFR 1301.13(e)(4), authorize a properly registered NTP operating a mobile component to dispense narcotic drugs for addiction treatment to inmates at a correctional facility.

DEA Response: As stated before, the intent of this rule is to increase access to maintenance or detoxification treatment to those individuals who need it. As many of the commenters indicated, incarcerated individuals are a group who would greatly benefit from mobile NTPs servicing correctional facilities. The current use of mobile components by some NTPs in states such as New Jersey and Rhode Island, coupled with research presented by several commenters demonstrating lower recidivism rates as a result of treatment received while incarcerated, show that these mobile components are beneficial. Therefore, to avoid any possible confusion, in this final rule, DEA is adding an additional provision to 21 CFR 1301.13(e)(4) to clarify that NTPs may operate mobile components at correctional facilities where otherwise permitted by law. DEA would like to remind NTP registrants that they must follow all applicable, Federal, State, local, and tribal laws when operating these mobile components at correctional facilities.

Promulgation of Telemedicine Special Registration Regulation and Related Issues

Comments: Several commenters expressed concerns regarding the status of the telemedicine special registration that Congress mandated DEA implement by October 2019 in the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), Public Law 115–271, sec. 3232, 132 Stat. 3894, 3950 (2018). One commenter mentioned that while this proposed rule was a step in the right direction, it falls short of the special registration for telemedicine, which would help more people who struggle to find access to buprenorphine providers. One commenter similarly noted that the proposed rule was an important step in expanding access to care for those with OUDs; this commenter, along with the others, also urged DEA to promulgate regulations implementing the telemedicine special registration as quickly as possible.

DEA Response: Although these comments regarding telemedicine special registration are beyond the scope of this rule, DEA understands commenters' frustration with the delay. DEA intends to promulgate regulations for the telemedicine special registration in the near future.

Comment: One commenter suggested that the definition of mobile NTPs be expanded to include mobile internet-based health applications.

DEA Response: In this final rule, DEA will not expand the definition of mobile NTPs to include mobile internet health-based applications. The dispensing of controlled substances through internet applications raises risks and other issues quite different than those raised by dispensing through a mobile conveyance. Thus, such internet dispensing is beyond the scope of this rule, but will be considered in the context of the aforementioned special telemedicine registration rulemaking.

Other Comments

Comments: One commenter discussed how some State treatment agencies have already experienced staffing shortages or may in the future, and how it is also possible for an agency to suffer full closure due to the COVID–19 public health emergency. The commenter stated that both the lack of treatment facilities and staffing shortages would negatively impact an agency's ability to admit clients into treatment, and that this will become more apparent due to the predicted increase in admissions following the public health emergency. Another commenter mentioned that DEA, SAMHSA, State regulators, and NTPs have taken steps to ensure continued access to treatment by changing dosing schedules to limit face-to-face contact, facilitating access to telehealth, and allowing home delivery of medications for OUD treatment to quarantined patients to prevent the spread of COVID–19. Finally, one commenter stated that due to the ongoing public health crisis, DEA should follow a tiered approach and immediately begin approving mobile components while devoting resources to finalizing this rule. The commenter further stated that DEA used its authority granted by 21 U.S.C. 822(d) to approve mobile components on an ad hoc basis prior to 2007, and thus there is no legal constraint on DEA to finalize this rule before beginning to approve mobile components on an ad hoc basis.

Several commenters expressed concern that SAMHSA's current requirement of daily dosing at the initiation of methadone treatment would limit the reach of newly operationalized mobile components to just one region/one community, given that a mobile component would have to repeatedly return to the same location(s) each day to provide daily methadone doses to newly initiated patients. To expand access to treatment, the commenters urged DEA to work with SAMHSA to revise regulations restricting take-home medications. Four commenters also suggested that DEA should work with SAMHSA to allow NTP providers to prescribe medications to be filled at community pharmacies and to allow non-NTP providers to prescribe methadone.

DEA Response: DEA has worked closely with SAMHSA during the COVID–19 public health emergency to provide guidance and support to NTPs to ensure that any individual who relies on MAT is able to continue treatment without disruption. It is DEA's intent that mobile NTP components will be able to help agencies facing lack of treatment facilities and staffing shortages resulting from COVID–19 or any other public health or environmental emergency that impacts NTP access. DEA will continue to work with SAMHSA and its other partners after this public health emergency has ended to ensure that those suffering from OUD face fewer barriers to treatment.

DEA is using its discretion to approve mobile components under the authority granted to it by the CSA. 21 U.S.C. 822(d). Any NTP that wishes to use a mobile component for maintenance or detoxification treatment will be able to start the approval process once the final rule has been published to ensure that all interested NTPs would be subject to the same requirements.

Comments: Two commenters noted that the proposed rule does not reference mobile NTPs' need to adhere to Health Insurance Portability and Accountability Act (HIPAA)/privacy requirements. These commenters assumed that these same requirements applied to mobile NTPs but advised DEA to clarify this matter in the final rule to prevent misinterpretation. One of these commenters advised DEA to include a reference to "best practice" standards as defined by SAMHSA in *TIP 63: Medications for Opioid Use Disorder.*[11] The commenter also recommended that DEA work closely with SAMHSA to develop a companion document to accompany the new requirements related to the administration of an NTP.

DEA Response: Regarding the commenters seeking clarity regarding HIPAA/privacy requirements for the mobile NTPs, DEA proposed requiring the records of the mobile components to be stored at the registered location of the NTP in a manner that meets all applicable security and confidentiality requirements. *See* NPRM, 85 FR 11008, 11010–12 (proposed 21 CFR 1304.24(b)). These same requirements will apply in the final rule. NTPs already have protocols in place to protect patient information to ensure that they are in compliance with all Federal, State, local, or tribal requirements; the final rule is supplementary to these existing protocols. NTPs also have protocols and procedures in place to ensure that they are in compliance with all Federal, State, local, and tribal laws dealing with patient care, and best practices; therefore, DEA will not include a reference to "best practice" standards as defined by SAMHSA in *TIP 63: Medications for Opioid Use Disorder.* In sum, DEA does not anticipate any significant differences in how NTPs protect the privacy of patients served by registered NTPs and those served by their mobile components.

Comment: One commenter noted that it is also important to be clear that adding new mobile components does not imply that treatment standards would be different or less stringent than those of registered NTPs. The commenter suggested that in order to ensure high quality treatment, the rule provide additional information about clinical requirements and the States' role in that area, leaving less room for problems as new mobile NTPs become operational. Two commenters also noted that the proposed rule focused exclusively on the operational aspects of administering a methadone clinic, but did not address any counseling activities that are required for NTPs. One commenter stated that DEA should extend the regulations to require mobile components to have minimum treatment standards and use a multifaceted approach (*e.g.,* counseling, recovery network, mandatory number of treatment visits per month for each patient).

One commenter recommended that the rule acknowledges that States may have additional requirements for NTPs beyond the Federal regulations. The commenter also inquired if all requirements that apply to a registered NTP location apply to a mobile component. The commenter expressed concern that without explicit guidance, it could lead to a misinterpretation of NTP requirements. The commenter also recommended adding language to the proposed regulation to clarify the expectation that a mobile NTP will provide services beyond the administration of the medication, such as counseling.

DEA Response: Under the rule, mobile NTPs are part of their DEA-registered NTP locations: Their dispensing of controlled substances through their mobile components is now a coincident activity allowed under their NTP's DEA registration. Thus, except where otherwise provided for by this rule or other laws or regulations, mobile NTPs are subject to the same standards as the NTPs of which they are a part.

DEA's NTP regulations seek to minimize diversion or abuse of the controlled substances dispensed by NTPs, but DEA does not establish broader treatment standards for NTPs. Thus, to the degree commenters wish

[11] Substance Abuse and Mental Health Services Administration. (2020). Treatment Improvement Protocol (TIP) 63: Medications for Opioid Use Disorder (HHS Publication No. PEP20–02–01–006). *https://store.samhsa.gov/SMA18-5063FULLDOC* (last accessed: 9/2/2020).

the government to clarify treatment standards specific to the mobile components of NTPs, they should contact the government entities that establish and enforce those standards.

Comment: One commenter stated that in the final rule DEA should consider clarifying that the ability of mobile vans to convey injectable and implantable buprenorphine products that are administered to patients will not be restricted. The commenter also requested that DEA consider clarifying in the final rule's preamble section "the role of 'Hospital/Clinic' as 'non-practitioner' registrants to provide buprenorphine products for the treatment of [OUD] in accordance with 21 CFR 1301.28."

DEA Response: The purpose of this rule is to waive the requirement of a separate registration for NTPs that utilize mobile components and to allow an NTP to dispense narcotic drugs in schedules II–V at location(s) remote from, but within the same State as, the NTP's registered location, for the purpose of maintenance or detoxification treatment. The registered NTP, not DEA, should decide which narcotic drugs should be dispensed to its patients, both at the registered location and on the mobile component, in accordance with each individual patient's medical needs as determined by a medical professional authorized to make such a determination. Nothing in this final rule prevents a mobile NTP from providing the same treatment as would be available at the registered NTP location, as long as the mobile NTPs follow all applicable Federal, State, local, and tribal laws.

DEA regulations in 21 CFR 1301.28 include provisions for exemption from separate registration requirements for individual practitioners dispensing or prescribing schedule III–V narcotic controlled drugs approved by FDA for maintenance or detoxification treatment provided they meet certain conditions, including being a "qualifying physician" or "qualifying other practitioner," as defined in 21 U.S.C. 823(g)(2)(G)(ii) or (g)(2)(G)(iv), respectively. Thus, the request to clarify the role of Hospital/Clinic in accordance with 21 CFR 1301.28 is beyond the scope of this final rule.

Comment: Another commenter noted that the proposed rule does not include guidance on parking guidelines for the mobile component, and suggested that the NTP should be required to establish a standard operating procedure or obtain linkage agreements with organizations (*e.g.,* hospitals or programs operating needle exchange programs) where the vehicle will be parked. The commenter stated the linkage agreements must include the mobile component's days/date and hours of operation, and that without these agreements, there may be complaints and issues for local law enforcement agencies or community leaders.

DEA Response: Regarding the commenter's parking concerns for the mobile NTP, DEA appreciates the potential issues; however, DEA will not provide any guidance in this final rule. The NTP is responsible for establishing a protocol for parking, and to determine the appropriate organizations that might assist with parking. What constitutes an appropriate parking location for a mobile NTP will vary significantly from area to area based on local conditions and laws. Dictating what must be included in any agreements is thus outside the scope of this rulemaking and will not be addressed. DEA would like to remind NTP registrants of their obligations under any applicable Federal, State, or local laws when it comes to operating these mobile components.

Comment: One commenter suggested that DEA 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. The commenter stated that 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 commenter argued that other conditions in the proposed rule, combined with DEA's regular inspections, are sufficient to ensure diversion is not occurring at mobile components, especially since the NTPs that are already registered will be familiar with DEA diversion regulations and capable of complying with the conditions for mobile components. The commenter also suggested that in the preamble to the final rule, DEA should commit to conducting a retrospective review and collecting data to assess the impact of the rule on treatment accessibility and the risk of diversion. The commenter stated that if this final rule succeeds at expanding treatment for opioid use disorder to patients while simultaneously minimizing diversion risks, DEA should further expand the program.

DEA Response: DEA will not change the requirement that NTPs obtain pre-approval from the local DEA field office before operating a mobile component. DEA appreciates the commenters' concern about how possible delays in the approval process could have negative effects on those individuals who need access to treatment. Pre-approval from the local DEA field office is part of the registration process for the mobile component; without it, the NTP will not be permitted to operate the mobile component under the requirements set forth by this final rule.

DEA continually reviews the programs that fall under its regulatory authority; if it determines that adjustments are required to ensure compliance or to ensure that the rule's effect is more successful, the appropriate action will be taken.

Section-by-Section Analysis of the Final Rule

DEA is finalizing the proposed rule with certain modifications to 21 CFR 1300.01, 1301.13, and 1301.72. In brief, this rule slightly revises the mobile NTP definition at § 1300.01(b) from that proposed. The definition is revised to clarify that it is the operation of the mobile NTP (*i.e.,* administering maintenance and/or detoxification treatment from the mobile component) that is the coincident activity, not the vehicle itself. The application fee in § 1301.13(e)(1)(vii), in the table, is revised to reflect the new registration fee schedule that became effective on October 1, 2020.[12]

Also, this rule revises the proposed new § 1301.13(e)(4) by adding a third subparagraph (iii) to clarify that a mobile NTP may operate at a location or locations, including correctional facilities, away from, but within the same State as, the NTP's registered location. Previously, the proposed rule was silent as to correctional facilities. Relatedly, in several places, references in the proposed rule to the remote "location" where the mobile NTP operates are replaced with references to the mobile NTP's "location or locations" to clarify that a mobile NTP can operate at more than one remote location under appropriate circumstances.

This rule revises the proposed new § 1301.72(e) to allow the mobile component to be parked at the registered location or any secure, fenced-in area when the mobile component is not in use. Prior to parking the conveyance at a secure, fenced-in location, all controlled substances must be removed from the conveyance and returned to the registered location and, the local DEA office must be notified of the location of

[12] 85 FR 44710 (July 24, 2020).

the secure, fenced-in area. The proposed new paragraph did not previously address this security condition.

This final rule does not change the proposed new requirement in § 1301.72(e), that upon completion of the operation of the mobile NTP 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. However, this rule adds a provision in § 1301.72(e) that expressly allows NTPs to apply for an exception to this requirement, following the process set forth in 21 CFR 1307.03, which allows any person to apply for an exception to any provision of the DEA regulations. In addition, the revised § 1301.72(e) specifically provides that the application must include certain other information, and that DEA will evaluate each application on a case-by-case basis to determine whether the applicant has demonstrated exceptional circumstances that warrant a waiver of the daily return requirement.

Finally, this rule makes a variety of minor changes in capitalization, abbreviation, word choice, and grammar throughout the regulatory text, but these are not intended as substantive revisions. For example, whereas the proposed text used both "narcotic treatment program" and "NTP," the revised text more consistently uses "NTP" throughout. Similarly, proposed new § 1301.74(j) and (l) referred to an NTP "physician," whereas the revised text uses the more general term "practitioner."

Below are summaries of provisions contained in the final rule.

Part 1300: Definitions

In section 1300.01, DEA adds a definition for a mobile NTP. This definition reflects that a mobile NTP is an NTP operating from a motor vehicle that serves as a mobile component of the NTP. As such, a mobile NTP engages in maintenance and/or detoxification treatment with narcotic drugs in schedules II–V, at a location or locations remote from, but within the same State as, the registered NTP, and operates under the registration of the NTP. Because the mobile NTP definition references a motor vehicle, DEA also separately defines "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, a trailer could not serve as a mobile NTP.

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 final rule contains provisions (described below) that require NTPs to secure controlled substances while operating a mobile component away from the registered location.

In this final rule, DEA revises 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 reduce 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 a registered NTP will not have to apply for a separate registration, as its operation is considered coincident activity. In addition, DEA specifies in the regulations that the records generated during the operations of a mobile component of an NTP shall be maintained at the NTP's registered location, rather than requiring such records to be stored in the mobile component. Section 1301.13 is also revised to explicitly state that registered NTPs may operate mobile components at correctional facilities where otherwise permitted by law.

DEA revises section 1301.72 to ensure controlled substances in a mobile component of an NTP are protected against theft and diversion. To achieve this end, the security requirements under 21 CFR 1301.72(a)(1) and 21 CFR 1301.72(d) apply to the mobile component of an NTP. The storage area for controlled substances in a mobile component of an NTP must not be accessible from outside the vehicle. The 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 requiring 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 requiring 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 mobile NTP on a given day, the conveyance will need to immediately return to the registered location, and all controlled substances removed from the conveyance and secured within the registered location. After the controlled substances have been removed, the conveyance may be parked until its next use at the registered location or any secure, fenced-in area, once the local DEA office has been notified of the location of this secure, fenced-in area. If the mobile component is disabled for any reason (mechanical failure, accident, fire, etc.), the registrant will 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 will need to be removed and secured at the registered location.

NTPs will 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 at the NTP's registered location. NTPs are also required to provide State and local licensing and registration documentation to DEA at the time of inspection and prior to transporting controlled substances away from their registered location.

Regarding the requirement for the mobile NTP to return daily to the registered location, and to store its controlled substances at the registered location, DEA revises 21 CFR 1301.72(e) to expressly allow the NTP to apply for an exception to this requirement, following the process set forth in 21 CFR 1307.03. In addition, the revised § 1301.72(e) specifically provides that the application must include the proposed alternate return period, enhanced security measures, and any other factors the applicant wishes the Administrator to consider. DEA will evaluate each application on a case-by-case basis to determine whether the

applicant has demonstrated exceptional circumstances that warrant a waiver of the daily return requirement. DEA will consider the applicant's security and recordkeeping as well as other factors relevant to determining whether effective controls against diversion will be maintained.

DEA revises 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 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 now requiring that persons enrolled in any NTP, including those who receive treatment at a mobile NTP, 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.

Mobile NTPs may only be stocked with narcotic drugs in schedules II–V from the registered NTP location. Personnel designated to transfer narcotic drugs in schedules II–V from the registered location to mobile NTPs are not 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 to the registered NTP location for disposal from the dispensing location(s) of the mobile component shall be secured and disposed of in compliance with 21 CFR part 1317 and all other applicable Federal, State, tribal, and local laws and regulations.

Finally, the physical security controls of mobile components will 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 comply with the theft and significant loss reporting requirements in 21 CFR 1301.74(c).

Part 1304: Records and Reports of Registrants

Under the final rule, the recordkeeping requirements of 21 CFR part 1304 apply to mobile components of NTPs. DEA revises sections 1304.04 and 1304.24 to include mobile components. As with registered NTP locations, the records of the mobile components will 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.

21 CFR 1304.24(b) requires that an NTP maintain the records, required by 21 CFR 1304.24(a), in a dispensing log at the registered location. It is understood that this log is in paper form. As an alternative to maintaining a paper dispensing log, DEA is permitting an NTP or its mobile component to also use an automated/computerized data processing system for the storage and retrieval of its 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 daily dispensing log, which is then initialed appropriately by each practitioner who dispensed medication to the NTP's patients; and the automated system is approved by DEA.

The NTP's computer software program must be capable of producing accurate summary dispensing reports for the registered NTP location and its mobile component, for any time-frame selected by DEA personnel during an investigation. Further, if summary reports are maintained in hard copy form, they should be stored in a systematically organized file at the registered location of the NTP. Additionally, a back-up of all computer generated records of dispensing by the NTP and its mobile component is required to be maintained off-site.

Finally, NTPs are required to retain all records for the registered NTP location as well as any mobile components for 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 final 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 final rule. This is the standard analytic framework codified in the Office of Management and Budget (OMB) Circular A–4, published on September 17, 2003. This final rule is an enabling rule designed to expand access to 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 final rule's regulatory environment, in which a registered NTP may begin to operate a mobile component as a coincident activity, if authorized by DEA. This analysis, detailed below, finds that this final 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 final rule is likely to result in benefits in the form of economic burden reductions (healthcare 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 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 final 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.[13] While SAMHSA estimated that 2 million Americans have an OUD involving medications, and another 526,000 had an OUD involving heroin, in 2018, only 19.7 percent of Americans with an OUD received any specialty treatment.[14] A review of private insurance data collected from 2010 to 2014 found that, following an opioid-related hospitalization, fewer than 11 percent of covered patients received

[13] 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.

[14] 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.

MAT in combination with psychosocial services. An additional 6 percent received MAT without psychosocial services, and 43 percent received psychosocial services only.[15] As of 2016, over 90 percent of NTPs were located in urban areas, forcing rural patients to travel great distances to receive their doses of medication.[16] According to research published in 2014, some rural patients reported that the burden of traveling daily to receive their medication effectively prevents them from working,[17] further increasing the risk that they will discontinue treatment.[18]

Without this rule permitting registered NTPs to operate mobile components as coincident activity, an NTP wishing to provide MAT services to patient populations with little or no access to an NTP would be required to register and open another NTP 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 $296 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 SAMHSA. Additionally, opening a new location would entail additional staffing and facilities costs. Under the final rule's regulatory provisions, registrants are able to operate a mobile component as a coincident activity of their existing registered location, foregoing the expenses of opening and operating a new registered location, 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 registered 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 final rule does not change the requirements for the personnel that are authorized to dispense controlled substances. Whether an NTP expands via a new registered location or a 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 registered 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 associated registered NTP. DEA assumes that a new registered NTP location requires one medical assistant, and calculates the total annual compensation for this medical assistant to be $48,994.[19]

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 an alarm system compliant with 21 CFR 1301.72(a)(iii). Such startup costs are accordingly also omitted from this analysis. Whether MAT services are being rendered via a mobile NTP or the traditional office environment, the same type and quantity of labor, medical equipment, and security equipment is assumed necessary 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 (the most recent year in which this figure was updated).[20] 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 percent discount rate and $210,666.53 at a 3 percent discount rate. In comparison, commercial vehicles suitable for service as a mobile NTP range in price from $30,000 to $40,000.[21] Furthermore, the final rule does not require an NTP to obtain a separate registration for the mobile component at a cost of $296 per year, which is a cost that a new registered NTP location would incur. The present value of registration costs per registrant over a five-year period is $1,213.66 at a 7 percent discount rate and $1,355.59 at a 3 percent discount rate.

There are also several operating expenses that are unique to a mobile component 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 component and a traditional NTP office require a safe, the confined space of a mobile component 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 safe[22] and attributed that full amount to the

[15] 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.*

[16] 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.*

[17] 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.

[18] 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.*

[19] 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 × (1 + 0.4577) = $48,994.17.

[20] "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.*

[21] 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 NTP registrants for mobile components.

[22] 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.

mobile component, while attributing only the purchase price of the safe to the cost of a stationary 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 expenses.[23] Based on DEA's knowledge of the operations of existing mobile NTPs, DEA estimates that a mobile NTP operating under the final rule will travel an average of 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.[24]

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 an additional NTP location over a five-year period yields a net present value of cost savings between $319,069 (at a 7 percent discount rate) and $359,369 (at a 3 percent 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 COSTS FOR ADDITIONAL NTP LOCATIONS *

Office rent per year	$46,000.00				
Cost of safe[25]	899.00				
Labor Cost	48,994.00				
Registration fee	296.00				
NPV 3%	Year 1	Year 2	Year 3	Year 4	Year 5
$437,274	$96,189.00	$95,290.00	$95,290.00	$95,290.00	$95,290.00
NPV 7%	Year 1	Year 2	Year 3	Year 4	Year 5
$391,549	$96,189.00	$95,290.00	$95,290.00	$95,290.00	$95,290.00

* All figures rounded to the nearest whole dollar.

FINAL RULE'S REGULATORY ENVIRONMENT—TOTAL MOBILE NTP COSTS *

Vehicle purchase price	$40,000.00				
Cost to install DEA compliant safe	1,798.00				
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 NTP locations 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, registered NTPs are more limited in their geographic service area than a mobile NTP would be. 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 nineteen such NTP registrants, and there are currently eight with mobile components still in operation. Therefore, DEA considers it a reasonable assumption that at least eleven additional NTP registrants will begin operating a mobile NTP after this final rule is published, bringing the total number of mobile NTPs to at least the previous total of nineteen. This yields a total cost savings for all of those NTPs over a five-year period of $3,509,759[26] (at a 7 percent discount rate) to $3,953,059[27] (at a 3 percent 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 final rule results in a cost reduction for NTP registrants that wish to expand their services to new geographic areas, and will spur an increase in the number of mobile NTPs. Therefore, this final rule is a deregulatory action that will result in a net cost savings between $3,509,759 and $3,953,059.

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

This final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to

[23] 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.*

[24] $1.63 per mile × 5,000 miles per year = $8,150.

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

[26] The final rule's regulatory environment yields a five-year cost savings (discounted at 7%) of $318,855 over the current regulatory environment. $319,069 × 11 = $3,509,759.

[27] The final rule's regulatory environment yields a five-year cost savings (discounted at 3%) of $359,131 over the current regulatory environment. $359,369 × 11 = $3,953,059.

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). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review established in E.O. 12866. DEA expects that this final 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 final 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 will result from this final rule. This final rule is an enabling rule designed to expand the supply of 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 final rule's regulatory environment in which a registered NTP may begin to operate a mobile component as a coincident activity, subject to the provisions of this final rule. DEA's analysis, summarized in the preceding section, finds that this final rule will result in a net cost-savings between $3,509,759 and $3,953,059, and is therefore below the $100 million threshold.

For a number of years, DEA has allowed registered NTPs to utilize mobile components as part of their programs through special arrangements with local DEA field offices. The use of these mobile components 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 substance use disorder, 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 components associated with the registered NTP were seen as an alternative because they increased accessibility to treatment in the areas that needed it.

This final rule builds on the existing experience and provides additional flexibility for NTPs in operating mobile components, subject to regulatory restrictions put into place to prevent the diversion of controlled substances. DEA is revising 21 CFR 1301.13 to make operating a mobile component of an NTP a coincident activity of an existing NTP registration, and this provision will reduce the regulatory burden on NTPs by waiving the separate DEA registration requirement. These mobile NTPs are required to maintain effective security to guard against theft and diversion of controlled substances in accordance with 21 CFR 1301.72. The mobile NTPs are also subject to the recordkeeping requirements in 21 CFR 1304.04 and 1304.24. Many of the current mobile NTPs are already following these regulatory requirements. This final rule ensures that these regulatory requirements can be enforced consistently over any current or future NTP wishing to operate a mobile NTP.

Thus, this final rule will 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 component 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.

While the findings of the regulatory impact analysis of this final rule support the conclusion that this rulemaking is not economically significant, the Office of Information and Regulatory Affairs (OIRA) has nonetheless determined that the final rule is a "significant regulatory action" under E.O. 12866, section 3(f). Accordingly, this rule has been reviewed by OIRA.

Executive Order 12988, Civil Justice Reform

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

Executive Order 13132, Federalism

This final rule does not have federalism implications warranting the application of E.O. 13132. The final 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 final rule does not have tribal implications warranting the application of E.O. 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 final rule on small entities. DEA's evaluation of economic impact by size category indicates that the final rule will not 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 final 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) [28] 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 0.56, 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	6,919	12,449	0.56
622210—Psychiatric and Substance Abuse Hospitals	396	623	.64
621420—Outpatient Mental Health and Substance Abuse Centers	6,523	11,826	.55

Source: SUSB.[29] (Accessed 9/8/2020).

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 0.56 to the 1,832 NTP registrations in DEA's database to estimate the number of NTP entities, resulting in an estimate of 1,026 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	1,832	0.56	1,026
Grand Total	.....	1,832	.....	1,026

Thus, based on these calculations, DEA estimates that 1,026 entities could currently operate a mobile NTP, including the eight NTP entities that currently operate mobile NTP components. Of these, DEA estimates that at least an additional eleven entities will choose to operate a mobile NTP as a coincident activity in response to the final rule, matching the previous total of nineteen mobile NTPs that were in operation over the previous five years. Because the final 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 NTP units will be affected by the rule. Therefore, DEA estimates that 1.07 percent (11 of 1,026) of total NTP entities in the United States will be affected by this final 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,

[28] 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: September 1, 2020).

[29] Data for NAICS codes related to NTPs are based on the 2017 SUSB Annual Datasets by Establishment Industry, last revised on July 16, 2020. 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 NAICS codes.

U.S. Small Business Administration (SBA) [30] 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	41.5	
621420	Outpatient Mental Health and Substance Abuse Centers	16.5	

Source: SBA, August 19, 2019. (Accessed 9/8/20120).

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,[31] 180 of 411 (43.78%) firms within code 622210 fell below the SBA size standard and thus were small firms.[32] 4,369 of 4,987 (87.61 percent) 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 2017 SUSB Annual Datasets by Establishment Industry, resulting in approximately 173 firms (43.78 percent of the total 396) within code 622210 and 5,714 firms (87.61 percent of the total 6,523) within code 621420 classified as small firms. Combining these values indicates that, for these codes, 5,887 of 6,919 firms, or 85.1 percent, are small firms. Thus, since these are the NAICS codes that most closely correspond to NTP entities, DEA estimates that 85.1 percent of NTP entities are small firms. As described above, DEA has concluded that there are roughly 1,026 total NTP entities in the United States. Accordingly, DEA estimates that 873 (85.1 percent) of the total 1,026 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	1,832	0.56	1,026	85.1	873
Percent Small Entity					85.1%

In consultation with the SBA's Office of Advocacy, DEA has adopted the SBA standard that the amount of small entities affected by a final rule is "substantial" if 30% or more of the relevant group of small entities will be affected by the rule. As described in the Summary of Costs and Benefits section, this final rule is an enabling rule and a deregulatory action resulting in a total cost savings of at least $3,509,759 over a five-year period. The final 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 eleven entities will choose to operate a mobile NTP as a coincident activity in response to the final rule. Because the final 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 1.85 percent (19 of 1,026) of total NTP entities in the United States are affected by this final rule. DEA estimates that 11 NTPs not already operating a mobile NTP (or 1.07 percent of all NTPs) will choose to operate a mobile NTP. 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 1,026, or 1.07 percent), especially since most NTP entities are small. Thus, DEA estimates that 1.07 percent (9 of the 873 [33]) 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 nine affected small entities are estimated to realize the same cost savings as other affected entities, as calculated above: Between $319,069 (at a 7 percent discount rate) and $359,369 (at a 3 percent 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 an entity, and recognizes that this amount of cost savings rises above that threshold for those small entities.

[30] 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: 9/8/2020).

[31] 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.

[32] 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.

[33] $0.0107 \times 873 = 9.3411$. Rounding down to the nearest whole number yields 9.

However, since the percentage of affected small entities is less than 30 percent (1.07 percent), this final rule does not impact a substantial number of small entities. Therefore, this final 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 ..	873	9	1.07% (Not Substantial)	Not significant.

DEA examined the economic impact of the final rule for each affected industry for various size ranges. Based on the analysis above, and because of these facts, DEA certifies this final rule 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 will 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 million 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 will not impose new recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. Although the final 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.

Congressional Review Act

This final rule is not a major rule as defined by the Congressional Review Act (CRA), 5 U.S.C. 804. This final rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. Accordingly, this final rule is not subject to the reporting requirements under the CRA.

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 amends 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 definitions 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 narcotic treatment program (NTP) operating from a motor vehicle, as defined in this section, that serves as a mobile component (conveyance) and is operating under the registration of the NTP, and engages in maintenance and/or detoxification treatment with narcotic drugs in schedules II–V, at a location or locations remote from, but within the same State as, its registered location. Operating a mobile NTP is a coincident activity of an existing NTP, as listed in § 1301.13(e) of this chapter.

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), 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) * * *

(vii) Narcotic Treatment Program (including compounder).	Narcotic Drugs in Schedules II–V.	New–363 ..... Renewal–363a	296	1	May operate one or more mobile narcotic treatment programs as defined under § 1300.01(b), provided approval has been obtained under § 1301.13(e)(4).

* * * * *

(4) For any narcotic treatment program (NTP) intending to operate a mobile NTP, the registrant must notify the local DEA office, in writing, of its intent to do so, and the NTP must receive explicit written approval from the local DEA office prior to operating the mobile NTP. The mobile NTP may only operate in the same State in which the NTP is registered.

(i) Registrants are not required to obtain a separate registration for conveyances (mobile components) utilized by the registrant to transport controlled substances away from registered locations for dispensing at unregistered locations as part of a mobile NTP. Vehicles must possess valid county/city and State information (*e.g.,* a vehicle information number (license plate number) on file at the registered location of the NTP. Registrants are also 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.

(ii) A mobile NTP is not permitted to reverse distribute, share, or transfer controlled substances from one mobile component to another mobile component while deployed away from the registered location. NTPs 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. Mobile components of NTPs may not function as hospitals, long-term care facilities, or emergency medical service vehicles, and will not transport patients.

(iii) A mobile NTP may operate at any remote location or locations within the same State as its registered location, including correctional facilities, so long as doing so is otherwise consistent with applicable Federal, State, tribal, and local laws and regulations, and so long as the local DEA office, when notified pursuant to this section, does not otherwise direct.

* * * * *

■ 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.* (1) For any conveyance operated as a mobile narcotic treatment program (NTP), a 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 in 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. Personnel transporting the controlled substances on behalf of the mobile NTP are required to retain control over all controlled substances when transferring them between the registered location and the conveyance, while en route to and from the dispensing location or locations, and when dispensing at the dispensing location or locations. At all other times during transportation, all controlled substances must be properly secured in the safe. Upon completion of the operation of the mobile NTP 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. After the conveyance has returned to the registered location and the controlled substances have been removed, the conveyance may be parked until its next use at the registered location or any secure, fenced-in area, once the local DEA office has been notified of the location of this secure, fenced-in area. All 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 all controlled substances on the inoperable conveyance are accounted for, removed from the inoperable conveyance, and secured at the registered location.

(2) With regard to the requirement of paragraph (e)(1) of this section, that upon completion of the operation of the mobile NTP 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, an NTP may apply for an exception to this requirement as provided in this paragraph. The application for such an exception must be submitted in accordance with § 1307.03 of this chapter and must include the proposed alternate return period, enhanced security measures, and any other factors the applicant wishes the Administrator to consider. The Administrator may grant such an exception in his discretion and will evaluate each application on a case-by-case basis in determining whether the applicant has demonstrated exceptional circumstances that warrant the exception. In making this determination, the Administrator will consider the applicant's security and recordkeeping as well as any other factors he deems relevant to determining whether effective controls against diversion will be maintained.

■ 6. In § 1301.74:

■ a. Revise the section heading;

■ b. Revise paragraphs (j) through (l);

■ c. Redesignate paragraph (m) as paragraph (o); and

■ d. Add new paragraphs (m) and (n).

The revisions and additions 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 (NTP), including those receiving treatment at a mobile NTP, 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 must wait outside of a mobile NTP component if that conveyance 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 practitioner and NTP employees.

(k) All NTPs, including mobile NTPs, 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 NTP or mobile NTP for unsupervised use (*e.g.,* take home or non-directly observed therapy).

(l) DEA may exercise discretion regarding the degree of security required in NTPs, including mobile NTPs, based on such factors as the location of a program, the number of patients enrolled in a program, and the number of practitioners, 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, DEA will consider such factors when evaluating existing security or requiring new security at a narcotic treatment program or mobile NTP.

(m) Any controlled substances being transported for disposal from the dispensing location of a mobile NTP 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.

* * * * *

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) introductory text 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 (NTP), including a mobile NTP, 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.

* * * * *

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–13519 Filed 6–25–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 45

[Docket ID: DOD–2021–OS–0047]

RIN 0790–AL22

Medical Malpractice Claims by Members of the Uniformed Services; Correction

AGENCY: Department of Defense (DoD) Office of General Counsel, DoD.

ACTION: Interim final rule; correction.

SUMMARY: The Department of Defense is correcting an interim final rule that appeared in the **Federal Register** on June 17, 2021. The interim final rule implements requirements of the National Defense Authorization Act (NDAA) for Fiscal Year 2020 permitting members of the uniformed services or their authorized representatives to file claims for personal injury or death caused by a Department of Defense (DoD) health care providers in certain military medical treatment facilities. Because Federal courts do not have jurisdiction to consider these claims, DoD is issued this rule to provide uniform standards and procedures for considering and processing these actions.

DATES: This correction is effective on July 19, 2021.

FOR FURTHER INFORMATION CONTACT: Patricia Toppings, 571–372–0485.

SUPPLEMENTARY INFORMATION: In FR Doc. 2021–12815, appearing at 86 FR 32194–32215 in the **Federal Register** on Thursday, June 17, 2021, the following correction is made:

§ 45.11 [Corrected]

■ 1. On page 32213, in the third column, line 47 from the top, in § 45.11, the second paragraph (g)(5) and paragraphs (g)(6) and (7) that follow are redesignated as (g)(6) through (8).

Dated: June 22, 2021.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–13632 Filed 6–25–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2020–0694]

RIN 1625–AA09

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Madeira Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the operating schedule that governs the Welch Causeway (SR 699) Bridge, Gulf Intracoastal Waterway mile 122.8, at Madeira Beach, Florida. This change will place the drawbridge on a daily operating schedule to alleviate vehicle congestion due to on demand bridge openings and balance the needs of all modes of transportation due to the